



# **Agricultural and Veterinary Chemicals Code Regulations 1995**

**Statutory Rules No. 27, 1995**

made under the

*Agricultural and Veterinary Chemicals Code Act 1994*

## **Compilation No. 45**

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## About this compilation

### This compilation

This is a compilation of the *Agricultural and Veterinary Chemicals Code Regulations 1995* that shows the text of the law as amended and in force on 7 June 2022 (the **compilation date**).

The notes at the end of this compilation (the **endnotes**) include information about amending laws and the amendment history of provisions of the compiled law.

### Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register ([www.legislation.gov.au](http://www.legislation.gov.au)). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

### Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

### Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

### Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

### Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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## **Part 1—Preliminary**

### **Division 1.1A—Name and commencement**

#### **1 Name of Regulations**

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

## **Division 1.1B—Orders**

### **2 Orders**

For the purposes of paragraph 7(1)(b) of the Act, the matters covered by subsections 6(1), (2) and (3) of the Act (other than paragraph 6(2)(i)) are declared to be matters to which section 7 of the Act applies.

Note: The Minister may make orders under section 7 of the Act in relation to these matters.

## Division 1.1—Definitions

### 3 Interpretation

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

*Act* means the *Agricultural and Veterinary Chemicals Code Act 1994*.

**active constituent number**, for an active constituent for a proposed or existing chemical product for which approval is sought in an application under section 10 of the Code, means the number that the APVMA gives to the active constituent after the application is lodged.

**application information details**, for an item of information contained in or accompanying an application, means the following details:

- (a) the title shown on the item of information;
- (b) the name of the author, or each of the authors, of the information;
- (c) the date shown on the item of information (if any);
- (d) if no date is shown on the item of information—the date when the preparation of the information was completed;
- (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;
- (f) a unique identifier for the item of information that indicates the location of the item in the application;
- (g) the name and address of the authorising party for the information.

Example: An example for paragraph (f) is the volume and page number where the item of information is located in the application.

**application number**, for an application under section 10 or 27 of the Code, means the number that the APVMA gives to the application after the application is lodged.

**APVMA CEO** means the Chief Executive Officer of the APVMA.

**assessment period**, in relation to an application, means the period specified in column 2 of the table in clause 2.1 of Schedule 6 for an application of that kind.

Note: See also Division 9.3 (notification, assessment periods and review).

**Australian GMP Code** means the *Australian Code of Good Manufacturing Practice for Veterinary Chemical Products*, published by the APVMA.

**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

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

**category 1 licence** means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is:

- (a) registered as being, represented to be, or required to be sterile; or
- (b) an immunobiological product;

whether or not the licence also authorises the carrying out of steps in the manufacture of other chemical products.

**category 2 licence** means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product, other than a veterinary chemical product mentioned in the definition of:

- (a) category 1 licence; or
- (b) category 3 licence; or
- (c) category 4 licence; or
- (d) category 6 licence.

**category 3 licence** means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is an externally applied ectoparasiticide.

**category 4 licence** means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product that is a premix or stockfood supplement.

**category 6 licence** means a licence issued under Part 8 of the Code to carry out only one or more of the following steps in the manufacture of a veterinary chemical product:

- (a) processing;
- (b) assembling;
- (c) packaging;
- (d) labelling;
- (e) storage;
- (f) sterilising;
- (g) testing;
- (h) releasing for supply.

**chemical product number**, for a chemical product for which registration is sought in an application under section 10 of the Code, means the number that the APVMA gives to the chemical product after the application is lodged.

**Code** has the same meaning as **this Code** in section 3 of the Schedule to the Act.

**collecting agency** has the meaning given by subsection 3(1) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*.

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



**current Poisons Standard** has the meaning given by subsection 52A(1) of the *Therapeutic Goods Act 1989*.

**EDTA** means ethylenediaminetetraacetic acid.

**emergency use**, in relation to a chemical product or an active constituent, means a use of the product or constituent in the genuine belief that the use is required because of an emergency or impending emergency.

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

**extended assessment period**, for an application: see subregulation 76A(4).

**FAO and WHO Specifications for Pesticides** means specifications for pesticides or plant protection products published by the Food and Agriculture Organization of the United Nations or the World Health 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.

**formulation type** means:

- (a) for an agricultural chemical product—the formulation code and description that:
  - (i) are set out in guidelines made under section 6A of the Code as in force from time to time; and
  - (ii) apply to the product; and
- (b) for a veterinary chemical product—the form of the product.

Examples: A capsule, emulsifiable concentrate, injectable solution, implant, intramammary treatment, oral drench or tablet.

**GMP audit**: see subregulation 61(8).

**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.

**identifying information**, for a person, means the following information:

- (a) if the person is an individual—the person's name;
  - (b) the person's ABN or ACN (if any);
  - (c) the person's trading name (if any);
  - (d) whether the person is an individual or a body corporate;
  - (e) the person's street address;
  - (f) if the person's postal address is different from the person's street address—the person's postal address.
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### Regulation 3

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**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.

**interchangeable constituent determination** means a determination under regulation 19AEA.

**labelling standard** means a standard made by the APVMA under paragraph 6E(1)(c) of the Code.

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

**lodged**: see regulation 5A.

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

**minor use**: see regulation 3AA.

**modular assessment fee** has the meaning given by subregulation 70A(4).

**modular assessment period** has the meaning given by regulation 77.

**multi-category licence** means a licence issued under Part 8 of the Code to carry out steps in the manufacture of a veterinary chemical product mentioned in the definition of one of the following terms:

- (a) category 2 licence;
- (b) category 3 licence;
- (c) category 4 licence;

at the same premises as are used to carry out steps in the manufacture of veterinary chemical products mentioned in the definition of at least one other of those terms.

**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 current Poisons Standard.

***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.

***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.

***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 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;
- (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).

***timeshift application***: see regulation 3BA.

***United States Pharmacopeia*** means the book of that name published by the United States Pharmacopeia Convention.

## Regulation 3AA

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Note: Several other words and expressions used in these Regulations have the meaning given by section 3 of the Code in the Schedule to the Act. For example:

- active constituent
- agricultural chemical product
- approved label
- holder
- label
- relevant particulars
- veterinary chemical product.

- (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.

### 3AA Definition of *minor use*

- (1) A *minor use*, in relation to a chemical product or an active constituent, is 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).
- (2) A *minor use*, in relation to a chemical product, is a use of the product where the following apply:
  - (a) instructions for that use are in the Register in relation to one or more registered chemical products;
  - (b) none of those registered chemical products is available for sale anywhere in Australia.

### 3A Meaning of *reference active constituent*

For these Regulations, *reference active constituent*, for an application under section 10 or 27 of the Code (the *primary application*), means an active constituent that:

- (a) is or was 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 under section 10 or 27 of the Code (the *primary application*), means a chemical product that:

- (a) is or was 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.

### **3BA Definition of *timeshift application***

- (1) An application is a *timeshift application* if:
  - (a) it is covered by subregulation (2); and
  - (b) the applicant and the APVMA have agreed that it will be assessed in accordance with assessment periods set out in a project plan for the application agreed to by the applicant and the APVMA.
- (2) An application is covered by this subregulation if:
  - (a) the application is of a kind described in column 1 of item 1, 2, 3, 4, 5, 10, 11, 14 or 15 of the table in clause 2.1 of Schedule 6; and
  - (b) if the application is of a kind described in column 1 of item 10 or 14—the APVMA has determined that at least 2 of the modules at items 2 to 10 of the table in Schedule 7 are necessary for the application.

Note: The table in clause 2.1 of Schedule 6 sets out the assessment periods and fees applicable to applications. For timeshift applications, see item 27 of the table.

### **3C Definition of *confidential commercial information*—section 3 of the Code**

For paragraph (e) of the definition of *confidential commercial information* in section 3 of the Code, the following information is prescribed:

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

### **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.

## Regulation 5A

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Note: Division 3 of Part 4 of the Code dealing with date-controlled chemical products does not apply to listed chemical products or reserved chemical products: see regulation 43A.

### 5A Meaning of *lodged*

- (1) For the definition of *lodged* in subsection 3(1) of the Code, an application is lodged when the applicant gives:
  - (a) the information in the approved form for the application; and
  - (b) any other information specified for the application under section 8B of the Code;to the APVMA, in the manner (if any) required by regulation 65.
- (2) However, if the applicant does not give the information mentioned in paragraph (1)(b) to the APVMA within 7 days of giving the information mentioned in paragraph (1)(a) to the APVMA, the applicant is taken to have lodged the application 7 days after giving the APVMA the information mentioned in paragraph (1)(a).

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

- (1) For subsection 4(3) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances listed in Part 2 of Schedule 3 is declared to be an agricultural chemical product.
- (2) For paragraph 4(4)(b) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances listed in Part 3 of Schedule 3 is declared not to be an agricultural chemical product.

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

- (1) For paragraph 5(3)(b) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances listed in Part 2 of Schedule 3AA is declared to be a veterinary chemical product.
- (2) For paragraph 5(4)(b) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances listed in Division 3.1 of Part 3 of Schedule 3AA is declared not to be a veterinary chemical product.

#### 8AA Safety criteria—active constituents

For subparagraph 5A(2)(a)(vii) of the Code, the method of analysis (if any) of the chemical composition of the active constituent concerned is a prescribed matter.

#### 8AB Safety criteria—chemical products

- (1) For subparagraph 5A(3)(a)(vii) of the Code, the following are prescribed matters for a chemical product:

- (a) for all chemical products—the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product;
  - (b) for a product manufactured in Australia—whether each step in the manufacture of the product complies, or will comply, with the manufacturing principles and the Australian GMP Code;
  - (c) for a product manufactured outside Australia—whether each step in the manufacture of the product complies, or will comply, with a standard that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code;
  - (d) for a molluscicide in the form of a bait and of which the active constituent is metaldehyde:
    - (i) whether the product contains sufficient green pigment or dye to colour the bait a distinctive green colour; and
    - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
  - (e) for a molluscicide in the form of a bait and of which the active constituent is methiocarb:
    - (i) whether the product contains sufficient blue pigment or dye to colour the bait a distinctive blue colour; and
    - (ii) whether the product contains, in the bait, any bone meal or other product of animal origin;
  - (f) for an agricultural chemical product to be applied to seeds to be stored before planting or sowing—whether the product contains sufficient pigment or dye to colour the seed to enable the seed to be readily distinguished from seed to which the product has not been applied.
- (2) However, paragraphs (1)(b) and (c) do not apply if the product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code.

### **8AD Trade criteria**

- (1) For subsection 5C(3) of the Code, this regulation sets out the extent to which the APVMA is required to have regard to the matters set out in subsections 5C(1) and (2) of the Code in determining whether a chemical product meets the trade criteria.
- (2) If it can be reasonably expected that the chemical product will be used in relation to:
  - (a) a crop or animal, a product of which might be provided to a place outside Australia; or
  - (b) a crop that will be fed to an animal mentioned in paragraph (a);the APVMA must have full regard to all of the matters set out in subsections 5C(1) and (2) of the Code.
- (3) In any other case, the APVMA is to have regard to the matters set out in subsections 5C(1) and (2) of the Code to the extent that the APVMA thinks is relevant.

## Regulation 8AE

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### 8AE Labelling criteria

- (1) For paragraph 5D(1)(j) of the Code, the following are prescribed matters:
  - (a) for a chemical product that is a veterinary chemical product—the duration of any treatment using the product;
  - (b) the prevention of undue prejudice to trade or commerce between Australia and places outside of Australia;
  - (c) the appropriate signal words (if any) required by the current Poisons Standard;
  - (d) for a chemical product that is a date-controlled chemical product—the storage of containers for the product;
  - (e) any other matter determined by the APVMA CEO under subregulation (2).
- (2) For paragraph 6(2)(c) of the Act, the APVMA CEO may determine matters in relation to which a label must contain adequate instructions.

### 8AF Standards made by APVMA

- (1) Before making or varying a standard under section 6E of the Code, the APVMA must:
  - (a) consider whether it is necessary to make the standard or variation, having regard to any relevant standards specified in any of the following:
    - (i) the British Pharmacopoeia;
    - (ii) the British Pharmacopoeia (Veterinary);
    - (iii) the European Pharmacopoeia;
    - (iv) the United States Pharmacopoeia;
    - (v) the FAO and WHO Specifications for Pesticides; and
  - (b) publish a notice in the *Gazette* and on the APVMA's website stating:
    - (i) that it proposes to make or vary the standard; and
    - (ii) the reasons that the APVMA considers it is necessary to make the standard or variation; and
    - (iii) how to obtain more information about the proposed standard or variation; and
  - (c) prepare a draft of the standard or variation the APVMA proposes to make; and
  - (d) publish on the APVMA's website:
    - (i) the draft standard or variation; and
    - (ii) if the APVMA determines that the standard or variation is necessary to prevent imminent risk to persons of death, serious injury or serious illness—a statement to that effect; and
    - (iii) an invitation to the public to make a written submission on the draft standard or variation within the period stated in the invitation.
- (2) The period mentioned in subparagraph (1)(d)(iii) must be not less than 28 days after the publication of the invitation, unless the APVMA determines that the standard or variation is necessary to prevent imminent risk to persons of death, serious injury or serious illness.



- (3) In deciding whether to make the standard or variation, the APVMA must consider any submissions received in accordance with the invitation mentioned in subparagraph (1)(d)(iii).
- (4) If the APVMA makes or varies a standard under section 6E of the Code, the APVMA must publish a notice in the *Gazette* and on the APVMA's website stating:
- (a) that it has made the standard or variation; and
  - (b) its reasons for making or varying the standard; and
  - (c) how to obtain more information about the standard or variation.
- (4A) For the purposes of subparagraph 6(2)(a)(iii) of the Act, a labelling standard must include requirements relating to one or more of the following:
- (a) the presentation of the label, including the size, colour, legibility, dimensions, layout and format of the label;
  - (b) the display of the label;
  - (c) the information contained on the label.
- Note: A label can contain information in addition to the information required by legislation.
- (5) If the APVMA decides, after taking into account the matters mentioned in subregulation (3), not to make the standard or variation, the APVMA must publish a notice in the *Gazette* stating:
- (a) that it has abandoned the development of the standard or variation; and
  - (b) the reasons for abandoning the development of the standard or variation; and
  - (c) how to obtain more information about the decision to abandon the development of the standard or variation.

## **Division 1.2—General provisions about applications**

### **8AFA Application requirements—chemical product registration renewal applications**

For subparagraph 8A(a)(v) of the Code, an application for the renewal of the registration of a chemical product must nominate whether the application is for a 5 year or 12 month renewal period.

### **8AG Application requirements—timeshift applications**

- (1) For paragraph 8A(d) of the Code, a timeshift application must include a project plan agreed to by the applicant and the APVMA that includes:
  - (a) timeframes for the applicant to provide information; and
  - (b) assessment periods for assessing the application.
- (2) The applicant and the APVMA may, at any time, agree to vary a timeframe or assessment period set out in the project plan.

### **8AH Application requirements—copies of applications**

For paragraph 8A(d) of the Code, if the APVMA gives an applicant a notice under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations, asking the applicant to provide copies of the application, the applicant must provide the requested number of copies, in the form requested, to the APVMA within 28 days of the date of the notice.

### **8AHAA When other information may be taken into account in determining applications**

- (1) For the purposes of subsection 8C(2A) of the Code, the information is information that clarifies or updates information referred to in subparagraph 8C(1)(a)(i) or (ii) of the Code.
- (2) For the purposes of subsection 8C(2A) of the Code, the circumstances are that the information is provided by, or on behalf of, the applicant on the request of the APVMA and is provided before the end of the period of 14 days beginning on the day the request is made.

## **Division 1.3—General provisions about notices**

### **8AHA Published notice of approvals of labels and variations of relevant particulars or conditions of approvals**

- (1) If the APVMA approves a label for a container for a chemical product, or varies the relevant particulars or conditions of the approval, it must, unless it thinks that in the circumstances it is unnecessary to do so, publish notice of the approval or variation.
- (2) The notice must:
  - (a) be published in the Gazette, as soon as practicable, and in any other manner that the APVMA thinks appropriate; and
  - (b) for an approval—state that the label has been approved, and the date of the approval as provided by section 22 of the Code; and
  - (c) for a variation—state that the relevant particulars or conditions of the approval have been varied and the day on which the variation took place; and
  - (d) include any information set out under regulation 8AN.

### **8AK Information to be given in notice to holder**

For paragraph 8F(2)(e) of the Code, the following information is prescribed for a notice given to a holder under subsection 8F(1) of the Code:

- (a) for the approval of an active constituent:
  - (i) the information required by section 8H of the Code in relation to the approval; and
  - (ii) the date of the approval under section 22 of the Code; and
  - (iii) the date on which the notice is given to the holder; and
  - (iv) any other details entered in the Record about the active constituent that the APVMA thinks appropriate;
- (b) for the registration of a chemical product:
  - (i) the information required by section 8H of the Code in relation to the registration; and
  - (ii) the date of the registration under section 22 of the Code; and
  - (iii) the distinguishing name of the chemical product; and
  - (iv) the date on which the notice is given to the holder; and
  - (v) any other details about the chemical product, entered in the Register, that the APVMA thinks appropriate;
- (c) for the approval of a label:
  - (i) the date of the approval under section 22 of the Code; and
  - (ii) the distinguishing number of the label; and
  - (iii) the date on which the notice is given to the holder; and
  - (iv) any other details about the label, entered in the relevant APVMA file, that the APVMA thinks appropriate;

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- (d) for the variation of a relevant particular or condition:
  - (i) the information required by section 8J of the Code in relation to the variation; and
  - (ii) the date of the variation under section 22 of the Code; and
  - (iii) the date on which the notice is given to the holder; and
  - (iv) for a variation of a relevant particular or condition of an approval of an active constituent—any other details entered in the Record about the active constituent that the APVMA thinks appropriate; and
  - (v) for a variation of a relevant particular or condition of a registration of a chemical product—any other details about the chemical product, entered in the Register, that the APVMA thinks appropriate; and
  - (vi) for a variation of a relevant particular or condition of an approval of a label—any other details about the label, entered in the relevant APVMA file, that the APVMA thinks appropriate.

### **8AL Information to be given on refusal of application to vary prescribed relevant particular**

For paragraph 8G(2)(c) of the Code, a notice of refusal of an application to vary a prescribed relevant particular of an approval or registration, made under Division 2A of Part 2 of the Code, must inform the holder of the approval or registration that the holder may apply to have the particular varied under Division 3 of Part 2 of the Code.

### **8AM Publication requirements—approvals and variations of approvals of active constituents**

- (1) For paragraphs 8H(2)(e) and 8J(2)(d) of the Code, this regulation sets out the information that must be included in a notice published in the *Gazette* under those sections in relation to:
  - (a) the approval of an active constituent; or
  - (b) the variation of the relevant particulars or conditions of the approval of an active constituent.
- (2) The information is:
  - (a) the name of the applicant for the approval or variation; and
  - (b) the application number for the application for approval or variation; and
  - (c) the name of the active constituent; and
  - (d) the distinguishing number given to the active constituent by the APVMA when the APVMA approved the active constituent; and
  - (e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used.
- (3) The following information must also be published by the APVMA on the APVMA website:
  - (a) the information mentioned in paragraphs (2)(a) to (e);
  - (b) brief details about the APVMA's decision.

- (4) For each item of information relied on by the APVMA in making its decision, the following details must also be published by the APVMA on the APVMA website:
- (a) the details for the information mentioned in paragraphs (a) to (e) of the definition of **application information details** in subregulation 3(1);
  - (b) if the item of information was given to the APVMA in connection with the application by the applicant or a person on behalf of the applicant:
    - (i) the data number given to the item of information by the APVMA; and
    - (ii) unless the information is publicly available—the name and address of the authorising party for the item of information.

### **8AN Publication requirements—registrations, variations of registrations and approval of labels**

- (1) For the purposes of paragraphs 8H(2)(e) and 8J(2)(d) of the Code and paragraph 8AHA(2)(d) of these Regulations, this regulation sets out the information that must be included in the Gazette in relation to:
- (a) the registration of a chemical product; or
  - (b) the approval of a label for containers for a chemical product; or
  - (c) the 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 information is:
- (a) the name of the applicant for the registration, approval or variation; and
  - (b) the application number for the application for registration, approval or variation; and
  - (c) the name of the chemical product; and
  - (d) for a registration of a chemical product or variation of the relevant particulars or conditions of the registration of a chemical product—the distinguishing number given to the product by the APVMA when the APVMA registered the product; and
  - (e) for approval of a label or variation of the relevant particulars or conditions of the approval of a label—the distinguishing number given to the label by the APVMA when the APVMA approved the label; and
  - (f) the name of the active constituents of the chemical product; and
  - (g) a short description of the application and its purpose, including the way in which the chemical product is intended to be used.
- (3) The following information must also be published by the APVMA on the APVMA website:
- (a) the information mentioned in paragraphs (2)(a) to (e);
  - (b) brief details about the APVMA’s decision.
- (4) For each item of information relied on by the APVMA in making its decision, the following details must also be published by the APVMA on the APVMA website:
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- (a) the details for the information mentioned in paragraphs (a) to (e) of the definition of **application information details** in subregulation 3(1);
- (b) if the item of information was given to the APVMA in connection with the application by the applicant or a person on behalf of the applicant:
  - (i) the data number given to the item of information by the APVMA; and
  - (ii) unless the information is publicly available—the name and address of the authorising party for the item of information.

**8AO Matters for notice following preliminary assessment**

- (1) For subparagraphs 11(2)(a)(ii) and 28(2)(a)(ii) and paragraph 110A(2)(b) of the Code, this regulation prescribes the matters that must be set out in a notice under subsection 11(2), 28(2) or 110A(2) of the Code.
- (2) The matters are the following:
  - (a) that the application to which the notice relates has passed preliminary assessment;
  - (b) the section of the Code under which the application will be determined;
  - (c) the date on which the assessment of the application will commence;
  - (d) if an amount of application fee payable in relation to the application under subregulation 70(2) is unpaid:
    - (i) the balance of the application fee that is payable; and
    - (ii) that the balance must be paid within 28 days of the date of the notice;
  - (e) that the APVMA may determine that:
    - (i) the application is more correctly categorised as an application mentioned in a different item of the table in clause 2.1 of Schedule 6 to the item in relation to which any fee has been paid; or
    - (ii) different modules, levels and types mentioned in Schedule 7 are necessary for the application;and that if it does so, a further amount of application fee may be payable and the assessment period may change;
  - (f) the number of copies (if any) of the application that must be given to the APVMA and the form in which those copies must be given;
  - (g) that if copies of the application are required, the copies must be given to the APVMA within 28 days of the date of the notice;
  - (h) the assessment period for the application and the expected date by which the application will be determined;
  - (i) if the modular assessment period applies to the application—the modules to be completed in relation to the application;
  - (j) that if the APVMA or another prescribed authority makes a request under section 159 of the Code, the assessment period will be extended;
  - (k) for an applicant who is a nominated agent for an approval or registration—the applicant's obligations under subsection 152(2) of the Code;
  - (l) that if the applicant becomes aware of any information (**new information**) that contradicts any information given to the APVMA or shows that the constituent or product to which the application relates may not meet the

safety criteria, the trade criteria or the efficacy criteria, the applicant must give the new information to the APVMA in accordance with sections 160A and 161 of the Code;

- (m) that if the APVMA does not determine the application within the assessment period for the application (or the extended application period, if applicable), the applicant may:
  - (i) notify the APVMA under subsection 165(3) of the Code that the applicant wishes to treat the application as having been refused; and
  - (ii) apply under subsection 167(1) of the Code for a review of the decision;
- (n) that the applicant may withdraw the application in accordance with section 8D of the Code.

