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

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
EXPOSURE DRAFT

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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

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisions</td>
<td>Commencement</td>
<td>Date/Details</td>
</tr>
<tr>
<td>1. The whole of this instrument</td>
<td>The day after this instrument is registered.</td>
<td></td>
</tr>
</tbody>
</table>

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.
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
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.
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”.

   ...
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:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Carbon dioxide or nitrogen used as a fumigant</td>
</tr>
<tr>
<td>26</td>
<td>Citronella oil used for a purpose other than as an insect repellent for use on human beings</td>
</tr>
</tbody>
</table>

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

Repeal the item.
Schedule 1: Amendments

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
(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.
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.
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.
Schedule 1 Amendments
Part 5 Hormonal growth promotants

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:

<table>
<thead>
<tr>
<th></th>
<th>Contravention</th>
<th>Penalty</th>
<th>Reparations</th>
</tr>
</thead>
<tbody>
<tr>
<td>57</td>
<td>A contravention of subregulation 47C(1)</td>
<td>30</td>
<td>250</td>
</tr>
<tr>
<td>58</td>
<td>A contravention of subregulation 48(1)</td>
<td>30</td>
<td>250</td>
</tr>
<tr>
<td>59</td>
<td>A contravention of subregulation 49(1)</td>
<td>18</td>
<td>150</td>
</tr>
<tr>
<td>60</td>
<td>A contravention of subregulation 50(1)</td>
<td>18</td>
<td>150</td>
</tr>
<tr>
<td>61</td>
<td>A contravention of subregulation 51(2)</td>
<td>18</td>
<td>150</td>
</tr>
<tr>
<td>62</td>
<td>A contravention of subregulation 53(2)</td>
<td>30</td>
<td>250</td>
</tr>
<tr>
<td>63</td>
<td>A contravention of subregulation 54(3)</td>
<td>18</td>
<td>150</td>
</tr>
</tbody>
</table>
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.
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”.
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”.
Part 8—Assessment periods and fees

*Agricultural and Veterinary Chemicals Code Regulations 1995*

49 Part 2 of Schedule 6

Repeal the Part, substitute:
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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product</td>
<td>18 months</td>
<td>25 months</td>
<td></td>
<td>$1,400 $96,135</td>
</tr>
<tr>
<td>2</td>
<td>Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical product</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td></td>
<td>$1,400 The modular assessment fee</td>
</tr>
</tbody>
</table>
**Fees and assessment periods**

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>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</td>
<td>18 months</td>
<td>25 months</td>
<td>$1,050</td>
<td>$64,620</td>
</tr>
<tr>
<td>4</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) a full assessment of the chemical product is required; and</td>
<td>18 months</td>
<td>25 months</td>
<td>$1,050</td>
<td>$36,675</td>
</tr>
</tbody>
</table>
### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Application for:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) registration of a chemical product containing an approved active constituent and approval of the product label; or</td>
<td>8 months</td>
<td>12 months</td>
<td>$700</td>
<td>$4,870</td>
</tr>
<tr>
<td></td>
<td>(b) registration of a chemical product, approval of the active constituent in the chemical product and approval of the product label; or</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(c) registration of a chemical product and approval of the product label; if:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(d) the chemical product is similar to a registered chemical product; and</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(e) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(c) there are no relevant maximum residue limits; and
(d) poison schedule classification is required
### Schedule 1  Amendments

#### Part 8  Assessment periods and fees

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>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 compendia standard in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia; and (g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged</td>
<td>8 months</td>
<td>12 months</td>
<td>$700</td>
<td>$4,290</td>
</tr>
</tbody>
</table>

**Application for:**
(a) registration of a chemical product containing an approved active constituent and approval
### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
</table>

- 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
**Schedule 1  Amendments**

**Part 8  Assessment periods and fees**

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Description of application</td>
<td>Assessment period</td>
<td>Extended assessment period</td>
<td>Maximum pre-application assistance rebate</td>
<td>Fee</td>
</tr>
<tr>
<td>7</td>
<td>compendia standard in the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia; and (g) for an application mentioned in paragraph (c)—a separate application for the approval of the active constituent in the chemical product has been lodged</td>
<td>3 months</td>
<td>5 months</td>
<td>$350</td>
<td>$1,755</td>
</tr>
</tbody>
</table>

*Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the*
### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name</td>
<td>3 months</td>
<td>5 months</td>
<td>$350</td>
<td>$1,655</td>
</tr>
<tr>
<td>9</td>
<td>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</td>
<td>2 months</td>
<td>4 months</td>
<td>$350</td>
<td>$1,595</td>
</tr>
<tr>
<td>10</td>
<td>Application for: (a) registration of a chemical product containing an</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td>$350</td>
<td>The modular assessment fee</td>
</tr>
</tbody>
</table>
## Fees and assessment periods

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

### Applications to vary a registration or approval

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of application</th>
<th>Assessment period</th>
<th>Extended assessment period</th>
<th>Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Application to vary relevant particulars or conditions of registration or label approval where a full assessment of the chemical product is</td>
<td>10 months</td>
<td>15 months</td>
<td>$1,050</td>
</tr>
</tbody>
</table>

