

# EXPOSURE DRAFT



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## **Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018**

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I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2018

Peter Cosgrove  
Governor-General

By His Excellency's Command

David Littleproud **DRAFT ONLY—NOT FOR SIGNATURE**  
Minister for Agriculture and Water Resources

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## 1 Name

This instrument is the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018*.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under the following:

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

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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Schedule 1 Amendments  
Part 1 Timeshift applications

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## Schedule 1—Amendments

### Part 1—Timeshift applications

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

##### **1 Subregulation 3(1) (definition of *modular assessment period*)**

Omit “subregulation 77(2)”, substitute “regulation 77”.

##### **2 Subregulation 3(1) (definition of *timeshift application*)**

Repeal the definition, substitute:

*timeshift application*: see regulation 3BA.

##### **3 After regulation 3B**

Insert:

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

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

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

##### **4 Regulation 77**

Repeal the regulation, substitute:

##### **77 Meaning of *modular assessment period***

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

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

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Amendments **Schedule 1**  
Timeshift applications **Part 1**

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application to undergo—the longest of the periods specified in column 2 of the table for those items; and

- (ii) for the type of finalisation set out in items 11.1 to 11.3 of the table in Schedule 7 that the APVMA considers necessary for the finalisation of the application—the period specified for that item.

## **5 Schedule 7 (table items 2.4, 3.4, 4.2, 5.6, 6.4, 7.4, 8.4 and 10.4)**

Repeal the items.

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Schedule 1 Amendments  
Part 2 Ministerial orders

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## Part 2—Ministerial orders

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

#### **6 After Division 1.1A**

Insert:

#### **Division 1.1B—Orders**

##### **2 Orders**

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

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

##### **7 Paragraph 15(1)(b)**

Omit “an order, publication or approval referred to in regulation 42 that specifies the standard for the active constituent for the purposes of that regulation”, substitute “the standard prescribed in respect of the active constituent for the purposes of paragraph 87(1)(a) of the Code”.

##### **8 Subregulations 42(2) and 55(1)**

Repeal the subregulations.

##### **9 Subregulation 55(2)**

Omit “(2) For”, substitute “For”.



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Amendments **Schedule 1**  
Chemical product declarations **Part 3**

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## Part 3—Chemical product declarations

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

#### **10 Part 3 of Schedule 3 (table item 1, paragraph (c))**

Omit “a pesticide”, substitute “an agricultural chemical product”.

#### **11 Part 3 of Schedule 3 (at the end of the table)**

Add:

25 Carbon dioxide or nitrogen used as a fumigant

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26 Citronella oil used for a purpose other than as an insect repellent for use on human beings

#### **12 Clause 2 of Schedule 3AA (table item 6)**

Repeal the item.

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Schedule 1 Amendments

Part 4 Notifiable variations and prescribed variations

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## Part 4—Notifiable variations and prescribed variations

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

#### **13 Regulation 8AFB**

Repeal the regulation.

#### **14 Subdivision 2.2.2 (heading)**

Repeal the heading, substitute:

#### **Subdivision 2.2.2—Interchangeable constituent determinations**

#### **15 Regulation 19AE**

Repeal the regulation.

#### **16 Subdivision 2.2.3**

Repeal the Subdivision.

#### **17 Regulation 69AA**

Repeal the regulation, substitute:

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

##### *Prescribed fee*

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

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

- (2) However, a prescribed fee is not payable for lodging a notice under Division 2AA of Part 2 of the Code for:
  - (a) variations of the relevant particulars of the registration of a chemical product in respect of one or more active constituents of the product if the variation:
    - (i) is to vary the particulars of one or more constituents listed for the product in an interchangeable constituent determination; and
    - (ii) in the case of a product in respect of which 9 or more constituents are entered in the Register—is to no more than 25% of those constituents; and
    - (iii) in the case of a product in respect of which fewer than 9 constituents are entered in the Register—is to no more than 2 of those constituents; or
  - (b) variations of the relevant particulars of the approval of a label for containers for a chemical product if:
    - (i) the variation is the result of a notifiable variation of a kind mentioned in subregulation (3); and