### **8AP Matters for notice—applications for technical assessments etc.**

- (1) The APVMA must give a person a notice if:
  - (a) the person lodges an application for the APVMA to provide an assessment of a technical nature, and the APVMA decides to provide that assessment (see regulation 8AS); or
  - (b) the person lodges an application for the APVMA to:
    - (i) make an interchangeable constituent determination (see regulation 19AEB); or
    - (ii) make or vary an ingredient determination (see clause 10 of Schedule 3AA).
- (2) The notice must set out the following:
  - (a) the date on which the assessment or the determination will commence;
  - (b) if an amount of application fee payable for the application under subregulation 70(2) is unpaid:
    - (i) the balance of the application fee that is payable; and
    - (ii) that the balance must be paid within 28 days of the date of the notice;
  - (c) if the applicant must give copies of the application to the APVMA:
    - (i) the number of copies that must be given; and
    - (ii) the form in which those copies must be given; and
    - (iii) that the copies must be given to the APVMA within 28 days of the date of the notice;
  - (d) the assessment period for the application and the expected date by which the application will be determined;
  - (e) the modules to be completed in relation to the application;
  - (f) that the assessment period will be extended if the APVMA or another prescribed authority makes a request under section 159 of the Code;
  - (g) that if the APVMA does not determine the application within the assessment period for the application (or the extended application period, if applicable), the applicant may:
    - (i) notify the APVMA under subsection 165(3) of the Code that the applicant wishes to treat the application as having been refused; and

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- (ii) apply under subsection 167(1) of the Code for review of the decision;
  - (h) that the applicant may withdraw the application in accordance with section 8D of the Code.
- (3) The notice must be given to the person within 1 month of the day on which the person lodges the application.
- (4) If a person lodges an application under regulation 8AS for the APVMA to provide an assessment of a technical nature, and the APVMA decides not to provide that assessment, the APVMA must notify the person of that decision within 1 month of the day on which the person lodges the application.

**8AQ Matters for notice in relation to extension of permit**

- (1) This regulation applies to an application for an extension or extensions of a permit under subsection 115(3) of the Code.
- (2) Within 1 month of the application being lodged, the APVMA must give the applicant a notice setting out the following:
  - (a) that the application will be determined under section 115 of the Code;
  - (b) the date on which the assessment of the application will commence;
  - (c) if an amount of application fee payable in relation to the application under subregulation 70(2) is unpaid:
    - (i) the balance of the application fee that is payable; and
    - (ii) that the balance must be paid within 28 days of the date of the notice;
  - (d) the number of copies (if any) of the application that must be given to the APVMA and the form in which those copies must be given;
  - (e) that any copies must be given to the APVMA within 28 days of the date of the notice;
  - (f) the assessment period for the application and the expected date by which the application will be determined;
  - (fa) that the assessment period will be extended if the APVMA or another prescribed authority makes a request under section 159 of the Code;
  - (g) if the modular assessment period applies to the application—the modules to be completed in relation to the application;
  - (h) that if the applicant becomes aware of any information (*new information*) that contradicts any information given to the APVMA or shows that the constituent or product to which the application relates may not meet the safety criteria, the trade criteria or the efficacy criteria, the applicant must give the new information to the APVMA in accordance with sections 160A and 161 of the Code;
  - (i) that if the APVMA does not determine the application within the assessment period for the application (or the extended application period, if applicable), the applicant may:
    - (i) notify the APVMA under subsection 165(3) of the Code that the applicant wishes to treat the application as having been refused; and
    - (ii) apply under subsection 167(1) of the Code for review of the decision;



- (j) that the applicant may withdraw the application in accordance with section 8D of the Code.

**Part 1** Preliminary

**Division 1.6** Listed chemical products

Regulation 8AR

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## **Division 1.6—Listed chemical products**

### **8AR Listed chemical products**

For subsection 8T(1) of the Code, the chemical products, or classes of chemical products, specified in Schedule 3B are listed chemical products for the purposes of the Code.

## **Part 2—Approvals and registration**

### **Division 2.1A—Pre-application assessments and assistance**

#### **8AS APVMA may provide technical assessments**

If a person applies to the APVMA for an assessment of a technical nature (a *technical assessment*) before making an application, the APVMA may provide the technical assessment.

Example: Assessment of data an applicant is considering submitting to the APVMA as part of a proposed application for registration of a chemical product or approval of an active constituent.

Note: Regulation 70 provides for fees for making an application for a technical assessment.

#### **8AT APVMA may provide pre-application assistance**

- (1) A person may apply to the APVMA for assistance (*pre-application assistance*) in preparing or making an application to the APVMA under the Code or these Regulations.
- (2) If a person makes an application for pre-application assistance in accordance with subregulation (1), the APVMA may provide the pre-application assistance.

Note: Regulation 69B prescribes the fees payable for pre-application assistance.

## **Division 2.1—Granting or refusing approvals and registrations**

### **Subdivision 2.1.1—Preliminary applications—summaries of applications**

#### **8B Summaries of applications for active constituents for chemical products**

- (1) This regulation applies to an application for the approval of an active constituent for a proposed or existing chemical product.
- (2) For paragraph 11(2)(b) of the Code, 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 subparagraph 8A(a)(v) of the Code, including the application information details for the item of information; and
  - (h) any other information that the APVMA considers to be relevant to its decision on the application.

#### **8D Summaries of applications for chemical products that are not the same as a registered chemical product**

- (1) This regulation applies to an application for:
  - (a) registration of a chemical product that is not a chemical product mentioned in paragraph 8E(1)(a); or
  - (b) approval of a label for a container for a chemical product mentioned in paragraph (a).
- (2) For paragraph 11(2)(b) of the Code, 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:
  - (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 subparagraph 8A(a)(v) of the Code, including the application information details for the item of information; and
- (j) any other information that the APVMA considers to be relevant to its decision on the application.

### **8E Summaries of applications for chemical products that are the same as a registered chemical product**

- (1) This regulation applies to an application for:
  - (a) registration of any kind of chemical product that is:
    - (i) the same as a registered chemical product; and
    - (ii) 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 a chemical product mentioned in paragraph (a).
- (2) For paragraph 11(2)(b) of the Code, the details prescribed 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.

### **Subdivision 2.1.3—Particulars for approvals, registrations and labelling**

#### **15 Particulars of approved active constituents to be recorded**

- (1) For paragraph 19(c) of the Code, the following particulars are prescribed:
  - (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

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the standard prescribed in respect of the active constituent for the purposes of paragraph 87(1)(a) of the Code;

- (c) the name of the active constituent;
- (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) identifying information for the holder of the approval of the active constituent;
- (h) the date of entry of these particulars in the Record of Approved Active Constituents;
- (j) identifying information for any nominated agent for the approval.

- (2) A particular mentioned in paragraphs (1)(c) to (j) is only prescribed for an active constituent approved in accordance with section 14A of the Code if the particular is readily available to the APVMA.

### 16 Particulars of registered chemical products to be recorded

For paragraph 20(1)(c) of the Code, the following particulars are prescribed:

- (a) the distinguishing name of the chemical product;
- (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;
- (da) the formulation type for the chemical product;
- (db) the net contents for the chemical product;
- (e) identifying information for the holder of the registration of the chemical product;
- (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) identifying information for any nominated agent for the registration.

### 17 Particulars for label

- (1) For paragraph 21(a) of the Code, the following particulars are prescribed:
- (a) the appropriate signal words required by the current Poisons Standard;
  - (b) the name of the chemical product that is to appear on a label for containers 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 constituent for the product that is:
    - (i) not an active constituent; and

- (ii) classified as a poison in the current Poisons Standard;
  - (f) the proportion of each constituent referred to in paragraph (e);
  - (h) the net contents of the product;
  - (j) particulars determined by the APVMA CEO under subregulation (2).
- (2) For paragraph 6(2)(c) of the Act, the APVMA CEO may determine additional particulars to be placed on a label for a product.
- (3) For subparagraph 21(c)(iva) of the Code, the following information is prescribed in relation to the approval of a label for a chemical product, unless the information has already been recorded for the approval of the label as part of the registration of the chemical product:
- (a) identifying information for the holder of the approval;
  - (b) identifying information for any nominated agent for the approval;
  - (c) the distinguishing name of the chemical product that is prescribed under paragraph 16(a) and entered in the Register;
  - (d) the distinguishing number of the chemical product that is entered in the Register.

### **Subdivision 2.1.4—Conditions of approval—active constituents and chemical products**

#### **17C Conditions of approval or registration—active constituents and chemical products**

- (1) For paragraph 23(1)(a) of the Code, the table sets out conditions to which the approval of an active constituent for a proposed or existing chemical product is subject.

<b>Conditions for approval of active constituent</b>	
<b>Item</b>	<b>Condition</b>
1	The active constituent must be manufactured in accordance with the composition and purity entered for the active constituent in the Record in accordance with paragraph 15(1)(d)
2	The active constituent must be manufactured by the manufacturer whose name is entered for the active constituent in the Record in accordance with paragraph 15(1)(e)
3	The active constituent must be manufactured at a site of manufacture entered for the active constituent in the Record in accordance with paragraph 15(1)(f)
4	The identifying information for the holder of the approval, and the nominated agent (if any), of the active constituent must be the identifying information for the holder and nominated agent (if any) entered for the active constituent in the Record

- (2) For paragraph 23(1)(a) of the Code, the table sets out conditions to which the registration of a chemical product is subject.

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**Conditions for registration of chemical product**

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<b>Item</b>	<b>Condition</b>
1	The chemical product must contain each of the constituents entered for the chemical product in the Register in accordance with paragraph 16(b)
2	The chemical product must be manufactured: (a) in accordance with the particulars entered for the chemical product in the Register in accordance with paragraphs 16(b), (c), (d) and (da); and (b) by a manufacturer whose name is entered for the chemical product in the Register in accordance with paragraph 16(g); and (c) at a site of manufacture entered for the chemical product in the Register in accordance with paragraph 16(h)
3	A chemical product manufactured in Australia must not be supplied unless the APVMA has determined it is satisfied that each holder of a licence to carry out steps in the manufacture of the product is complying with the following conditions of the licence: (a) any conditions imposed on the licence under subsections 126(1) and (2) of the Code; (b) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition; (c) any of the conditions mentioned in subregulations 61(3) to (7A) to which the licence is subject
4	A chemical product manufactured outside Australia must not be supplied unless: (a) the holder of the registration of the product has, on request by the APVMA, given the APVMA, or arranged for the manufacturer of the product to give the APVMA, evidence that each step in the manufacture of the product complies with a standard that the APVMA has determined is comparable to manufacturing principles and the Australian GMP Code (an <i>overseas GMP compliance assessment</i> ); and (b) the APVMA has assessed the overseas GMP compliance assessment and is satisfied that each step in the manufacture of the product complies with a standard that the APVMA has determined is comparable to manufacturing principles and the Australian GMP Code
5	The formulation type of the chemical product as supplied must be the formulation type entered for the chemical product in the Register in accordance with paragraph 16(da)
6	The net contents for the chemical product as supplied must be the net contents entered for the chemical product in the Register in accordance with paragraph 16(db)
7	The identifying information for the holder of the registration, and the nominated agent (if any), for the chemical product as supplied must be the identifying information for the holder and nominated agent (if any) entered for the chemical product in the Register

- (3) Items 3 and 4 of the table in subregulation (2) do not apply in relation to a chemical product if:
- (a) the chemical product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code; or
  - (b) the holder of the registration of the product is an exempt person within the meaning given by regulation 59A, 59B, 59C or 59D.



## **18 Conditions of registration of chemical products—containers**

- (1) For paragraph 23(1)(a) of the Code, the registration of a chemical product is subject to the condition that the product is supplied only in a container that meets the requirements mentioned in subregulation (2).
- (2) The container 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.
- (3) Nothing in subregulation (2) is intended to affect the operation of any other law that applies in relation to containers for chemical products.

### **Subdivision 2.1.6—Conditions of approval—labels**

#### **18B Prescribed conditions for approval of labels**

For paragraph 23(1)(a) of the Code, the approval of a label for containers for a chemical product is subject to the conditions prescribed by this Subdivision.

#### **18C Label must be attached to containers for chemical products**

The label must be attached to the container for the chemical product to which it relates before the supply of the product.

Note: For *supply*, see section 3 of the Code.

#### **18D Information on label**

- (1) Unless authorised by a permit, the label must state the following information:
  - (a) the information recorded for the label in the relevant APVMA file under subparagraphs 21(c)(iii) and (iv) of the Code;
  - (b) the batch number of the chemical product;
  - (c) the expiry date of the chemical product (if applicable);
  - (d) the date of manufacture of the chemical product (if applicable);

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- (e) the name and address of the person primarily responsible for marketing the product.

Note: A label can contain information in addition to the information required by legislation.

- (2) The label must not contain information that is contrary to the information mentioned in subregulation (1).
- (3) The information mentioned in subregulation (1), on the label, must not be altered, defaced, obliterated, obscured or destroyed.

#### 18E Labelling standards and requirements

The label must comply with the requirements of:

- (a) if a labelling standard has been made by the APVMA—the labelling standard; or
- (b) if a labelling standard has not been made by the APVMA—either:
  - (i) if the product is a veterinary chemical product—the *Veterinary Labelling Code* made by the APVMA, as in force from time to time; or
  - (ii) if the product is an agricultural chemical product—the *Agricultural Labelling Code* made by the APVMA, as in force from time to time.

Note: The *Veterinary Labelling Code* and the *Agricultural Labelling Code* are available at <http://www.apvma.gov.au>.

#### 18F Requirements for information on labels

- (1) The label must not contain misleading or deceptive information about either:
  - (a) the information required by subregulation 18D(1) to be stated on the label; or
  - (b) the use, safety, environmental impact or efficacy of the chemical product to which the label relates.
- (2) If the label is, or is required to be, attached to a container, information must not accompany or be placed on the container, including in the form of another label, if the information expressly or impliedly:
  - (a) negates or varies information required by subregulation 18D(1) to be stated on the label; or
  - (b) qualifies or minimises the substance or effect of the information required by subregulation 18D(1) to be stated on the label.
- (3) To avoid doubt, the label must not contain instructions about the circumstances in which, or the purposes for which, the chemical product can be used, if those instructions are inconsistent with the instructions for use approved for the label by the APVMA.

#### 18G Requirements about claims inconsistent with labels

- (1) The holder of the approval of the label in relation to the label must not make any claim, or cause or permit any claim to be made, about:
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- (a) a registered chemical product; or
  - (b) a chemical product that contains a registered chemical product;  
that is inconsistent with an instruction on the label for a container for the  
chemical product.
- (2) Subregulation (1) does not apply to:
- (a) a claim exempted by the APVMA from the operation of section 84 of the  
Code; or
  - (b) a claim made in a notice published under paragraph 45A(1)(b) of the Code;  
or
  - (c) a claim permitted to be made under a law of the Commonwealth; or
  - (d) a claim about conduct the person is authorised to engage in by a permit  
issued by the APVMA.

### **18H Retention of label and information about label**

- (1) The holder of the approval of the label must:
- (a) retain a copy of each form of the label that is attached to a container, or a  
series of containers, released for supply; and
  - (b) record either:
    - (i) if the form of the label states a sequential batch number of the  
chemical product—the first batch number in the sequence for the form  
of label; or
    - (ii) if the form of the label does not state a sequential batch number of the  
chemical product—each batch number for the form of label; and
  - (c) record the day on which the series of containers on which the form of the  
label is attached is first released for supply.
- (2) The label and information mentioned in subregulation (1) must be retained:
- (a) in a secure manner; and
  - (b) for a 5 year period commencing on the last day on which the chemical  
product is supplied in a container with the label attached.
- (3) For paragraphs (1)(a) and (c), a container is ***released for supply*** on the day when  
the container is sent from a manufacturing or packaging facility for the purposes  
of distribution or sale.

### **18I Providing label and information about label to APVMA**

- (1) The holder of the approval of the label must, on a written request by the APVMA  
for:
- (a) a copy of a form of the label mentioned in paragraph 18H(1)(a); and
  - (b) information about the label mentioned in paragraphs 18H(1)(b) and (c);
- provide the label and information requested to the APVMA.
- (2) If the request is for a copy of a form of a label, the copy must be accompanied by  
a declaration that the copy is of a form of label that has been attached to a  
container to which it relates.

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- (3) The label and information must be provided to the APVMA on the earlier of the following:
  - (a) within 10 days of the day on which the request for the label and information is received;
  - (b) on a day advised by the APVMA.
- (4) The APVMA must not advise a date for paragraph (3)(b) unless:
  - (a) the APVMA believes it is necessary to receive the label or information before the end of the period mentioned in paragraph (3)(a) to prevent imminent risk to persons of death, serious illness or serious injury; and
  - (b) the APVMA provides the reasons for the early date in the written request.

**18J Identifying information recorded for holder and nominated agent**

The approval of a label for containers for a chemical product is subject to the condition that the identifying information for the holder of the approval, and the nominated agent (if any) for the holder, must be the identifying information for the holder, and the nominated agent (if any), recorded for the label in the relevant APVMA file.

**Subdivision 2.1.6A—Incorrect particulars and conditions**

**18K Incorrect particulars and conditions APVMA must correct**

For paragraph 26(1)(b) of the Code, the following kinds of relevant particulars or conditions are prescribed:

- (a) the signal words required by the current Poisons Standard in relation to an approved label;
- (b) the following information about the holder of an approval or registration or the nominated agent (if any) for the approval or registration:
  - (i) the name of the holder or agent;
  - (ii) the ABN (if any) of the holder or agent;
  - (iii) the trading name (if any) of the holder or agent;
  - (iv) the street address of the holder or agent;
  - (v) the postal address of the holder or agent, if it is different from the street address.

## **Division 2.2—Granting or refusing applications for variation of relevant particulars, or conditions, of approvals or registration**

### **Subdivision 2.2.1—Variation applications—summaries of applications**

#### **19AD Summaries of applications for variation for chemical products**

- (1) This regulation applies to an application for variation of the relevant particulars or conditions of:
  - (a) the registration of a chemical product; or
  - (b) the approval of a label for a container for a chemical product.
- (2) For paragraph 28(2)(b) of the Code, 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 subparagraph 8A(a)(v) of the Code, including the application information details for the item of information; and
  - (ia) if the APVMA were to make a variation as a result of the application and this may result in:
    - (i) an extension of a protection period in relation to protected information; or
    - (ii) an extension of a limitation period for information covered by an item in the table in subsection 34M(1) of the Code;a statement in relation to this matter; and

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

**Subdivision 2.2.2—Interchangeable constituent determinations**

**19AEA Interchangeable constituent determinations**

*APVMA may determine interchangeable constituents*

- (1) The APVMA may, by legislative instrument, determine that one or more constituents of a chemical product or a class of chemical products may be interchanged with another constituent.
- (2) Without limiting subregulation (1), the interchangeable constituent determination may authorise a constituent being interchanged with another constituent if one or more requirements specified in the determination are met.
- (3) The power under subregulation (1) may be exercised on the APVMA's own initiative or on application under regulation 19AEB.
- (4) If an interchangeable constituent determination can be made in relation to a class of chemical products, or varied so that it applies to a class of chemical products, the APVMA must make or, if varying a determination, vary the determination accordingly.

*APVMA to be satisfied of certain matters*

- (5) Before making or varying an interchangeable constituent determination, the APVMA must be satisfied that:
  - (a) the constituent to be interchanged is not an active constituent of the product; and
  - (b) the interchange of the constituents does not introduce material of human or animal origin into the product; and
  - (c) the interchange of the constituents would not require variation to:
    - (i) the signal words required by the current Poisons Standard to be contained on the label of the product; or
    - (ii) the formulation type of the product entered in the Register; and
  - (d) after the constituents are interchanged, the chemical product would continue to:
    - (i) meet the safety criteria, the trade criteria and the efficacy criteria; and
    - (ii) comply with any requirements prescribed for the purposes of paragraph 8A(b) or 41(1)(c) of the Code.
- (6) For the purposes of being satisfied of the matters mentioned in subregulation (5), the APVMA must have regard to any requirements to which the interchange of a constituent is, or could be, subject.

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*Variation or revocation of an interchangeable constituent determination*

- (7) If the APVMA proposes to vary or revoke an interchangeable constituent determination, the APVMA must:
  - (a) publish on its website a notice setting out the proposed variation or reasons for the proposed revocation; and
  - (b) invite written submissions on the variation or revocation to be made on or before a specified date (the **consultation period**).
- (8) The notice must:
  - (a) be published at least 28 days before the interchangeable constituent determination is so varied or revoked; and
  - (b) remain on the APVMA's website until the determination is so varied or revoked.
- (9) The APVMA must consider submissions made during the consultation period.
- (10) The APVMA may make a submission public, unless the person that made the submission has requested that the submission, or a part of it, be kept confidential.

### **19AEB Applying for an interchangeable constituent determination**

- (1) A person may apply to the APVMA for the making of an interchangeable constituent determination in relation to a chemical product or a class of chemical products.
- (2) The application must specify the following for each constituent covered by the application:
  - (a) the identity of the constituent, including:
    - (i) the common name of the constituent; and
    - (ii) if a name is given to the constituent by the International Union of Pure and Applied Chemistry—that name; and
    - (iii) the chemical abstract service number for the constituent;
  - (b) the purpose of the constituent in the chemical product;
  - (c) any requirements (including, for example, minimum purity or other quality specifications) for the constituent.
- (3) The APVMA must make an interchangeable constituent determination if the APVMA is satisfied:
  - (a) that the application meets the application requirements; and
  - (b) of the matters mentioned in subregulation 19AEA(5).
- (4) The APVMA must, within 14 days of making an interchangeable constituent determination:
  - (a) inform the applicant, in writing, of that fact; and
  - (b) provide the applicant with a copy of the determination.

Note: For notification requirements if the APVMA refuses an application, see section 8G of the Code.

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- (5) The following provisions of the Code apply in relation to an application under subregulation (1) as if the application were an application made under the Code in relation to an active constituent for a proposed or existing chemical product:
- (a) section 157 (samples to be given for analysis);
  - (b) section 159 (requiring information to determine an application).

Note 1: A number of provisions in the Code apply automatically in relation to applications made under it (including applications made under these Regulations). See, for example, sections 8B to 8D, and sections 8G, 8S, 156A, 164 and 165, of the Code.

Note 2: Regulation 19AEC applies certain other provisions in relation to applications made under this regulation.

### **19AEC Limits on information that may be used for interchangeable constituent determinations**

*Overseas trials and experiments, consultation and information, reports or samples*

- (1) The following provisions apply in relation to the making, variation or revocation of an interchangeable constituent determination as if the constituent to which the determination relates were an active constituent for a proposed or existing chemical product:
- (a) section 159 of the Code (requiring information to determine an application);
  - (b) subsections 160(2) and (3) of the Code (overseas trials and experiments);
  - (c) section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (consultation).

*Limits on use of information*

- (2) The APVMA must not use information given to it in connection with an application under the Code:
- (a) to assess an application made under regulation 19AEB; or
  - (b) to make any other decision in relation to the making, variation or revocation of an interchangeable constituent determination;
- unless the information was given to it in connection with the application mentioned in paragraph (a) or the decision mentioned in paragraph (b).
- (3) A person or body consulted under section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as that section applies under subregulation (1), must not, for the purposes of providing information or advice in relation to the making, variation or revocation of an interchangeable constituent determination, use information that the APVMA must not, under subregulation (2), use in relation to the interchangeable constituent determination.
- (4) The following provisions of the Code apply in relation to subregulations (2) and (3) in the same way as they apply in relation to subsections 34G(1) and (3) of the Code:



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- (a) subsections 34G(1B) and (2);
  - (b) sections 34H to 34M.
- (5) For subregulation (4), the condition in subsection 34J(4) of the Code is taken to be replaced by the condition that:
- (a) the information relates to the making, variation or revocation of an interchangeable constituent determination in relation to a constituent; and
  - (b) the information shows that a matter mentioned in subregulation 19AEA(5) may not be satisfied in relation to the constituent.
- (6) For subregulation (4), if the APVMA relies on information to make, vary or revoke an interchangeable constituent determination, a limitation period is taken to apply to the information under section 34M of the Code that ends 3 years after the day the determination is made, varied or revoked.

