



Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013

Select Legislative Instrument No. 179, 2013

I, Quentin Bryce AC CVO, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the Acts mentioned in section 3.

Dated 25 July 2013

Quentin Bryce
Governor-General

By Her Excellency's Command

Peter Douglas Sidebottom
Parliamentary Secretary for Agriculture, Fisheries and Forestry

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No. 179, 2013 *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013* *i*

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1 Name of regulation

This regulation is the *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013*.

2 Commencement

This regulation commences on 1 July 2014.

3 Authority

This regulation is made under the following Acts:

- (a) the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*;
- (b) the *Agricultural and Veterinary Chemicals (Administration) Act 1992*;
- (c) the *Agricultural and Veterinary Chemicals Code Act 1994*;
- (d) the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995

1 Subregulation 6A(3) (heading)

Repeal the heading, substitute:

2013-2014 financial year

2 Subregulation 6A(3)

Omit “and each succeeding financial year”.

3 At the end of regulation 6A

Add:

2014-2015 financial year and subsequent years

- (4) For section 12C of the Act, the following rates are prescribed in respect of the 2014-2015 financial year and each succeeding financial year:
- (a) for the part of leviable disposals not exceeding \$1 000 000—0.63%;
 - (b) for the part of leviable disposals exceeding \$1 000 000 but not exceeding \$5 000 000—0.35%;
 - (c) for the part of leviable disposals exceeding \$5 000 000—0.25%.

4 Regulation 7

Repeal the regulation, substitute:

8 Disclosure of information to collecting agency

- (1) This regulation applies if the Minister has specified an agency under section 3A of the Act to be the collecting agency.

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- (2) The APVMA may give the collecting agency any information that the collecting agency reasonably requires in order to carry out its functions under the Act and these Regulations.

5 Schedule 2

Repeal the Schedule.

Agricultural and Veterinary Chemicals (Administration) Regulations 1995

6 After Part 1

Insert:

Part 1A—Annual operational plan and annual report

1A.1 Information for inclusion in annual report

The APVMA must include in its annual report a list of:

- (a) the standards made under section 6E of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* during the year to which the annual report relates; and
- (b) the standards made under section 6E that were varied by the APVMA during the year to which the annual report relates.

1A.2 Information for inclusion in annual operational plan

For paragraph 55(2)(c) of the Act, the following information is prescribed:

- (a) the number of reconsiderations to be commenced by the APVMA under section 31 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the **Agvet Code Act**) during the period to which the annual operational plan relates;
- (b) the number of reconsiderations to be concluded by the APVMA under Division 4 of Part 2 of the Schedule to the Agvet Code Act during that period;

- (c) brief details of how the APVMA plans to progress those reconsiderations during that period.

1A.3 Performance indicators for inclusion in annual report

For subparagraph 61(2)(c)(ii) of the Act, the following performance indicators are prescribed:

- (a) the number of reconsiderations commenced by the APVMA under section 31 of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the **Agvet Code Act**) during the year to which the annual report relates;
- (b) the number of reconsiderations concluded by the APVMA under Division 4 of Part 2 of the Schedule to the Agvet Code Act during that year;
- (c) brief details of the progress of reconsiderations that were scheduled to progress in that year;
- (d) the number of applications mentioned in each item of Part 2 of Schedule 6 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* that were:
 - (i) made under the Schedule to the Agvet Code Act during that year; and
 - (ii) not determined within the period required for the application by regulations made under section 165 of that Schedule;
- (e) the number of reports (known as adverse experience reports) received by the APVMA during that year;
- (f) the number of adverse experience reports mentioned in paragraph (e) that the APVMA determined were related to each of the following:
 - (i) human health;
 - (ii) environment;
 - (iii) animal health;
 - (iv) crop health;
 - (v) efficacy for agricultural chemical products or veterinary chemical products;
- (g) a summary of any action taken by the APVMA during that year in relation to adverse experience reports.

Note: Adverse experience reports are received under the Adverse Experience Reporting Program (AERP) which is a post-registration quality assurance program established by the APVMA.

7 After Part 3

Insert:

Part 3A—Infringement notices

3A.01 Infringement notices

- (1) For the definition of *prescribed civil penalty provision* in section 4 of the Act, each civil penalty provision mentioned in Schedule 5 is prescribed.
- (2) For subsection 69EKA(3) of the Act:
 - (a) the amount (in penalty units) mentioned for an individual in an item of Schedule 5 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 5 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.

8 Regulation 4.15

Repeal the regulation, substitute:

4.15 Method of securing samples

- (1) This regulation applies to an inspector who exercises:
 - (a) the monitoring power mentioned in paragraph 69EAC(1)(g) of the Act to take and keep samples of any thing on any premises; or
 - (b) the investigation power mentioned in paragraph 69EBA(1)(g) of the Act to take a sample and keep samples of any thing on any premises.

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- (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.

9 Schedules 2 to 5

Repeal the Schedules, substitute:

Schedules 2 to 4

Note: Schedules 2 to 4 are reserved for future use.

Schedule 5—Infringement notices

Note: See regulation 3A.01.

Penalty amounts for infringement notices			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
Civil penalty provisions of the Act			
1	A contravention of subparagraph 69B(1)(a)(i) of the Act involving: <ul style="list-style-type: none"> (a) at least 10 kg of an active constituent for a veterinary chemical product; or (b) at least 100 kg of an active constituent for an agricultural chemical product 	90	750
2	A contravention of subparagraph 69B(1)(a)(i) of the Act involving: <ul style="list-style-type: none"> (a) at least 1 kg, but less than 10 kg, of an active constituent for a veterinary chemical product; or 	45	375
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Penalty amounts for infringement notices			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
	(b) at least 10 kg, but less than 100 kg, of an active constituent for an agricultural chemical product		
3	A contravention of subparagraph 69B(1)(a)(i) of the Act involving: (a) less than 1 kg of an active constituent for a veterinary chemical product; or (b) less than 10 kg of an active constituent for an agricultural chemical product	9	75
4	A contravention of subparagraph 69B(1)(a)(ii) involving at least 500 containers	90	750
5	A contravention of subparagraph 69B(1)(a)(ii) involving at least 50 containers but fewer than 500 containers	45	375
6	A contravention of subparagraph 69B(1)(a)(ii) involving fewer than 50 containers	9	75
7	A contravention of subsection 69CD(1)	15	125
8	A contravention of section 69E	15	125
9	A contravention of subsection 69EA(1)	15	125
10	A contravention of subsection 69EA(1A)	15	125
Civil penalty provisions of the Collection Act			
11	A contravention of section 15 of the Collection Act	15	125
12	A contravention of section 20 of the Collection Act	15	125
13	A contravention of section 36 of the Collection Act	15	125

10 Schedule 6

Repeal the Schedule.

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

11 Before regulation 1

Insert:

Division 1.1A—Name and commencement

12 After regulation 2

Insert:

Division 1.1—Definitions

13 Subregulation 3(1)

Insert:

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.

14 Subregulation 3(1) (definition of *approved active constituent*)

Repeal the definition.

15 Subregulation 3(1)

Insert:

APVMA CEO means the Chief Executive Officer of the APVMA.

16 Subregulation 3(1)

Insert:

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

17 Subregulation 3(1) (definition of *CSIRO*)

Omit “Organization”, substitute “Organisation”.

18 Subregulation 3(1) (definition of *emergency use*)

Repeal the definition, substitute:

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.

19 Subregulation 3(1)

Insert:

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.

20 Subregulation 3(1) (definition of *FAO Specifications for Plant Protection Products*)

Repeal the definition.

21 Subregulation 3(1)

Insert:

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).