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Amendments **Schedule 1**  
Notifiable variations and prescribed variations **Part 4**

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- (ii) the varied label would not include misleading or deceptive information about the use, safety, environmental impact or efficacy of the product.
- (3) For the purposes of subparagraph (2)(b)(i), the kinds of notifiable variations are the following:
- (a) a variation of the net contents of an agricultural chemical product, but only if:
    - (i) the variation will not result in the instructions for the use or disposal of the product, or the containers for the product, being modified or affected; and
    - (ii) the net contents of the product, as varied, is in the range recorded in the Register for the product;
  - (b) a variation of the instructions for the use of a chemical product, but only if:
    - (i) the variation is to remove the use of the product from the instructions; and
    - (ii) the variation of the instructions will not otherwise modify or affect the instructions for another use of the product.

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Schedule 1 Amendments

Part 5 Hormonal growth promotants

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## Part 5—Hormonal growth promotants

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

#### **18 Subregulation 47C(1)**

Omit “may supply a hormonal growth promotant only if”, substitute “must not supply a hormonal growth promotant unless”.

#### **19 Subregulation 47C(1) (penalty)**

Repeal the penalty, substitute:

Penalty: 50 penalty units.

#### **20 Subregulation 47C(1A)**

Repeal the subregulation.

#### **21 At the end of regulation 47C**

Add:

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

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

#### **22 Subregulation 48(1)**

Omit “may supply a hormonal growth promotant only if”, substitute “must not supply a hormonal growth promotant unless”.

#### **23 Subregulation 48(1) (penalty)**

Repeal the penalty, substitute:

Penalty: 50 penalty units.

#### **24 Subregulation 48(2)**

Repeal the subregulation.

#### **25 At the end of regulation 48**

Add:

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

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

#### **26 Subregulation 49(1) (penalty)**

Repeal the penalty, substitute:

Penalty: 30 penalty units.

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Amendments **Schedule 1**  
Hormonal growth promotants **Part 5**

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## **27 Subregulation 49(2)**

Repeal the subregulation.

## **28 At the end of regulation 49**

Add:

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

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

## **29 Subregulation 50(1) (penalty)**

Repeal the penalty, substitute:

Penalty: 30 penalty units.

## **30 At the end of regulation 50**

Add:

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

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

## **31 Subregulation 51(2) (penalty)**

Repeal the penalty, substitute:

Penalty: 30 penalty units.

## **32 Subregulation 51(3)**

Repeal the subregulation.

## **33 At the end of regulation 51**

Add:

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

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

## **34 Subregulation 53(2) (penalty)**

Repeal the penalty, substitute:

Penalty: 50 penalty units.

## **35 Subregulation 53(3)**

Repeal the subregulation.

## **36 At the end of regulation 53**

Add:

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

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## Schedule 1 Amendments

### Part 5 Hormonal growth promotants

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

#### 37 Subregulation 54(3) (penalty)

Repeal the penalty, substitute:

Penalty: 30 penalty units.

#### 38 Subregulation 54(4)

Repeal the subregulation.

#### 39 At the end of regulation 54

Add:

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

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

#### 40 Schedule 5A (at the end of the table)

Add:

57	A contravention of subregulation 47C(1)	30	250
58	A contravention of subregulation 48(1)	30	250
59	A contravention of subregulation 49(1)	18	150
60	A contravention of subregulation 50(1)	18	150
61	A contravention of subregulation 51(2)	18	150
62	A contravention of subregulation 53(2)	30	250
63	A contravention of subregulation 54(3)	18	150

## Part 6—Section 88 exemption

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

#### **41 After regulation 42**

Insert:

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

- (1) For the purposes of paragraph 6(3)(c) of the Act, a substance or a chemical product is exempt from the operation of section 88 of the Code (which provides that certain notices are not to be published) if the substance or chemical product is:
  - (a) an active constituent that is exempted by the APVMA from the operation of subparagraph 15(1)(a)(i) of the Code; or
  - (b) an active constituent for a listed chemical product; or
  - (c) an active constituent for a proposed or existing chemical product in respect of which the APVMA has issued a permit covered by subregulation (2); or
  - (d) a chemical product in respect of which the APVMA has issued a permit covered by subregulation (2).
- (2) A permit in respect of an active constituent or chemical product is covered by this subregulation if the permit authorises an act or omission in relation to the constituent or product that would otherwise be an offence against, or a contravention of a civil penalty provision mentioned in, section 74, 75, 76 or 78 of the Code.