## Division 2.3—Reconsideration of approval or registration

### 20 Reconsideration work plan

- (1) For subsection 31(2) of the Code, a work plan for a proposed reconsideration must include the following:
  - (a) the date of any relevant notice published under section 30 of the Code;
  - (b) the date on which the APVMA will commence the reconsideration;
  - (c) the proposed timeframe for the reconsideration and how the timeframe has been calculated for regulation 78B;
  - (d) the matters the APVMA proposes dealing with in the reconsideration;
  - (e) the expected date on which a notice will be given to the holder under subsection 32(1) of the Code;
  - (f) both:
    - (i) the expected date on which the APVMA proposes to inform persons about the reconsideration; and
    - (ii) the persons proposed to be informed;
  - (g) the expected date on which a notice (if any) will be given to the holder under subsection 33(1) of the Code, and a summary of the type of information, report, result or sample it is anticipated will be required by the notice;
  - (h) the expected date on which a notice (if any) will be given under section 34AB of the Code, and the anticipated recipients of the notice;
  - (i) the expected date on which a decision will be made in relation to the reconsideration under section 34 of the Code.
- (2) For paragraph 31(3)(a) of the Code:
  - (a) the APVMA must review and update the work plan at least once a year; and
  - (b) if the APVMA issues a notice or information mentioned in paragraph (1)(e), (f), (g) or (h), the APVMA must update the work plan to include the date the notice or information was issued; and
  - (c) if the APVMA makes a decision in relation to the reconsideration under section 34 of the Code, the APVMA must include in the work plan details of the decision and the date of the decision; and
  - (d) if the APVMA varies the instructions on a label for containers for a chemical product under section 34A of the Code in relation to the reconsideration—the APVMA must include in the work plan details of the variation; and
  - (e) if the APVMA issues a permit in relation to the reconsideration—the APVMA must include in the work plan details of the permit; and
  - (f) if the APVMA takes any suspension, cancellation or recall action, in relation to the reconsideration, under section 34AA, 41, 101, 102 or 103 of the Code, the APVMA must include in the work plan details of the action taken and the date of the action.

## **21 Period for giving information, reports, results or samples**

- (1) For subsection 33(1A) of the Code, the period stated in a notice issued under subsection 33(1) of the Code must not exceed the period that is half of the period in which the APVMA is required, under regulation 78B, to conclude the reconsideration to which the notice relates.
- (2) For subregulation (1), the period in which the APVMA is required, under regulation 78B, to conclude the reconsideration, is to be calculated as at the date of the notice.
- (3) For subsection 33(1B) of the Code, the APVMA may allow a further period if an extraordinary event or circumstance beyond the control of the holder prevents the holder from fulfilling the holder's obligations in the notice.

## **22 Notice of decision on reconsideration**

For paragraph 34AC(2)(d) of the Code, the following information is prescribed:

- (a) particulars of the notice published under paragraph 34AC(1)(b) of the Code in relation to the affirmation;
- (b) the date on which the notice is given to the holder;
- (c) the date the APVMA affirmed the approval or registration;
- (d) for an affirmation of a registration of a chemical product—the distinguishing name of the chemical product;
- (e) for an affirmation of an approval of a label—the distinguishing number of the label;
- (f) any other details entered in the Record, Register or relevant APVMA file for the active constituent, chemical product or label that the APVMA thinks appropriate.

## **22AA Reconsideration by APVMA of approval of label**

For subsection 34AF(1) of the Code, the prescribed matters are either or both of the following:

- (a) the matters mentioned in paragraphs 5D(1)(g), (h) and (i) of the Code;
- (b) the matters mentioned in paragraphs 8AE(1)(a), (b), (c) and (d) of these Regulations.

## **Division 2.6—Late applications**

### **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:
    - (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) if:
    - (i) after the end of the period for making an application referred to in subsection 48(2) of the Code and before the registration of the product ends, the applicant requests in writing that the APVMA accept a late application; and
    - (ii) the APVMA agrees to that request.
- (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.

## **Division 2.7—Renewal of registration**

### **23A When renewed registration ends**

For paragraph 50(2)(b) of the Code, the method for working out the date the registration of a chemical product (as renewed) ends is:

- (a) if the holder applies for the registration of the product to be renewed, or further renewed, as the case may be, for a period of 5 years—add 5 years to the date on which the registration would otherwise end; or
- (b) if the holder applies for the registration of the product to be renewed, or further renewed, as the case may be, for a period of 12 months—add 12 months to the date on which the registration would otherwise end.

## 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) is intended to affect the operation of any other law that applies in relation to containers for chemical products.

### 23I 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 the purposes of 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 *FAISD Handbook* of the APVMA, as changed from time to time.

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Note: The FAISD Handbook is the *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals*. The FAISD Handbook could in 2019 be viewed on the APVMA's website (<http://www.apvma.gov.au>).

## **Part 3—Compensation for provider of certain information in respect of continued registration of certain chemical products**

### **Division 3.1—Notices**

#### **24 Prescribed information—notice to primary holder**

For the purposes of subparagraph 60(3)(a)(i) of the Code, the following information about the secondary holder, and the secondary active constituent or the secondary chemical product, is prescribed:

- (a) if the notice relates to a secondary active constituent that is an approved active constituent:
  - (i) the name and business address of the secondary holder entered in the Record; and
  - (ii) the particulars of the secondary active constituent entered in the Record;
- (b) if the notice relates to a secondary active constituent that is not an approved active constituent—the name and business address of the secondary holder included in the application for approval of the secondary active constituent;
- (c) if the notice relates to a secondary chemical product that is a registered chemical product:
  - (i) the name and business address of the secondary holder entered in the Register; and
  - (ii) the particulars of the secondary chemical product entered in the Register or, if each primary holder so requests, the particulars of the approved active constituent for the registered chemical product entered in the Record;
- (d) if the notice relates to a secondary chemical product that is not a registered chemical product—the name and business address of the secondary holder contained in the application for registration of the secondary chemical product.

#### **25 Prescribed information—notice to secondary holder**

For the purposes of subparagraph 60(3)(a)(ii) of the Code, the following information about each primary holder, and each primary active constituent or primary chemical product, is prescribed:

- (a) if the notice relates to a primary active constituent:
  - (i) the name and business address of each primary holder entered in the Record; and
  - (ii) the particulars of each primary active constituent entered in the Record;
- (b) if the notice relates to a primary chemical product:



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- (i) the name and business address of each primary holder entered in the Register; and
- (ii) the particulars of each primary chemical product entered in the Register or, if the secondary holder so requests, the particulars of each approved active constituent entered in the Record; and
- (iii) the information mentioned in paragraph 21(c) of the Code about the approved labels for containers for each primary chemical product.

## **Division 3.2—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 holder in the matter to be arbitrated; and
  - (b) the secondary holder in the matter; and
  - (c) the mediator in the matter.
- (2) The notice must be given within 14 days after the appointment.

### **28 Parties to give information to arbitrator**

As soon as practicable after being notified of the arbitrator's appointment, a holder must tell the arbitrator in writing about any proposal as to the terms of compensation that was made by the holder 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 holders 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 parties notice of 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 holder does not attend 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 holder 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 a holder 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 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).
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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 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 each primary holder are as follows:

- (a) the time that has elapsed since the protected information was obtained by each primary holder;
- (b) the value of sales of the primary chemical product concerned since the registration of the product;
- (c) whether each primary holder has already received compensation for the use of the protected information by the APVMA;
- (d) the cost of obtaining the protected 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.
- (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 holders as a civil debt in a court of competent jurisdiction.

### 38 Holders' cost 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 4.1—General**

#### **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

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- (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 Parts 9 and 9A of the Code (which deal with investigative powers and 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) For the purposes of paragraphs 83(1)(a) and 102(1)(b) of the Code, the prescribed extent is:
  - (a) the extent to which a difference of constituents is permitted by the standards prescribed by regulation 42; or
  - (b) if those standards do not permit a difference of constituents—nil.
- (2) For the purposes of paragraphs 83(1)(b) and 102(1)(c) of the Code, the prescribed extent in relation to a constituent is:
  - (a) the extent to which a difference of concentration of the constituent is:
    - (i) permitted by the standards prescribed by regulation 42 (including the standard set out in subregulation 42(4)); or
    - (ii) necessary because of a difference of concentration of another constituent; or
  - (b) if those standards do not permit any such difference of concentration, and no difference is necessary as mentioned in subparagraph (a)(ii)—nil.
- (3) For the purposes of paragraphs 83(1)(c) and 102(1)(d) of the Code, the prescribed extent is:
  - (a) the extent to which a difference of composition or purity is permitted by the standards prescribed by regulation 42; or
  - (b) if those standards do not permit a difference of composition or purity—nil.

### **42 Prescribed standards for chemical products**

- (1) For the purposes of subparagraph 87(1)(b)(ii) of the Code (which deals with standards for chemical products), all chemical products are prescribed.
- (3) For paragraph 87(1)(a) of the Code, the standard prescribed for a chemical product, or a constituent contained in a chemical product, is:

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- (a) for a product or constituent in respect of which a standard is specified in an order under section 7 of the Act—that standard; or
- (b) for a product or constituent (other than a product or constituent to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code—that standard; or
- (c) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in column 2 of item 1 of Part 2 of Schedule 3B—the established standard for the product; or
- (d) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in column 2 of item 2 of Part 2 of Schedule 3B—the established standard for the product; or
- (e) for a veterinary chemical product or a constituent (other than a product or constituent to which paragraph (a), (b), (c) or (d) applies) 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
- (f) for a product or constituent (other than a product or constituent to which paragraph (a), (b), (c), (d) or (e) applies) in respect of which a standard is specified in the FAO and WHO Specifications for Pesticides—that standard; or
- (g) for a product or constituent (other than a product or constituent to which paragraph (a), (b), (c), (d), (e) or (f) applies) in respect of which the APVMA approved a standard before 1 July 2014 and the approval is still in force—that standard.

- (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:

<b>Concentration of each active constituent as specified on the product label (g/kg or g/L at 20°C)</b>	<b>Standard (allowable variation)</b>
500 or more	± 25 g/kg or g/L of the active constituent
From 250 up to but not including 500	± 5% of the content of the active constituent
From 100 up to but not including 250	± 6% of the content of the active constituent
Less than 100	± 10% of the content of the active constituent

**42A Substances and chemical products exempted from section 88 of the Code**

- (1) For the purposes of paragraph 6(3)(c) of the Act, a substance or a chemical product is exempt from the operation of section 88 of the Code (which provides

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that certain notices are not to be published) if the substance or chemical product is:

- (a) an active constituent that is exempted by the APVMA from the operation of subparagraph 15(1)(a)(i) of the Code; or
  - (b) an active constituent for a listed chemical product; or
  - (c) an active constituent for a proposed or existing chemical product in respect of which the APVMA has issued a permit covered by subregulation (2); or
  - (d) a chemical product in respect of which the APVMA has issued a permit covered by subregulation (2).
- (2) A permit in respect of an active constituent or chemical product is covered by this subregulation if the permit authorises an act or omission in relation to the constituent or product that would otherwise be an offence against, or a contravention of a civil penalty provision mentioned in, section 74, 75, 76 or 78 of the Code.

Note: Sections 74, 75, 76 and 78 of the Code generally prohibit the supply of unapproved active constituents or unregistered or unreserved chemical products, and related acts or omissions.

### 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.

### 43A Division 3 of Part 4 of the Code does not apply to listed chemical products or reserved chemical products

For the purposes of section 89A of the Code, listed chemical products and reserved chemical products are prescribed.

Note: Listed chemical products are specified in Schedule 3B and reserved chemical products are specified in Schedule 3C.



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**44 Record of manufacture or import of date-controlled chemical product**

- (1) For the purposes of paragraph 90(1)(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 Parts 9 and 9A of the Code (which deal with investigative powers and 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(1)(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 must not supply a chemical product unless:
  - (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.

- (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

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- (b) in such a way as to ensure that the record is readily accessible for the purposes of Parts 9 and 9A of the Code (which deal with investigative powers and 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 4.2—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 \$429 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 subregulation 47A(2) 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.

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**47C Hormonal growth promotant not to be supplied etc**

- (1) A person must not supply a hormonal growth promotant unless:
- (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: 50 penalty units.

- (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.

- (3) Subregulation (1) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

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

- (1) A person must not supply a hormonal growth promotant unless:
- (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: 50 penalty units.

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

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

- (4) Subregulation (1) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

#### **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: 30 penalty units.

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

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

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

- (4) Subregulation (1) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

#### **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;

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- (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;
- (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: 30 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*.

- (3) Subregulation (1) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

## 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: 30 penalty units.

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

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

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

- (5) Subregulation (2) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

## **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 Parts 9 and 9A of the Code (which deal with investigative powers and 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: 50 penalty units.

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

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

- (5) Subregulation (2) is a civil penalty provision.

**Part 4** Control of chemical products

**Division 4.2** Supply of hormonal growth promotants

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Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.

**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)(a) 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: 30 penalty units.

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

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

(6) Subregulation (3) is a civil penalty provision.

Note: Division 2 of Part 9A of the Code provides for pecuniary penalties for contraventions of civil penalty provisions.



## Part 5—Analysis

### 55 Analysis of chemical products—tests

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;
- (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 United States Pharmacopoeia;
- (d) any other test approved by the APVMA in writing.

### 55A Prescribed standards for supplied substances

For the purposes of subparagraph 99(3)(j)(i) of the Code, the standard prescribed for an active constituent contained in a chemical product, or a chemical product, is:

- (a) for an active constituent or chemical product in respect of which a standard is specified in an order under section 7 of the Act—that standard; or
- (b) for an active constituent or chemical product (other than a constituent or product to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code—that standard; or
- (c) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in item 1 of Part 2 of Schedule 3B in respect of which there is an established standard—the established standard for the product; or
- (d) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in item 2 of Part 2 of Schedule 3B—the established standard for the product; or
- (e) for a veterinary chemical product or an active constituent (other than a product or constituent to which paragraph (a), (b), (c) or (d) applies) 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;

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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

- (f) for an active constituent or chemical product (other than a constituent or product to which paragraph (a), (b), (c), (d) or (e) applies) in respect of which a standard is specified in the FAO and WHO Specifications for Pesticides—that standard; or
- (g) for an active constituent or chemical product (other than a constituent or product to which paragraph (a), (b), (c), (d), (e) or (f) applies) in respect of which the APVMA approved a standard before 1 July 2014 and the approval is still in force—that standard.

### **56 Analysis at an accredited laboratory**

For the purposes of paragraph 99(4A)(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.

## **Part 5A—Recall notices**

### **56A When a notice of recall is not required to be published**

For the purposes of subsection 106(7) of the Code, the circumstances are that:

- (a) the chemical product has not been supplied to premises where a person can purchase the product; and
- (b) the chemical product has not been supplied to a user of the product.

## Part 6—Permits

### 57 Requirements for issue of permit on application

- (1) Subregulation (2) applies to the issue by the APVMA of a permit on application for a person to do, or omit to do, any thing which would, apart from the permit, be an offence against an eligible law of this jurisdiction.
- (2) For paragraph 112(2)(e) of the Code, the use of the active constituent or chemical product, as proposed in the application for the issue of the permit, must be:
  - (a) a minor use; or
  - (b) an emergency use; or
  - (c) for the purpose of research.

Note: Subregulation (2) does not affect permits issued in relation to an offence mentioned in paragraph 109(a) of the Code or a contravention mentioned in paragraph 109(c) of the Code.

- (3) For paragraph 112(2)(e) of the Code, if the permit is issued for a person to do, or omit to do, any thing which would, apart from the permit, be:
  - (a) an offence against section 121 of the Code; or
  - (b) a contravention of the civil penalty provision referred to in section 121 of the Code;the permit must be expressed to be in force for a period of not more than 90 days.

### 57A Requirements for issue of permit on APVMA's own initiative

For paragraph 112A(2)(b) of the Code, if a permit issued by the APVMA on its own initiative would permit a person to do, or omit to do, any thing which would, apart from the permit, be:

- (a) an offence against section 121 of the Code; or
- (b) a contravention of the civil penalty provision referred to in section 121 of the Code;

the permit must be expressed to be in force for a period of not more than 90 days.

### 57B Duration of permit—extension for further period

For paragraph 115(3A)(b) of the Code, the APVMA must be satisfied that:

- (a) the requirements mentioned in paragraphs 112(2)(e) and (f) of the Code will continue to be met in respect of the permit; and
- (b) for a permit in respect of an active constituent where the APVMA considers that its assessment for paragraph 112(2)(c) of the Code in relation to the issue of the permit is no longer valid—that the requirement mentioned in paragraph 112(2)(c) of the Code is met in respect of the permit; and

- (c) for a permit in respect of a chemical product where the APVMA considers that its assessment for paragraph 112(2)(d) of the Code in relation to the issue of the permit is no longer valid—that the requirement mentioned in paragraph 112(2)(d) of the Code is met in respect of the permit; and
- (d) the holder will continue to be able to comply with the conditions of the permit unless the APVMA is satisfied that special circumstances make the extension for a further period appropriate despite this requirement not being met; and
- (e) none of subparagraphs 112(4)(b)(iv) to (xi) of the Code applies to:
  - (i) the holder; or
  - (ii) any other person who makes, or participates in making, decisions that affect the whole, or a substantial part, of the holder's affairs; or
  - (iii) if the holder is a body corporate—a major interest holder of the body corporate;unless the APVMA is satisfied that special circumstances make the extension for a further period appropriate despite this requirement not being met; and
- (f) the permit is not a permit to which paragraph 112(2)(g) of the Code applied at the time the permit was issued; and
- (g) the permit is not a permit that was taken to have been issued under section 45B or 47D of the Code; and
- (h) if an application has not been made by any person for variation of a relevant particular or condition of approval or registration for the active constituent or chemical product in respect to which the permit is issued—that there are reasonable grounds for the application not having been made.

## Part 7—Manufacture of chemical products

### 59 Part 8 of the Code does not apply to listed chemical products, reserved chemical products and certain other products

- (1) For the purposes of section 120A of the Code, the following chemical products are prescribed:
- (aa) any listed chemical product;
  - (ab) any reserved chemical product;
    - (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:
    - (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.

Note: Listed chemical products are specified in Schedule 3B and reserved chemical products are specified in Schedule 3C.

(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 prescribed**

For the purposes of paragraph 121(4)(a) of the Code, if a product ceases to be prescribed for the purposes of section 120A of the Code, 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 prescribed for the purposes of section 120A of the Code, for a licence authorising the performance of that step in relation to the product;

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is an exempt person in relation to that product during the period beginning when the product ceases to be prescribed for the purposes of section 120A of the Code 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) For paragraph 121(4)(a) of the Code, 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:
  - (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) For paragraph 121(4)(a) of the Code, 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.

### **59E Requirements for issue of licence**

For paragraph 123(1)(b) of the Code, it is a requirement for the issue of a licence that, if directed to do so by the APVMA CEO, the applicant for the licence:

- (a) undergoes an audit by an APVMA inspector, or another person authorised in writing by the APVMA, of the facilities, equipment, systems, processes, procedures and personnel to be used in the manufacture of the chemical products; and
- (b) demonstrates to the satisfaction of the APVMA that the applicant will comply with the conditions to be imposed on the licence if the licence is issued.

### **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.

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- (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;
  - (e) any complaint or product failure in relation to the chemical products, and the investigations and actions undertaken in relation to the complaint or product failure.
- (3A) The holder of a licence must manufacture the chemical products in accordance with:
- (a) the manufacturing principles; and
  - (b) the Australian GMP Code.
- (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

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- (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.
- (7A) The holder of a licence may sub-contract the manufacture of the chemical products only to:
- (a) a manufacturer, or laboratory, licensed by the APVMA to perform a step in the manufacture of the chemical products; or
  - (b) a manufacturer or laboratory located outside Australia that the APVMA has determined complies with a standard of manufacture comparable to the manufacturing principles and the Australian GMP Code.
- (8) If directed by the APVMA CEO, the holder of a licence must:
- (a) undergo an audit by an APVMA inspector, or another person authorised in writing by the APVMA (an *auditor*), of the facilities, equipment, systems, processes, procedures and personnel used in the manufacture of the chemical products (a *GMP audit*); and
  - (b) demonstrate to the satisfaction of the APVMA that the holder is complying with the following conditions of the licence:
    - (i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;
    - (ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;
    - (iii) any of the conditions mentioned in subregulations (3) to (7A) to which the licence is subject.
- (8A) For the purposes of a GMP audit, the holder of the licence:
- (a) must give the auditor access to all facilities, equipment, systems, processes, procedures and personnel used in the manufacture of the chemical products, and any information relevant to the GMP audit; and
  - (b) must not conceal or withhold relevant information from the auditor.
- (8B) If the audit identifies a non-conformance by the holder of the licence that, in the auditor's opinion, is a critical non-conformance, the holder must notify the APVMA in writing of the critical non-conformance within 3 working days of being told of the critical non-conformance by the auditor.
- (8C) Following a GMP audit of the holder of a licence, the holder must:
- (a) within the period determined by the APVMA, give to the APVMA:
    - (i) the original audit report, signed by the auditor, and any associated audit report supplements; and
    - (ii) details of the corrective action the holder proposes to take in relation to any non-conformance identified in the audit report; and
    - (iii) a proposed period for taking the corrective action; and
  - (b) implement the corrective action within the period agreed to or specified by the APVMA; and

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- (c) give to the APVMA evidence demonstrating that the holder is complying with the following conditions of the licence:
  - (i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;
  - (ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;
  - (iii) any of the conditions mentioned in subregulations (3) to (7A) to which the licence is subject.
- (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 a Chapter 5 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 a Chapter 5 body corporate within 3 months after that occurrence.

### **61A Determination following GMP audit**

- (1) For paragraph 6(2)(c) of the Act, this regulation applies if the holder of a licence is directed by the APVMA CEO to undergo a GMP audit under subregulation 61(8).
- (2) On receipt of the information mentioned in subregulation 61(8C), the APVMA must:
  - (a) assess the information, having regard to the following:
    - (i) whether the audit report identified any non-conformances;
    - (ii) whether any non-conformances identified in the audit report have been rectified following corrective action;
    - (iii) any other matters the APVMA considers relevant; and
  - (b) determine whether the APVMA is satisfied that the holder is complying with the following conditions of the licence:
    - (i) any conditions imposed on the licence under subsections 126(1) and (2) of the Code;
    - (ii) the condition mentioned in paragraph 126(4)(a) of the Code, if the licence is subject to that condition;
    - (iii) any of the conditions mentioned in subregulations 61(3) to (7A) to which the licence is subject.

**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

- (1) This regulation applies to an inspector who exercises the power mentioned in paragraph 131A(1)(g) or 132A(1)(g) of the Code to take and keep samples of any thing on any premises.
- (2) The inspector 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 Infringement notices

- (1) For subsection 145DA(1) of the Code, each civil penalty provision mentioned in Schedule 5A is prescribed.
- (2) For subsection 145DB(3) of the Code:
  - (a) the amount (in penalty units) mentioned for an individual in an item of Schedule 5A is the amount that applies for an alleged contravention by the individual of the provision mentioned in the item in the circumstances (if any) mentioned in the item; and
  - (b) the amount (in penalty units) mentioned for a corporation in an item of Schedule 5A is the amount that applies for an alleged contravention by the corporation of the provision mentioned in the item in the circumstances (if any) mentioned in the item.

## Part 9—Miscellaneous

### Division 9.1—Information

#### 65 Information that must be given electronically

- (1) For subsection 156A(2) of the Code, the information mentioned in an item in column 2 of the following table, given to the APVMA in relation to an application or a notice mentioned in column 1 for the item, must be given to the APVMA electronically.