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

- (a) 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.

timeshift application means an application that:

- (a) is for:
 - (i) approval of an active constituent that is not a previously endorsed active constituent; or
 - (ii) registration of a chemical product containing an active constituent that is not an active constituent contained in any other registered chemical product; and
- (b) will, by agreement of the applicant and the APVMA, be assessed in accordance with assessment periods set out in a project plan for the application agreed to by the applicant and the APVMA.

22 Subregulation 3(1) (note)

Omit “interested person”, substitute “holder”.

23 After regulation 5

Insert:

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).

24 Regulation 6

Repeal the regulation.

25 At the end of Part 1

Add:

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:
- (a) an exempt product within the meaning given by regulation 59; or
 - (b) a listed chemical product; or
 - (c) a reserved chemical product.

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.

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 a standard for a chemical product, a constituent of a chemical product, or a label for containers for a chemical product under section 6E of the Code, or varying a standard made under that section, 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.

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- (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 for a chemical product or active constituent, 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 for the product or constituent; and
 - (b) its reasons for making or varying the standard; and
 - (c) how to obtain more information about the standard or variation.
 - (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

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 regulation 8AO, 8AP or 8AQ 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.

Division 1.3—General provisions about notices

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;
- (d) for the variation of a relevant particular or condition:

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- (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:

- (a) the holder may apply to have the particular varied under Division 3 of Part 2 of the Code; and
- (b) if such an application is made, the fee for the application must be reduced by the amount of any fee paid for the application under Division 2A of Part 2 of the Code, in accordance with subsection 27(4) 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 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 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:
 - (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 paragraphs 29E(2)(b) and 110A(2)(b) and subparagraphs 11(2)(a)(ii) and 28(2)(a)(ii) of the Code, this regulation sets out the matters that must be included in a notice under subsection 11(2), 28(2), 29E(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) for an application other than an application under section 29D of the Code:
 - (i) that the APVMA may determine that:

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- (A) the application is more correctly categorised as an application mentioned in a different item in Part 2 of Schedule 6 to the item in relation to which any fee has been paid; or
 - (B) different modules, levels and types mentioned in Schedule 7 are necessary for the application; and
- (ii) 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:
 - (i) for an application for re-approval or re-registration—the applicant must comply with the request within 28 days of the request; and
 - (ii) in any other case—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 section 160A of the Code;
 - (m) that if the APVMA does not determine the application within the assessment period for the application and any extension
-

to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code;

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

8AP Matters for notice for technical assessment

- (1) This regulation applies to an application for a technical assessment under regulation 8AS.
- (2) Within 1 month of receiving the application, the APVMA must give the applicant a notice setting out the following:
 - (a) that a technical assessment will be provided for that regulation;
 - (b) the date on which the technical assessment will commence;
 - (c) if an amount of application fee payable in relation to the application under subregulation 70(2) is unpaid—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;
 - (g) the modules to be completed in relation to the application;
 - (h) that the assessment period will be extended if the APVMA or another prescribed authority makes a request under section 159 of the Code;
 - (i) that if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code;
 - (j) that the applicant may withdraw the application in accordance with section 8D of the Code.

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 receiving the application, 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—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;
 - (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 section 160A of the Code;
 - (i) that if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code;
 - (j) that the applicant may withdraw the application in accordance with section 8D of the Code.

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.

26 Before Division 2.1 of Part 2

Insert:

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.

Examples: Assessment of a trial protocol.

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.

27 Regulation 8A

Repeal the regulation.

28 Regulation 8B (heading)

Repeal the heading, substitute:

8B Summaries of applications for active constituents for chemical products**29 Subregulation 8B(1)**

Omit “product that is not a companion animal product”, substitute “product”.

30 Subregulation 8B(2)

Omit “subregulation 11B (2)”, substitute “paragraph 11(2)(b)”.

31 Paragraph 8B(2)(g)

Omit “details set out in subregulation (3)”, substitute “application information details for the item of information”.

32 Subregulation 8B(3)

Repeal the subregulation.

33 Regulation 8C

Repeal the regulation.

34 Regulation 8D (heading)

Repeal the heading, substitute:

8D Summaries of applications for chemical products that are not the same as a registered chemical product**35 Paragraph 8D(1)(a)**

Repeal the paragraph, substitute:

- (a) registration of a chemical product that is not a chemical product mentioned in paragraph 8E(1)(a); or

36 Subregulation 8D(2)

Omit “subsection 11B (2)”, substitute “paragraph 11(2)(b)”.

37 Paragraph 8D(2)(i)

Omit “details set out in subregulation (3)”, substitute “application information details for the item of information”.

38 Subregulation 8D(3)

Repeal the subregulation.

39 Regulation 8E (heading)

Repeal the heading, substitute:

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

40 Subdivision 2.1.2

Repeal the Subdivision.

41 Subregulation 15(1)

Omit “19 (2) (a)”, substitute “19(1)(c)”.

42 Paragraph 15(1)(c)

Repeal the paragraph, substitute:

(c) the name of the active constituent;

43 Paragraph 15(1)(g)

Repeal the paragraph, substitute:

(g) identifying information for the holder of the approval of the active constituent;

44 Paragraph 15(1)(j)

Repeal the paragraph, substitute:

(j) identifying information for any nominated agent for the approval.

45 Regulation 16

Omit “20 (2) (a)”, substitute “20(1)(c)”.

46 Paragraph 16(a)

Repeal the paragraph, substitute:

- (a) the distinguishing name of the chemical product;

47 After paragraph 16(d)

Insert:

- (da) the formulation type for the chemical product;
- (db) the net contents for the chemical product;

48 Paragraph 16(e)

Repeal the paragraph, substitute:

- (e) identifying information for the holder of the registration of the chemical product;

49 Paragraph 16(k)

Repeal the paragraph, substitute:

- (k) identifying information for any nominated agent for the registration.

50 Subregulation 17(1)

Omit “21 (2) (a)”, substitute “21(a)”.

51 Paragraph 17(1)(b)

Before “name”, insert “distinguishing”.

52 Paragraphs 17(1)(g) and (i)

Repeal the paragraphs.

53 Paragraph 17(1)(j)

After “the APVMA”, insert “CEO”.

54 Subregulation 17(1) (note)

Repeal the note.

55 Subregulation 17(2)

After “the APVMA”, insert “CEO”.

56 At the end of regulation 17

Add:

- (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.

57 After Subdivision 2.1.3

Insert:

Subdivision 2.1.3A—End dates for approvals and last renewal dates for registrations

17A End date for approvals and re-approvals of active constituents

- (1) For subsections 19(2), 29J(2) and 34AE(2) of the Code, this regulation prescribes the method for working out the end date for an approval of an active constituent, including:
 - (a) an approval as re-approval of the active constituent; and
 - (b) a variation of the end date by the APVMA following a reconsideration of the approval under Division 4 of Part 2 of the Code.
- (2) The end date for the approval of an active constituent mentioned in column 1 of an item in the following table is as follows:
 - (a) if the APVMA determines that the end date should be aligned with the end date for another approval of the same active constituent—the date mentioned in column 2 for the item;
 - (b) in any other case—the date mentioned in column 3 for the item.

