



# **Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014**

## **Select Legislative Instrument No. 67, 2014**

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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 regulation.

Dated 12 June 2014

Peter Cosgrove  
Governor-General

By His Excellency's Command

Barnaby Joyce  
Minister for Agriculture

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*OPC60395 - B*



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## 1 Name of regulation

This regulation is the *Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014*.

## 2 Commencement

Each provision of this regulation 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  |
| Provision(s)   | Commencement  |
| 1. Sections 1 to 4 and anything in this regulation not elsewhere covered by this table | The day after this regulation is registered.  |
| 2. Schedule 1  | Immediately after the commencement of the <i>Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013</i> .  |
| 3. Schedule 2  | Immediately before the commencement of the <i>Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013</i> . |

## 3 Authority

This regulation is made under the following Acts:

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

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#### **4 Schedule(s)**

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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2                    *Agricultural and Veterinary Chemicals Legislation Amendment  
Regulation 2014*                    *No. 67, 2014*  
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## **Schedule 1—Main amendments**

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

#### **1 Regulation 3**

Repeal the regulation.

#### **2 Subregulation 6A(3) (heading)**

Repeal the heading, substitute:

*2012-2013 financial year*

#### **3 Subregulation 6A(4) (heading)**

Repeal the heading, substitute:

*2013-2014 financial year and each succeeding financial year*

#### **4 Subregulation 6A(4)**

Omit “2014-2015”, substitute “2013-2014”.

#### **5 Schedule 1**

Repeal the Schedule.

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

#### **6 After paragraph 1A.3(c)**

Insert:

- (ca) a summary of any action taken by the APVMA under section 99 of the Schedule to the Agvet Code Act during that year;

#### **7 Regulation 4.10**

Repeal the regulation, substitute:

**4.10 Annual returns—active constituents**

- (1) For the purposes of paragraph 69E(2)(a) of the Act, active constituents that are not made into, or included in, chemical products are prescribed.
- (2) For the purposes of paragraph 69E(2)(b) of the Act, the prescribed quantity is as follows:
  - (a) for active constituents for proposed or existing veterinary chemical products or active constituents included in veterinary chemical products—3kg;
  - (b) for active constituents for proposed or existing agricultural chemical products or active constituents included in agricultural chemical products—10kg.

**8 Item 31 of Part 2 of Schedule 1 (table item dealing with conditions or restrictions)**

Omit “Subject to notification of final regulatory action by Australia”.

**9 Item 39 of Part 2 of Schedule 1 (table item dealing with conditions or restrictions)**

Repeal the table item, substitute:

|                                   |  |
|-----------------------------------|--|
| <b>Conditions or restrictions</b> | Import prohibited except with written permission under paragraph 3.65(1)(a)              |
|                                   | Manufacture prohibited in all cases  |
|                                   | Use prohibited in all cases  |
|                                   | Export prohibited except with written permission under paragraph 3.230(1)(a), (b) or (c) |

**10 Item 70 of Part 2 of Schedule 1 (table item dealing with conditions or restrictions)**

Omit “Subject to notification of final regulatory action by Australia”.

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

**11 Subregulation 3(1) (definition of active constituent number)**

Omit “mentioned in section 11B”, substitute “under section 10”.



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**12 Subregulation 3(1) (definition of *application number*)**

Omit “mentioned in section 11B, 28B or 34G”, substitute “under section 10 or 27”.

**13 Subregulation 3(1) (definition of *chemical product number*)**

Omit “mentioned in section 11B”, substitute “under section 10”.

**14 Subregulation 3(1) (paragraph (a) of the definition of *identifying information*)**

Repeal the paragraph, substitute:

- (a) if the person is an individual—the person’s name;

**15 Subregulation 3(1) (definition of *labelling standard*)**

Repeal the definition, substitute:

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

**16 Subregulation 3(1)**

Insert:

*lodged*: see regulation 5A.

**17 Subregulation 3(1) (definition of *modular assessment fee*)**

Omit “in regulation 71”, substitute “by subregulation 70A(4)”.