Information that must be given electronically		
Item	Column 1 Application	Column 2 Information
1	Application to which paragraph 10(1)(c) or 27(1)(c) of the Code relates	Information required by the APVMA about a label for a container for the chemical product to which the application relates
1A	Notice under section 26AB of the Code	Information given in relation to the notice
1B	Application under section 26B of the Code	Information given in relation to the application
2	Application to which regulation 8AT applies	Information given in relation to the application
3	Application to which regulation 8B relates	The information mentioned in paragraph 8B(2)(g)
4	Application to which regulation 8D relates	The information mentioned in paragraph 8D(2)(i)
5	Application to which regulation 19AD relates	The information mentioned in paragraph 19AD(2)(i)

- (2) For subsection 156A(2) of the Code, all information required or permitted to be given to the APVMA in an approved form mentioned in subparagraph 8A(a)(i) of the Code or paragraph 26AD(1)(a) or 122(1)(a) of the Code must be given to the APVMA electronically.

#### 65A Period for giving additional information, report or sample—applications

- (1) For subsection 159(1AA) of the Code, subregulations (2) to (4) set out the maximum period that may be stated as the period in which the applicant or holder to whom a notice is issued under section 159 of the Code (the *recipient*) must respond to the notice.
- (2) For an application (other than a timeshift application) for approval, registration, or a permit (other than a permit for emergency use), the maximum period is to be worked out as follows:

$$MP = XP - 1 \text{ month}$$

## Regulation 65B

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where:

*MP* means the maximum period.

*XP* means the extended assessment period mentioned for the application in column 3 of the table in clause 2.1 of Schedule 6 minus the assessment period mentioned for the application in column 2 of that table.

- (3) For a timeshift application, the maximum period is the period agreed to by the APVMA and the applicant.
- (5) For subsection 159(1AB) of the Code, the APVMA may allow a further period if an extraordinary event or circumstance beyond the control of the recipient prevents the recipient from complying with the notice in the period stated in the notice.

### **65B Period for giving additional information, report or sample—suspensions and cancellations**

For subsection 159(1AA) of the Code, the period of 28 days is prescribed for a notice for the purposes of paragraph 159(1)(d) of the Code to suspend or cancel an approval, registration or permit.

### **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 information may be disclosed to a person (*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 holder of the registration of the protected chemical product.
- (3) Information about a chemical product that is not compensatable protected 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 information* means protected information in respect of which compensation for use 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;
- (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

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- (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).

### **69AAA Disclosure of information given with applications under these Regulations**

- (1) Section 162 of the Code applies, with the modifications set out in this regulation:
- (a) in relation to the disclosure of information, about an ingredient in a substance or in a mixture of substances, that is given to the APVMA in connection with an application under these Regulations—as if:
    - (i) the ingredient were an active constituent for a proposed or existing chemical product; and
    - (ii) subparagraphs (3)(a)(i) and (ii) of that section were omitted; and
  - (b) in relation to the disclosure of information, about a substance or a mixture of substances, that is given to the APVMA in connection with an application under these Regulations—as if:
    - (i) the substance or mixture were a chemical product; and
    - (ii) subparagraphs (3)(b)(i) and (ii) of that section were omitted; and
  - (c) if either paragraph (a) or (b) of this subregulation applies—as if subsections (11), (13) and (13A) of that section were omitted.
- (2) The maximum penalty for an offence committed against subsection 162(1), (8) or (9) of the Code, as those subsections apply under subregulation (1), is 50 penalty units.
- (3) For subregulation (1), a reference in section 162 of the Code to confidential commercial information is taken to be a reference to:
- (a) a trade secret relating to the substance, mixture or ingredient; or
  - (b) any other information relating to the substance, mixture or ingredient that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
  - (c) any other information that:
    - (i) concerns the lawful commercial or financial affairs of a person, organisation or undertaking; and
    - (ii) relates to the manufacture, distribution or supply of the substance, mixture or ingredient; and
    - (iii) if it were disclosed, could unreasonably affect the person, organisation or undertaking in an adverse manner.

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- (4) Section 8X of the Code applies in relation to conduct engaged in, in the performance of a function or duty or the exercise of a power, under a provision mentioned in subsection (1) of that section (to the extent that the provision applies in relation to an application made under these Regulations), as if:
- (a) the reference in that section to confidential commercial information were a reference to information covered by paragraph (3)(a), (b) or (c) of this regulation; and
  - (b) the reference in that section to section 162 of the Code were a reference to section 162 of the Code as it applies under subregulation (1); and
  - (c) the reference in that section to subsection 162(1A) of the Code were a reference to that subsection as it applies under subregulation (1).

## Division 9.2—Fees

### 69A Payment of fees

A fee prescribed by these Regulations and payable under the Code:

- (a) is payable to the APVMA; and
- (b) must be paid by electronic means.

Note: Unless otherwise specified, GST is not payable in respect of fees prescribed by these Regulations.

### 69AA Prescribed fee for notices of notifiable variations

#### *Prescribed fee*

- (1) For the purposes of subsection 164(1) of the Code, \$50 is the prescribed fee for lodging a notice under Division 2AA of Part 2 of the Code.

#### *Notices for which prescribed fee is not payable*

- (2) However, a prescribed fee is not payable for lodging a notice under Division 2AA of Part 2 of the Code for:
  - (a) variations of the relevant particulars of the registration of a chemical product in respect of one or more active constituents of the product if the variation:
    - (i) is to vary the particulars of one or more constituents listed for the product in an interchangeable constituent determination; and
    - (ii) in the case of a product in respect of which 9 or more constituents are entered in the Register—is to no more than 25% of those constituents; and
    - (iii) in the case of a product in respect of which fewer than 9 constituents are entered in the Register—is to no more than 2 of those constituents; or
  - (b) variations of the relevant particulars of the approval of a label for containers for a chemical product if:
    - (i) the variation is the result of a notifiable variation of a kind mentioned in subregulation (3); and
    - (ii) the varied label would not include misleading or deceptive information about the use, safety, environmental impact or efficacy of the product.
- (3) For the purposes of subparagraph (2)(b)(i), the kinds of notifiable variations are the following:
  - (a) a variation of the net contents of an agricultural chemical product, but only if:
    - (i) the variation will not result in the instructions for the use or disposal of the product, or the containers for the product, being modified or affected; and

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- (ii) the net contents of the product, as varied, is in the range recorded in the Register for the product;
- (b) a variation of the instructions for the use of a chemical product, but only if:
  - (i) the variation is to remove the use of the product from the instructions; and
  - (ii) the variation of the instructions will not otherwise modify or affect the instructions for another use of the product.

**69B Fees for pre-application assistance**

- (1) For section 164 of the Code, this regulation provides for the fees payable in respect of pre-application assistance provided by the APVMA under regulation 8AT.
- (3) The fee for one unit, or a part of one unit, of pre-application assistance is \$192.50 (GST inclusive).
- (4) A person applying for pre-application assistance under regulation 8AT must pay the fee that would be payable for 2 units of pre-application assistance (regardless of the assistance to be given by APVMA) when the application is lodged.
- (5) If more than 2 units of pre-application assistance are provided by the APVMA to the person in relation to the application, the person must pay the fee for each additional unit, or part of a unit, of pre-application assistance provided to the person when the APVMA issues an invoice for the fee.

Note: Regulation 70 provides for pre-application assistance fees to be rebated from fees payable for certain applications, up to a maximum rebate amount.

**70 Fees for applications**

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

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

- (2) The fee (the **application fee**) payable for an application of a kind described in column 1 of an item of the table in clause 2.1 of Schedule 6 is as follows:
  - (a) if the application is a timeshift application—the fee in column 5 of item 27 of the table; and
  - (b) otherwise—the fee in column 5 of the applicable item.
- (2A) Without limiting paragraph (2)(b), a fee in column 5 of an item of the table may be expressed as an amount specified in, or worked out in accordance with, a legislative instrument made by the APVMA.
- (3) If any pre-application assistance fee is paid in relation to an application, the application fee for the application is reduced by the amount of pre-application assistance fee paid (excluding GST).

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(4) However, the maximum amount by which the application fee may be reduced under subregulation (3), for an application of a kind mentioned in Column 1 of an item of the table in clause 2.1 of Schedule 6, is the amount mentioned in column 4 for the item.

(4AA) Without limiting subregulation (4), an amount in column 4 of an item of the table may be expressed as an amount (if any) specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

(4A) Subject to subregulation (4), the reduction in application fee provided by subregulation (3) in relation to an application lodged by an applicant may be applied in respect of any application lodged by the applicant.

(5) A reference in column 5 of an item of the table in clause 2.1 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 70A.

(6) The minimum amount of the application fee that is required to be paid at the time of making an application is as follows:

(a) if the application fee for the application is less than \$710—the total amount of the application fee;

(b) in any other case—\$710.

Note: Subparagraph 8A(a)(iii) of the Code states that an application must be accompanied by so much of the prescribed fee as is required to be paid when the application is made.

(7) The balance, if any, of the application fee is payable within 28 days of the date of the notice given to the applicant in relation to the application under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations.

(8) 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 Modular assessment fees

(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 mentioned in an item in Schedule 7, in relation to an application, is the fee (if any) mentioned for the item in column 3 of Schedule 7.
- (4) The **modular assessment fee** for an application is the sum of the fees payable for:
  - (a) the preliminary 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 11.3 in Schedule 7 that the application must undergo.

### **70B Recategorised applications**

- (1) This regulation applies if:
    - (a) both of the following apply:
      - (i) the fee mentioned in subregulation 70(2) (the **application fee**) has been paid in relation to an application on the basis that the application is of a kind mentioned in an item of the table in clause 2.1 of Schedule 6 (the **original item**);
      - (ii) the APVMA determines, at any time after preliminary assessment of the application, that the application is more correctly categorised as an application of a kind mentioned in a different item of the table (the **recategorised item**); or
    - (b) both of the following apply:
      - (i) the application fee has been paid in relation to an application on the basis that particular modules, levels and types mentioned in Schedule 7 (the **original modules**) are necessary for the application;
      - (ii) the APVMA considers, at any time after preliminary assessment of the application, that different modules, levels and types mentioned in Schedule 7 (the **recategorised modules**) are necessary for the application.
  - (2) If the application fee is the same as the fee payable under subregulation 70(2) for the recategorised item or recategorised modules, the APVMA must notify the applicant, in writing:
    - (a) that the APVMA has recategorised the application and will proceed with the assessment of the application; and
    - (b) if the assessment period for the recategorised item or recategorised modules is different from the assessment period for the original item or original modules—of the assessment period for the application.
  - (3) If the application fee is less than the fee payable under subregulation 70(2) for the recategorised item or recategorised modules:
    - (a) the APVMA must notify the applicant, in writing:
      - (i) that the APVMA has recategorised the application; and
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- (ii) that the applicant must pay the difference between the application fee and the fee payable under subregulation 70(2) for the recategorised item or recategorised modules (the **additional amount**) before the APVMA can determine the application; and
  - (iii) that the additional amount is payable within 28 days of the date of the notice; and
  - (iv) that the APVMA must refuse the application if the additional amount is not paid by that date; and
  - (v) that the applicant may withdraw the application; and
  - (vi) if the assessment period for the recategorised item or recategorised modules is different from the assessment period for the original item or original modules—of the assessment period for the recategorised item or recategorised modules; and
  - (b) for section 164 of the Code, the applicant must pay the additional amount within 28 days of the date of the notice; and
  - (c) for paragraph 164(8)(b) of the Code, the APVMA may waive the additional amount if the application is refused on the basis that the additional amount has not been paid within 28 days of the date of the notice.
- (4) If the application fee is more than the fee payable under subregulation 70(2) for the recategorised item or recategorised modules:
- (a) the APVMA must notify the applicant, in writing:
    - (i) that the APVMA has recategorised the application; and
    - (ii) of the amount of the fee for the recategorised item or recategorised modules; and
    - (iii) that the applicant is entitled to a refund of the difference between the application fee and the fee payable under subregulation 70(2) for the recategorised item or recategorised modules; and
    - (iv) that the APVMA will proceed with the assessment of the application; and
    - (v) if the assessment period for the recategorised item or recategorised modules is different from the assessment period for the original item or original modules—of the assessment period for application; and
  - (b) the APVMA must, as soon as practicable, remit to the applicant the difference between the application fee and the fee payable under subregulation (2) for the recategorised item or recategorised modules.

### 71A Fees for continued registration of chemical product

- (1) For the purposes of section 164 of the Code, the fee payable for an application for the renewal, or further renewal, of the registration of a chemical product that is made in a financial year specified in an item of column 1 of the table is:
- (a) if the application is for the renewal, or further renewal, of the product for a period of 12 months—the amount specified in column 2 of the item; or
  - (b) if the application is for the renewal, or further renewal, of the product for a period for 5 years—the amount specified in column 3 of the item.



<b>Item</b>	<b>Column 1 Financial year</b>	<b>Column 2 12 month renewal</b>	<b>Column 3 5 year renewal</b>
1	Financial year beginning on 1 July 2020	\$550	\$3,350
2	Financial year beginning on 1 July 2021 and later financial years	\$600	\$3,650

- (2) In addition, for section 164 of the Code, an annual fee (the *overseas GMP compliance assessment fee*) is payable by the holder, in relation to the registration of a veterinary chemical product, for each site outside Australia at which:
- the product is manufactured; or
  - a step in the manufacture of the product occurs.
- (3) However, the overseas GMP compliance assessment fee is not payable:
- in relation to a site if the holder has, in the financial year in respect of which the fee is payable, already paid an overseas GMP compliance assessment fee in relation to another chemical product manufactured at the same site; or
  - in relation to a chemical product that is prescribed under regulation 59 for the purposes of section 120A of the Code.
- (4) The amount of the overseas GMP compliance assessment fee is \$1 000 for each financial year for which the registration is in force.
- (5) The overseas GMP compliance assessment fee for a financial year is payable on or before the last day for payment of the fee shown on an invoice issued for the fee by the APVMA for the financial year.
- (6) A fee payable under this regulation is not refundable if the registration of the chemical product is subsequently suspended or cancelled.

### **71B Overseas GMP compliance assessment**

- (1) This regulation applies in relation to the registration of a veterinary chemical product if:
- the product is manufactured outside Australia; and
  - the product is not prescribed under regulation 59 for the purposes of section 120A of the Code; and
  - the registration of the product is subject to a condition that each step in the manufacture of the product complies with any of the following:
    - the Code;
    - the manufacturing principles;
    - the Australian GMP Code;
    - any standards that apply to the chemical products;

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- (v) any standard determined by the APVMA to be comparable to the manufacturing principles or the Australian GMP Code; and
  - (d) the registration of the product is subject to a condition that the holder in relation to the registration must, if directed by the APVMA CEO, give to the APVMA, or arrange for the manufacturer of the product to give to the APVMA, evidence of compliance with the condition mentioned in paragraph (c).
- (2) For paragraph 6(2)(c) of the Act, subregulations (3) and (4) apply if the APVMA CEO has directed the holder to provide evidence of compliance with the condition mentioned in paragraph (1)(c).
- (3) If a GMP audit was carried out, and a report of the audit has been given to the APVMA, the APVMA must assess the report having regard to:
- (a) whether the audit report identified any non-conformances; and
  - (b) whether any non-conformances identified in the audit report have been rectified following corrective action; and
  - (c) any other matters that the APVMA considers relevant.
- (4) The APVMA must:
- (a) assess any evidence of compliance with the condition given to the APVMA by the holder or on behalf of the holder; and
  - (b) determine whether the APVMA is satisfied that the condition has been complied with.
- (3) In this regulation:

**GMP audit** has the meaning given by paragraph 61(8)(a).

### 71C Fees for applications relating to holder or nominated agent

For section 164 of the Code, the following fees are prescribed:

- (a) for an application under section 8L of the Code to change the holder of an approval or registration—\$50;
- (b) for an application under section 8M of the Code to nominate a nominated agent—\$50;
- (c) for an application under section 8P of the Code to change a nominated agent—\$50.

### 72 Remission and waiver of fees for applications

- (1) For paragraph 164(8)(b) of the Code, this regulation prescribes circumstances in which the APVMA may remit the whole or part of a fee that has been paid, or waive a fee that is payable.
- (2) The APVMA may remit the whole or part of a fee paid in respect of an application if:
  - (a) the APVMA refuses the application under subsection 11(3), 28(3) or 110A(4) of the Code; or

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- (b) the APVMA refuses the application under paragraph 8A(d) of the Code on the basis that:
- (i) the applicant failed to give the APVMA the number of copies of the application required by the notice issued for the application under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations; or
  - (ii) failed to give the APVMA the copies in the form required by that notice.

Note: The APVMA may also waive a fee that is payable, or remit a fee that was paid, in respect of an application to the APVMA that is to be or has been withdrawn—see paragraph 164(8)(a) of the Code.

- (3) The APVMA may remit the whole or part of a fee paid in respect of an application, other than an application for the renewal of the registration of a chemical product or for a permit, if the application is not determined within the period worked out for the application under regulation 76.
- (4) The APVMA may remit the whole or part of a fee paid in respect of a module of assessment specified in Schedule 7 if the module is not completed within the time specified for the module in Schedule 7.
- (5) If the APVMA refuses an application on the basis that the applicant failed to pay the balance of the application fee for the application, as required by a notice issued for the application under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations, the APVMA may waive the balance of the application fee.
- (6) In any other circumstances, the APVMA may waive or remit the whole or part of a fee payable or paid under the Code or these Regulations, if the APVMA considers it desirable to do so.
- (7) In this regulation:  
*application fee* has the meaning given by subregulation 70(2).

**72A Fees for licences**

- (1) For section 164 of the Code, this regulation prescribes matters relating to fees payable in respect of licences issued under Part 8 of the Code.

*Fee for licence application*

- (2) The fee payable for an application for the issue of a licence is \$900.

*Annual licence fee*

- (3) The holder of a licence must pay an annual licence fee, for each financial year in which the licence is held, as follows:
  - (a) for a category 1 licence—\$7 500;
  - (b) for a category 2, 3 or 4 licence—\$5 000;
  - (c) for a category 6 licence—\$1 800;

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(d) for a multi-category licence—\$7 500.

- (4) However, if a licence is issued on a date other than on 1 July in a financial year, the annual licence fee payable for the first financial year of the licence is a pro rata amount of the fee mentioned for the licence in subregulation (3) for the number of whole months of the financial year remaining on the date the licence is issued.
- (5) The annual licence fee payable for a licence for the second financial year, and each subsequent financial year, in which the licence is held is reduced by 50% if the licence holder gives the APVMA satisfactory evidence that the total notional wholesale value of the chemical products manufactured under the licence in the previous financial year was less than \$50 000.
- (6) If a licence is not in force on 1 July of a financial year because the licence is suspended:
- (a) an annual licence fee is not payable for the licence for that financial year unless the suspension is revoked later in the financial year; and
  - (b) the amount payable is a pro rata amount of the fee mentioned for the licence in subregulation (3) for the number of whole months of the financial year remaining on the date of the revocation.
- (7) The annual licence fee is payable on receipt of an invoice for the fee issued by the APVMA.

*Fee for variation of licence*

- (8) An additional fee of \$1 800 is payable in respect of a licence if:
- (a) the holder of the licence requests that the APVMA vary the licence; and
  - (b) the APVMA determines that a GMP audit is required in order to assess the request.
- (10) In this regulation:

**GMP audit** has the meaning given by paragraph 61(8)(a).

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

- (11) In subregulation (5):
- (a) 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
  - (b) a reference to the chemical products manufactured does not include veterinary products that are prescribed under regulation 59 for the purposes of section 120A of the Code.

Note: Section 3 of the *Agricultural and Veterinary Chemical Products (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.”

### 73 Fees for copies and extracts

- (1) Subject to subregulation (3), the prescribed fee:
  - (aa) under subsection 8W(2) of the Code—for a copy of, or extract from, a document (other than a document in any part of the Record or Register) in the possession or custody of the APVMA in relation to an approved active constituent or registered chemical product; or
  - (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) \$95; and
  - (b) \$95 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
  - (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, in respect of any matter referred to in subregulation (1), by:
  - (i) an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159(1)(a), (b), or (d) of the Code; or
  - (ii) the collecting agency.

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**73A Fees for converting information and documents into electronic form**

- (1) This regulation applies if, on or after 1 July 2015:
  - (a) a person gives to the APVMA information or documents (***required material***) in hard copy form that, under the Code or these Regulations, must or may accompany an application; and
  - (b) under the Code or these Regulations the required material is not required to be given electronically.
- (2) The APVMA must notify the person that:
  - (a) the APVMA will convert the required material into electronic form; and
  - (b) the person will be required to pay the prescribed fee, as worked out under subregulation (6), for the conversion of the required material.
- (3) If the APVMA converts the required material into electronic form it must give the person a written notice specifying the prescribed fee to be paid for the conversion and the period within which the fee must be paid.
- (4) The person must pay the prescribed fee specified in the notice under subregulation (3) within the period specified in the notice.
- (5) The period specified in the notice under subregulation (3) must not be more than 14 days after the day the notice is given.
- (6) The prescribed fee is the sum of:
  - (a) \$90; and
  - (b) \$90 for each hour or part of an hour, after the first hour, of work done by the APVMA to convert the required material into electronic form.

## **Division 9.3—Notification, assessment periods and review**

### **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 subsection 165(1) of the Code, the period for determining an application of a kind specified in column 1 of an item of the table in clause 2.1 of Schedule 6 is the period (if any) specified in column 2 of that item, subject to regulations 76A and 76B.

(1A) Without limiting subregulation (1), a period specified in column 2 of an item of the table may be expressed as a period specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

(1B) If:

- (a) an application is of the kind mentioned in section 10 or 27 of the Code (the *primary application*); and
- (b) the applicant makes another application of the same kind as the primary application (the *secondary application*); and
- (c) the secondary application is made at the same time as the primary application; and
- (d) the applicant nominates the secondary application as an application related to the primary application; and
- (e) the chemical products to which the primary and secondary applications relate would have, if the applications were approved:
  - (i) the same identifying information for the holder of the registration of the chemical products; and
  - (ii) the same manufacturer; and
  - (iii) the same address at which the chemical products are manufactured; and
  - (iv) the same active constituent on the label of the chemical products;

then, the period applicable under subregulation (1) and applicable to the primary application also applies to the secondary application.

(2) A reference in column 2 or 3 of an item of the table in clause 2.1 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;

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the APVMA must determine the application as soon as is practicable in the circumstances of the case.

### 76A Extended assessment periods

- (1) This regulation specifies extended assessment periods that apply to applications.
- (2) An extended assessment period applies to an application of a kind mentioned in an item of the table in clause 2.1 of Schedule 6 (other than a timeshift application) if the APVMA gives a notice to the applicant under section 159 of the Code in relation to the application.
- (3) However subregulation (2) does not apply to an application if the application is an application to which an extended assessment period has previously applied under subregulation (2).
- (4) The *extended assessment period* for an application to which subregulation (2) applies is the period mentioned in column 3 of the table in clause 2.1 of Schedule 6 for the item.
- (5) Without limiting subregulation (4), a period mentioned in column 3 of an item of the table may be expressed as a period specified in, or worked out in accordance with, a legislative instrument made by the APVMA.

### 76B Extension of assessment period or extended assessment period for recategorised applications

- (1) The assessment period or extended assessment period for an application is extended if:
  - (a) the APVMA recategorises the application under regulation 70B; and
  - (b) an additional amount is payable by the applicant under subregulation 70B(3).
- (2) The extension of the assessment period or extended assessment period for the application is the period:
  - (a) starting on the date of the notice given by the APVMA under subregulation 70B(3); and
  - (b) ending on the date on which the applicant pays the additional amount.