End date for approvals and re-approvals of active constituents			
Item	Column 1 Active constituent	Column 2 End date if approval aligned with another approval	Column 3 End date if approval not aligned with another approval
1	Active constituent mentioned in Part 2 or 3 of Schedule 1 to the <i>Agricultural and Veterinary Chemicals (Administration) Regulations 1995</i>	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.
2	Methyl bromide (bromomethane)	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.
3	Active constituent mentioned in Schedule 9 or Appendix C to the current Poisons Standard	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the approval event.
4	Active constituent mentioned in Schedule 8 to the current Poisons Standard, other than an active constituent mentioned in item 1, 2 or 3	The date determined by the APVMA. The date must be not less than 7 years, and less than 10 years, after the approval event.	The date determined by the APVMA. The date must be not less than 8 years, and less than 10 years, after the approval event.
5	Active constituent contained in a restricted chemical product	The date determined by the	The date determined by the
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Schedule 1 Amendments

End date for approvals and re-approvals of active constituents			
Item	Column 1 Active constituent	Column 2 End date if approval aligned with another approval	Column 3 End date if approval not aligned with another approval
	mentioned in Schedule 4 to these Regulations, other than an active constituent mentioned in item 1, 2, 3 or 4	APVMA. The date must be not less than 7 years, and less than 10 years, after the approval event.	APVMA. The date must be not less than 8 years, and less than 10 years, after the approval event.
6	Active constituent: (a) mentioned in Schedule 7 to the current Poisons Standard; and (b) classified in Table 3.1 of Annex VI to the European Community Regulation Number 1272/2008 as Aquatic Acute 1 or Aquatic Chronic 1; other than an active constituent mentioned in any of items 1 to 5	The date determined by the APVMA. The date must be not less than 7 years, and less than 10 years, after the approval event.	The date determined by the APVMA. The date must be not less than 8 years, and less than 10 years, after the approval event.
7	Active constituent mentioned in Schedule 7 to the current Poisons Standard, other than an active constituent mentioned in any of items 1 to 6	The date determined by the APVMA. The date must be not less than 7 years, and less than 13 years, after the approval event.	The date determined by the APVMA. The date must be not less than 10 years, and less than 13 years, after the approval event.
8	Active constituent classified in Table 3.1 of Annex VI to the European Community Regulation Number 1272/2008 as Aquatic Acute 1 or Aquatic Chronic 1, other than an active constituent mentioned in any of items 1 to 7	The date determined by the APVMA. The date must be not less than 7 years, and less than 13 years, after the approval event.	The date determined by the APVMA. The date must be not less than 10 years, and less than 13 years, after the approval event.

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End date for approvals and re-approvals of active constituents			
Item	Column 1	Column 2	Column 3
	Active constituent	End date if approval aligned with another approval	End date if approval not aligned with another approval
9	Active constituent not mentioned in any of items 1 to 8	The date determined by the APVMA. The date must be not less than 7 years, and less than 15 years, after the approval event.	The date determined by the APVMA. The date must be not less than 13 years, and less than 15 years, after the approval event.

Note: The APVMA may also determine an end date that is less than 7 years so that the end date is the same as the end date for another approval of the same active constituent: see subsections 19(3), 29J(3) and 34AE(3) of the Code.

- (3) An end date determined by the APVMA under this regulation must be the last day of a calendar month.
- (4) In determining an end date under this regulation, the APVMA must have regard to the efficient allocation of the resources of the APVMA for determining and assessing re-approval and re-registration applications.
- (5) In this regulation:

approval event:

- (a) for the approval of an active constituent—means the date on which the approval takes place; and
- (b) for the approval as re-approval of an active constituent—means the date on which the re-approval takes place; and
- (c) for a variation of the end date for the approval of an active constituent, following a reconsideration of the approval under Division 4 of Part 2 of the Code—means the date on which the variation takes place.

end date, for an approval of an active constituent, means the date on which the approval ends.

- (6) In this regulation, references to the European Community Regulation Number 1272/2008 are to that Regulation as amended from time to time.

17B Last renewal dates for registrations and re-registrations of chemical products

- (1) For subsections 20(2), 29K(2) and 34AE(2) of the Code, this regulation prescribes the method for working out the last renewal date for the registration of a chemical product, including:
- (a) a registration as re-registration of the chemical product; and
 - (b) a variation of the last renewal date by the APVMA following a reconsideration of the registration under Division 4 of Part 2 of the Code.

Note: See also sections 26D, 29B and 34A of the Code for entering last renewal dates when relevant particulars or conditions are varied.

- (2) The last renewal date for the registration of a chemical product mentioned in column 1 for an item in the following table is as follows:
- (a) if the APVMA determines that the last renewal date should be aligned with the last renewal date for another chemical product containing one or more of the same active constituents—the date mentioned in column 2 for the item;
 - (b) in any other case—the date mentioned in column 3 for the item.

Last renewal dates for registrations and re-registrations of chemical products			
Item	Column 1 Chemical product	Column 2 Last renewal date if aligned with last renewal date for another chemical product	Column 3 Last renewal date if not aligned with last renewal date for another chemical product
1	Chemical product containing an active constituent mentioned in	The date determined by the	The date determined by the

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Last renewal dates for registrations and re-registrations of chemical products			
Item	Column 1 Chemical product	Column 2 Last renewal date if aligned with last renewal date for another chemical product	Column 3 Last renewal date if not aligned with last renewal date for another chemical product
	Part 2 or 3 of Schedule 1 to the <i>Agricultural and Veterinary Chemicals (Administration) Regulations 1995</i>	APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.	APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.
2	Chemical product containing methyl bromide (bromomethane)	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.
3	Chemical product containing an active constituent mentioned in Schedule 9 or Appendix C of the current Poisons Standard	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.	The date determined by the APVMA. The date must be not less than 7 years, and less than 8 years, after the registration event.
4	Chemical product containing an active constituent mentioned in Schedule 8 to the current Poisons Standard, other than a chemical product mentioned in item 1, 2 or 3	The date determined by the APVMA. The date must be not less than 7 years, and less than 10 years, after the registration event.	The date determined by the APVMA. The date must be not less than 8 years, and less than 10 years, after the registration event.
5	Chemical product containing an active constituent contained in a restricted chemical product	The date determined by the APVMA. The date	The date determined by the APVMA. The date

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Schedule 1 Amendments

Last renewal dates for registrations and re-registrations of chemical products			
Item	Column 1 Chemical product	Column 2 Last renewal date if aligned with last renewal date for another chemical product	Column 3 Last renewal date if not aligned with last renewal date for another chemical product
	mentioned in Schedule 4 to these Regulations, other than a chemical product mentioned in item 1, 2, 3 or 4	must be not less than 7 years, and less than 10 years, after the registration event.	must be not less than 8 years, and less than 10 years, after the registration event.
6	Chemical product containing an active constituent: (a) mentioned in Schedule 7 to the current Poisons Standard; and (b) classified in Table 3.1 of Annex VI to the European Community Regulation Number 1272/2008 as Aquatic Acute 1 or Aquatic Chronic 1; other than a chemical product mentioned in any of items 1 to 5	The date determined by the APVMA. The date must be not less than 7 years, and less than 10 years, after the registration event.	The date determined by the APVMA. The date must be not less than 8 years, and less than 10 years, after the registration event.
7	Chemical product containing an active constituent mentioned in Schedule 7 to the current Poisons Standard, other than a chemical product mentioned in any of items 1 to 6	The date determined by the APVMA. The date must be not less than 7 years, and less than 13 years, after the registration event.	The date determined by the APVMA. The date must be not less than 10 years, and less than 13 years, after the registration event.
8	Chemical product containing an active constituent classified in Table 3.1 of Annex VI to the European Community Regulation Number 1272/2008 as Aquatic Acute 1 or Aquatic Chronic 1, other than a chemical product mentioned in any of items 1 to 7	The date determined by the APVMA. The date must be not less than 7 years, and less than 13 years, after the registration event.	The date determined by the APVMA. The date must be not less than 10 years, and less than 13 years, after the registration event.

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Last renewal dates for registrations and re-registrations of chemical products			
Item	Column 1	Column 2	Column 3
	Chemical product	Last renewal date if aligned with last renewal date for another chemical product	Last renewal date if not aligned with last renewal date for another chemical product
9	Chemical product containing an active constituent, other than a chemical product mentioned in any of items 1 to 8	The date determined by the APVMA. The date must be not less than 7 years, and less than 15 years, after the registration event.	The date determined by the APVMA. The date must be not less than 13 years, and less than 15 years, after the registration event.