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

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

**19 Subregulation 3(1) (after subparagraph (a)(i) of the definition of *timeshift application*)**

Insert:

- (ia) registration of a chemical product which contains a previously endorsed active constituent and for which a full assessment is required; or

**20 Subregulation 3(1)**

Insert:

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

**21 Subregulation 3(1) (definition of *United States Pharmacopoeia*)**

Repeal the definition.

**22 Regulation 3A**

Omit “mentioned in section 11B or 28B”, substitute “under section 10 or 27”.

**23 Paragraph 3A(a)**

Omit “is the subject”, substitute “is or was the subject”.

**24 Regulation 3B**

Omit “mentioned in section 11B or 28B”, substitute “under section 10 or 27”.

**25 Paragraph 3B(a)**

Omit “is the subject”, substitute “is or was the subject”.

**26 Paragraph 8AE(1)(b)**

Omit “commence”, substitute “commerce”.

**27 Subregulation 8AF(1)**

Omit all the words from and including “Before making a standard” to and including “that section”, substitute “Before making or varying a standard under section 6E of the Code”.

**28 Subparagraph 8AF(1)(a)(iv)**

Omit “Pharmacopoeia”, substitute “Pharmacopeia”.

**29 Subregulation 8AF(4)**

Repeal the subregulation, substitute:

- 
- (4) If the APVMA makes or varies a standard under section 6E of the Code, the APVMA must publish a notice in the Gazette and on the APVMA's website stating:
- (a) that it has made the standard or variation; and
  - (b) its reasons for making or varying the standard; and
  - (c) how to obtain more information about the standard or variation.
- (4A) For the purposes of subparagraph 6(2)(a)(iii) of the Act, a labelling standard must include requirements relating to one or more of the following:
- (a) the presentation of the label, including the size, colour, legibility, dimensions, layout and format of the label;
  - (b) the display of the label;
  - (c) the information contained on the label.

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

### **30 Before regulation 8AK**

Insert:

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

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

**31 Subregulation 8AN(1)**

Omit all the words from and including “For paragraphs” to and including “under those sections”, substitute “For the purposes of paragraphs 8H(2)(e) and 8J(2)(d) of the Code and paragraph 8AHA(2)(d) of these Regulations, this regulation sets out the information that must be included in the Gazette”.

**32 Subregulation 8AO(1)**

Omit “sets out the matters that must be included”, substitute “prescribes the matters that must be set out”.

**33 Paragraph 8AO(2)(I)**

Omit “section 160A”, substitute “sections 160A and 161”.

**34 Paragraph 8AP(2)(c)**

Repeal the paragraph, substitute:

- (c) if an amount of application fee payable in relation to the application under subregulation 70(2) is unpaid:
  - (i) the balance of the application fee that is payable; and
  - (ii) that the balance must be paid within 28 days of the date of the notice;

**35 Subregulation 8AQ(2)**

Omit “receiving the application”, substitute “the application being lodged”.

**36 Paragraph 8AQ(2)(c)**

Repeal the paragraph, substitute:

- (c) if an amount of application fee payable in relation to the application under subregulation 70(2) is unpaid:
  - (i) the balance of the application fee that is payable; and
  - (ii) that the balance must be paid within 28 days of the date of the notice;

**37 After paragraph 8AQ(2)(f)**

Insert:

- (fa) that the assessment period will be extended if the APVMA or another prescribed authority makes a request under section 159 of the Code;

**38 Paragraph 8AQ(2)(h)**

Omit “section 160A”, substitute “sections 160A and 161”.

**39 Paragraphs 8B(2)(g) and 8D(2)(i)**

Omit “paragraph 11(1)(b)”, substitute “subparagraph 8A(a)(v)”.

**40 Subregulation 8E(2)**

Omit “subsection 11B(2) of the Code, the details”, substitute “paragraph 11(2)(b) of the Code, the details prescribed”.

**41 Subregulation 17C(1) (table item 2)**

Omit “a manufacturer”, substitute “the manufacturer”.

**42 Subdivision 2.1.5 of Division 2.1 of Part 2**

Repeal the Subdivision.