### 77 Meaning of *modular assessment period*

For the purposes of the table in clause 2.1 of Schedule 6, the *modular assessment period* for an application of a kind specified in column 1 of that table is:

- (a) in the case of a timeshift application—the assessment period set out in the project plan for the application; and
- (b) in the case of any other kind of application—the sum of:
  - (i) for each of the assessment modules set out in items 2.1 to 10.3 of the table in Schedule 7 that the APVMA considers necessary for the



- application to undergo—the longest of the periods specified in column 2 of the table for those items; and
- (ii) for the type of finalisation set out in items 11.1 to 11.3 of the table in Schedule 7 that the APVMA considers necessary for the finalisation of the application—the period specified for that item.

## **78 Commencement of assessment period**

- (1) For an application of a kind mentioned in an item of the table in clause 2.1 of Schedule 6 (other than item 13A), the period specified in column 2 or 3 of the item commences on the following date:
- (a) if the notice issued in relation to the application under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations, required the applicant to pay an amount of application fee for the application, or provide a number of copies of the application, or both—the date on which the applicant complies with all requirements in the notice;
- (b) in any other case—on the date of the notice issued under subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations, in relation to the application.
- (2) For an application of a kind mentioned in item 13A of the table in clause 2.1 of Schedule 6, the period specified in column 2 or 3 of the item commences when the application is lodged.

## **78A Period for determining applications relating to holders and nominated agents**

For subsection 165(1) of the Code, the APVMA must determine an application made under section 8L, 8M or 8P of the Code within 1 month after the application is lodged.

## **78AA Period for determining applications for renewal of registration**

For the purposes of subsection 165(1) of the Code, the APVMA must determine an application for the renewal of the registration of a chemical product within 1 month after the application is lodged.

## **78B Period within which APVMA is to conclude reconsiderations**

- (1) This regulation is made for subsection 165A(1) of the Code.
- (2) The reconsideration period starts immediately after the end of the period specified in the notice given by the APVMA in relation to the reconsideration under paragraph 32(1)(b) of the Code.
- (3) A reconsideration of an approval or registration is concluded when the APVMA:
- (a) gives a notice in relation to the reconsideration under paragraph 34AC(1)(a) of the Code; or

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(b) suspends or cancels the approval or registration under section 34AA of the Code.

(4) The period in which the APVMA must conclude a reconsideration of an approval or registration (the *reconsideration assessment period*) is to be worked out in accordance with the formula in subregulation (5).

(5) The formula is:

$$A + B + 2E + 3C + J + D + X$$

where:

*A* means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 3.1, 3.2, 3.3, 4.1, 7.1, 7.2, and 7.3 of Schedule 7 that the APVMA determines are necessary for the reconsideration.

Example: If the APVMA determines that items 3.1, 4.1 and 7.3 of Schedule 7 are necessary for the reconsideration, *A* is the longest of the periods in column 2 for those items, which is 13 months (the period for item 3.1).

*B* means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 2.1 to 2.3, 5.1, 5.2, 5.4, 6.1 to 6.3, 9, and 10.1 to 10.3 of Schedule 7 that the APVMA determines are necessary for the reconsideration.

*C* means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 11.1, 11.2 or 11.3 of Schedule 7 that the APVMA determines are necessary for the reconsideration.

*D* means 4 months.

*E* means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 8.1, 8.2 or 8.3 of Schedule 7 that the APVMA determines are necessary for the reconsideration.

*J* means:

- (a) if the APVMA must consult each coordinator designated for a jurisdiction about the reconsideration in accordance with subsection 34A(3) of the Code—3 months; and
- (b) in any other case—nil.

*X* means:

- (a) if the APVMA appoints an arbitrator under section 64 of the Code—3 months; and
- (b) in any other case—nil.

### 78C Review of decisions by Administrative Appeals Tribunal

For paragraph 167(1)(y) of the Code, the following decisions are prescribed:

- (a) a decision to refuse an application under subsection 8L(3) of the Code;
- (b) a decision to refuse an application under subsection 8M(3) of the Code;
- (c) a decision to refuse an application under subsection 8P(3) of the Code;

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- (caa) a decision to refuse an application under regulation 8AS;
- (ca) a decision to refuse an application, in whole or part, made under regulation 19AEB;
- (d) a decision to refuse an application under subclause 10(4) of Schedule 3AA.

## Division 9.4—Logo of APVMA

### 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.

## **Part 10—Transitional and application provisions**

### **Division 10.1—Transitional provisions for Agricultural and Veterinary Chemicals Legislation Amendment Act 2013**

#### **80 Definitions**

In this Division:

*Amendment Act* means the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

*commencement time* means the time when item 1 of Schedule 1 to the Amendment Act commences.

*old Code application* means an application:

- (a) lodged with the APVMA before 1 July 2014; and
- (b) in respect of which a notice was given to an approved person under section 11A of the old Code before 1 July 2014; and
- (c) not determined before 1 July 2015.

#### **82 Continuation of old Code requirements for old Code applications**

For subitem 58(1) of Schedule 6 to the Amendment Act, and despite item 47 of Schedule 6 to the Amendment Act, the requirements of paragraphs 11(1)(b), 28(1)(b), 56J(1)(b), 56T(1)(b), 110(2)(b) and 122(1)(b) of the old Code continue to apply to an old Code application on and after 1 July 2015.

#### **83 Preliminary notices issued under old Code**

- (1) This regulation applies to an old Code application if:
  - (a) a notice was issued under subsection 11A(3) of the old Code requiring the applicant to rectify defects in the application; and
  - (b) the period for rectifying the defects (the *rectification period*)—ends after 30 June 2015; and
  - (c) the applicant has not rectified the defects before 1 July 2015.

Note: Paragraph 11A(3)(a) of the old Code provides that the notice must require the applicant to rectify the defects within 1 month or such further period as the APVMA allows.

- (2) For subitem 58(1) of Schedule 6 to the Amendment Act, the APVMA must:
  - (a) for an application made under section 10 of the old Code:
    - (i) complete a preliminary assessment of the application under section 11 of the new Code within 1 month of the earlier of the following dates:
      - (A) the day the applicant has rectified all of the defects;
      - (B) the last day of the rectification period; and

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- (ii) comply with the requirements of subsection 11(2) and (3) of the new Code; and
- (b) for an application made under section 27 of the old Code:
  - (i) complete a preliminary assessment of the application under section 28 of the new Code within 1 month of the earlier of the following dates:
    - (A) the day the applicant has rectified all of the defects;
    - (B) the last day of the rectification period; and
  - (ii) comply with the requirements of subsection 28(2) and (3) of the new Code.

### 84 Assessment periods for old Code applications

- (1) For subitem 58(1) of Schedule 6 to the Amendment Act, the remaining period, after 30 June 2015, within which the APVMA must determine an old Code application (the *remaining period*) is to be worked out in accordance with the following formula:

$$\left( P \times 30 \right) - \left( O - R \right)$$

where:

**O** means the number of days in the period starting on the day the assessment period for the application commenced under regulation 78 or 78A of the old Code (the *commencement date*), and ending on 30 June 2015.

**P** means the number of months within which the APVMA would have been required to determine the application, under subregulation 76(1) or (1A), if the application had been made on or after 1 July 2014.

**R** means the number of days in the period starting on the commencement date and ending on 30 June 2015 to which no regard was to be had, under paragraph 165(2)(a) of the old Code, in working out the period within which the application was to be determined under the old Code.

- (2) If the remaining period worked out under subregulation (1) for an application is zero or less than zero, no remaining period applies to the application.
- (3) The remaining period (if any) within which the APVMA must determine the application, worked out in accordance with subregulation (1), commences on 1 July 2015.
- (4) However, if:
- (a) the APVMA issues a notice under subsection 159(1) of the old Code before 1 July 2015 requiring the applicant to comply with a requirement; and
  - (b) the applicant has not, before 1 July 2015, complied with the notice; and
  - (c) the time specified in the notice for complying with the notice, or extended by the APVMA under subsection 159(1) (the *compliance date*) ends on or after 1 July 2015;

the remaining period does not commence until the earliest of the following dates:

- (d) the day the applicant complies with the notice;
  - (e) the compliance date.
- (5) This regulation has effect despite regulations 76, 76A, 76B and 78.

### **85 Reconsiderations commenced under old Code**

- (1) This regulation applies to a reconsideration begun under Division 4 of Part 2 of the old Code before 1 July 2014, but not concluded by 1 July 2015.
- (2) Section 31 of the new Code applies to the reconsideration as if the reference in subsection 31(2) to “commencing the reconsideration” were a reference to “1 July 2015”.

Note: Section 31 of the new Code requires the APVMA to prepare and maintain a work plan for each reconsideration.

- (3) For subsection 165A(1) of the Code, the remaining period, after 30 June 2015, within which the APVMA must conclude the reconsideration (the **reconsideration assessment period**) is to be worked out in accordance with the formula:

$$A + B + 2E + 3C + J + D + X$$

where:

**A** means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 3.1, 3.2, 3.3, 4.1, 7.1, 7.2, and 7.3 of Schedule 7 that the APVMA determines are necessary after 1 July 2015 for the reconsideration.

Example: If the APVMA determines that items 3.1, 4.1 and 7.3 of Schedule 7 are necessary after 1 July 2015 for the reconsideration, **A** is the longest of the periods in column 2 for those items, which is 13 months (the period for item 3.1).

**B** means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 2.1 to 2.3, 5.1, 5.2, 5.4, 6.1 to 6.3, 9, and 10.1 to 10.3 of Schedule 7 that the APVMA determines are necessary after 1 July 2015 for the reconsideration.

**C** means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 11.1, 11.2 or 11.3 of Schedule 7 that the APVMA determines are necessary after 1 July 2015 for the reconsideration.

**D** means 4 months.

**E** means the longest of the periods, in months, mentioned in column 2 of Schedule 7 for whichever of items 8.1, 8.2 or 8.3 of Schedule 7 that the APVMA determines are necessary after 1 July 2015 for the reconsideration.

**J** means:

- (a) if the APVMA must, after 1 July 2015, consult each coordinator designated for a jurisdiction about the reconsideration in accordance with subsection 34A(3) of the Code—3 months; and

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**Division 10.1** Transitional provisions for Agricultural and Veterinary Chemicals Legislation Amendment Act 2013

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(b) in any other case—nil.

**X** means:

(a) if the APVMA appoints an arbitrator under section 64 of the Code after 1 July 2015—3 months; and

(b) in any other case—nil.

(4) The remaining period within which the APVMA must conclude the reconsideration, worked out in accordance with subregulation (3), commences on 1 July 2015.

(5) However, if:

(a) the APVMA issues a notice in relation to the reconsideration under subsection 33(1) or 159(1) of the old Code before 1 July 2015; and

(b) the holder of the approval or registration under reconsideration has not, before 1 July 2015, complied with the notice; and

(c) the time specified in the notice for complying with the notice (the **compliance date**) ends on or after 1 July 2015;

the remaining period does not start until the earliest of the following dates:

(a) the day the holder complies with the notice;

(b) the compliance date.

(6) Subregulations (3) to (5) have effect despite regulation 78B.



**Division 10.2—Amendments made by the Agricultural and  
Veterinary Chemicals Legislation Amendment  
Regulation 2014**

**86 Operation of Schedule 1 to the *Agricultural and Veterinary Chemicals  
Legislation Amendment Regulation 2014***

The amendments of these Regulations made by Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014* apply to acts, omissions, matters and things happening on or after the commencement of that Schedule.

## **Division 10.3—Application of amendments made by the Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014**

### **87 Application of amendments in relation to existing approvals of labels**

- (1) This regulation applies if:
  - (a) immediately before 1 January 2015 the distinguishing name (the **approved product name**) of a chemical product is contained on a label for containers of the chemical product; and
  - (b) an approval of the label (the **label approval**) with the approved product name was in force immediately before 1 January 2015.
- (2) Subject to these Regulations, on and after 1 January 2015 the label approval continues in force as follows:
  - (a) the approved product name is taken to be the name of the chemical product that is to appear on a label for containers of the chemical product as prescribed under paragraph 17(1)(b);
  - (b) the approved product name is taken to be recorded in the relevant APVMA file in relation to the label approval in accordance with subparagraph 21(c)(iva) of the Code; and
  - (c) the distinguishing number of the chemical product that is entered in the Register immediately before 1 January 2015 in relation to the label approval is taken to be recorded in the relevant APVMA file in accordance with subparagraph 21(c)(iva) of the Code.

Note: The *Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014* amended these Regulations by substituting a new paragraph 17(1)(b) and inserting new paragraphs 17(3)(c) and (d). The effect of the amendments was to change how approvals of labels for containers for chemical products take place. The amendments commenced on 1 January 2015.

## **Division 10.4—Amendments made by the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019**

### **88 Definitions**

In this Division:

*amending regulations* means the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019*.

*commencement day* means the day on which the amending regulations commence.

### **89 Applications**

The amendments of these Regulations made by the amending regulations apply in relation to applications made on or after the commencement day.

### **90 Exemption from operation of section 88 of the Code**

Regulation 42A, as inserted by the amending regulations, applies to a substance or chemical product covered by paragraph 42A(1)(a), (b), (c) or (d) whether the substance or chemical product first meets the requirement of the applicable paragraph before, on or after the commencement day.

**Part 10** Transitional and application provisions

**Division 10.5** Amendments made by the Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020

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**Division 10.5—Amendments made by the Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020**

**91 Notices of intention to supply hormonal growth promotant**

The amendment of subregulation 47(2) of these Regulations made by the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020* applies in relation to a notice given on or after 1 July 2020.

**92 Applications**

The amendments of Schedules 6 and 7 to these Regulations made by the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020* apply in relation to applications made on or after 1 July 2020.

**Division 10.6—Amendments made by the Agricultural and  
Veterinary Chemicals Code Amendment (Miscellaneous  
Measures) Regulations 2021**

**93 Minor use**

Regulation 3AA, as inserted by Schedule 1 to the *Agricultural and Veterinary Chemicals Code Amendment (Miscellaneous Measures) Regulations 2021*, applies in relation to applications made under section 110 of the Code on or after the commencement of this regulation.

**Part 10** Transitional and application provisions

**Division 10.7** Amendments made by the Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021

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**Division 10.7—Amendments made by the Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021**

**94 Applications for variation for chemical products**

The amendment of regulation 19AD made by Part 3 of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021* applies in relation to applications made under section 27 of the Code on or after the commencement of this regulation.

## **Schedule 1—Date-controlled agricultural chemical products**

(paragraph 4(b))

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- |   |  |
|---|--|
| 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   |
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## Schedule 3—Definition of agricultural chemical product

(regulation 7)

### Part 1—Preliminary

#### 1 Definitions

In this Schedule:

**air conditioning** means any cooling, heating or ventilation system that modifies the condition of the air.

**cooling tower** means:

- (a) a device for lowering the temperature of water or other liquid by evaporative cooling; and
- (b) an evaporative condenser that incorporates a device containing a refrigerant or heat exchanger.

**open water cooling system** means a water cooling system through which water flows once with no recirculation.

**ore extraction and processing** means the crushing and separating of ore into valuable substances or waste.

**sewage** means waste matter, including, but not limited to, household waste liquid from toilets, baths, showers, kitchens and sinks, that is disposed of using sewers.

**sewage treatment** means the physical, chemical and biological processes applied to sewage to remove physical, chemical and biological contaminants to produce wastewater, and a solid waste or sludge, suitable for disposal or re-use in the environment.

**wastewater** means the water remaining at the end of sewage treatment that may be released into the environment for re-use.

**water cooling system** means a cooling tower and its associated equipment and pipe work.



## **Part 2—Substances or mixtures declared to be agricultural chemical products**

<b>Item</b>	<b>Class of substance or mixture of substances</b>
1	Dairy cleansers for on-farm use
2	Any substance used in conjunction with an agricultural chemical product to identify areas treated with that product
3	Insect repellents for use on human beings
4	Sanitisers for use in swimming pool or spa water, including chlorine-based swimming pool and spa products
5	Any biocidal substance contained or used in a device for the sanitising of swimming pool or spa water
6	Parts of a vertebrate animal, material produced from a vertebrate animal or matter the production of which involves the use of a vertebrate animal, if represented supplied or used for a purpose mentioned in subsection 4(2) of the Code

## Part 3—Substances or mixtures declared not to be agricultural chemical products

Item	Class of substance or mixture of substances
1	Any mould inhibitor for use in the manufacture of paper, paper pulp, glue, plywood, carpets, plastics, glass, fabrics, domestic items, bedding material, leather goods or surface coatings (including paint but excluding antifouling paint), if: <ul style="list-style-type: none"> <li>(a) the mould inhibitor is incorporated into the product during manufacture for the protection of the goods; and</li> <li>(b) the mould inhibitor is not released into the environment from the manufactured product; and</li> <li>(c) the manufactured product is not claimed to have any effect as an agricultural chemical product</li> </ul>
2	Any fungicide, bactericide or deodorant for use in footwear and clothing
3	Any soil ameliorant, conditioner or fertiliser applied to soil or other growing media if the product is not claimed to have any effect as a regulator of plant growth
4	Invertebrate pest management lures based on food and not containing any active constituent
5	Vertebrate pest management lures
6	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 pool or spa water
7	Cyanuric acid for use in swimming pools as a chlorine stabiliser
8	Cut flower preservatives
9	Any hay inoculant, silage inoculant or legume inoculant, if the product is based on bacteria, enzymes or both
10	Any predatory insect, predatory mite or macroscopic parasite
11	The nematode <i>Deladenus siricidicola</i> for the control of <i>Sirex</i> species wood wasps in pine plantations
12	Any industrial biocide used in the manufacture of paper pulp
13	Head lice or body lice treatments for human beings
14	Substances that present a physical barrier to a pest that: <ul style="list-style-type: none"> <li>(a) do not contain a biocide; and</li> <li>(b) do not otherwise affect the pest; and</li> <li>(c) are not released into the environment</li> </ul>
15	Products (such as soils and potting mixtures) that contain naturally occurring <i>Trichoderma</i> species, if the product: <ul style="list-style-type: none"> <li>(a) does not control or claim to control specific diseases; and</li> <li>(b) does not claim to promote plant growth; and</li> <li>(c) is not otherwise represented, supplied or used as an agricultural chemical product</li> </ul>
16	Substances used to adjust the pH of swimming pool or spa water
17	Ozone generated on site for treatment of swimming pool or spa water

Definition of agricultural chemical product **Schedule 3**  
Substances or mixtures declared not to be agricultural chemical products **Part 3**

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<b>Item</b>	<b>Class of substance or mixture of substances</b>
18	Hot water and steam treatments solely based on water and not containing other constituents
19	Any product for domestic use by householders in controlling a plant disease or pest, that: (a) is a food normally consumed by human beings; and (b) is not a plant extract or other manufactured compound; and (c) is not claimed to have effect as an agricultural chemical product; and (d) is not expressly supplied as an agricultural chemical product
20	Biocides used to control organisms in air conditioning or water-cooling systems, other than open water-cooling systems through which water flows once with no recirculation
21	Biocides used in sewage treatment to control organisms in sewage and wastewater
22	Biocides used to control organisms in water effluent from ore extraction and processing
23	Biocides to control organisms in water, used for the purpose of maintaining equipment associated with the extraction of coal seam gas in serviceable condition
23A	Biocides used to control organisms in fuel, including aviation fuel, fuel oil and marine diesel
23B	Biocides used to control organisms in oil, including lubricating oil and hydraulic oil
24	Whole vertebrate animals if represented, supplied or used for a purpose mentioned in subsection 4(2) of the Code
25	Carbon dioxide or nitrogen used as a fumigant
26	Citronella oil, including in candles and sticks, unless the citronella oil is used: (a) as an insect repellent on human beings; or (b) as an insect repellent on food producing species or food crops

# Schedule 3AA—Definition of veterinary chemical product

(regulation 8)

## Part 1—Preliminary

### 1 Definitions

Note: A number of expressions used in this Schedule are defined in regulation 3, including the following:

- (a) block or lick;
- (b) premix;
- (c) stockfood;
- (d) stockfood supplement.

In this Schedule:

***excluded nutritional or digestive product*** has the meaning given by clause 4.

***Food Standards Code*** means the Australia New Zealand Food Standards Code as defined in section 4 of the *Food Standards Australia New Zealand Act 1991*.

***ingredient determination*** means a determination under subclause 9(1).

***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.

***quality specification*** for an ingredient includes any requirement as to the composition, quality or purity of the ingredient.

## **Part 2—Substances or mixtures declared to be veterinary chemical products**

### **2 Substances or mixtures declared to be veterinary chemical products**

The following table sets out the classes of substances or mixtures of substances that are declared to be veterinary chemical products:

<b>Item</b>	<b>Class of substance or mixture of substances</b>
1	Allergenic substances supplied or used for administration to an animal by any means, or for consumption by an animal, except excluded nutritional or digestive products
2	Medicated blocks or licks
3	Enzymes supplied or used for administration to an animal by any means, or for consumption by an animal, except an enzyme that is an excluded nutritional or digestive product or that is a product covered by item 6 of the table in clause 3 of this Schedule
7	Teat sealants
8	Parts of a vertebrate animal, material produced from a vertebrate animal or matter the production of which involves the use of a vertebrate animal, if represented supplied or used for a purpose mentioned in subsection 5(2) of the Code

## **Part 3—Substances or mixtures declared not to be veterinary chemical products**

### **Division 3.1—Substances or mixtures declared not to be veterinary chemical products—general**

#### **3 Substances or mixtures declared not to be veterinary chemical products**

The following table sets out the classes of substances or mixtures of substances that are declared not to be veterinary chemical products:

<b>Item</b>	<b>Class of substance or mixture of substances</b>
1	Animal feed products that incorporate an excluded nutritional or digestive product, if: (a) the container for the animal feed product is labelled in accordance with the instructions on the label for the container for the excluded nutritional or digestive product; and (b) the excluded nutritional or digestive product is incorporated at a rate of use in accordance with the label for the container for the excluded nutritional or digestive product; and (c) the claims made for the animal feed product do not exceed the claims made for the incorporated nutritional or digestive product.
2	Medicated stockfoods and medicated premixes, 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
3	Excluded nutritional or digestive products
4	Colour intensifiers for aviary birds
5	Any bitterant product for application to a building, piece of equipment or other object, that: (a) is solely for reducing or preventing animals that are not food producing species from biting or chewing the building, piece of equipment or other object; and (b) contains no antiseptic, antimicrobial, antibiotic or other active constituent other than a bitterant
6	Any product applied topically to the teeth, hair, fur or intact skin of an animal to cosmetically alter the animal's appearance or odour, that: (a) contains no antiseptic, antimicrobial, or antibiotic active constituent, and (b) is solely for cosmetic purposes; and (c) is not claimed to have any benefits other than cosmetic benefits; and (d) is not supplied or used for any therapeutic benefit other than to cosmetically alter the animal's appearance or odour

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<b>Item</b>	<b>Class of substance or mixture of substances</b>
7	Any product for topical application to an animal to provide a physical barrier, that: (a) is chemically inert; and (b) does not act by biochemical means; and (c) is not a teat sealant; and (d) contains no antiseptic, antimicrobial, antibiotic or other active constituent; and (e) is not claimed to have any effect other than as a physical barrier
8	Any autograft, allograft or xenograft product supplied to veterinary surgeons for surgical procedures, except blood, blood products, stem cells or stem cell products
9	Any product for use as an extender for sperm, ova or semen, if: (a) the product contains no ingredients other than antibiotics, albumins, electrolytes, amino acids, EDTA, buffers or stabilising agents; and (b) any antibiotic in the product is not at a concentration greater than 0.1 mg/mL or 0.1 mg/g
10	Any product for topical application to an animal to act as a lubricant, that: (a) is chemically inert; and (b) does not act by biochemical means; and (c) is not a teat sealant; and (d) contains no antiseptic, antimicrobial, antibiotic or other active constituent; and (e) is not claimed to have any effect other than as a lubricant
11	Semen, ova or embryos if represented, supplied or used for the purpose of reproduction
12	Whole vertebrate animals if represented, supplied or used for a purpose mentioned in subsection 5(2) of the Code

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## Division 3.2—Excluded nutritional or digestive products

### 4 Excluded nutritional or digestive products

- (1) A substance or mixture of substances is an *excluded nutritional or digestive product* if:
  - (a) the substance or mixture is intended for consumption by an animal; and
  - (b) the following requirements are met in relation to the substance or mixture:
    - (i) the ingredient requirements under clause 5;
    - (ii) the claims requirements under clause 6;
    - (iii) the labelling requirements under clause 7;
    - (iv) the manufacturing requirements under clause 8.
- (2) Subparagraph (1)(b)(iv) does not apply if the substance or mixture is a block or lick that only contains one or more of the following:
  - (a) vitamins;
  - (b) minerals;
  - (c) amino acids;
  - (d) binders.
- (3) Despite subclause (1), none of the following is an *excluded nutritional or digestive product*:
  - (a) a substance or mixture of substances included in a class of substances or mixtures of substances set out in the table in clause 2 (substances or mixtures declared to be veterinary chemical products);
  - (b) an intraruminal bolus;
  - (c) a substance or mixture of substances intended for direct application by a person to an animal's digestive tract.