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

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Schedule 1 Amendments  
Part 7 Restricted information

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## Part 7—Restricted information

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

#### **42 Clause 1.1 of Schedule 6 (definition of *protected information*)**

Repeal the definition.

#### **43 Clause 1.1 of Schedule 6**

Insert:

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

#### **44 Clause 1.5 of Schedule 6**

Repeal the clause, substitute:

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

- (1) Despite clauses 1.2, 1.3 and 1.4, a proposed chemical product and a reference chemical product are not *closely similar, similar* or the *same* if:
  - (a) the APVMA is required to use information in determining an application in respect of the proposed chemical product; and
  - (b) the use of the information by the APVMA in determining that application is restricted.
- (2) The use of information by the APVMA in determining an application is *restricted* if the APVMA is restricted from using the information in determining the application by:
  - (a) Division 4A of Part 2 of the Code; or
  - (b) Part 3 of the Code.

#### **45 Clause 1.6 of Schedule 6 (heading)**

Repeal the heading, substitute:

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

#### **46 Subclause 1.6(1) of Schedule 6**

Omit “information about an active constituent is protected information”, substitute “the use of information by the APVMA about an active constituent is restricted”.

#### **47 Subclause 1.6(2) of Schedule 6**

Omit “information about a registered chemical product is protected information”, substitute “the use of information by the APVMA about a registered chemical product is restricted”.



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Amendments **Schedule 1**  
Restricted information **Part 7**

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## **48 Subclause 1.6(3) of Schedule 6**

Omit “information about an approved label for containers for a chemical product is protected information”, substitute “the use of information by the APVMA about an approved label for containers for a chemical product is restricted”.

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Schedule 1 Amendments

Part 8 Assessment periods and fees

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## Part 8—Assessment periods and fees

*Agricultural and Veterinary Chemicals Code Regulations 1995*

### 49 Part 2 of Schedule 6

Repeal the Part, substitute:

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## Part 2—Assessment periods and fees

### 2.1 Table of assessment periods and fees

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

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
<b>Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label</b>					
1	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product	18 months	25 months	\$1,400	\$96,135
2	Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical	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

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## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	product				
<b>Applications for registration of a chemical product containing an approved active constituent and approval of the product label</b>					
3	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:  (a) there is no registered chemical product containing the active constituent; and  (b) a full assessment of the chemical product is required	18 months	25 months	\$1,050	\$64,620
4	Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:  (a) there is a registered chemical product containing the active constituent; and  (b) a full assessment of the chemical product is required; and	18 months	25 months	\$1,050	\$36,675

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Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	(c) there are no relevant maximum residue limits; and (d) poison schedule classification is required				
5	Application for: (a) registration of a chemical product containing an approved active constituent and approval of the product label; or (b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or (c) registration of a chemical product and approval of the product label; if: (d) the chemical product is similar to a registered chemical product; and (e) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the	8 months	12 months	\$700	\$4,870

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## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	<p>similarity of the chemical product to the registered chemical product; and</p> <p>(f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or compendia standard in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia; and</p> <p>(g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged</p>				
6	<p>Application for:</p> <p>(a) registration of a chemical product containing an approved active constituent and approval</p>	8 months	12 months	\$700	\$4,290

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Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

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<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
	<b>Description of application</b>	<b>Assessment period</b>	<b>Extended assessment period</b>	<b>Maximum pre-application assistance rebate</b>	<b>Fee</b>
	of the product label; or (b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or (c) registration of a chemical product and approval of the product label; if: (d) the chemical product is closely similar to a registered chemical product; and (e) chemistry and manufacture data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product; and (f) for an application mentioned in paragraph (b)—the active constituent complies with a monograph or				