**43 Regulation 18B**

Omit “conditions in”, substitute “conditions prescribed by”.

**44 Paragraph 18D(1)(a)**

Repeal the paragraph, substitute:

- (a) the information recorded for the label in the relevant APVMA file under subparagraphs 21(c)(iii) and (iv) of the Code;

**45 Subregulation 18D(1) (notes 1 and 2)**

Repeal the notes, substitute:

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

**46 Paragraphs 18E(a) and (b)**

Omit “Chief Executive Officer for regulation 18A”, substitute “APVMA”.

**47 Paragraph 18F(1)(a)**

Repeal the paragraph, substitute:

- (a) the information required by subregulation 18D(1) to be stated on the label; or

**48 Regulation 18J**

Omit “for the holder (if any), must be the identifying information for the holder, and”, substitute “(if any) for the holder, must be the identifying information for the holder, and the nominated”.

**49 Paragraph 19AD(2)(i)**

Omit “paragraph 11(1)(b)”, substitute “subparagraph 8A(a)(v)”.

**50 Subregulation 20(1)**

Omit “31(2) of the Act”, substitute “31(2) of the Code”.

**51 Paragraph 20(1)(f)**

Repeal the paragraph, substitute:

(f) both:

- (i) the expected date on which the APVMA proposes to inform persons about the reconsideration; and
- (ii) the persons proposed to be informed;

**52 Regulation 22AA**

After “matters are”, insert “either or both of the following”.

**53 Paragraph 22AA(a)**

Omit “Code; and”, substitute “Code;”.

**54 Paragraph 22AA(b)**

Omit “subregulation 8AE(1)”, substitute “paragraphs 8AE(1)(a), (b), (c) and (d) of these Regulations”.

**55 Subregulation 42(3)**

Omit “the standard for”, substitute “the standard prescribed for”.

**56 Paragraph 42(3)(c)**

Omit “*Listable Chemical Product (Home Swimming Pool and Spa Products) Standard 2007*”, substitute “established standard for the product”.

**57 Paragraph 42(3)(d)**

Omit “*Listable Chemical Product (Joint Health Products for Dogs and Horses) Standard 2007*”, substitute “established standard for the product”.

**58 Paragraph 42(3)(e)**

Omit “applies)”, substitute “applies”.

**59 Regulation 65**

Before “For subsection”, insert “(1)”.

**60 Regulation 65 (cell at table item 3, column 2)**

Omit “The short description of the application”, substitute “The information”.

**61 Regulation 65 (cell at table item 4, column 2)**

Omit “The short description of the application”, substitute “The information”.

**62 Regulation 65 (cell at table item 5, column 2)**

Omit “The short description of the application”, substitute “The information”.

**63 At the end of regulation 65**

Add:

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

**64 Regulation 65A (heading)**

Repeal the heading, substitute:

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

**65 After regulation 65A**

Insert:

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

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

**66 Before regulation 69B**

Insert:

**69A Payment of fees**

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

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

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

**67 Subregulation 69B(2)**

Repeal the subregulation.

**68 Subregulation 69B(3)**

Omit "\$175", substitute "\$192.50 (GST inclusive)".

**69 At the end of subregulation 70(3)**

Add "(excluding GST)".

**70 After subregulation 70(4)**

Insert:

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

**71 Subregulation 70A(4) (note)**

Repeal the note.

**72 Subregulation 73(1)**

Omit "the fee payable", substitute "the prescribed fee".



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**73 After regulation 73**

Insert:

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

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

**74 Regulation 74**

Repeal the regulation.

**75 Subregulation 78B(5) (definition of A)**

Omit “7.3 in”, substitute “7.3 of”.

**76 Subregulation 78B(5) (example at the end of the definition of A)**

After “7.3”, insert “of Schedule 7”.

**77 Subregulation 78B(5) (example at the end of the definition of A)**

Omit “12 months”, substitute “13 months”.

**78 Subregulation 80D(7)**

Omit “2015”, substitute “2017”.