Note: The APVMA may also determine a last renewal date that is less than 7 years so that the last renewal date is the same as the last renewal date for the registration of another chemical product containing one or more of the same active constituents: see subsections 20(3), 29K(3) and 34AE(3) of the Code.

- (3) If more than one item in the table in subregulation (2) applies to a chemical product, the item with the lowest item number is to be used to work out the last renewal date for the product.

Example: If the chemical product contains methyl bromide (active constituent in item 2) and an active constituent mentioned in item 7, the last renewal date is to be determined in accordance with item 2.

- (4) A last renewal date determined by the APVMA under this regulation must be the last day of a calendar month.
- (5) In determining a last renewal date under this regulation, the APVMA must have regard to the efficient allocation of the resources of the APVMA for determining and assessing re-approval and re-registration applications.
- (6) In this regulation:

last renewal date, for the registration of a chemical product, means the date after which the registration cannot be renewed under Division 6 of Part 2 of the Code.

registration event:

- (a) for the registration of a chemical product—means the date on which the registration takes place; and
 - (b) for the registration as re-registration of a chemical product—means the date on which the re-registration takes place; and
 - (c) for a variation of the last renewal date for the registration of a chemical product, following a reconsideration of the registration under Division 4 of Part 2 of the Code—means the date on which the variation takes place.
- (7) In this regulation, references to the European Community Regulation Number 1272/2008 are to that Regulation as amended from time to time.

58 Before regulation 18 in Subdivision 2.1.4

Insert:

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.

Conditions for approval of active constituent	
Item	Condition
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 a 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

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Conditions for approval of active constituent

Item	Condition
	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.

Conditions for registration of chemical product

Item	Condition
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	<p>The chemical product must be manufactured:</p> <ul style="list-style-type: none"> (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	<p>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:</p> <ul style="list-style-type: none"> (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	<p>A chemical product manufactured outside Australia must not be supplied unless:</p> <ul style="list-style-type: none"> (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 overseas GMP compliance assessment); and (b) the APVMA has assessed the overseas GMP compliance assessment and

Conditions for registration of chemical product

Item	Condition
	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:

(i) an exempt product within the meaning given by regulation 59; or

(ii) a listed chemical product; or

(iii) a reserved chemical product; 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.

59 Regulation 18 (heading)

Repeal the heading, substitute:

18 Conditions of registration of chemical products—containers

60 Subregulation 18(1)

Repeal the subregulation, substitute:

(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).

61 Regulation 18B

Repeal the regulation, substitute:

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 in this Subdivision.

62 At the end of subregulation 18D(1)

Add:

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

63 Subregulation 18G(1)

Omit “An interested person”, substitute “The holder of the approval of the label”.

64 Paragraph 18G(2)(b)

Omit “section 55”, substitute “paragraph 45A(1)(b)”.

65 Subregulations 18H(1) and 18I(1)

Omit “An interested person in relation to the label”, substitute “The holder of the approval of the label”.

66 Paragraph 18I(4)(a)

Omit “to public health or to occupational health or safety”, substitute “to persons of death, serious illness or serious injury”.

67 After regulation 18I

Insert:

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 for the holder (if any), must be the identifying information for the holder, and agent (if any), recorded for the label in the relevant APVMA file.

68 After Subdivision 2.1.6

Insert:

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 information mentioned at paragraphs (e) and (f) of the definition of *identifying information* in subregulation 3(1) for:
 - (i) the holder of an approval or registration; and
 - (ii) the nominated agent (if any) of a holder of an approval or registration.

69 Subdivision 2.1.7

Repeal the subdivision.

70 Regulations 19AA, 19AB and 19AC

Repeal the regulations.

71 Regulation 19AD (heading)

Repeal the heading, substitute:

19AD Summaries of applications for variation for chemical products**72 Subregulation 19AD(1)**

Repeal the subregulation, substitute:

- (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.

73 Subregulation 19AD(2)

Omit “subsection 28B (2)”, substitute “paragraph 28(2)(b)”.

74 Paragraph 19AD(2)(i)

Omit “details set out in subregulation (3)”, substitute “application information details for the item of information”.

75 Subregulation 19AD(3)

Repeal the subregulation.

76 Subdivision 2.2.2

Repeal the Subdivision.

77 Before Division 2.3

Insert:

Division 2.2A—Re-approving and re-registering**19A Late application for re-approval or re-registration**

- (1) This regulation is made for subsection 29D(3) of the Code.
- (2) The APVMA may accept a late application for re-approval of an active constituent, or re-registration of a chemical product, if the fee mentioned in subregulation (3) is paid when the application is made.

- (3) The fee payable for making a late application is \$500, and is payable in addition to the application fee payable under regulation 70.

Note 1: Subsection 29D(3) of the Code sets out when the application must be made.

Note 2: For the end date for approvals and last renewal date for registrations, following re-approval or re-registration, see regulations 17A and 17B.

78 Regulations 20 to 22AA

Repeal the regulations, substitute:

20 Reconsideration work plan

- (1) For subsection 31(2) of the Act, 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) the expected date on which any information will be given under subsection 32(2) of the Code, and the anticipated recipients of that information;
 - (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:

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- (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)(e) 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.

Note: For the end dates for approvals and last renewal dates for registrations, see regulations 17A and 17B.

22AA Reconsideration by APVMA of approval of label

For subsection 34AF(1) of the Code, the prescribed matters are:

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

79 Division 2.4 of Part 2

Repeal the Division.

80 Division 2.5 of Part 2

Repeal the Division, substitute:

Division 2.5—Variation of dates for approval or registration**22D Prescribed overseas regulatory action**

For paragraph 47A(1)(a) of the Code, the following foreign regulators of agricultural or veterinary chemicals are prescribed:

- (a) the United States Environmental Protection Agency;
- (b) the Centre for Veterinary Medicine of the US Food and Drug Administration;
- (c) the Ministry for Primary Industries of New Zealand;
- (d) the New Zealand Environmental Protection Authority;
- (e) the Pest Management Regulatory Agency of Health Canada;
- (f) the Veterinary Drugs Directorate of Health Canada;
- (g) the Chemicals Regulation Directorate of the Health and Safety Executive of the United Kingdom;
- (h) the Veterinary Medicines Directorate of the Department for Environment, Food and Rural Affairs of the United Kingdom.

81 Part 2A

Repeal the Part.

82 Division 1 of Part 3 (heading)

Repeal the heading, substitute:

Division 3.1—Notices**83 Regulation 24 (heading)**

Repeal the heading, substitute:

24 Protected registered information—notice to primary holder**84 Regulation 24**

Omit “a primary applicant”, substitute “each primary holder”.

85 Regulation 24

Omit “secondary applicant” (wherever occurring), substitute “secondary holder”.

86 Subparagraph 24(a)(i)

Omit “of Chemical Products”.

87 Subparagraph 24(a)(ii)

Repeal the subparagraph, substitute:

- (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 entered in the Record; and

88 Subparagraph 24(a)(iii)

Repeal the subparagraph, substitute:

- (iii) the matters about the approved label recorded in the relevant APVMA file for paragraph 21(c) of the Code.

89 Regulation 25 (heading)

Repeal the heading, substitute:

25 Protected registered information—notice to secondary holder

90 Regulation 25

Omit “applicant” (wherever occurring), substitute “holder”.

91 Paragraph 25(b)

Repeal the paragraph, substitute:

- (b) 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

92 Paragraph 25(c)

Repeal the paragraph, substitute:

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- (c) the matters about the approved label recorded in the relevant APVMA file for paragraph 21(c) of the Code.