### 5 Ingredient requirements for excluded nutritional or digestive products

- (1) The ingredient requirements under this clause are met in relation to a substance or a mixture of substances if, at the time it is supplied:
  - (a) each ingredient used in the substance or mixture is covered by subclause (2) or (3); and
  - (b) each ingredient used in the substance or mixture meets the quality specification requirements under subclause (5); and
  - (c) the substance or mixture does not contain any ingredient referred to in subclause (7).

#### *Ingredients that may be in substance or mixture*

- (2) An ingredient is covered by this subclause if the ingredient is a substance of plant or animal origin that is edible by an animal, including:
  - (a) an edible grain and a processing by-product of an edible grain; and
  - (b) whey powder and any other milk by-product.



- (3) An ingredient used in a substance or a mixture of substances for a particular purpose is covered by this subclause if:
- (a) the use of the ingredient in the substance or mixture for that purpose is (subject to subclause (4)) authorised in a particular country by, or in accordance with, a standard, rule, code, specification or method referred to in an item in the following table; and
  - (b) if the ingredient's use for that purpose is authorised by, or in accordance with, more than one such standard, rule, code, specification or method—the ingredient's use for that purpose is in accordance with the most stringent standard, rule, code, specification or method that is applicable.

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**Ingredients authorised for use by certain standards, rules, codes, specifications or methods**

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Item	Standards, rules, codes, specifications and methods
1	The following ingredients authorised by the Food Standards Code, as existing at the time of the supply: <ul style="list-style-type: none"><li>(a) permitted flavouring substances;</li><li>(b) generally permitted processing aids;</li><li>(c) food additives (including colourings) specified in Schedule 16 to the Food Standards Code</li></ul>
3	A determination under section 8B of the Agricultural Compounds and Veterinary Medicines Act 1997 of New Zealand (substances generally recognised as safe for use as or in an agricultural compound), as existing on 5 March 2015
4	Annex I (list of additives) of the <i>European Union Register of Feed Additives</i> established in accordance with Article 17 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, as existing at the time of the supply
5	Parts 573, 582 and 584 of Title 21 of the Code of Federal Regulations of the United States of America, as existing at the time of the supply
6	Chapter 6 (Feed Terms and Ingredient Definitions) of the <i>Official Publication of the Association of American Feed Control Officials</i> , as existing at the time of the supply
7	<i>Handbook of Pharmaceutical Excipients</i> published by the Royal Pharmaceutical Society, as existing at the time of the supply
8	An ingredient determination (see Division 3.3), as existing at the time of the supply
9	Part 1 of Schedules IV and V to the <i>Feeds Regulations 1983</i> of Canada, as existing at the time of the supply

- (4) For paragraph (3)(a):
- (a) the use of an ingredient is only authorised by, or in accordance with, the Annex referred to in item 4 of the table if:
    - (i) the ingredient is not referred to as a category 5 substance in the Annex; and
    - (ii) the Annex specifies an expiry date for authorisations for the ingredient; and
  - (b) the use of an ingredient is only authorised by, or in accordance with, the Chapter referred to in item 6 of the table if the ingredient is not specified as a tentative listing in that Chapter; and

**Schedule 3AA** Definition of veterinary chemical product

**Part 3** Substances or mixtures declared not to be veterinary chemical products

**Division 3.2** Excluded nutritional or digestive products

Clause 6

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- (c) the use of an ingredient is only authorised by, or in accordance with, the Handbook referred to in item 7 of the table if the substance or mixture in which the ingredient is used is for canine or equine consumption.

*Quality specification requirements*

- (5) An ingredient used in a substance or a mixture of substances for a particular purpose meets the quality specification requirements under this subclause if the use of the ingredient for that purpose is, at the time it is supplied, in accordance with any quality specification under:
  - (a) a standard (however described) about animal feed, as existing at that time, provided for by or under a law of the Commonwealth; or
  - (b) if no such standard exists at that time—a law of this jurisdiction; or
  - (c) if neither paragraph (a) nor (b) applies—a standard about animal feed published by Standards Australia, as existing at that time.
- (6) If there is no quality specification of a kind mentioned in subclause (5) that applies in relation to the use of an ingredient for a particular purpose in a substance or a mixture of substances at the time it is supplied, then the ingredient is taken to meet the quality specification requirements under that subclause in relation to its use for that purpose.

*Ingredients that cannot be in substance or mixture*

- (7) For paragraph (1)(c), the substance or mixture must not contain any of the following:
  - (a) a hormone;
  - (b) if the substance or mixture is intended for consumption by ruminants—any of the following:
    - (i) any part of a vertebrate animal;
    - (ii) material produced from a vertebrate animal;
    - (iii) matter the production of which involves the use of a vertebrate animal;  
other than tallow, gelatine, an oil, whey power or any other milk by-product;
  - (c) an antibiotic substance listed in Schedule 2, 3, 4, 7, 8 or 9 of the current Poisons Standard;
  - (d) an antibiotic substance listed in Schedule 6 of the current Poisons Standard, unless the antibiotic substance is used in the substance or mixture as a preservative;
  - (e) an ingredient determined by the APVMA, by legislative instrument, for the purposes of this paragraph.

## **6 Claims requirements for excluded nutritional or digestive products**

The claims requirements under this clause are met in relation to a substance or a mixture of substances if:

- (a) a label for a container of the substance or mixture, and any accompanying information, does not, at the time the substance or mixture is supplied, expressly or impliedly claim or represent that it:
  - (i) alleviates or prevents a disease or condition in an animal; or
  - (ii) modifies the physiology of an animal; or
  - (iii) cures a disease or condition in an animal; or
- (b) if such a claim or representation is made—the substance or mixture is supplied by, or in accordance with the instructions of, a veterinary surgeon, being a supply that would be permitted under a law of this jurisdiction if the substance or mixture were a chemical product; or
- (c) if a claim or representation covered by subparagraph (a)(i) or (ii) is made—the claim or representation is substantiated, having regard to either or both of the following:
  - (i) scientific studies that are published in a reputable, refereed scientific journal, or that are of a standard publishable in such a journal;
  - (ii) information showing that the claim or representation would, if EU Commission Directive 2008/38/EC (as in force at the time of the supply) applied in relation to the substance or mixture, be established under that Directive.

## 7 Labelling requirements for excluded nutritional or digestive products

- (1) The labelling requirements under this clause are met in relation to a substance or a mixture of substances if the following information is included on a label for a container of the substance or mixture, or accompanies the substance or mixture, at the time it is supplied:
  - (a) the name of the substance or mixture;
  - (b) instructions for use of the substance or mixture for each species for which it is intended to be used, including:
    - (i) application or dosage rates for each species; and
    - (ii) the length of the period during which it may be used for each species;
  - (c) instructions for the safe handling of the product;
  - (d) a crude or a key nutrient analysis relating to the claims made about the product;
  - (e) a list of the ingredients in the substance or mixture, ordered by decreasing mass of:
    - (i) the ingredients; or
    - (ii) if the ingredients are grouped as mentioned in subclause (3)—the grouped ingredients;
  - (f) the name of, and an address and telephone number for, the party primarily responsible for marketing the product;
  - (g) a batch number;
  - (h) an expiry date (or equivalent);
  - (i) if the claims requirements under clause 6 are met in relation to the substance or mixture only because of paragraph 6(b)—a statement that the substance or mixture is for veterinary supply only;

Clause 8

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- (j) if the claims requirements under clause 6 are met in relation to the substance or mixture only because of subparagraph 6(c)(ii)—any information required to be included on a label by a standard, rule, code, specification or method set out in EU Commission Directive 2008/38/EC (as in force at the time of the supply) in relation to a claim established under that Directive;
  - (k) if the current Poisons Standard requires signal words in relation to the supply of the substance or mixture:
    - (i) the appropriate signal words; and
    - (ii) first aid instructions for the substance or mixture; and
    - (iii) poisons information centre contact details.
- (2) Paragraph (1)(b), (c), (d), (e) or (h) is taken to be satisfied in relation to a substance or a mixture of substances if:
- (a) the information mentioned in that paragraph is made available for downloading from a website; and
  - (b) the label or information that accompanies the substance or mixture includes, at the time the substance or mixture is supplied:
    - (i) the URL of the website; or
    - (ii) another method by which a person may download that information from the website.
- (3) For paragraph (1)(e), the ingredients may be grouped in accordance with any of the following standards, rules, codes, specifications or methods as existing at the time of the supply:
- (a) the Collective Terms outlined in Chapter 6 (Feed Terms and Ingredient Definitions) of the *Official Publication of the Association of American Feed Control Officials*;
  - (b) the Group names outlined in Types 7, 8 and 11 of Section 2 “CODEX Classification of Foods and Animal Feeds” in CODEX Alimentarius Commission, *CODEX Alimentarius*, Volume 2, Pesticides Residues in Food;
  - (c) sections 1.2.4—3, 1.2.4—4, 1.2.4—6, 1.2.4—7 and 1.2.4—8 of the Food Standards Code;
  - (d) any applicable Australian industry code of practice.

## 8 Manufacturing requirements for excluded nutritional or digestive products

The manufacturing requirements under this clause are met in relation to a substance or a mixture of substances if the substance or mixture is manufactured in accordance with any of the following standards, rules, codes, specifications or methods as existing at the time of manufacture:

- (a) both the manufacturing principles and the Australian GMP Code;
- (b) any applicable Australian industry code of practice;
- (c) the quality assurance requirements for animal feed products applicable to substances or mixtures of that kind in:
  - (i) a member state of the European Union; or

(ii) the United States of America.

## Division 3.3—Ingredient determinations

### 9 Ingredient determinations

- (1) The APVMA may, by legislative instrument, determine that one or more ingredients, or classes of ingredients, are authorised to be used in one or more classes of substances or mixtures of substances.

Note 1: An ingredient may be used in a substance or a mixture of substances if the use of the ingredient in the substance or mixture is authorised by the ingredient determination (see item 8 of the table in subclause 5(3)).

Note 2: A determination under this subclause is referred to in this Schedule as an *ingredient determination* (see clause 1).

Note 3: For variation and revocation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

- (2) Without limiting subclause (1), an ingredient determination may do either or both of the following:
- (a) authorise an ingredient's use only for one or more specified purposes in a class of substances or mixtures of substances;
  - (b) authorise an ingredient's use in a class of substances or mixtures of substances for a particular purpose only if one or more requirements specified in the ingredient determination are met.
- (3) The power under subclause (1) may be exercised on the APVMA's own initiative or on application under clause 10.

#### *APVMA to be satisfied of certain matters*

- (4) Before making or varying an ingredient determination, the APVMA must be satisfied that the use of a substance or a mixture of substances in a class covered by the ingredient determination as made or varied:
- (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.
- (5) The APVMA must revoke or vary an ingredient determination if the APVMA is no longer satisfied as to any of the matters mentioned in subclause (4) in relation to the ingredient determination.
- (6) For the purposes of being satisfied as to the matters mentioned in paragraphs (4)(a), (b) and (c), the APVMA:
- (a) must have regard to the following:
    - (i) the toxicity of substances or mixtures in the class and their residues, including metabolites and degradation products, in relation to relevant organisms and ecosystems, including human beings;

- (ii) the relevant poison classification of substances or mixtures in the class under the law in force in this jurisdiction;
    - (iii) how substances or mixtures in the class are formulated;
    - (iv) the composition and form of the ingredients of substances or mixtures in the class; and
  - (b) may have regard to such other matters as it thinks relevant.
- (7) For the purposes of being satisfied as to the matter mentioned in paragraph (4)(d):
- (a) if it can reasonably be expected that a substance or mixture in a class covered by an ingredient determination will be used in relation to an animal, a product of which might be provided to a place outside Australia—the APVMA must have full regard to the matter mentioned in that paragraph; and
  - (b) otherwise—the APVMA is to have regard to the matter mentioned in that paragraph to the extent that the APVMA thinks is relevant.

*Publishing ingredient determinations*

- (8) The APVMA must publish an ingredient determination, as existing from time to time, on its website.

## **10 Applying for ingredient determinations**

- (1) A person may apply to the APVMA to make or vary an ingredient determination to authorise the use of one or more ingredients in one or more classes of substances or mixtures of substances specified in the application.
- (2) The application must specify the following for each ingredient covered by the application:
- (a) one or more purposes for which the ingredient determination would authorise the use of the ingredient in the classes of substances or mixtures of substances specified in the application;
  - (b) any requirements (including quality specifications) that would need to be met for the use of the ingredient for those purposes in the classes of substances or mixtures of substances specified in the application to be authorised by the ingredient determination.
- (3) The APVMA must make or vary an ingredient determination in accordance with the application if the APVMA is satisfied:
- (a) that the application meets the application requirements (other than the requirement set out in paragraph 8A(b) of the Code); and
  - (b) of the matters mentioned in subclause 9(4), in accordance with subclauses 9(6) and (7).
- (4) If the APVMA is not satisfied as mentioned in subclause (3), the APVMA must refuse the application.

Clause 11

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- (5) The APVMA must give written notice to the applicant, within 14 days of making or varying the ingredient determination, stating that it has been made or varied in accordance with the application.
- (6) The following provisions of the Code apply in relation to an application under subclause (1) in relation to an ingredient as if the application were an application made under the Code in relation to an active constituent for a proposed or existing chemical product:
  - (a) section 157 (samples to be given for analysis);
  - (b) section 159 (requiring information to determine application).

Note 1: A number of provisions in the Code apply automatically in relation to applications made under it (including applications made under these Regulations). See, for example, sections 8B to 8D, and sections 8G, 8S, 156A, 164 and 165, of the Code.

Note 2: Clause 11 applies certain other provisions in relation to applications made under this clause.

## 11 Information that may be used for ingredient determinations

### *Overseas trials and experiments, and consultation*

- (1) The following provisions apply in relation to the making, variation or revocation of an ingredient determination in relation to an ingredient as if the ingredient were an active constituent for a proposed or existing chemical product:
  - (a) subsections 160(2) and (3) of the Code (overseas trials and experiments);
  - (b) section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (consultation).

### *Limits on use of information*

- (2) The APVMA must not use information given to it in connection with an application under the Code:
  - (a) to assess an application made under clause 10 in relation to an ingredient; or
  - (b) to make any other decision in relation to the making, variation or revocation of an ingredient determination in relation to an ingredient;unless the information was given to it in connection with the application mentioned in paragraph (a) or the decision mentioned in paragraph (b).
- (3) A person or body consulted under section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as that section applies under subclause (1), must not, for the purposes of providing information or advice in relation to the making, variation or revocation of an ingredient determination, use information that the APVMA must not, under subclause (2), use in relation to the ingredient determination.
- (4) The following provisions of the Code apply in relation to subclauses (2) and (3) in the same way as they apply in relation to subsections 34G(1) and (3) of the Code:
  - (a) subsections 34G(1B) and (2);



- (b) sections 34H to 34M.
- (5) For subclause (4), the condition in subsection 34J(4) of the Code is taken to be replaced by the condition that:
  - (a) the information relates to the making, variation or revocation of an ingredient determination in relation to an ingredient; and
  - (b) the information shows that a matter mentioned in subclause 9(4) of this Schedule may not be satisfied in relation to the ingredient.
- (6) For subclause (4), if the APVMA relies on information given in connection with an application under clause 10 to make or vary an ingredient determination in accordance with the application, a limitation period is taken to apply to the information under section 34M of the Code that ends 3 years after the information is given.
- (7) To avoid doubt, this clause applies in relation to the making, variation or revocation of an ingredient determination whether on the APVMA's own initiative or on application under clause 10.

## **Schedule 3B—Listed chemical products**

Note: See regulation 8AR.

### **Part 1—Preliminary**

#### **1 Particulars of listed 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 listed 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—Listed chemical products

<b>Item</b>	<b>Chemical product or class of chemical product</b>	<b>Chemical product or class of chemical product use</b>
1	<p>An agricultural chemical product or class of chemical products that:</p> <p>(a) destroys bacteria, viruses and protozoa; and</p> <p>(b) contains only 1 of the following as an active constituent:</p> <p style="padding-left: 20px;">(i) calcium hypochlorite;</p> <p style="padding-left: 20px;">(ii) lithium hypochlorite;</p> <p style="padding-left: 20px;">(iii) sodium dichloroisocyanurate;</p> <p style="padding-left: 20px;">(iv) sodium hypochlorite;</p> <p style="padding-left: 20px;">(v) trichloroisocyanuric acid; and</p> <p>(c) does not contain stabilisers, enhancers or flocculants</p>	Used in home swimming pools and spas
2	<p>A veterinary chemical product or class of chemical products that:</p> <p>(a) provides an exogenous source of biologically active ingredients to help improve the health of joints in dogs or horses; and</p> <p>(b) contains any 1 or more of the following as an active constituent:</p> <p style="padding-left: 20px;">(i) chondroitin;</p> <p style="padding-left: 20px;">(ii) glucosamine</p>	Administered orally to dogs and horses (in the form of oral powder, chewable or non-chewable tablets, capsules containing powder or dry medicated food)

## Part 3—Active constituents in listed chemical products

### Division 3.1—Agricultural chemical products

#### Subdivision 3.1.1 Home swimming pool and spa products

##### 1 Calcium hypochlorite

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

##### 2 Lithium hypochlorite

Common name	Lithium hypochlorite
Synonym	Hypochlorous acid – lithium salt
Australian approved name	None
Chemical name	Lithium hypochlorite
Chemical abstract service (CAS) number	13840-33-0
Monograph or compendial standard with which active constituent is required to comply	None

##### 3 Sodium dichloroisocyanurate

Common name	Sodium dichloroisocyanurate
Synonyms	Dichloroisocyanuric acid sodium salt Sodium 1,3-dichloroisocyanurate
Australian approved name	None
Chemical name	1,3-dichloro-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione, sodium salt
Chemical abstract service (CAS) number	2893-78-9
Monograph or compendial standard with which active constituent is required to comply	None

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#### **4 Sodium hypochlorite**

Common name	Sodium hypochlorite
Synonyms	Hypochlorous acid – sodium salt Sodium oxychloride
Australian approved name	Sodium hypochlorite
Chemical name	Sodium hypochlorite
Chemical abstract service (CAS) number	7681-52-9
Monograph or compendial standard with which active constituent is required to comply	None

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#### **5 Trichloroisocyanuric acid**

Common name	Trichloroisocyanuric acid
Synonyms	1,3,5-trichloroisocyanuric acid, trichloro-s-triazinetriene 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	United States Pharmacopoeia (USP) for glucosamine hydrochloride or glucosamine sulfate

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**2 Glucosamine**  
required to comply

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## 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

Item	Chemical product or class of chemical product	Active constituent(s) of chemical product or class of chemical product
1	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	Benzalkonium chloride
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
5	An agricultural chemical product used as a disinfectant if the product contains the active constituent specified in column 3	Ortho-phenylphenol
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

<b>Item</b>	<b>Chemical product or class of chemical product</b>	<b>Active constituent(s) of chemical product or class of chemical product</b>
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
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

<b>1 Benzalkonium chloride</b>	
Common name	Benzalkonium chloride
Synonyms	Alkyl-benzyl-dimethylammonium chloride Alkylbenzyl dimethyl chloride
Australian approved name	Benzalkonium chloride
Chemical name	Benzalkonium chloride
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)
<b>2 Glutaraldehyde</b>	
Common name	Glutaraldehyde
Synonyms	Gluteraldehyde 1,3-diformylpropane 1,5-pentanedial 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)
<b>3 Hydrogen peroxide</b>	
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)
<b>4 O-benzyl-p-chlorophenol</b>	
Common name	O-benzyl-p-chlorophenol

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

### **5 Ortho-phenylphenol**

Common name	Ortho-phenylphenol
Synonyms	(1,1'-biphenyl)-2-ol 1,1'-biphenyl-2-ol 2-biphenylol 2-phenylphenol Hydroxy-2-phenylbenzene
Australian approved name	Ortho-phenylphenol
Chemical name	1,1'-biphenyl-2-ol
Chemical abstract service (CAS) number	90-43-7
Monograph or compendial standard with which active constituent is required to comply	None

### **6 Peroxyacetic acid**

Common name	Peroxyacetic acid
Synonyms	Acetic peroxide Acetyl hydroperoxide Peracetic acid
Australian approved name	Peracetic acid
Chemical name	Peroxyacetic acid
Chemical abstract service (CAS) number	79-21-0
Monograph or compendial standard with which active constituent is required to comply	None

### **7 Phosphoric acid**

Common name	Phosphoric acid
Synonym	Orthophosphoric acid
Australian approved name	None
Chemical name	Phosphoric acid

**Schedule 3C** Reserved Schedule**Part 3** Active constituents in reserved chemical products**Division 3.1** Agricultural chemical products

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Chemical abstract service (CAS) number	7664-38-2
Monograph or compendial standard with which active constituent is required to comply	British Pharmacopoeia (BP); or European Pharmacopoeia (EP)

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**8 Sodium hydroxide**

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Common name	Sodium hydroxide
Synonym	Caustic soda
Australian approved name	Sodium hydroxide
Chemical name	Sodium hydroxide
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)

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**9 Sodium hypochlorite**

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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	7681-52-9
Monograph or compendial standard with which active constituent is required to comply	None

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**10 Sulfamic acid**

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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	5329-14-6
Monograph or compendial standard with which active constituent is required to comply	None

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**11 Sulfuric acid**

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Common name	Sulfuric acid
Synonyms	Hydrogen sulfate Sulphuric acid

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**11 Sulfuric acid**

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Australian approved name	Sulfuric acid
Chemical name	Sulfuric acid
Chemical abstract service (CAS) number	7664-93-9
Monograph or compendial standard with which active constituent is required to comply	British Pharmacopoeia (BP); or European Pharmacopoeia (EP)

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**Schedule 3C** Reserved Schedule

**Part 3** Active constituents in reserved chemical products

**Division 3.2** Veterinary chemical products

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## **Division 3.2—Veterinary chemical products**

Note: This Division is reserved for future use.



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## Schedule 4—Restricted chemical products

(regulation 45)

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1	A chemical product containing ethylene dibromide (also known as EDB)
2	A chemical product containing 4-aminopropiophenone (also known as PAPP)
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 ( <i>RHDV</i> ) (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
12	A vertebrate pest control chemical product containing fenthion, alphachloralose or 4-aminopyridine
13	All chemical products with formulations containing, as active constituents, all 3 of the following in various chemical forms: (a) copper; (b) chromium; (c) arsenic

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## Schedule 5A—Infringement notices

Note: See regulation 64.

