



# **Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014**

## **Select Legislative Instrument No. 118, 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 21 August 2014

Peter Cosgrove  
Governor-General

By His Excellency's Command

Barnaby Joyce  
Minister for Agriculture

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## 1 Name of regulation

This regulation is the *Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) 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
Provisions	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, items 1 to 8	The day after this regulation is registered.
3. Schedule 1, items 9 and 10	1 January 2015
4. Schedule 1, items 11 to 13	The day after this regulation is registered.
5. Schedule 1, item 14	1 January 2015
6. Schedule 1, items 15 to 51	The day after this regulation is registered.
7. Schedule 1, item 52	1 January 2015
8. Schedule 1, items 53 to 55	The day after this regulation is registered.

## 3 Authority

This regulation is made under the following Acts:

- (a) the *Agricultural and Veterinary Chemicals Code Act 1994*;

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(b) the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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2      *Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014*      No. 118, 2014

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## **Schedule 1—Amendments relating to re-approvals and re-registrations**

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

#### **1 At the end of regulation 4**

Add:

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

#### **2 Subregulation 8AB(2)**

Omit all the words after “if the product”, substitute “is prescribed under subregulation 59(1) for the purposes of section 120A of the Code”.

#### **3 Regulation 8AL**

Omit all the words after “inform the holder of the”, substitute “approval or registration that the holder may apply to have the particular varied under Division 3 of Part 2 of the Code”.

#### **4 Subregulation 8AO(1)**

Omit “paragraphs 29E(2)(b) and 110A(2)(b) and subparagraphs 11(2)(a)(ii) and 28(2)(a)(ii)”, substitute “subparagraphs 11(2)(a)(ii) and 28(2)(a)(ii) and paragraph 110A(2)(b)”.

#### **5 Subregulation 8AO(1)**

Omit “, 29E(2)”.

#### **6 Paragraph 8AO(2)(e)**

Repeal the paragraph, substitute:

- (e) that the APVMA may determine that:
- (i) the application is more correctly categorised as an application mentioned in a different item in Part 2 of Schedule 6 to the item in relation to which any fee has been paid; or
  - (ii) different modules, levels and types mentioned in Schedule 7 are necessary for the application;

and that if it does so, a further amount of application fee may be payable and the assessment period may change;

**7 Paragraph 8AO(2)(j)**

Repeal the paragraph, substitute:

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

**8 Paragraph 16(f)**

Repeal the paragraph.

**9 Paragraph 17(1)(b)**

Repeal the paragraph, substitute:

- (b) the name of the chemical product that is to appear on a label for containers of the chemical product;

**10 At the end of subregulation 17(3)**

Add:

- ; (c) the distinguishing name of the chemical product that is prescribed under paragraph 16(a) and entered in the Register;
- (d) the distinguishing number of the chemical product that is entered in the Register.

**11 Subdivision 2.1.3A of Division 2.1 of Part 2**

Repeal the Subdivision.

**12 Paragraph 17C(3)(a)**

Repeal the paragraph, substitute:

- (a) the chemical product is prescribed under subregulation 59(1) for the purposes of section 120A of the Code; or

**13 Paragraph 18K(b)**

Repeal the paragraph, substitute:

- (b) the following information about the holder of an approval or registration or the nominated agent (if any) for the approval or registration:
  - (i) the name of the holder or agent;
  - (ii) the ABN (if any) of the holder or agent;



- (iii) the trading name (if any) of the holder or agent;
- (iv) the street address of the holder or agent;
- (v) the postal address of the holder or agent, if it is different from the street address.

**14 At the end of Division 2.2 of Part 2**

Add:

**Subdivision 2.2.2—Notifiable variations****19AE Notifiable variations**

- (1) The following table prescribes, as notifiable variations for the purposes of subparagraph 26AB(3)(a)(ii) of the Code, variations of the relevant particulars that are listed in an item in the table, for approvals or registrations listed in the table for that item.

<b>Notifiable variations</b>		
<b>Item</b>	<b>Notifiable variation of relevant particular</b>	<b>Approval or registration</b>
1	A variation of the name of the manufacturer of an active constituent for a chemical product	any approval of an active constituent
2	A variation of the distinguishing name of a chemical product	any registration of a chemical product
3	A variation of the net contents of an agricultural product, but only if: (a) the variation will not result in the instructions for use, or disposal, of the product or containers for the products, being modified or affected; and (b) the net contents is in the range recorded in the Register for the product	any registration of an agricultural chemical product
4	A variation of the instructions for a use of a chemical product if: (a) the variation is to remove the use of the chemical product from the instructions; and (b) the variation of the instructions will not otherwise modify or affect the instructions for another use of the	any registration of a chemical product