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_Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018_
### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
<th>Column 2 Assessment period</th>
<th>Column 3 Extended assessment period</th>
<th>Column 4 Maximum pre-application assistance rebate</th>
<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>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</td>
<td>3 months</td>
<td>5 months</td>
<td>$350</td>
<td>$1,170</td>
</tr>
<tr>
<td>13</td>
<td>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</td>
<td>3 months</td>
<td>5 months</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>13A</td>
<td>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</td>
<td>1 month</td>
<td>Not applicable</td>
<td>Nil</td>
<td>$175</td>
</tr>
<tr>
<td>14</td>
<td>Application to vary relevant particulars or conditions of</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period,</td>
<td>$350</td>
<td>The modular assessment fee</td>
</tr>
</tbody>
</table>
### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1 Description of application</th>
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<th>Column 5 Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>registration or label approval if the application is not of a kind described in any of items 11 to 13A</td>
<td>rounded up to the nearest whole month, plus 1 month</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Applications for approval of an active constituent</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Application for approval of an active constituent requiring a full assessment</td>
<td>14 months</td>
<td>20 months</td>
<td>$1,400</td>
<td>$30,550</td>
</tr>
<tr>
<td>16</td>
<td>Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment</td>
<td>9 months</td>
<td>13 months</td>
<td>$700</td>
<td>$18,805</td>
</tr>
<tr>
<td>17</td>
<td>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)</td>
<td>7 months</td>
<td>11 months</td>
<td>$700</td>
<td>$3,155</td>
</tr>
<tr>
<td></td>
<td><strong>Applications for variation to an approved active constituent</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Application to vary relevant particulars or conditions of an approved active constituent</td>
<td>7 months</td>
<td>11 months</td>
<td>$700</td>
<td>$2,465</td>
</tr>
<tr>
<td></td>
<td><strong>Applications for permits</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Application for a permit, or</td>
<td>3 months</td>
<td>5 months</td>
<td>$350</td>
<td>$350</td>
</tr>
</tbody>
</table>

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*Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018*
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<tr>
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<th>Column 1 Description of application</th>
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<th>Column 5 Fee</th>
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<tbody>
<tr>
<td></td>
<td>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</td>
<td>3 months</td>
<td>5 months</td>
<td>$350</td>
<td>$350</td>
</tr>
<tr>
<td>20</td>
<td>Application for a permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required</td>
<td>The modular assessment period</td>
<td>The modular assessment period, plus 6 months (unless the APVMA and the applicant agree to a shorter period)</td>
<td>$350</td>
<td>$350</td>
</tr>
<tr>
<td>21</td>
<td>Application for a permit, or extension of a permit, where the proposed use is a minor use</td>
<td>Not applicable—(see subregulation 76(4))</td>
<td>Not applicable</td>
<td>Nil (see paragraph 70(8)(b))</td>
<td>Nil (see paragraph 70(8)(b))</td>
</tr>
<tr>
<td>22</td>
<td>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</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Schedule 1  Amendments

#### Part 8  Assessment periods and fees

#### Fees and assessment periods

<table>
<thead>
<tr>
<th>Item</th>
<th>Column 1</th>
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<tbody>
<tr>
<td></td>
<td>Description of application</td>
<td>Assessment period</td>
<td>Extended assessment period</td>
<td>Maximum pre-application assistance rebate</td>
<td>Fee</td>
</tr>
<tr>
<td>23</td>
<td>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</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td>$350</td>
<td>The modular assessment fee</td>
</tr>
<tr>
<td>24</td>
<td>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)</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td>$350</td>
<td>The modular assessment fee</td>
</tr>
<tr>
<td>25</td>
<td>Application made under regulation 8AS for a technical assessment</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td>Nil</td>
<td>The modular assessment fee plus GST</td>
</tr>
<tr>
<td>27</td>
<td>Timeshift application (see regulation 3BA)</td>
<td>The modular assessment period</td>
<td>Not applicable</td>
<td>$1,400</td>
<td>The modular assessment fee</td>
</tr>
<tr>
<td>28</td>
<td>Application made under subclause 10(1) of Schedule 3AA to make or vary an ingredient determination</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month</td>
<td>Nil</td>
<td>The modular assessment fee</td>
</tr>
<tr>
<td>29</td>
<td>Application made under regulation 19AEB to make</td>
<td>The modular assessment period</td>
<td>One and one third of the modular assessment period</td>
<td>Nil</td>
<td>The modular assessment fee</td>
</tr>
</tbody>
</table>

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26  Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018
## Fees and assessment periods

<table>
<thead>
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<td>Description of application</td>
<td>Assessment period</td>
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<td>Maximum pre-application assistance rebate</td>
<td>Fee</td>
</tr>
<tr>
<td>an interchangeable constituent determination</td>
<td></td>
<td></td>
<td>rounded up to the nearest whole month, plus 1 month</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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;
(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”.

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


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.
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)

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”.

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Agricultural and Veterinary Chemicals Legislation Amendment (Timeshift Applications and Other Measures) Regulations 2018
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”.

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