<b>Infringement notice penalty amounts</b>			
<b>Item</b>	<b>Civil penalty provision</b>	<b>Amount for individual (penalty units)</b>	<b>Amount for corporation (penalty units)</b>
1	A contravention of section 26 of the Code	9	75
2	A contravention of section 32 of the Code	36	300
3	A contravention of section 33 of the Code	36	300
4	A contravention of section 45C of the Code	90	750
5	A contravention of section 47E of the Code	90	750
6	A contravention of section 74 of the Code involving: (a) at least 10 kg of an active constituent of a veterinary product; or (b) at least 100 kg of an active constituent of an agricultural chemical product	60	500
7	A contravention of section 74 of the Code involving: (a) at least 1 kg, but less than 10 kg, of an active constituent of a veterinary product; or (b) at least 10 kg, but less than 100 kg, of an active constituent of an agricultural chemical product	30	250
8	A contravention of section 74 of the Code involving: (a) less than 1 kg of an active constituent of a veterinary product; or (b) less than 10 kg of an active constituent of an agricultural chemical product	6	50
9	A contravention of section 75 of the Code involving at least 500 containers	60	500
10	A contravention of section 75 of the Code involving at least 50 containers but fewer than 500 containers	30	250
11	A contravention of section 75 of the Code involving fewer than 50 containers	6	50
12	A contravention of section 76 of the Code involving: (a) at least 10 kg of an active constituent of a veterinary chemical product; or (b) at least 100 kg of an active constituent of an agricultural chemical product	90	750

<b>Infringement notice penalty amounts</b>			
<b>Item</b>	<b>Civil penalty provision</b>	<b>Amount for individual (penalty units)</b>	<b>Amount for corporation (penalty units)</b>
13	A contravention of section 76 of the Code involving: (a) at least 1 kg, but less than 10 kg, of an active constituent of a veterinary chemical product; or (b) at least 10 kg, but less than 100 kg, of an active constituent of an agricultural chemical product	45	375
14	A contravention of section 76 of the Code involving: (a) less than 1 kg of an active constituent of a veterinary chemical product; or (b) less than 10 kg of an active constituent of an agricultural chemical product	9	75
15	A contravention of section 77 of the Code	90	750
16	A contravention of section 78 of the Code involving at least 500 containers	90	750
17	A contravention of section 78 of the Code involving at least 50 containers but fewer than 500 containers	45	375
18	A contravention of section 78 of the Code involving fewer than 50 containers	9	75
19	A contravention of section 79 of the Code	90	750
20	A contravention of section 79B of the Code	90	750
21	A contravention of section 80 of the Code involving at least 500 containers	90	750
22	A contravention of section 80 of the Code involving at least 50 containers but fewer than 500 containers	45	375
23	A contravention of section 80 of the Code involving fewer than 50 containers	9	75
24	A contravention of section 81 of the Code involving at least 500 containers	90	750
25	A contravention of section 81 of the Code involving at least 50 containers but fewer than 500 containers	45	375
26	A contravention of section 81 of the Code involving fewer than 50 containers	9	75
27	A contravention of section 83 of the Code	90	750
28	A contravention of section 84 of the Code	90	750
29	A contravention of section 85 of the Code	90	750
30	A contravention of section 86 of the Code	90	750
31	A contravention of section 87 of the Code	90	750

Schedule 5A Infringement notices

<b>Infringement notice penalty amounts</b>			
<b>Item</b>	<b>Civil penalty provision</b>	<b>Amount for individual (penalty units)</b>	<b>Amount for corporation (penalty units)</b>
32	A contravention of section 88 of the Code	15	125
33	A contravention of section 89 of the Code	15	125
34	A contravention of section 90 of the Code involving at least 500 containers	36	300
35	A contravention of section 90 of the Code involving at least 50 containers but fewer than 500 containers	18	150
36	A contravention of section 90 of the Code involving fewer than 50 containers	3	30
37	A contravention of section 91 of the Code involving at least 500 containers	36	300
38	A contravention of section 91 of the Code involving at least 50 containers but fewer than 500 containers	18	150
39	A contravention of section 91 of the Code involving fewer than 50 containers	3	30
40	A contravention of section 92 of the Code	36	300
41	A contravention of section 94 of the Code	36	300
42	A contravention of section 95 of the Code	36	300
43	A contravention of section 99 of the Code	36	300
44	A contravention of section 105 of the Code	36	300
44A	A contravention of subsection 106(2) of the Code	36	300
45	A contravention of section 116 of the Code	90	750
46	A contravention of subsection 121(3) of the Code	72	600
47	A contravention of subsection 121(4) of the Code relating to a step in the manufacture of a veterinary chemical product mentioned in the definition of <i>category 1 licence</i>	72	600
48	A contravention of subsection 121(4) of the Code relating to a step in the manufacture of a veterinary chemical product mentioned in the definition of <i>category 2 licence</i> or <i>category 3 licence</i>	36	300
49	A contravention of subsection 121(4) of the Code relating to a step in the manufacture of a veterinary chemical product mentioned in the definition of <i>category 4 licence</i>	7	60
50	A contravention of subsection 121(4) of the Code relating to a step in the manufacture of a veterinary chemical product mentioned in the definition of <i>category 6 licence</i>	7	60
51	A contravention of subsection 121(5) of the Code	36	300

<b>Infringement notice penalty amounts</b>			
<b>Item</b>	<b>Civil penalty provision</b>	<b>Amount for individual (penalty units)</b>	<b>Amount for corporation (penalty units)</b>
	involving non-compliance with a condition other than a condition mentioned in items 52, 53 or 54		
52	A contravention of subsection 121(5) of the Code involving non-compliance with a condition mentioned in subregulation 61(4), (7) or (7A)	18	150
53	A contravention of subsection 121(5) of the Code involving non-compliance with a condition mentioned in subregulation 61(10)	3	30
54	A contravention of subsection 121(5) of the Code involving non-compliance with a condition mentioned in subregulation 61(2) or (9) or regulation 62	1	5
54A	A contravention of subsection 146(3) of the Code	90	750
54B	A contravention of subsection 146(4) of the Code	18	150
55	A contravention of section 160A of the Code	90	750
56	A contravention of section 161 of the Code	90	750
57	A contravention of subregulation 47C(1)	30	250
58	A contravention of subregulation 48(1)	30	250
59	A contravention of subregulation 49(1)	18	150
60	A contravention of subregulation 50(1)	18	150
61	A contravention of subregulation 51(2)	18	150
62	A contravention of subregulation 53(2)	30	250
63	A contravention of subregulation 54(3)	18	150

Note: The terms category 1 licence, category 2 licence, category 3 licence, category 4 licence and category 6 licence are defined at regulation 3.

## Schedule 6—Application fees and assessment periods

Note: See regulations 70, 70B, and 76 to 78.

### Part 1—Preliminary

#### 1.1 Definitions

In this Schedule:

***closely similar***, used of 2 chemical products, has the meaning given by clause 1.2 and subclause 1.5(1).

***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.

***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.

***restricted***, in relation to the use of information by the APVMA in determining an application: see subclause 1.5(2).

***similar***, used of 2 chemical products, has the meaning given by clause 1.3 and subclause 1.5(1).

***the same***, used of 2 chemical products, has the meaning given by clause 1.4 and subclause 1.5(1).

#### 1.2 When chemical products are closely similar

- (1) Subject to clause 1.5, 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.
- (3) Subject to clause 1.5, 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
-

Clause 1.3

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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.

### 1.3 When chemical products are similar

- (1) Subject to clause 1.5, 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.
- (3) Subject to clause 1.5, 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) chemistry and manufacture, efficacy or target species safety data is required to demonstrate similarity of the proposed chemical product to the reference chemical product.

### 1.4 When chemical products are *the same*

Subject to clause 1.5, 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.

### 1.5 When chemical products are not *closely similar, similar or the same*

- (1) Despite clauses 1.2, 1.3 and 1.4, a proposed chemical product and a reference chemical product are not ***closely similar, similar or the same*** if:
  - (a) the APVMA is required to use information in determining an application in respect of the proposed chemical product; and
  - (b) the use of the information by the APVMA in determining that application is restricted.



- (2) The use of information by the APVMA in determining an application is **restricted** if the APVMA is restricted from using the information in determining the application by:
- (a) Division 4A of Part 2 of the Code; or
  - (b) Part 3 of the Code.

### **1.6 Effect on fees when the use of information is restricted**

- (1) If the use of information by the APVMA about an active constituent is restricted, 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 the use of information by the APVMA about a registered chemical product is restricted, 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 the use of information by the APVMA about an approved label for containers for a chemical product is restricted, 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.

**Schedule 6** Application fees and assessment periods

**Part 2** Assessment periods and fees

Clause 2.1

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## Part 2—Assessment periods and fees

### 2.1 Table of assessment periods and fees

The following table sets out the assessment periods and fees for different kinds of applications under the Code.

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
<b>Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label</b>					
1	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	18 months	25 months	\$1,400	\$116,501
2	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	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$1,400	The modular assessment fee

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	assessment of the active constituent and chemical product				
<b>Applications for registration of a chemical product containing an approved active constituent and approval of the product label</b>					
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	18 months	25 months	\$1,050	\$83,511
4	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	18 months	25 months	\$1,050	\$44,644

**Schedule 6** Application fees and assessment periods

**Part 2** Assessment periods and fees

Clause 2.1

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	(b) a full assessment of the chemical product is required; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required				
5	Application for: (a) registration of a chemical product containing an approved active constituent and approval of the product label; or (b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or (c) registration of a chemical product and approval of the product label; if: (d) the chemical product is	8 months	12 months	\$700	\$7,566

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	similar to a registered chemical product; and (e) chemistry and manufacture data, efficacy data and target species safety data are the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and (f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopoeia; and (g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical				

**Schedule 6** Application fees and assessment periods

**Part 2** Assessment periods and fees

Clause 2.1

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	product has been lodged				
6	Application for: (a) registration of a chemical product containing an approved active constituent and approval of the product label; or (b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or (c) registration of a chemical product and approval of the product label; if: (d) the chemical product is closely similar to a registered chemical product; and (e) chemistry and manufacture data are the only data required to demonstrate the similarity of the chemical product to the	8 months	12 months	\$700	\$6,406

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	registered chemical product; and (f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or compendial standard in the British Pharmacopoeia, British Pharmacopoeia (Veterinary), European Pharmacopoeia or United States Pharmacopoeia; and (g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged				
7	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is	3 months	5 months	\$350	\$2,632

**Schedule 6** Application fees and assessment periods**Part 2** Assessment periods and fees

## Clause 2.1

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	<p>closely similar to a registered chemical product; and</p> <p>(b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and</p> <p>(c) chemistry and manufacture data are not required</p>				
8	<p>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:</p> <p>(a) the chemical product is the same as a registered chemical product; and</p> <p>(b) the chemical product is to be registered with a different name</p>	3 months	5 months	\$350	\$2,632
9	Application for registration of a listed chemical product and approval of a product label where the product and label	2 months	4 months	\$350	\$2,632



**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	comply with an established standard that has been approved in accordance with section 8U of the Code				
10	Application for: (a) registration of a chemical product containing an approved active constituent and approval of the product label; or (b) registration of a chemical product and approval of the active constituent in the chemical product; or (c) registration of a chemical product and approval of the product label (but only if a separate application for the approval of the active constituent in the chemical product has been lodged); for all situations other than those described in items 1 to 9	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
10A	Application for approval of a label for containers for a	The modular assessment period	One and one third of the modular assessment period,	\$350	The modular assessment fee

**Schedule 6** Application fees and assessment periods**Part 2** Assessment periods and fees

## Clause 2.1

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	registered chemical product		rounded up to the nearest whole month, plus 1 month		
<b>Applications for approval or registration for prescribed active constituents, chemical products or labels</b>					
10B	Application under subsection 14C(1), 14D(1) or 14E(1) of the Code	A period specified in, or worked out in accordance with, a legislative instrument made by the APVMA	A period specified in, or worked out in accordance with, a legislative instrument made by the APVMA	An amount (if any) specified in, or worked out in accordance with, a legislative instrument made by the APVMA	An amount specified in, or worked out in accordance with, a legislative instrument made by the APVMA
<b>Applications to vary a registration or approval</b>					
11	Application to vary relevant particulars or conditions of registration or label approval where a full assessment of the chemical product is required	10 months	15 months	\$1,050	\$36,205
12	Application to vary relevant 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	3 months	5 months	\$350	\$2,018
13	Application to vary relevant particulars or conditions of registration or label approval	3 months	5 months	Nil	Nil

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	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				
13A	Application to vary a relevant particular of an approval or registration where the variation of the relevant particular is a prescribed variation under section 26B of the Code	1 month	Not applicable	Nil	\$175
14	Application to vary relevant particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 13A	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
<b>Applications for approval of an active constituent</b>					
15	Application for approval of an active constituent requiring a full assessment	14 months	20 months	\$1,400	\$38,776
16	Application for approval of an	9 months	13 months	\$700	\$27,031

**Schedule 6** Application fees and assessment periods**Part 2** Assessment periods and fees

## Clause 2.1

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	active constituent requiring less than full assessment but requiring a toxicological assessment				
17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment (unless item 5, 6 or 10 applies)	7 months	11 months	\$700	\$5,442
<b>Applications for variation to an approved active constituent</b>					
18	Application to vary relevant particulars or conditions of an approved active constituent	7 months	11 months	\$700	\$4,252
<b>Applications for permits</b>					
19	Application for a permit, or extension of 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, where no data of a technical nature is required	3 months	5 months	\$350	\$350

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
20	Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required	3 months	5 months	\$350	\$350
21	Application for a permit, or extension of a permit, where the proposed use is a minor use	The modular assessment period	The modular assessment period, plus 6 months (unless the APVMA and the applicant agree to a shorter period)	\$350	\$350
22	Application for a permit, or extension of 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	Not applicable—(see subregulation 76(4))	Not applicable	Nil (see paragraph 70(8)(b))	Nil (see paragraph 70(8)(b))
23	Application for a permit, or extension of 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 22	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee

**Schedule 6** Application fees and assessment periods**Part 2** Assessment periods and fees

## Clause 2.1

**Fees and assessment periods**

<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
<b>Other applications</b>					
24	Application made under section 10 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17)	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
25	Application made under regulation 8AS for a technical assessment	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee, plus GST
27	Timeshift application (see regulation 3BA)	The modular assessment period	Not applicable	\$1,400	The modular assessment fee
28	Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee
29	Application made under regulation 19AEB to make an interchangeable constituent determination	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee

## Schedule 7—Table of fees and periods for completion of modules, levels and types of assessments

Note: See regulations 70A and 77.

<b>Table of fees and periods for completion of modules, levels and types of assessments</b>			
<b>Item</b>	<b>Column 1 Module, level or type</b>	<b>Column 2 Period for completion</b>	<b>Column 3 Fee (\$)</b>
<b>1</b>	<b>Preliminary assessment</b>		902
<b>2</b>	<b>Chemistry</b>		
2.1	Chemistry—level 1	13 months	11,074
2.2	Chemistry—level 2	9 months	3 075
2.3	Chemistry—level 3	6 months	1,954
<b>3</b>	<b>Toxicology (not requiring poison schedule classification)</b>		
3.1	Toxicology—level 1	13 months	27 920
3.2	Toxicology—level 2	9 months	15 795
3.3	Toxicology—level 3	5 months	4 050
<b>4</b>	<b>Toxicology (requiring poison schedule classification)</b>		
4.1	Toxicology requiring poison schedule classification	13 months	2 435
<b>5</b>	<b>Residues</b>		
5.1	Residues—level 1	13 months	25,650
5.2	Residues—level 2	8 months	11,149
5.3	Residues—level 3	8 months	16,400
5.4	Residues—level 4	4 months	7 465
5.5	Residues—level 5	4 months	4,000
<b>6</b>	<b>Work health and safety</b>		
6.1	Work health and safety—level 1	13 months	8,820
6.2	Work health and safety—level 2	7 months	3 185
6.3	Work health and safety—level 3	4 months	3,913
<b>7</b>	<b>Environment</b>		
7.1	Environment—level 1	13 months	26 390
7.2	Environment—level 2	7 months	7,659
7.3	Environment—level 3	4 months	2,979
<b>8</b>	<b>Efficacy and safety</b>		
8.1	Efficacy and safety—level 1	6 months	4,740
8.2	Efficacy and safety—level 2	4 months	1,950
8.3	Efficacy and safety—level 3	3 months	1,160

**Schedule 7** Table of fees and periods for completion of modules, levels and types of assessments

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<b>Table of fees and periods for completion of modules, levels and types of assessments</b>			
<b>Item</b>	<b>Column 1 Module, level or type</b>	<b>Column 2 Period for completion</b>	<b>Column 3 Fee (\$)</b>
<b>9</b>	<b>Non-food trade</b>	6 months	1 175
<b>10</b>	<b>Special data</b>		
10.1	Special data—level 1	13 months	nil
10.2	Special data—level 2	7 months	nil
10.3	Special data—level 3	7 months	nil
<b>11</b>	<b>Finalisation</b>		
11.1	Finalisation—type 1	3 months	8,110
11.2	Finalisation—type 2	2 months	3,090
11.3	Finalisation—type 3	2 months	1,730
<b>12</b>	<b>Limits on use of information</b>		460

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## **Schedule 8—Logo of the Australian Pesticides and Veterinary Medicines Authority (APVMA)**

(regulation 79)



## Endnotes

Endnote 1—About the endnotes

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## Endnotes

### Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

### Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

### Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

### Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

### Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe how an amendment is to be made. If, despite the misdescription, the amendment can be given effect as intended, then the misdescribed amendment can be incorporated through an editorial change made under section 15V of the *Legislation Act 2003*.

If a misdescribed amendment cannot be given effect as intended, the amendment is not incorporated and “(md not incorp)” is added to the amendment history.

**Endnote 2—Abbreviation key**

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

## Endnotes

### Endnote 3—Legislation history

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### Endnote 3—Legislation history

Number and year	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
1995 No. 27	28 Feb 1995	15 Mar 1995 (r 2)	
1995 No. 54	29 Mar 1995	15 Mar 1995 (r 1)	—
1995 No. 137	15 June 1995	r 4 and 5: 1 July 1995 Remainder: 15 June 1995	—
1995 No. 187	4 July 1995	4 July 1995	—
1996 No. 83	5 June 1996	5 June 1996	—
1996 No. 111	20 June 1996	20 June 1996	r 9
1996 No. 162	24 July 1996	24 July 1996	—
1996 No. 216	2 Oct 1996	2 Oct 1996	—
1997 No. 264	24 Sept 1997	24 Sept 1997	—
1999 No. 215	16 Sept 1999	16 Sept 1999	—
1999 No. 247	27 Oct 1999	31 Oct 1999	—
2002 No. 60	5 Apr 2002	5 Apr 2002	—
2002 No. 207	12 Sept 2002	12 Sept 2002	—
2003 No. 8	27 Feb 2003	27 Feb 2003	—
2004 No. 224	28 July 2004	28 July 2004	—
2004 No. 225	28 July 2004	28 July 2004	—
2004 No. 251	26 Aug 2004	1 Jan 2005 (. 2)	—
2004 No. 353	23 Dec 2004	23 Dec 2004	—
2004 No. 354	23 Dec 2004	1 Jan 2005 (r 2)	—
2005 No. 105	9 June 2005 (F2005L01410)	Sch 2: 1 July 2005 Remainder: 10 June 2006	—
2005 No. 152	12 July 2005 (F2005L01916)	13 July 2005	—
2006 No. 75	19 April 2006 (F2006L01163)	20 Apr 2006	—
2007 No. 278	27 Sept 2007 (F2007L03839)	28 Sept 2007	—
2009 No. 1	9 Feb 2009 (F2009L00269)	10 Feb 2009	—
2009 No. 341	15 Dec 2009 (F2009L04598)	16 Dec 2009	—
2010 No. 75	11 May 2010 (F2010L00976)	12 May 2010	—
2010 No. 108	4 June 2010 (F2010L01482)	5 June 2010	—
2010 No. 144	29 June 2010 (F2010L01805)	1 July 2010	—
2011 No. 16	17 Mar 2011 (F2011L00441)	18 Mar 2011	—
2012 No. 72	28 May 2012 (F2012L01093)	1 July 2012	—
108, 2013	17 June 2013 (F2013L01016)	Sch 1 (items 6–29): 1 July 2013	—
179, 2013	29 July 2013 (F2013L01458)	Sch 1 (items 11–174): 1 July 2014	—

## Endnote 3—Legislation history

Number and year as amended by	FRLI registration or gazettal	Commencement	Application, saving and transitional provisions
67, 2014	13 June 2014 (F2014L00714)	Sch 2: 1 July 2014 ( s 2(1) items 2, 3)	—
67, 2014	13 June 2014 (F2014L00714)	Sch 1 (items 11–103): 1 July 2014 ( s 2(1) items 2, 3)	—
91, 2014	27 June 2014 (F2014L00860)	Sch 1: 1 July 2014 (s 2(1) item 2) Remainder: 28 June 2014	—
118, 2014	25 Aug 2014 F2014L01115)	Sch 1 (items 9, 10, 14 and 52): 1 Jan 2015 (s 2 items 3, 5, 7) Remainder: 26 Aug 2014 (s 2 items 1, 2, 4, 6, 8)	—
5, 2015	3 Mar 2015 (F2015L00247)	Sch 1: 5 Mar 2015 (s 2 item 2) Sch 3: 4 Mar 2015 (s 2 item 3)	—
219, 2015	16 Dec 2015 (F2015L02042)	Sch 1 (items 4–7): 17 Dec 2015 (s 2(1) item 2) Sch 2: 1 Mar 2016 (s 2(1) item 3) Sch 3: 1 July 2016 (s 2(1) item 4)	—

Name	Registration	Commencement	Application, saving and transitional provisions
Corporations and Other Legislation Amendment (Insolvency Law Reform) Regulation 2016	13 Dec 2016 (F2016L01926)	Sch 1 (item 2): 1 Mar 2017 (s 2(1) item 2)	—
Agricultural and Veterinary Chemicals Legislation Amendment (Reconsideration Participation Review) Regulations 2017	28 June 2017 (F2017L00771)	Sch 1 (item 2): 29 June 2017 (s 2(1) item 1)	—
Agricultural and Veterinary Chemicals Code Amendment (Fuel and Oil Biocides) Regulations 2018	3 Aug 2018 (F2018L01086)	4 Aug 2018 (s 2(1) item 1)	—
Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2019	22 Mar 2019 (F2019L00357)	Sch 1 (items 1–49, 52–108): 23 Mar 2019 (s 2(1) item 1)	—

## Endnotes

### Endnote 3—Legislation history

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<b>Name</b>	<b>Registration</b>	<b>Commencement</b>	<b>Application, saving and transitional provisions</b>
Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020	15 May 2020 (F2020L00581)	1 July 2020 (s 2(1) item 1)	—
Agricultural and Veterinary Chemicals Code Amendment (Miscellaneous Measures) Regulations 2021	20 Dec 2021 (F2021L01849)	21 Dec 2021 (s 2(1) item 1)	—
Agricultural and Veterinary Chemicals Legislation Amendment (Improvements) Regulations 2021	20 Dec 2021 (F2021L01862)	Sch 1 (items 1–8): 7 June 2022 (s 2(1) items 2, 3) Sch 1 (items 9, 10, 17–19): 7 Mar 2022 (s 2(1) items 4, 6, 7)	—

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**Endnote 4—Amendment history**