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## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	<p>compendia standard in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopoeia; and</p> <p>(g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged</p>				
7	<p>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:</p> <p>(a) the chemical product is closely similar to a registered chemical product; and</p> <p>(b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the</p>	3 months	5 months	\$350	\$1,755



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Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	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 product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name	3 months	5 months	\$350	\$1,655
9	Application for registration of a listed chemical product and approval of a product label where the product and label comply with an established standard that has been approved in accordance with section 8U of the Code	2 months	4 months	\$350	\$1,595
10	Application for: (a) registration of a chemical product containing an	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

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## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	<p>approved active constituent and approval of the product label; or</p> <p>(b) registration of a chemical product and approval of the active constituent in the chemical product; or</p> <p>(c) registration of a chemical product and approval of the product label (but only if a separate application for the approval of the active constituent in the chemical product has been lodged);</p> <p>for all situations other than those described in items 1 to 9</p>				
10A	Application for approval of a label for containers for a registered chemical product	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
<b>Applications to vary a registration or approval</b>					
11	Application to vary relevant particulars or conditions of registration or label approval where a full assessment of the chemical product is	10 months	15 months	\$1,050	\$28,610

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Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	required				
12	Application to vary relevant particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required	3 months	5 months	\$350	\$1,170
13	Application to vary relevant particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA	3 months	5 months	Nil	Nil
13A	Application to vary a relevant particular of an approval or registration where the variation of the relevant particular is a prescribed variation under section 26B of the Code	1 month	Not applicable	Nil	\$175
14	Application to vary relevant particulars or conditions of	The modular assessment period	One and one third of the modular assessment period,	\$350	The modular assessment fee

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## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	registration or label approval if the application is not of a kind described in any of items 11 to 13A		rounded up to the nearest whole month, plus 1 month		
<b>Applications for approval of an active constituent</b>					
15	Application for approval of an active constituent requiring a full assessment	14 months	20 months	\$1,400	\$30,550
16	Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment	9 months	13 months	\$700	\$18,805
17	Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment (unless item 5, 6 or 10 applies)	7 months	11 months	\$700	\$3,155
<b>Applications for variation to an approved active constituent</b>					
18	Application to vary relevant particulars or conditions of an approved active constituent	7 months	11 months	\$700	\$2,465
<b>Applications for permits</b>					
19	Application for a permit, or	3 months	5 months	\$350	\$350

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Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
	extension of a permit, to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product, where no data of a technical nature is required				
20	Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required	3 months	5 months	\$350	\$350
21	Application for a permit, or extension of a permit, where the proposed use is a minor use	The modular assessment period	The modular assessment period, plus 6 months (unless the APVMA and the applicant agree to a shorter period)	\$350	\$350
22	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use	Not applicable—(see subregulation 76(4))	Not applicable	Nil (see paragraph 70(8)(b))	Nil (see paragraph 70(8)(b))

# EXPOSURE DRAFT

# EXPOSURE DRAFT

## Schedule 1 Amendments

### Part 8 Assessment periods and fees

<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1 Description of application</b>	<b>Column 2 Assessment period</b>	<b>Column 3 Extended assessment period</b>	<b>Column 4 Maximum pre-application assistance rebate</b>	<b>Column 5 Fee</b>
23	Application for a permit, or extension of a permit, in respect of a chemical product or an active constituent if the application is not of a kind described in any of items 19 to 22	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
<b>Other applications</b>					
24	Application made under section 10 of the Code requiring assessment of a technical nature (other than those of the kinds described in any of items 1 to 10, 15, 16 or 17)	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	\$350	The modular assessment fee
25	Application made under regulation 8AS for a technical assessment	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee, plus GST
27	Timeshift application (see regulation 3BA)	The modular assessment period	Not applicable	\$1,400	The modular assessment fee
28	Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee
29	Application made under regulation 19AEB to make	The modular assessment period	One and one third of the modular assessment period,	Nil	The modular assessment fee