93 Division 2 of Part 3 (heading)

Repeal the heading, substitute:

Division 3.2—Conduct of arbitration

94 Paragraphs 27(1)(a) and (b)

Omit “applicant”, substitute “holder”.

95 Subregulation 27(2)

Omit “a reasonable period”, substitute “14 days”.

96 Regulation 28

Omit “an applicant”, substitute “a holder”.

97 Regulation 28

Omit “the applicant”, substitute “the holder”.

98 Regulation 29

Omit “applicants”, substitute “holders”.

99 Regulation 31 (heading)

Repeal the heading, substitute:

31 Arbitrator to give parties notice of hearing

100 Regulation 32 (heading)

Repeal the heading, substitute:

32 Arbitrator’s powers if holder does not attend hearing

101 Regulation 32

Omit “applicant”, substitute “holder”.

102 Subregulation 34(3)

Omit “an applicant”, substitute “a holder”.

103 Regulation 36

Omit “a primary applicant”, substitute “each primary holder”.

104 Regulation 36

Omit “the primary applicant” (wherever occurring), substitute “each primary holder”.

105 Subregulation 37(3)

Omit “applicants”, substitute “holders”.

106 Regulation 38 (heading)

Repeal the heading, substitute:

38 Holders’ cost of arbitration

107 Division 1 of Part 4 (heading)

Repeal the heading, substitute:

Division 4.1—General

108 Regulation 40A

Repeal the regulation.

109 Paragraph 40(8)(a)

Omit “Part 9 of the Code (which deals with enforcement)”, substitute “Parts 9 and 9A of the Code (which deal with investigative powers and enforcement)”.

110 Subregulation 41(1)

Omit “83A,”.

111 Subregulation 41(2)

Omit “83A (1) (a),”.

112 Subregulation 41(2)

Omit “or registered listed chemical product”.

113 Subregulation 41(3)

Omit “83A (1) (b),”.

114 Subregulation 41(3)

Omit “or registered listed chemical product”.

115 Subregulation 42(1)

Omit “section 87”, substitute “ subparagraph 87(1)(b)(ii)”.

116 Subregulation 42(3)

Repeal the subregulation, substitute:

- (3) For paragraph 87(1)(a) of the Code, the standard for a chemical product, or a constituent contained in a chemical product, is:
- (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 that does not have a last renewal date in the Register—the *Listable Chemical Product (Home Swimming Pool and Spa Products) Standard 2007*; 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 that does not have a last renewal date in the Register—the *Listable Chemical Product (Joint Health Products for Dogs and Horses) Standard 2007*; 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.

117 At the end of regulation 42

Add:

- (5) In this regulation, the *last renewal date* for a chemical product is the date after which the registration of the product cannot be renewed under Division 6 of Part 2 of the Code.

118 Subregulation 44(1)

Omit “90 (a)”, substitute “90(1)(a)”.

119 Subparagraph 44(1)(a)(ii)

Omit “Part 9 of the Code (which deals with enforcement)”, substitute “Parts 9 and 9A of the Code (which deal with investigative powers and enforcement)”.

120 Subregulation 44(2)

Omit “90 (b)”, substitute “90(1)(b)”.

121 Subregulations 46(1A), (1B) and (1C)

Repeal the subregulations.

122 Paragraph 46(2)(b)

Omit “Part 9 of the Code (which deals with enforcement)”, substitute “Parts 9 and 9A of the Code (which deal with investigative powers and enforcement)”.

123 Division 2 of Part 4 (heading)

Repeal the heading, substitute:

Division 4.2—Supply of hormonal growth promotants**124 Paragraph 52(b)**

Omit “Part 9 of the Code (which deals with enforcement)”, substitute “Parts 9 and 9A of the Code (which deal with investigative powers and enforcement)”.

125 Subregulation 54(2)

Omit “48 (1) (b)”, substitute “48(1)(a)”.

126 Regulation 57

Repeal the regulation, substitute:

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

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- (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.

127 Regulation 58

Repeal the regulation.

128 Regulation 59C(1)

Omit “The legal personal representative”, substitute “For paragraph 121(4)(a) of the Code, the legal personal representative”.

129 Regulation 59D(1)

Omit “A person who”, substitute “For paragraph 121(4)(a) of the Code, a person who”.

130 Regulation 59E

Omit “It is a requirement”, substitute “For paragraph 123(1)(b) of the Code, it is a requirement”.

131 Regulation 63

Repeal the regulation, substitute:

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.

132 Regulation 64

Repeal the regulation, substitute:

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.

133 Regulation 65

Repeal the regulation, substitute:

Division 9.1—Information

65 Information that must be given electronically

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 mentioned in column 1 for the item, must be given to given to the APVMA electronically.

Information that must be given electronically		
Item	Column 1 Application	Column 2 Information
1	Application to which subsection 26B(1) or 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
2	Application to which regulation 8AT applies	Information given in relation to the application
3	Application to which regulation 8B relates	The short description of the application mentioned in paragraph 8B(2)(g)
4	Application to which regulation 8D relates	The short description of the application mentioned in paragraph 8D(2)(i)
5	Application to which regulation 19AD relates	The short description of the application mentioned in paragraph 19AD(2)(i)

65A Period for giving additional information, report or sample

- (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:
$$MP = XP - 1 \text{ month}$$
where:
MP means the maximum period.
XP means the extended assessment period mentioned for the application in column 3 of Part 2 of Schedule 6 minus the assessment period mentioned for the application in column 2 of Part 2 of Schedule 6.
- (3) For a timeshift application, the maximum period is the period agreed to by the APVMA and the applicant.
- (4) For an application for re-approval or re-registration, the maximum period is 28 days after the date of the notice.
- (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.

134 Subregulation 66(2)

Omit “interested person in relation to”, substitute “holder of the registration of”.

135 Subregulation 69(5)

Repeal the subregulation.

136 After regulation 69

Insert:

Division 9.2—Fees

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.
- (2) The APVMA:
 - (a) must, by legislative instrument, set out what constitutes a unit of pre-application assistance for different kinds of assistance that might be provided; and
 - (b) must state in the instrument whether a unit is based on:
 - (i) the work of one person or 2 or more people; or
 - (ii) a face to face meeting; or
 - (iii) work done to prepare for a meeting.

Example: The instrument may state that a unit is a period of work performed by one person or a total period of work performed by 2 or more people.

- (3) The fee for one unit, or a part of one unit, of pre-application assistance is \$175.
- (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.

137 Subregulations 70(1) to (5)

Repeal the subregulations, substitute:

No. 179, 2013 Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013 57

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- (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 mentioned in column 1 of an item in Part 2 of Schedule 6 is as follows:
- (a) for an application lodged on or after 1 July 2014 but before 1 January 2015—the fee (if any) mentioned for the item in Column 5 of Part 2 of Schedule 6;
 - (b) for an application lodged on or after 1 January 2015—the fee (if any) mentioned for the item in Column 6 of Part 2 of Schedule 6.
- (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.
- (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 in Part 2 of Schedule 6, is the amount mentioned in column 4 for the item.
- (5) A reference in Column 5 or 6 of an item in Part 2 of Schedule 6 to a modular assessment fee is a reference to the modular assessment fee in respect of the application to which that item refers, worked out in accordance with regulation 70A.
- (6) The minimum amount of the application fee that is required to be paid at the time of making an application (the ***minimum assessment fee***) is as follows:
- (a) for an application lodged on or after 1 July 2014 and before 1 January 2015:
 - (i) if the application fee for the application is less than \$620—the minimum assessment fee is the total amount of the application fee; and
 - (ii) in any other case—the minimum assessment fee is \$620;
 - (b) for an application lodged on or after 1 January 2015:

- (i) if the application fee for the application is less than \$710—the minimum assessment fee is the total amount of the application fee; and
- (ii) in any other case—the minimum assessment fee is \$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 regulation 8AO, 8AP or 8AQ.