<b>Provision affected</b>	<b>How affected</b>
<b>Part 1</b>	
<b>Division 1.1A</b>	
Division 1.1A heading .....	ad No 179, 2013
r 1 .....	rs No 215, 1999
<b>Division 1.1B</b>	
Division 1.1B .....	ad F2019L00357
r 2 .....	rep LA s 48D ad F2019L00357
<b>Division 1.1</b>	
Division 1.1 heading.....	ad No 179, 2013
r 3 .....	am No 83, 1996; No 247, 1999; No 353, 2004; No 354, 2004; No 105, 2005; No 75, 2010; No 108, 2010; No 16, 2011; No 108, 2013; No 179, 2013; No 67, 2014; F2015L02042; F2019L00357; F2021L01849
r 3AA.....	ad F2021L01849
r. 3A .....	ad. 2004 No. 354 am No 67, 2014
r 3B.....	ad No 354, 2004 am No 67, 2014
r 3BA.....	ad F2019L00357
r. 3C.....	ad. 2011 No. 16
r 4 .....	ad No 118, 2014
r. 5 .....	rep. No. 108, 2013
r 5A .....	ad No 179, 2013
r 6 .....	rep No 179, 2013
r. 7 .....	rs. 2010 No. 75
r. 8 .....	am. 2004 No. 225 rs. 2010 No. 75 am No 5, 2015
r 8AA.....	ad No 179, 2013
r 8AB.....	ad No 179, 2013 am No 118, 2014
r 8AD.....	ad No 179, 2013
r 8AE.....	ad No 179, 2013 am No 67, 2014
r 8AF .....	ad No 179, 2013 am No 67, 2014
r 8AFA .....	ad No 219, 2015
r 8AFB.....	ad F2015L02042

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
	rep F2019L00357
<b>Division 1.2</b>	
Division 1.2 .....	ad No 179, 2013
r 8AG.....	ad No 179, 2013
r 8AH.....	ad No 179, 2013
	am F2019L00357
r 8AHAA .....	ad F2021L01862
<b>Division 1.3</b>	
Division 1.3 .....	ad No 179, 2013
r 8AHA.....	ad No 67, 2014
r 8AK.....	ad No 179, 2013
r 8AL.....	ad No 179, 2013
	am No 118, 2014
r 8AM.....	ad No 179, 2013
r 8AN.....	ad No 179, 2013
	am No 67, 2014
r 8AO.....	ad No 179, 2013
	am No 67, 2014; No 118, 2014; F2019L00357
r 8AP .....	ad No 179, 2013
	am No 67, 2014
	rs F2019L00357
r 8AQ.....	ad No 179, 2013
	am No 67, 2014; F2019L00357
<b>Division 1.6</b>	
Division 1.6 .....	ad No 179, 2013
r 8AR.....	ad No 179, 2013
<b>Part 2</b>	
<b>Division 2.1A</b>	
Division 2.1A .....	ad No 179, 2013
r 8AS .....	ad No 179, 2013
	am F2019L00357
r 8AT .....	ad No 179, 2013
<b>Division 2.1</b>	
Division 2.1 heading.....	ad. 2011 No. 16
<b>Subdivision 2.1.1</b>	
Subdivision 2.1.1 heading.....	ad. 2011 No. 16
r. 8A .....	ad. 2004 No. 354
	am. 2011 No. 16
	rep No 179, 2013
r. 8B.....	ad. 2004 No. 354



## Endnote 4—Amendment history

Provision affected	How affected
	am. 2011 No. 16; No 179, 2013; No 67, 2014; No 5, 2015
r. 8C.....	ad. 2004 No. 354
	am. 2011 No. 16
	rep No 179, 2013
r. 8D.....	ad. 2004 No. 354
	am. 2011 No. 16; No 179, 2013; No 67, 2014
r. 8E.....	ad. 2004 No. 354
	am. 2011 No. 16; No 179, 2013; No 67, 2014
Subdivision. 2.1.2 heading.....	ad. 2011. No. 16
	rep No 179, 2013
Subdivision 2.1.2.....	rep No 179, 2013
r. 9.....	am. 2004 No. 225; 2011 No. 16
	rep No 179, 2013
r. 10.....	am. 2004 No 225 and 353
	rep. 2009 No. 1
r. 11.....	am. 2004 No 225 and 353; 2011 No. 16
	rep No 179, 2013
r. 11A.....	ad. 1999 No. 247
	am. 2004 No. 225
	rep. 2011 No. 16
r. 12.....	am. 2004 No 225 and 353
	rs. 2011 No. 16
	rep No 179, 2013
r. 13.....	am. 2004 No. 353
	rs. 2011 No. 16
	rep No 179, 2013
r. 14.....	am. 2004 No 225 and 353
	rs. 2011 No. 16
	rep No 179, 2013
r. 14A.....	ad. No. 108, 2013
	rep No 179, 2013
<b>Subdivision 2.1.3</b>	
Subdivision 2.1.3 heading.....	ad. 2011. No. 16
r 15.....	am No 225, 2004; No 353, 2004; No 16, 2011; No 179, 2013; No 5, 2015; F2019L00357
r. 16.....	am. 2004 No 225 and 353; 2011 No. 16; No 179, 2013; No 118, 2014
r. 17.....	rep. 2004 No. 225
	ad. 2011 No. 16
	am No 179, 2013; No 118, 2014
Subdivision 2.1.3A.....	ad No 179, 2013
	rep No 118, 2014

## Endnotes

### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
r 17A .....	ad No 179, 2013 rs No 91, 2014 rep No 118, 2014
r 17B.....	ad No 179, 2013 rs No 91, 2014 rep No 118, 2014
r 17BA.....	ad No 91, 2014 rep No 118, 2014
r 17BB.....	ad No 91, 2014 rep No 118, 2014
r 17BC.....	ad No 91, 2014 rep No 118, 2014
r 17BD.....	ad No 91, 2014 rep No 118, 2014
<b>Subdivision 2.1.4</b>	
Subdivision 2.1.4 heading.....	ad. 2011. No. 16
r 17C.....	ad No 179, 2013 am No 67 and 118, 2014
r 18 .....	rs No 16, 2011 am No 179, 2013; F2019L00357
Subdivision 2.1.5 heading.....	ad No 16, 2011 rep No 67, 2014
Subdivision 2.1.5.....	rep No 67, 2014
r. 18A .....	ad. 2011 No. 16 rep No 67, 2014
<b>Subdivision 2.1.6</b>	
Subdivision 2.1.6 heading.....	ad. 2011. No. 16
r. 18B.....	ad. 2011. No. 16 rs No 179, 2013 am No 67, 2014
r. 18C.....	ad. 2011. No. 16
r. 18D .....	ad. 2011. No. 16 am No 179, 2013; No 67, 2014
r. 18E.....	ad. 2011. No. 16 am No 67, 2014
r. 18F .....	ad. 2011. No. 16 am No 67, 2014
r. 18G .....	ad. 2011. No. 16 am No 179, 2013
r. 18H .....	ad. 2011. No. 16

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Provision affected	How affected
	am No 179, 2013
r. 18I.....	ad. 2011. No. 16
	am No 179, 2013
r 18J.....	ad No 179, 2013
	am No 67, 2014
<b>Subdivision 2.1.6A</b>	
Subdivision 2.1.6A.....	ad No 179, 2013
r 18K.....	ad No 179, 2013
	am No 118, 2014
Subdivision 2.1.7 heading.....	ad. 2011. No. 16
	rep No 179, 2013
Subdivision 2.1.7.....	rep No 179, 2013
r. 19.....	am. 2004 No 225 and 353; 2011 No. 16
	rep No 179, 2013
<b>Division 2.2</b>	
Division 2.2 heading.....	ad. 2011 No. 16
<b>Subdivision 2.2.1</b>	
Subdivision 2.2.1 heading.....	ad. 2011 No. 16
r. 19AA.....	ad. 2004 No. 354
	rs. 2011 No. 16
	rep No 179, 2013
r. 19AB.....	ad. 2004 No. 354
	am. 2011 No. 16
	rep No 179, 2013
r. 19AC.....	ad. 2004 No. 354
	am. 2011 No. 16
	rep No 179, 2013
r 19AD.....	ad No 354, 2004
	am No 16, 2011; No 179, 2013; No 67, 2014; F2021L01862
Subdivision 2.2.2 heading.....	ad. 2011. No. 16
	rep No 179, 2013
Subdivision 2.2.2.....	rep No 179, 2013
r. 19A.....	ad. 2004 No. 225
	rs. 2011 No. 16
	rep No 179, 2013
Division 2.2A.....	ad No 179, 2013
	rep No 118, 2014
r 19A.....	ad No 179, 2013
	rep No 118, 2014

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### Endnote 4—Amendment history

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<b>Provision affected</b>	<b>How affected</b>
<b>Subdivision 2.2.2</b>	
Subdivision 2.2.2 heading.....	rs F2019L00357
Subdivision 2.2.2.....	ad No 118, 2014
r 19AE.....	ad No 118, 2014 am F2015L02042 rep F2019L00357
r 19AEA.....	ad F2015L02042
r 19AEB.....	ad F2015L02042
r 19AEC.....	ad F2015L02042
Subdivision 2.2.3.....	ad No 118, 2014 rep F2019L00357
r 19AF.....	ad No 118, 2014 am F2015L02042 rep F2019L00357
<b>Division 2.3</b>	
Division 2.3 heading.....	ad. 2011 No. 16
r. 20.....	am. 2004 No 225 and 353 rs No 179, 2013 am No 67, 2014
r. 21.....	am. 2004 No 225 and 353 rs No 179, 2013
r. 22.....	rs. 2004 No. 225 am. 2004 No. 353 rs. 2011 No. 16; No 179, 2013 am No 118, 2014
r. 22AA.....	ad. 2011 No. 16 rs No 179, 2013 am No 67, 2014
Division 2.4 heading.....	ad. 2011 No. 16 rep No 179, 2013
Division 2.4.....	rep No 179, 2013
r. 22A.....	ad. 2004 No. 354 rs. 2005 No. 105 rep No 179, 2013
Division 2.5 heading.....	ad. 2011 No. 16 rs No 179, 2013 rep No 91, 2014
Division 2.5.....	rs No 179, 2013 rep No 91, 2014
r. 22B.....	ad. 2004 No. 354

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Provision affected	How affected
	rs. 2005 No. 105
	rep No 179, 2013
r. 22A .....	ad. 2004 No. 251
	rep. 2005 No. 105
r. 22C.....	ad. 2005 No. 105
	rep No 179, 2013
r. 22D .....	ad No 179, 2013
	rep No 91, 2014
<b>Division 2.6</b>	
Division 2.6 heading.....	ad. 2011 No. 16
r. 23 .....	am. 2004 No. 353; 2005 No. 105; No 219, 2015
Part 2A .....	ad. 2004 No. 225
	rep No 179, 2013
<b>Division 2.7</b>	
Division 2.7.....	ad No 219, 2015
r. 23A .....	ad. 2004 No. 225
	rs. 2007 No. 278
	rep No 179, 2013
	ad No 219, 2015
r. 23AB.....	ad. 2011 No. 16
	rep No 179, 2013
r. 23B.....	ad. 2004 No. 225
	am. 2004 No. 353
	rep No 179, 2013
r. 23C.....	ad. 2004 No. 225
	rep No 179, 2013
r. 23D .....	ad. 2004 No. 225
	am. 2004 No. 353
	rep No 179, 2013
r. 23E.....	ad. 2004 No. 225
	am. 2004 No. 353
	rep No 179, 2013
r. 23F .....	ad. 2004 No. 225
	am. 2004 No. 353, 2005 No. 105
	rep No 179, 2013
<b>Part 2B</b>	
Part 2B heading.....	ad. 2004 No. 225
	rs. 2007 No. 278
Part 2B.....	am 2004 No. 225
	rs 2007 No. 278

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<b>Provision affected</b>	<b>How affected</b>
r. 23G .....	ad. 2007 No. 278
r 23H .....	ad No 278, 2007 am F2019L00357
r 23I .....	ad No 278, 2007 am F2019L00357
<b>Part 3</b>	
<b>Division 3.1</b>	
Division 3.1 heading (prev Division 1 heading) .....	ad No 179, 2013 renum No 179, 2013
r 24 .....	am No 16, 2011; No 179, 2013 rs F2019L00357
r 25 .....	am No 16, 2011; No 179, 2013 rs F2019L00357
<b>Division 3.2</b>	
Division 3.2 heading (prev Division 2 heading) .....	ad No 179, 2013 renum No 179, 2013
r. 27 .....	am. 2004 No. 353; No 179, 2013
r 28 .....	am No 179, 2013
r 29 .....	am No 179, 2013
r 31 .....	am No 179, 2013
r 32 .....	am No 179, 2013
r 34 .....	am No 179, 2013
r 35 .....	am No 60, 2002; F2019L00357
r 36 .....	am No 353, 2004; No 179, 2013; F2019L00357
r. 37 .....	am. 2004 No. 353; No 179, 2013
r 38 .....	am No 179, 2013
<b>Part 4</b>	
<b>Division 4.1</b>	
Division 4.1 heading (prev Division 1 heading) .....	ad No 179, 2013 renum No 179, 2013
r. 40A .....	ad. 1995 No. 54 rep No 179, 2013
r 40 .....	am No 179, 2013
r 41 .....	am No 225, 2004; No 179, 2013; No 118, 2014; No 5, 2015 rs F2021L01849
r 42 .....	am No 353, 2004; No 16, 2011; No 179, 2013; No 67, 2014; No 118, 2014; F2019L00357
r 42A .....	ad F2019L00357
r 43A .....	ad No 118, 2014
r 44 .....	am No 179, 2013
r. 45 .....	am. 2004 No. 353

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<b>Provision affected</b>	<b>How affected</b>
r 46 .....	am No 111, 1996; No 60, 2002; No 353, 2004; No 179, 2013; F2019L00357
<b>Division 4.2</b>	
Division 4.2 heading (prev Division 2 heading) .....	ad No 179, 2013 renum No 179, 2013
r 47 .....	rs. 1996 No. 111 am. 2004 No. 353; 2005 No. 105; 2010 No. 144; F2020L00581
r 47A .....	ad. 1996 No. 111 am. 1997 No. 264; 2004 No. 353
r 47AB .....	ad. 1997 No. 264 am. 2004 No. 353; No 5, 2015
r 47B .....	ad. 1996 No. 111
r 47C .....	ad No 111, 1996 am No 60, 2002; F2019L00357
r 48 .....	rs No 111, 1996; No 60, 2002 am No 353, 2004; F2019L00357
r 49 .....	rs No 111, 1996 am No 60, 2002; F2019L00357
r 50 .....	rs No 111, 1996 am No 60, 2002; F2019L00357
r 51 .....	rs No 111, 1996 am No 60, 2002; F2019L00357
r 52 .....	am No 179, 2013
r 53 .....	am No 60, 2002; No 353, 2004; F2019L00357
r 54 .....	am No 60, 2002; No 179, 2013; F2019L00357
<b>Part 5</b>	
r 55 .....	am No 111, 1996; No 353, 2004; No 118, 2014; F2019L00357
r 55A .....	ad No 118, 2014
r 56 .....	am. 2004 No. 353; No 118, 2014
<b>Part 5A</b>	
Part 5A .....	ad F2021L01862
r 56A .....	ad F2021L01862
<b>Part 6</b>	
r 57 .....	rs No 179, 2013
r 57A .....	ad No 179, 2013
r 57B .....	ad No 179, 2013
<b>Part 7</b>	
r 58 .....	rep No 179, 2013
r 59 .....	am. 1996 No. 162; No 118, 2014
r 59A .....	ad. 1996 No. 162

## Endnotes

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<b>Provision affected</b>	<b>How affected</b>
r. 59B.....	ad. 1996 No. 162 am. 2004 No. 353; No 118, 2014
r. 59C.....	ad. 1996 No. 162 am. 1997 No. 264; 2004 No. 353; No 179, 2013
r. 59D .....	ad. 1996 No. 162 am. 2004 No. 353; No 179, 2013
r. 59E.....	ad. No. 108, 2013 am No 179, 2013
r. 60 .....	am. 2004 No. 353
r. 61 .....	am. 1996 No. 162; 2004 No. 353; No. 108, 2013; F2016L01926
r. 61A .....	ad. No. 108, 2013
r. 62 .....	am. 2004 No. 353
<b>Part 8</b>	
r 63 .....	rs No 179, 2013
r 64 .....	rs No 179, 2013
<b>Part 9</b>	
<b>Division 9.1</b>	
Division 9.1 heading.....	ad No 179, 2013
r. 65 .....	am. 2004 No. 225 rs No 179, 2013 am No 67 and 118, 2014
r 65A .....	ad No 179, 2013 am No 67, 2014; No 118, 2014; F2019L00357
r 65B.....	ad No 67, 2014
r 66 .....	am No 353, 2004; No 179, 2013; F2019L00357
r. 69 .....	am. 2002 No. 60; 2004 No. 353; No 179, 2013
<b>Division 9.2</b>	
Division 9.2 heading.....	ad No 179, 2013
r 69A .....	ad No 67, 2014
r 69AA.....	ad No 118, 2014 rs F2019L00357
r 69AAA.....	ad No 5, 2015
r 69B.....	ad No 179, 2013 am No 67, 2014
r 70 .....	am No 137, 1995; No 83, 1996; No 225, 2004; No 105, 2005; No 144, 2010; No 108, 2013; No 179, 2013; No 67, 2014; F2019L00357; F2021L01862
r. 70A .....	ad. 1995 No. 54 am. 2004 No. 353 rs No 179, 2013 am No 219, 2015



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<b>Provision affected</b>	<b>How affected</b>
r 70B.....	ad No 179, 2013 am F2019L00357
r. 71 .....	rs. 2005 No. 105; No 144, 2010; No 16, 2011; No 108, 2013 rep No 179, 2013
r. 71A .....	ad. 1996 No. 83 am. 1999 No. 247; 2004 No. 225 rs. 2005 No. 105 am. No 144, 2010; No 108, 2013; No 179, 2013; No 118, 2014; No 219, 2015; F2020L00581
r. 71B.....	ad. 1996 No. 83 rep. 2005 No. 105 ad. No. 108, 2013 am No 179, 2013; No 118, 2014
r 71C.....	ad No 179, 2013
r 72 .....	am No 353, 2004; No 105, 2005 rs No 179, 2013 am F2019L00357
r. 72A .....	ad. 1996 No. 162 am. 2004 No. 353; 2005 No. 105; No 75, 2010; No 144, 2010 rs. No. 108, 2013 am No 179, 2013; No 118, 2014
r. 73 .....	am. 2004 No. 353; 2005 No. 105; No 108 and 179, 2013; No 67 and 118, 2014
r 73A .....	ad No 67, 2014
r. 74 .....	am. 2004 No. 353 rep No 67, 2014
<b>Division 9.3</b>	
Division 9.3 heading.....	ad No 179, 2013
r. 75 .....	am. 2004 No. 353
r 76 .....	am No 353, 2004; No 105, 2005; No 179, 2013; No 118, 2014; No 219, 2015; F2019L00357; F2021L01862
r 76A .....	ad No 179, 2013 am No 118, 2014; F2019L00357; F2021L01862
r 76B.....	ad No 179, 2013
r 77 .....	rs No 105, 2005 am No 179, 2013; No 219, 2015 rs F2019L00357
r 78 .....	am No 247, 1999; No 225, 2004; No 353, 2004 rs No 105, 2005 am No 144, 2010; No 108, 2013 rs No 179, 2013

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<b>Provision affected</b>	<b>How affected</b>
	am No 118, 2014; F2019L00357
r. 78A .....	ad. 2005 No. 105
	am. 2010 No. 144; No. 108, 2013
	rep No 179, 2013
r 78AA.....	ad No 118, 2014
r 78B.....	ad No 179, 2013
	am No 67, 2014
r 78C.....	ad No 179, 2013
	am No 5, 2015; F2015L02042; F2019L00357
<b>Division 9.4</b>	
Division 9.4 heading .....	ad No 179, 2013
r. 79 .....	ad. 2004 No. 224
Part 9A .....	ad No 179, 2013
	exp 30 June 2018 (r 80C)
	rep F2019L00357
r 80A .....	ad No 179, 2013
	exp 30 June 2018 (r 80C)
	rep F2019L00357
r 80B.....	ad No 179, 2013
	exp 30 June 2018 (r 80C)
	rep F2019L00357
r 80C.....	ad No 179, 2013
	exp 30 June 2018 (r 80C)
	rep F2019L00357
r 80D .....	ad No 179, 2013
	am No 67, 2014
	rep F2017L00771
r 80E.....	ad No 179, 2013
	am No 67, 2014
	exp 30 June 2018 (r 80C)
	rep F2019L00357
r 80F.....	ad No 179, 2013
	rep No 67, 2014
<b>Part 10</b>	
Part 10 .....	ad No 179, 2013
<b>Division 10.1</b>	
r 80 .....	ad No 179, 2013
	am No 91, 2014
r 81 .....	ad No 179, 2013
	am No 67, 2014

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Provision affected	How affected
	rs No 91, 2014
	rep No 118, 2014
r 82 .....	ad No 179, 2013
r 83 .....	ad No 179, 2013
r 84 .....	ad No 179, 2013
r 85 .....	ad No 179, 2013
	am No 67, 2014
<b>Division 10.2</b>	
Division 10.2 .....	ad No 67, 2014
r 86 .....	ad No 67, 2014
<b>Part 10</b>	
Part 10 .....	ad No 118, 2014
r 87 .....	ad No 118, 2014
<b>Division 10.4</b>	
Division 10.4 .....	ad No 5, 2015
	rep 5 Mar 2016 (r 89)
	ad F2019L00357
r 88 .....	ad No 5, 2015
	rep 5 Mar 2016 (r 89)
	ad F2019L00357
r 89 .....	ad No 5, 2015
	rep 5 Mar 2016 (r 89)
	ad F2019L00357
<b>Division 10.5</b>	
Division 10.5 .....	ad No 219, 2015
	rep 1 July 2017 (r 91)
	ad F2020L00581
r 90 .....	ad No 219, 2015
	rep 1 July 2017 (r 91)
	ad F2019L00357
r 91 .....	ad No 219, 2015
	rep 1 July 2017 (r 91)
	ad F2020L00581
r 92 .....	ad F2020L00581
<b>Division 10.6</b>	
Division 10.6 .....	ad F2021L01849
r 93 .....	ad F2021L01849
<b>Division 10.7</b>	
Division 10.7 .....	ad F2021L01862
r 94 .....	ad F2021L01862

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<b>Provision affected</b>	<b>How affected</b>
<b>Schedule 1</b>	
Schedule 1 .....	rs. 1997 No. 264
Schedule 2 .....	rep No 179, 2013
<b>Schedule 3</b>	
Schedule 3 .....	rs No 75, 2010 am No 108, 2010; No 108, 2013; F2018L01086; F2019L00357
<b>Schedule 3AA</b>	
Schedule 3AA .....	ad No 75, 2010 am No 108, 2010; No 108, 2013; No 5, 2015; No 219, 2015; F2019L00357; F2021L01849
Schedule 3A .....	ad. 2004 No. 251 am No 105, 2005 rep No 179, 2013
<b>Schedule 3B</b>	
Schedule 3B heading .....	rs No 179, 2013
Schedule 3B .....	ad. 2007 No. 278 am No 179, 2013; No 67, 2014
<b>Schedule 4</b>	
Schedule 4 .....	am. 1995 No. 187 rs. 1997 No. 264 am. 1999 No. 215; 2002 No. 207; 2003 No. 8; 2006 No. 75; 2009 No. 341; 2012 No. 72; No 179, 2013; No 219, 2015
Schedule 5 .....	rep No 179, 2013
<b>Schedule 5A</b>	
Schedule 5A .....	ad No 179, 2013 am F2019L00357; F2021L01862
<b>Schedule 6</b>	
Schedule 6 heading .....	rs No 179, 2013
Schedule 6 .....	am No 137, 1995; No 216, 1996; No 247, 1999; No 225, 2004; No 353, 2004 rs No 105, 2005 am No 152, 2005; No 144, 2010; No 16, 2011; No 108, 2013; No 179, 2013; No 67, 2014; No 118, 2014; No 5, 2015; F2015L02042; F2019L00357; F2020L00581; F2021L01862
<b>Schedule 7</b>	
Schedule 7 .....	am. 1995 No. 137; 1996 No. 216; 2004 No. 353 rs. 2005 No. 105 am. 2010 No. 144; No. 108, 2013 rs No 179, 2013 am No 67, 2014; No 219, 2015; F2019L00357; F2020L00581

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Provision affected	How affected
<b>Schedule 8</b>	
Schedule 8.....	ad. 2004 No. 224