# EXPOSURE DRAFT

Amendments **Schedule 1**  
Assessment periods and fees **Part 8**

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<b>Fees and assessment periods</b>					
<b>Item</b>	<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>	<b>Column 4</b>	<b>Column 5</b>
	<b>Description of application</b>	<b>Assessment period</b>	<b>Extended assessment period</b>	<b>Maximum pre-application assistance rebate</b>	<b>Fee</b>
	an interchangeable constituent determination		rounded up to the nearest whole month, plus 1 month		

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# EXPOSURE DRAFT

Schedule 1 Amendments

Part 9 Consequential and other amendments

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## Part 9—Consequential and other amendments

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

#### 50 Regulation 6A

Repeal the regulation, substitute:

##### 6A Rate of levy

For the purposes of the definition of *rate of levy* in section 12C of the Act, the following percentages are prescribed in respect of a chemical product and a financial year:

- (a) for the part of the total leviable value in respect of the product for the financial year not exceeding \$1,000,000—0.63%;
- (b) for the part (if any) of the total leviable value in respect of the product for the financial year exceeding \$1,000,000 but not exceeding \$5,000,000—0.35%;
- (c) for the part (if any) of the total leviable value in respect of the product for the financial year exceeding \$5,000,000—0.25%.

Note: The percentages are prescribed for the 2013-14 financial year and each succeeding financial year.

### *Agricultural and Veterinary Chemicals (Administration) Regulations 1995*

#### 51 Subregulation 3.550(3)

Repeal the subregulation (including the notes), substitute:

- (3) For the purposes of subsection 69D(1) of the Act, a fee is prescribed if the applicant requires the APVMA to request the performance, in relation to a certificate (whether original or subsequent), of a consular act for which a fee (the *consular fee*):
  - (a) is imposed under the *Consular Fees Act 1955*; and
  - (b) is payable by the APVMA.
- (4) The amount of the fee prescribed under subregulation (3) is an amount equal to the amount of the consular fee.

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

#### 52 Subregulation 3(1)

Insert:

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

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



## **53 Subregulation 3(1) (definition of *biological pesticide*)**

Repeal the definition.

## **54 Subregulation 3(1)**

Insert:

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

## **55 Subregulation 3(1)**

Repeal the following definitions:

- (a) definition of *pool or spa hypochlorite*;
- (b) definition of *total leviable value*.

## **56 Regulation 8AH**

Omit “regulation 8AO, 8AP or 8AQ”, substitute “subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations,”.

## **57 Subparagraph 8AO(2)(e)(i)**

Omit “in Part 2”, substitute “of the table in clause 2.1”.

## **58 Paragraph 8AO(2)(m)**

Repeal the paragraph, substitute:

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

## **59 Regulation 8AP**

Repeal the regulation, substitute:

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

- (1) The APVMA must give a person a notice if:
  - (a) the person lodges an application for the APVMA to provide an assessment of a technical nature, and the APVMA decides to provide that assessment (see regulation 8AS); or
  - (b) the person lodges an application for the APVMA to:
    - (i) make an interchangeable constituent determination (see regulation 19AEB); or
    - (ii) make or vary an ingredient determination (see clause 10 of Schedule 3AA).
- (2) The notice must set out the following:
  - (a) the date on which the assessment or the determination will commence;

# EXPOSURE DRAFT

## Schedule 1 Amendments

### Part 9 Consequential and other amendments

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- (b) if an amount of application fee payable for the application under subregulation 70(2) is unpaid:
    - (i) the balance of the application fee that is payable; and
    - (ii) that the balance must be paid within 28 days of the date of the notice;
  - (c) if the applicant must give copies of the application to the APVMA:
    - (i) the number of copies that must be given; and
    - (ii) the form in which those copies must be given; and
    - (iii) that the copies must be given to the APVMA within 28 days of the date of the notice;
  - (d) the assessment period for the application and the expected date by which the application will be determined;
  - (e) the modules to be completed in relation to the application;
  - (f) that the assessment period will be extended if the APVMA or another prescribed authority makes a request under section 159 of the Code;
  - (g) that if the APVMA does not determine the application within the assessment period for the application (or the extended application period, if applicable), the applicant may:
    - (i) notify the APVMA under subsection 165(3) of the Code that the applicant wishes to treat the application as having been refused; and
    - (ii) apply under subsection 167(1) of the Code for review of the decision;
  - (h) that the applicant may withdraw the application in accordance with section 8D of the Code.
- (3) The notice must be given to the person within 1 month of the day on which the person lodges the application.
- (4) If a person lodges an application under regulation 8AS for the APVMA to provide an assessment of a technical nature, and the APVMA decides not to provide that assessment, the APVMA must notify the person of that decision within 1 month of the day on which the person lodges the application.