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<b>Notifiable variations</b>		
<b>Item</b>	<b>Notifiable variation of relevant particular</b>	<b>Approval or registration</b>
	product	
5	A variation of either or both of the following particulars: (a) the name of a manufacturer of a chemical product; (b) the address of each site at which the product is manufactured by a manufacturer	any registration of a chemical product that is prescribed under subregulation 59(1)
6	A variation of an approved label as a result of a notifiable variation mentioned in items 3 and 4, but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product	any approval of a label for containers of chemical products
7	A variation of the name of a chemical product that is to appear on an approved label as mentioned in paragraph 17(1)(b), but only if a label for the chemical product as varied would not include any misleading or deceptive information about the use, safety, environmental impact or efficacy of the chemical product	any approval of a label for containers of chemical products

- (2) However, a variation listed in item 3 or 4 of the table is only a notifiable variation for a product listed in the item if, at the time the notice for the notifiable variation is lodged, notice is also lodged for a notifiable variation listed in item 6 of the table for any approved label for the product.

**Subdivision 2.2.3—Prescribed variations**

**19AF Prescribed variations**

The following table prescribes, as prescribed variations for the purposes of paragraph 26B(4)(b) of the Code, variations of the relevant particulars that are listed in an item in the table, for the registrations listed in the table for that item.

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**Prescribed variations**

<b>Item</b>	<b>Prescribed variation of relevant particular</b>	<b>Registration</b>
1	<p>A variation of either or both of the following particulars:</p> <p>(a) the name of a manufacturer in Australia of a chemical product;</p> <p>(b) the address of each site in Australia at which the product is manufactured by a manufacturer;</p> <p>but only if, under the varied particulars:</p> <p>(c) the manufacturer and the address of each manufacturing site are in Australia; and</p> <p>(d) either:</p> <p>(i) the manufacturer is the holder of a valid licence under Part 8 of the Code that authorises carrying out a step in the manufacture of the product at premises at a site mentioned in paragraph (b); or</p> <p>(ii) the manufacturer is an exempt person as mentioned in paragraph 121(4)(a) of the Code in relation to the manufacture of the product</p>	any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)

**15 Division 2.2A of Part 2**

Repeal the Division.

**16 Regulation 22**

Omit “34AC(2)(e)”, substitute “34AC(2)(d)”.

**17 Regulation 22 (note)**

Repeal the note.

**18 Subregulation 41(1)**

Omit “, 99”.

**19 Subregulation 41(2)**

Omit “, 99(2)(a)”.

**20 Subregulation 41(3)**

Omit “, 99(2)(b)”.

**21 Paragraphs 42(3)(c) and (d)**

Omit “that does not have a last renewal date in the Register”.

**22 Subregulation 42(5)**

Repeal the subregulation.

**23 After regulation 43**

Insert:

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

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

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

**24 Paragraph 55(2)(b)**

Repeal the paragraph.

**25 Paragraph 55(2)(d)**

Repeal the paragraph, substitute:

(d) any other test approved by the APVMA in writing.

**26 After regulation 55**

Insert:

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**55A Prescribed standards for supplied substances**

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

- (a) for an active constituent or chemical product in respect of which a standard is specified in an order under section 7 of the Act—that standard; or
- (b) for an active constituent or chemical product (other than a constituent or product to which paragraph (a) applies) in respect of which a standard has been made under section 6E of the Code—that standard; or
- (c) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in item 1 of Part 2 of Schedule 3B in respect of which there is an established standard—the established standard for the product; or
- (d) for a listed chemical product (other than a product to which paragraph (a) or (b) applies) mentioned in item 2 of Part 2 of Schedule 3B—the established standard for the product; or
- (e) for a veterinary chemical product or an active constituent (other than a product or constituent to which paragraph (a), (b), (c) or (d) applies) in respect of which a standard is specified in:
  - (i) the British Pharmacopoeia; or
  - (ii) the British Pharmacopoeia (Veterinary); or
  - (iii) the European Pharmacopoeia; or
  - (iv) the United States Pharmacopoeia;the standard specified in the first of those publications, in the order set out in this paragraph, that applies to the product or constituent; or
- (f) for an active constituent or chemical product (other than a constituent or product to which paragraph (a), (b), (c), (d) or (e) applies) in respect of which a standard is specified in the FAO and WHO Specifications for Pesticides—that standard; or
- (g) for an active constituent or chemical product (other than a constituent or product to which paragraph (a), (b), (c), (d), (e) or (f) applies) in respect of which the APVMA approved a standard before 1 July 2014 and the approval is still in force—that standard.

**27 Regulation 56**

Omit “99(4)(c)”, substitute “99(4A)(c)”.

**28 Regulation 59 (heading)**

Repeal the heading, substitute:

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

**29 Subregulation 59(1)**

Omit “paragraph 121(4)(a) of the Code (which deals with exempt products and persons in relation to manufacture), the following are exempt products”, substitute “section 120A of the Code, the following chemical products are prescribed”.