138 Subregulation 70(6)

Renumber as subregulation 70(8).

139 Regulations 70A and 71

Repeal the regulations, substitute:

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 as follows:
 - (a) for an application lodged on or after 1 July 2014 and before 1 January 2015—the fee (if any) mentioned for the item in column 3 of Schedule 7;
 - (b) for an application lodged on or after 1 January 2015—the fee (if any) mentioned for the item in column 4 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.

Note: The *Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2010* sets out criteria for working out which modules, level and types of assessment apply in a particular case.

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 Part 2 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
 - (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.

140 Subregulation 71A(1)

Omit “paragraph 49(1) (d)”, substitute “section 164”.

141 Subregulations 71A(2) and (3)

Omit “interested person”, substitute “holder”.

142 Subparagraph 71A(3)(b)(ii)

Omit “listable”, substitute “listed”.

143 Subregulation 71A(5)

Omit “interested person”, substitute “holder”.

144 Subparagraph 71B(1)(b)(ii)

Omit “listable”, substitute “listed”.

145 Paragraph 71B(1)(d)

Omit “interested person”, substitute “holder”.

146 Subregulations 71B(2) and (4)

Omit “interested person” (wherever occurring), substitute “holder”.

147 After regulation 71B

Insert:

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.

148 Regulation 72

Repeal the regulation, substitute:

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
 - (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 regulation 8AO, 8AP or 8AQ; 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 regulation 8AO, 8AP or 8AQ, 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).

149 Subregulation 72A(9)

Repeal the subregulation.

150 Subparagraph 72A(11)(b)(ii)

Omit “listable”, substitute “listed”.

151 Subregulation 73(3)

Repeal the subregulation, substitute:

- (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.

152 Before regulation 75

Insert:

Division 9.3—Notification, assessment periods and review**153 Subregulation 76(1)**

Repeal the subregulation, substitute:

- (1) For subsection 165(1) of the Code, the APVMA must determine an application of a kind specified in column 1 of an item in Part 2 of Schedule 6 within the period (if any) specified for the item in column 2 of that Schedule, plus any extension to the assessment period applying to the application under regulation 76B.
- (1A) However, if subregulation 76A(2) applies to the application, the APVMA must determine the application within the period (if any) specified for the item in column 3 of Part 2 of Schedule 6, plus any extension to the assessment period applying to the application under regulation 76B.

154 Subregulation 76(2)

Omit “Column 3” substitute “column 2 or 3”.

155 Regulation 76, note 1

Repeal note 1, substitute:

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

156 After regulation 76

Insert:

76A Extended assessment periods

- (1) For subregulation 76(1A), 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 in Part 2 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:
 - (a) an application to which an extended assessment period has previously applied under subregulation (2); or
 - (b) an application for re-approval of an active constituent or re-registration of a chemical product.

Note: The assessment period for an application for re-approval or re-registration does not include the period starting when the APVMA makes a requirement of the applicant in connection with the application and ending when the requirement is complied with—see subparagraph 165(2)(a)(i) of the Code.

- (4) The extended assessment period for an application to which subregulation (2) applies is the period mentioned in column 3 of Part 2 of Schedule 6 for the item.

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.

157 Subregulation 77(2)

Before “Column 3”, insert “Column 2 or”.

158 Paragraph 77(2)(b)

Omit “11.4”, substitute “11.3”.

159 Regulations 78 and 78A

Repeal the regulations, substitute:

78 Commencement of assessment period

- (1) For an application of a kind mentioned in an item in Part 2 of Schedule 6 (other than item 13A or 26), 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 regulation 8AO, 8AP or 8AQ 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 regulation 8AO, 8AP or 8AQ in relation to the application.
- (2) For an application of a kind mentioned in item 13A of Part 2 of Schedule 6, the period specified in column 2 or 3 of the item commences when the application is lodged.
- (3) For an application of a kind mentioned in item 26 of Part 2 of Schedule 6, the period specified in column 2 of the item commences on the day the approval of the constituent or registration of the product ends.

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.

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
 - (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 in 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 are necessary for the reconsideration, **A** is the longest of the periods in column 2 for those items, which is 12 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.

160 Before regulation 79

Insert:

Division 9.4—Logo of APVMA

161 After Part 9

Insert:

Part 9A—Review of prescribed matters

80A Purpose of Part 9A

For sections 5 and 6 of the Amendment Act, this Part prescribes matters for reviews relating to the powers and functions of the APVMA.

80B Definitions for Part 9A

In this Part:

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

user industries means industries that use chemical products.

80C Repeal of Part 9A

This Part ceases to have effect 5 years after the day the Amendment Act receives the Royal Assent.

80D Reconsideration participation review

- (1) A review (a *reconsideration participation review*) must be conducted in relation to strategies to encourage participation by industry in reconsiderations under Division 4 of Part 2 of the Code.

Terms of reference

- (2) The terms of reference for the reconsideration participation review must include terms that require the following:

-
- (a) the identification of any problems with the chemical industry and user industries participating in reconsiderations, including:
 - (i) any obstacles or disincentives to the provision of information to support ongoing registration of chemical products; and
 - (ii) compensation for providers of information;
 - (b) the identification of options for addressing any identified problems and for collaboratively generating information, including the following options:
 - (i) the task force approach adopted by the United States Environmental Protection Agency;
 - (ii) other relevant approaches used in comparable markets outside Australia;
 - (iii) other options to reduce the need for the generation and provision of information;
 - (c) an analysis of the costs and benefits of identified options for addressing problems, including an analysis of the impacts of the options on:
 - (i) different sectors of the chemical industry and user industries; and
 - (ii) the availability, and safe use of, chemical products;
 - (d) the making of recommendations, relating to matters within the APVMA's functions and powers, for preferred options to address any identified problems.

Persons conducting review

- (3) At least one of the persons conducting the review must not be otherwise appointed, employed or engaged in an ongoing capacity by the Commonwealth.

Use of external expertise

- (4) The persons conducting the review may draw on external expertise where necessary for the review.

Public consultation

- (5) The review must involve the publication of a public consultation document in relation to the review that includes a request for submissions in relation to the review from members of the public.
- (6) Submissions received in relation to the review must be:
 - (a) considered by the persons conducting the review; and
 - (b) made public, unless the person making the submission has requested that the submission, or a part of the submission, be kept confidential.

Time for completion of review

- (7) The review must be completed, and a written report of the review given to the Minister, no later than 30 June 2015.

Review report and response

- (8) The Minister must ensure that the report of the review is published on the Department's website within 6 weeks of receiving the report.
- (9) The Minister must ensure that the Minister's response to the report of the review is published on the Department's website within 3 months of receiving the report.

80E Work health and safety duplication review

- (1) A review (a ***work health and safety duplication review***) must be conducted in relation to any duplication of effort, and unnecessary costs, caused by the need to comply, in relation to chemical products, with both of the following kinds of legislation:
 - (a) work health and safety legislation;
 - (b) agricultural and veterinary chemical legislation.

Terms of reference

- (2) The terms of reference for the work health and safety duplication review must include terms that require the following:

-
- (a) the identification of any duplication of effort arising from the need to comply with both work health and safety legislation and agricultural and veterinary chemical legislation;
 - (b) the identification and analysis of options for streamlining the regulation of work health and safety in relation to chemical products, and addressing any identified duplication, including an analysis of:
 - (i) the costs and benefits of options; and
 - (ii) the consequences of options for the safe use of chemical products;
 - (c) the making of recommendations, relating to matters within the APVMA's functions and powers, for preferred options to:
 - (i) address any identified duplication; and
 - (ii) improve the regulation of work health and safety in relation to chemical products.