#### 60 Paragraph 8AQ(2)(i)

Repeal the paragraph, substitute:

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

#### 61 Regulation 8AS (examples)

Repeal the examples, substitute:

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

#### 62 Subparagraph 18(2)(e)(i)

Omit “any”, substitute “a”.

## 63 Subregulation 23H(2)

Repeal the subregulation, substitute:

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

## 64 Subregulation 23I(2)

Repeal the subregulation (including the note), substitute:

- (2) For the purposes of subsection 56ZU(3) of the Code, a label for a chemical product of the kind mentioned in Part 2 of Schedule 3C must include any first aid instructions and safety directions that apply to the product, based on its type and formulation, in accordance with the *FAISD Handbook* of the APVMA, as changed from time to time.

Note: The FAISD Handbook is the *Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals*. The FAISD Handbook could in 2018 be viewed on the APVMA's website (<http://www.apvma.gov.au>).

## 65 Regulations 24 and 25

Repeal the regulations, substitute:

### 24 Prescribed information—notice to primary holder

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

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

# EXPOSURE DRAFT

## Schedule 1 Amendments

### Part 9 Consequential and other amendments

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

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

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

#### 66 Paragraph 35(1)(a)

Omit “registration”.

#### 67 Regulation 36 (heading)

Omit “registration”.

#### 68 Paragraphs 36(a), (c) and (d)

Omit “registered”.

#### 69 Subparagraph 42(3)(e)(iv)

Omit “Pharmacopoeia”, substitute “Pharmacopeia”.

#### 70 Subregulation 46(1)

Omit “may supply a chemical product only if”, substitute “must not supply a chemical product unless”.

#### 71 Subparagraph 55(2)(c)(vi)

Omit “US Pharmacopoeia”, substitute “United States Pharmacopeia”.

#### 72 Subregulation 65A(2) (definition of *XP*)

Repeal the definition, substitute:

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

#### 73 Subregulations 66(2) and (3)

Omit “protected registration information”, substitute “protected information”.

## 74 Subregulation 66(5)

Repeal the subregulation, substitute:

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

## 75 Subregulation 70(2)

Repeal the subregulation, substitute:

- (2) The fee (the *application fee*) payable for an application of a kind described in column 1 of an item of the table in clause 2.1 of Schedule 6 is as follows:
  - (a) if the application is a timeshift application—the fee in column 5 of item 27 of the table; and
  - (b) otherwise—the fee in column 5 of the applicable item.

## 76 Subregulation 70(4)

Omit “in Part 2”, substitute “of the table in clause 2.1”.

## 77 Subregulation 70(5)

Omit “Column 5 or 6 of an item in Part 2”, substitute “column 5 of an item of the table in clause 2.1”.

## 78 Subregulation 70(6)

Repeal the subregulation, substitute:

- (6) The minimum amount of the application fee that is required to be paid at the time of making an application is as follows:
  - (a) if the application fee for the application is less than \$710—the total amount of the application fee;
  - (b) in any other case—\$710.

## 79 Subregulation 70(7)

Omit “regulation 8AO, 8AP or 8AQ”, substitute “subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations”.

## 80 Subparagraph 70B(1)(a)(i)

Omit “Part 2”, substitute “clause 2.1”.

## 81 Subparagraph 72(2)(b)(i)

Omit “regulation 8AO, 8AP or 8AQ”, substitute “subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations”.

## 82 Subregulation 72(5)

Omit “regulation 8AO, 8AP or 8AQ”, substitute “subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations”.