**30 Before paragraph 59(1)(a)**

Insert:

- (aa) any listed chemical product;
- (ab) any reserved chemical product;

**31 At the end of subregulation 59(1)**

Add:

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

**32 Regulation 59B (heading)**

Repeal the heading, substitute:

**59B Manufacture of chemical products—exempt persons—chemical  
product that ceases to be prescribed**

**33 Regulation 59B**

Omit “an exempt product under this Part”, substitute “prescribed for the purposes of section 120A of the Code”.

**34 Paragraph 59B(c)**

Omit “an exempt product”, substitute “prescribed for the purposes of section 120A of the Code”.

**35 Regulation 59B**

Omit “ceases to be exempt”, substitute “ceases to be prescribed for the purposes of section 120A of the Code”.

**36 Subregulation 65(1)**

Omit “mentioned in column 1 for the item, must be given to”, substitute “or a notice mentioned in column 1 for the item, must be”.

**37 Subregulation 65(1) (table item 1, column 1)**

Omit “subsection 26B(1) or”.

**38 Subregulation 65(1) (after table item 1)**

Insert:

1A	Notice under section 26AB of the Code	Information given in relation to the notice
1B	Application under section 26B of the Code	Information given in relation to the application

**39 Subregulation 65(2)**

Omit “subparagraph 8A(a)(i) or paragraph”, substitute “subparagraph 8A(a)(i) of the Code or paragraph 26AD(1)(a) or”.

**40 Subregulation 65A(4)**

Repeal the subregulation.

**41 After regulation 69A**

Insert:

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

For the purposes of paragraph 26AD(1)(c) of the Code, a fee of \$50 is prescribed for a notice of a notifiable variation:

- (a) of a kind determined by the APVMA under subsection 26AB(5) of the Code; or
- (b) mentioned in item 1, 2, 3, 4, 5 or 7 of the table in subregulation 19AE(1).

Note: There is no fee for a notifiable variation mentioned in item 6 of the table in subregulation 19AE(1).

**42 Paragraph 71A(3)(b)**

Repeal the paragraph, substitute:

- (b) in relation to a chemical product that is prescribed under regulation 59 for the purposes of section 120A of the Code.

**43 Paragraph 71B(1)(b)**

Repeal the paragraph, substitute:

- (b) the product is not prescribed under regulation 59 for the purposes of section 120A of the Code; and

**44 Paragraph 72A(11)(b)**

Repeal the paragraph, substitute:

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

**45 Before paragraph 73(1)(a)**

Insert:

- (aa) under subsection 8W(2) of the Code—for a copy of, or extract from, a document (other than a document in any part of the Record or Register) in the possession or custody of the APVMA in relation to an approved active constituent or registered chemical product; or

**46 Subregulation 76(1)**

Omit “subsection” substitute “subsections 26C(1) and”.

**47 Subregulation 76(4) (notes 1 and 2)**

Repeal the notes.

**48 Subregulation 76A(3)**

Repeal the subregulation, substitute:

- (3) However subregulation (2) does not apply to an application if the application is an application to which an extended assessment period has previously applied under subregulation (2).



**49 Subregulation 78(3)**

Repeal the subregulation.

**50 After regulation 78A**

Insert:

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

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

**51 Regulation 81**

Repeal the regulation.

**52 At the end of Part 10**

Add:

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

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

- (1) This regulation applies if:
  - (a) immediately before 1 January 2015 the distinguishing name (the *approved product name*) of a chemical product is contained on a label for containers of the chemical product; and
  - (b) an approval of the label (the *label approval*) with the approved product name was in force immediately before 1 January 2015.
- (2) Subject to these Regulations, on and after 1 January 2015 the label approval continues in force as follows:

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- (a) the approved product name is taken to be the name of the chemical product that is to appear on a label for containers of the chemical product as prescribed under paragraph 17(1)(b);
- (b) the approved product name is taken to be recorded in the relevant APVMA file in relation to the label approval in accordance with subparagraph 21(c)(iva) of the Code; and
- (c) the distinguishing number of the chemical product that is entered in the Register immediately before 1 January 2015 in relation to the label approval is taken to be recorded in the relevant APVMA file in accordance with subparagraph 21(c)(iva) of the Code.

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

**53 Paragraph 1.3(3)(c) of Schedule 6**

Omit “efficacy, safety or residues”, substitute “chemistry and manufacture, efficacy or target species safety”.

**54 Part 2 of Schedule 6 (table item 13A)**

Repeal the item, substitute:

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	Not applicable	Nil	175	175
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**55 Part 2 of Schedule 6 (table item 26)**

Repeal the item.