Persons conducting review

- (3) The review is to be conducted by the Department, with input from other relevant government agencies.

Use of external expertise

- (4) The Department may draw on external expertise where necessary for the review.

Submissions to review

- (5) The Department must request submissions in relation to the review from members of the public.
- (6) Submissions received in relation to the review must be:
 - (a) considered by the Department; and
 - (b) made public, unless the person making the submission has requested that the submission, or a part of the submission, be kept confidential.

Time for completion of review

- (7) The Department must complete the review, and give a written report of the review to the Minister, no later than 30 September 2014.

Review report and response

- (8) The Minister must ensure that the report of the review is published on the Department's website within 6 weeks of receiving the report.
- (9) The Minister must ensure that the Minister's response to the report of the review is published on the Department's website within 3 months of receiving the report.
- (10) In this regulation:

agricultural and veterinary chemicals legislation means the following:

- (a) the Code;
- (b) these Regulations;
- (c) the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and regulations made under that Act;
- (d) the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and regulations made under that Act.

work health and safety legislation means legislation that user industries must comply with that is enacted as required by the Intergovernmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety made by the Council of Australian Governments on 3 July 2008.

80F Minor use review

- (1) A review (a ***minor use review***) must be conducted in relation to mechanisms to improve access to chemical products for minor uses.

Terms of reference

- (2) The terms of reference for the minor use review must include terms that require the following:
- (a) a description of existing approaches to addressing problems of access to chemical products for minor uses, including existing arrangements for:
 - (i) varying chemical product registrations and label approvals for minor uses; and
 - (ii) issuing permits for minor uses;
 - (b) an analysis of the effectiveness and appropriateness of the existing approaches described in accordance with paragraph (a);
 - (c) the identification of any obstacles to varying chemical product registrations and label approvals to provide for minor uses;
 - (d) the panel conducting the review to seek proposals from relevant industries;
 - (e) the consideration of international strategies, and any proposals from relevant industries, for improvements to access to chemical products for minor uses;
 - (f) the identification and analysis of options for addressing any problems with access to chemical products for minor uses, including an analysis of:
 - (i) the costs and benefits of options; and
 - (ii) the impact of options on user industries and different sectors of the chemical industry;
 - (g) the making of recommendations, relating to matters within the APVMA's functions and powers, for preferred options to address any problems with access to chemical products for minor uses.

Persons conducting review

- (3) The review is to be conducted by a panel of experts with skills and experience in fields relevant to:
- (a) the agricultural and veterinary chemical industry; or
 - (b) the production of speciality crops or speciality animal species; or

- (c) the regulation of chemical products.

Public consultation

- (4) The review must involve the publication of a public consultation document in relation to the review that includes a request for submissions in relation to the review from members of the public.
- (5) Submissions received in relation to the review must be:
 - (a) considered by the expert panel conducting the review; and
 - (b) made public, unless the person making the submission has requested that the submission, or a part of the submission, be kept confidential.

Time for completion of review

- (6) The expert panel must complete the review, and give a written report of the review to the Minister, no later than 31 December 2015.

Review report and response

- (7) The Minister must ensure that the report of the review is published on the Department's website within 1 month of receiving the report.
- (8) The Minister must ensure that the Minister's response to the report of the review is published on the Department's website within 3 months of receiving the report.

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:

76 *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013* No. 179, 2013

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

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.

81 End dates and last renewal dates for existing approvals and registrations

- (1) This regulation applies to:
- (a) the approval of an active constituent mentioned in subregulation (4); or
 - (b) the registration of a chemical product containing an active constituent mentioned in subregulation (4);

to which item 51 of Schedule 6 to the Amendment Act applies.

Note: Item 51 of the Amendment Act applies to the approvals of an active constituent, and the registration of a chemical product (other than a listed registration), in force immediately before 1 July 2014 or that come into force within 12 months of that date because of the operation of item 47 of Schedule 6 to the Amendment Act.

- (2) However, this regulation does not apply if, on or before 1 July 2014, the APVMA has given written notice under subsection 32(1) of the Code in relation to the approval of the active constituent, or the registration of the chemical product.

Note: Subsection 32(1) of the Code requires the APVMA to give written notice if it proposes to reconsider an approval or registration.

- (3) For paragraph 51(3)(a) of the Amendment Act:
- (a) the end date for the approval of the active constituent mentioned in subregulation (4) is 30 June 2015; and
 - (b) the last renewal date for the registration of the chemical product containing an active constituent mentioned in subregulation (4) is 30 June 2015.

- (4) For subregulation (1), the active constituents are any of the following:

- (a) cadusafos;
- (b) carbofuran;
- (c) carbosulfan;
- (d) disodium methylarsonate (DSMA);
- (e) dichlorophen;
- (f) dimethipin;
- (g) ethion;
- (h) ethylene dichloride;
- (i) guazatine;
- (j) methoxyethylmercury chloride;
- (k) mevinphos;
- (l) naphthalophos;
- (m) oxadixyl;
- (n) tributyltin (naphthenate and oxide);
- (o) an active constituent that is:
 - (i) mentioned in Schedule 7 of the current Poisons Standard as in force on the day the *Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013* is registered on the Federal Register of Legislative Instruments (the **registration date**); and
 - (ii) classified as Aquatic Chronic 1 in Table 3.1 of Annex VI of the European Community Regulation Number 1272/2008 as in force on the registration date.

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
 - (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 in 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 are necessary after 1 July 2015 for the reconsideration, **A** is the longest of the periods in column 2 for those items, which is 12 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
- (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.

162 Schedules 2 and 3A

Repeal the Schedules.

163 Schedule 3B (heading)

Repeal the heading, substitute:

Schedule 3B—Listed chemical products

Note: See regulation 8AR.

164 Clause 1 of Part 1 of Schedule 3B (heading)

Repeal the heading, substitute:

1 Particulars of listed chemical products**165 Clause 2 of Part 1 of Schedule 3B (heading)**

Repeal the heading, substitute:

2 Active constituents in listed chemical products**166 Part 2 of Schedule 3B (heading)**

Repeal the heading, substitute:

Part 2—Listed chemical products**167 Part 3 of Schedule 3B (heading)**

Repeal the heading, substitute:

Part 3—Active constituents in listed chemical products**168 Items 2 and 3 of Schedule 4**

Repeal the items.

169 Schedule 5

Repeal the Schedule.

170 After Schedule 5

Insert:

Schedule 5A—Infringement notices

Note: See regulation 64.

Infringement notice penalty amounts			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
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	6	50

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Infringement notice penalty amounts			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
	of an agricultural chemical product		
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
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	45	375
<i>No. 179, 2013 Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013</i>			

Schedule 1 Amendments

Infringement notice penalty amounts			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
	than 500 containers		
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
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	18	150

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Infringement notice penalty amounts			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
	than 500 containers		
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
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	7	60

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Infringement notice penalty amounts			
Item	Civil penalty provision	Amount for individual (penalty units)	Amount for corporation (penalty units)
	manufacture of a veterinary chemical product mentioned in the definition of <i>category 4 licence</i>		
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 involving non-compliance with a condition other than a condition mentioned in items 52, 53 or 54	36	300
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
55	A contravention of section 160A of the Code	90	750
56	A contravention of section 161 of the Code	90	750

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

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171 Clause 1.1 of Part 1 of Schedule 6 (definition of *major food crop*)

Repeal the definition.