**79 Subregulation 80E(7)**

Omit “2014”, substitute “2016”.

**80 Regulation 80F**

Repeal the regulation.

**81 At the end of regulation 81**

Add:

- (5) For the purposes of subitem 58(1) of Schedule 6 to the Amendment Act, section 47B of the Code has effect in relation to an approval or registration to which this regulation applies as if:
- (a) the reference in subsection 47B(1) of the Code to “12 months” were a reference to “6 months”; and
  - (b) the reference in paragraph 47B(2)(b) of the Code to “6 months before the existing approval or registration ends” were a reference to “1 April 2015”; and
  - (c) the reference in subsection 47B(3) of the Code to “12 months” were a reference to “6 months”.

**82 Subregulation 85(3) (definition of A)**

Omit “7.3 in”, substitute “7.3 of”.

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**83 Subregulation 85(3) (example at the end of the definition of A)**

After “7.3”, insert “of Schedule 7”.

**84 Subregulation 85(3) (example at the end of the definition of A)**

Omit “12 months”, substitute “13 months”.

**85 At the end of Part 10**

Add:

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

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

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

**86 Subdivision 3.2.1 of Division 3.2 of Part 3 of Schedule 3B**

Omit “United States Pharmacopoeia” (wherever occurring), substitute “United States Pharmacopeia”.

**87 Section 1.1 of Schedule 6 (definition of *closely similar*)**

Omit “given in”, substitute “given by”.

**88 Section 1.1 of Schedule 6 (definition of *protected information*)**

Omit “given in”, substitute “given by”.

**89 Section 1.1 of Schedule 6 (definition of *similar*)**

Omit “given in”, substitute “given by”.

**90 Section 1.1 of Schedule 6 (definition of *the same*)**

Omit “given in”, substitute “given by”.

**91 Part 2 of Schedule 6 (table item 4, column 1)**

After “Application”, insert “(other than a timeshift application)”.

**92 Part 2 of Schedule 6 (after table item 10)**

Insert:

|     |  |                               |   |     |                            |                            |
|-----|--|-------------------------------|---|-----|----------------------------|----------------------------|
| 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 | The modular assessment fee |
|-----|--|-------------------------------|---|-----|----------------------------|----------------------------|

**93 Part 2 of Schedule 6 (cell at table item 22, column 2)**

Omit “regulation 76”, substitute “subregulation 76(4)”.

**94 Part 2 of Schedule 6 (cell at table item 22, column 3)**

Repeal the cell, substitute:

Not applicable

**95 Part 2 of Schedule 6 (cell at table item 22, column 4)**

Repeal the cell, substitute:

Nil (see paragraph 70(8)(b))

**96 Part 2 of Schedule 6 (cell at table item 22, column 5)**

Repeal the cell, substitute:

Nil (see paragraph 70(8)(b))

**97 Part 2 of Schedule 6 (cell at table item 22, column 6)**

Repeal the cell, substitute:

Nil (see  
paragraph 70(8)(b))

**98 Part 2 of Schedule 6 (cell at table item 23, column 1)**

Omit “21”, substitute “22”.

**99 Part 2 of Schedule 6 (cell at table item 25, column 5)**

Repeal the cell, substitute:

The modular  
assessment fee, plus  
GST

**100 Part 2 of Schedule 6 (cell at table item 25, column 6)**

Repeal the cell, substitute:

The modular  
assessment fee, plus  
GST

**101 Schedule 7 (cell at table item 6, column 1)**

Omit “Occupational”, substitute “Work”.

**102 Schedule 7 (cell at table items 6.1, 6.2, 6.3 and 6.4,  
column 1)**

Omit “Occupational”, substitute “Work”.

**103 Schedule 7 (cell at table item 12, column 1)**

Repeal the cell, substitute:

**Limits on use of  
information**

**Schedule 2—Amendment of the Agricultural  
and Veterinary Chemicals Legislation  
Amendment (2013 Measures No. 2)  
Regulation 2013**

**1 Item 23 of Schedule 1 (heading)**

Repeal the heading, substitute:

**23 After regulation 4**