# EXPOSURE DRAFT

## Schedule 1 Amendments

### Part 9 Consequential and other amendments

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#### 83 Subregulation 76(1)

Omit “in Part 2 of Schedule 6 within the period (if any) specified for the item in column 2 of that Schedule”, substitute “of the table in clause 2.1 of Schedule 6 within the period (if any) specified for the item of that table”.

#### 84 Subregulation 76(1A)

Omit “Part 2”, substitute “the table in clause 2.1”.

#### 85 Subregulations 76(2) and 76A(2)

Omit “in Part 2”, substitute “of the table in clause 2.1”.

#### 86 Subregulation 76A(3) (note)

Repeal the note.

#### 87 Subregulation 76A(4)

Repeal the subregulation, substitute:

- (4) The *extended assessment period* for an application to which subregulation (2) applies is the period mentioned in column 3 of the table in clause 2.1 of Schedule 6 for the item.

#### 88 Subregulation 78(1)

Omit “in Part 2 of Schedule 6 (other than item 13A or 26)”, substitute “of the table in clause 2.1 of Schedule 6 (other than item 13A)”.

#### 89 Paragraphs 78(1)(a) and (b)

Omit “regulation 8AO, 8AP or 8AQ”, substitute “subsection 11(2), 28(2) or 110A(2) of the Code, or subregulation 8AP(1) or 8AQ(2) of these Regulations,”.

#### 90 Subregulation 78(2)

Omit “Part 2”, substitute “the table in clause 2.1”.

#### 91 After paragraph 78C(c)

Insert:

- (caa) a decision to refuse an application under regulation 8AS;

#### 92 Part 9A

Repeal the Part.

#### 93 Subclause 5(3) of Schedule 3AA (table items 1 and 2)

Repeal the items, substitute:

- 1 The following ingredients authorised by the Food Standards Code, as existing at the time of the supply:
- (a) permitted flavouring substances;
  - (b) generally permitted processing aids;
  - (c) food additives (including colourings) specified in Schedule 16 to the Food Standards Code

**94 Paragraph 7(3)(c) of Schedule 3AA**

Repeal the paragraph, substitute:

(c) sections 1.2.4—3; 1.2.4—4, 1.2.4—6, 1.2.4—7 and 1.2.4—8 of the Food Standards Code;

**95 Clause 1.1 of Schedule 6 (definition of *closely similar*)**

Omit “section 1.2”, substitute “clause 1.2 and subclause 1.5(1)”.

**96 Clause 1.1 of Schedule 6 (definition of *similar*)**

Omit “section 1.3”, substitute “clause 1.3 and subclause 1.5(1)”.

**97 Clause 1.1 of Schedule 6 (definition of *the same*)**

Omit “section 1.4”, substitute “clause 1.4 and subclause 1.5(1)”.

**98 Subclause 1.2(1) of Schedule 6**

Omit “subsection (2)”, substitute “clause 1.5”.

**99 Subclause 1.2(2) of Schedule 6**

Repeal the subclause.

**100 Subclause 1.2(3) of Schedule 6**

Omit “subsection (4)”, substitute “clause 1.5”.

**101 Subclause 1.2(4) of Schedule 6**

Repeal the subclause.

**102 Subclause 1.3(1) of Schedule 6**

Omit “subsection (2)”, substitute “clause 1.5”.

**103 Subclause 1.3(2) of Schedule 6**

Repeal the subclause.

**104 Subclause 1.3(3) of Schedule 6**

Omit “subsection (4)”, substitute “clause 1.5”.

**105 Subclause 1.3(4) of Schedule 6**

Repeal the subclause.

**106 Subclause 1.4(1) of Schedule 6**

Omit “(1) Subject to subsection (2),”, substitute “Subject to clause 1.5,”.

**107 Subclause 1.4(2) of Schedule 6**

Repeal the subclause.

# EXPOSURE DRAFT

Schedule 1 Amendments

Part 10 Transitional provisions

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## Part 10—Transitional provisions

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

#### 108 In the appropriate position in Part 10

Insert:

#### **Division 10.4—Amendments made by the Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018**

##### 88 Definitions

In this Division:

*amending regulations* means the *Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018*.

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

##### 89 Applications

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

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

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