172 Schedule 6 (heading)

Repeal the heading, substitute:

Schedule 6—Application fees and assessment periods

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

173 Part 2 of Schedule 6

Repeal the Part, substitute:

Part 2—Table of fees and assessment periods

Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label						
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval	18	25	1 400	84 115	96 135
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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	of the product label requiring a full assessment of the active constituent and chemical product (other than a timeshift application)					
2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval	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	The modular assessment fee

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	of the product label requiring less than full assessment of the active constituent and chemical product (other than a timeshift application)					
Applications for registration of a chemical product containing an approved active constituent and approval of the product label						
3	Application for registration of a chemical product containing an approved active constituent, and	18	25	1 050	56 545	64 620

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	approval of the product label (other than a timeshift application), if: (a) there is no registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required					
4	Application for registration of a	18	25	1 050	32 090	36 675

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Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and					

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	(c) there are no relevant maximum residue limits; and (d) poison schedule classification is required					
5	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical	8	12	700	4 260	4 870

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	product is similar to a registered chemical product; and (b) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product					
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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
6	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not	8	12	700	3 755	4 290

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are required					
7	Application for registration of a chemical product containing an approved	3	5	350	1 535	1 755
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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to					
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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	the registered chemical product; and (c) chemistry and manufacture data are not required					
8	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical	3	5	350	1 455	1 655

Schedule 1 Amendments

Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name					
9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with	2	4	350	1 395	1 595

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	an established standard that has been approved in accordance with section 8U of the Code					
10	Application for registration of a chemical product containing an approved active constituent (or an active constituent for which the APVMA has received an application for approval) and approval	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	The modular assessment fee

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	of the product label for all situations other than those described in items 3 to 9					
Applications to vary a registration or label approval						
11	Application to vary particulars or conditions of registration or label approval where a full assessment of the chemical product is required	10	15	1 050	25 035	28 610
12	Application to vary	3	5	350	1 020	1 170

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	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					
13	Application to vary particulars or conditions of registration or label	3	5	Nil	Nil	Nil

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA					
Applications to vary relevant particular of an approval or registration						
13A	Application to vary a relevant particular of	2	4	Nil	385	385

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	an approval or registration where the relevant particular is set out in a legislative instrument made for section 26B of the Code					
14	Application to vary particulars or conditions of registration or label approval if the application is not of a kind described in any	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	The modular assessment fee

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
of items 11 to 13A						
Applications for approval of an active constituent						
15	Application for approval of an active constituent requiring a full assessment (other than a timeshift application)	14	20	1 400	26 730	30 550
16	Application for approval of an active constituent requiring less than full assessment but requiring a	9	13	700	16 455	18 805

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	toxicological assessment					
17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment	7	11	700	2 760	3 155
Applications for variation to an approved active constituent						
18	Application to vary particulars or	7	11	700	2 155	2 465

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	conditions of an approved active constituent					
Applications for permits						
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	3	5	350	350	350

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	chemical product, where no data of a technical nature is required					
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	5	350	350	350
21	Application for a permit, or extension of a permit, where the	The modular assessment period	The modular assessment period, plus 6 months	350	350	350
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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	proposed use is a minor use		(unless the APVMA and the applicant agree to a shorter period)			
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	Not applicable— (see regulation 76)	Nil—(see paragraph 70(8)(b))	Nil	Nil	Nil

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	emergency use					
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 21	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	The modular assessment fee
Other applications						
24	Application made under section 10 of the Code (other than those	The modular assessment period	One and one third of the modular assessment period,	350	The modular assessment fee	The modular assessment

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	of the kinds described in any of items 1 to 10, 15, 16 or 17) requiring assessment of a technical nature		rounded up to the nearest whole month, plus 1 month			fee
25	Application for a technical assessment made under regulation 8AS	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	The modular assessment fee
26	Application for re-approval or	12 months after the day	Not applicable	Nil	700	700

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Table of fees and assessment periods						
Item	Column 1 Description of application	Column 2 Assessment period (months)	Column 3 Extended assessment period (months)	Column 4 Maximum pre application assistance rebate (\$)	Column 5 Fee from 1 July 2014 (\$)	Column 6 Fee from 1 January 2015 (\$)
	re-registration made under section 29D of the Code	the approval of the constituent ends or the registration of the product cannot be renewed				
27	Timeshift application	The modular assessment period	Not applicable	1400	The modular assessment fee	The modular assessment fee

174 Schedule 7

Repeal the Schedule, substitute:

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

Note: See regulations 70A and 77.

Table of fees and periods for completion of modules, levels and types of assessments				
Item	Column 1 Module, level or type	Column 2 Period for completion	Column 3 Fee from 1 July 2014 (\$)	Column 4 Fee from 1 January 2015 (\$)
1	Preliminary assessment		620	710
2	Chemistry			
2.1	Chemistry—level 1	13 months	8 065	9 220
2.2	Chemistry—level 2	9 months	2 690	3 075
2.3	Chemistry—level 3	6 months	1 380	1 580
2.5	Chemistry—timeshift application	As set out in the project plan	8 065	9 220
3	Toxicology (not requiring poison schedule classification)			
3.1	Toxicology—level 1	13 months	24 430	27 920
3.2	Toxicology—level 2	9 months	14 620	15 795
3.3	Toxicology—level 3	5 months	3 540	4 050
3.4	Toxicology—timeshift application	As set out in the project plan	24 430	27 920
4	Toxicology (requiring poison schedule classification)			
4.1	Toxicology requiring poison schedule classification	13 months	2 435	2 435
4.2	Toxicology requiring poison	As set out in	2 435	2 435

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Table of fees and periods for completion of modules, levels and types of assessments				
Item	Column 1 Module, level or type	Column 2 Period for completion	Column 3 Fee from 1 July 2014 (\$)	Column 4 Fee from 1 January 2015 (\$)
	schedule classification— timeshift application	the project plan		
5	Residues			
5.1	Residues—level 1	13 months	15 900	18 170
5.2	Residues—level 2	8 months	9 210	10 525
5.3	Residues—level 3	8 months	7 175	8 200
5.4	Residues—level 4	4 months	6 535	7 465
5.5	Residues—level 5	4 months	1 750	2 000
5.6	Residues—timeshift application	As set out in the project plan	15 900	18 710
6	Occupational health and safety			
6.1	Occupational health and safety—level 1	13 months	4 310	4 410
6.2	Occupational health and safety—level 2	7 months	2 900	3 185
6.3	Occupational health and safety—level 3	4 months	3 480	3 980
6.4	Occupational health and safety—timeshift application	As set out in the project plan	4 310	4 410
7	Environment			
7.1	Environment—level 1	13 months	23 095	26 390
7.2	Environment—level 2	7 months	6 400	7 315
7.3	Environment—level 3	4 months	1 505	1 720
7.4	Environment—timeshift application	As set out in the project plan	23 095	26 390
8	Efficacy and safety			
8.1	Efficacy and safety—level 1	6 months	2 075	2 370

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Table of fees and periods for completion of modules, levels and types of assessments				
Item	Column 1 Module, level or type	Column 2 Period for completion	Column 3 Fee from 1 July 2014 (\$)	Column 4 Fee from 1 January 2015 (\$)
8.2	Efficacy and safety—level 2	4 months	855	975
8.3	Efficacy and safety—level 3	3 months	505	580
8.4	Efficacy and safety—timeshift application	As set out in the project plan	2 075	2 370
9	Non-food trade	6 months	1 175	1 175
10	Special data			
10.1	Special data—level 1	13 months	nil	nil
10.2	Special data—level 2	7 months	nil	nil
10.3	Special data—level 3	7 months	nil	nil
10.4	Special data—timeshift application	As set out in the project plan	nil	nil
11	Finalisation			
11.1	Finalisation—type 1	3 months	3 545	4 055
11.2	Finalisation—type 2	2 months	1 350	1 545
11.3	Finalisation—type 3	2 months	755	865
12	Data protection		400	460