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The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

Presented and read a first time

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

No. , 2014

(Agriculture)

A Bill for an Act to amend laws relating to agricultural and veterinary chemicals, and for other purposes

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A Bill for an Act to amend laws relating to agricultural and veterinary chemicals, and for other purposes

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*.

2 Commencement

(1) Each provision of this Act 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
Provision(s)	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Schedules 1 and 2	The later of: (a) the start of the day this Act receives the Royal Assent; and (b) immediately after the commencement of Schedule 1 to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*.	

Note: This table relates only to the provisions of this Act as originally enacted.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

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

3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Removing re-approval and re-registration

Part 1—Amendments

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

1 Subsection 36(1)

Omit "renewal of registration or re-registration", substitute "or the renewal of registration,".

Agricultural and Veterinary Chemicals Code Act 1994

2 Section 3 of the Code set out in the Schedule (paragraph (b) of the definition of *approval*)

Omit "product;", substitute "product.".

3 Section 3 of the Code set out in the Schedule (definition of *approval*)

Omit all the words after paragraph (b).

4 Section 3 of the Code set out in the Schedule (definition of *determine*)

Repeal the definition, substitute:

determine, in relation to an application, means:

(a) approve, register, renew, vary or issue upon the application; or

(b) refuse the application.

5 Section 3 of the Code set out in the Schedule (definition of *listed chemical product*)

Omit all the words after "means a chemical product", substitute:

that:

(a) is, or is included in a class of chemical products that is, listed by regulations under section 8T; and
(b) complies with the established standard for the product.

6 Section 3 of the Code set out in the Schedule (definition of *re-approval*)

Repeal the definition.

7 Section 3 of the Code set out in the Schedule (definition of *registration*)

Omit all the words after "chemical product".

8 Section 3 of the Code set out in the Schedule (definition of *relevant particulars*)

Omit "29G,".

9 Section 3 of the Code set out in the Schedule (definition of *re-registration*)

Repeal the definition.

10 Subsection 8B(2) of the Code set out in the Schedule

Repeal the subsection, substitute:

(2) The APVMA may specify information under subsection (1) only if the inclusion of the information would enable the APVMA to determine the application.

11 Subparagraph 8E(2)(c)(i) of the Code set out in the Schedule

Omit ", other than an application under section 29D".

12 Subparagraph 8E(2)(c)(ii) of the Code set out in the Schedule

Omit "29G,".

13 Paragraph 8F(1)(a) of the Code set out in the Schedule

Omit "(or re-approves)".

14 Paragraph 8F(1)(b) of the Code set out in the Schedule

Omit "(or re-registers)".

15 Subparagraph 8F(2)(a)(iii) of the Code set out in the Schedule

Repeal the subparagraph.

16 Paragraphs 8F(2)(b) and (c) of the Code set out in the Schedule

Repeal the paragraphs, substitute:

(b) for a registration—state the date the registration ends; and

(c) for the renewal of a registration:

(i) state that the registration of the chemical product has been renewed; and

(ii) state the date the registration (as renewed) ends; and

17 Subparagraphs 8F(2)(d)(iii) and (iv) of the Code set out in the Schedule

Repeal the subparagraphs, substitute:

(iii) of a registration—state the date the registration ends; and

18 Paragraph 8H(2)(c) of the Code set out in the Schedule

Repeal the paragraph.

19 Paragraph 8S(1)(b) of the Code set out in the Schedule

Omit "(or re-approves) or registers (or re-registers)", substitute "or registers".

20 Subsection 9(5) of the Code set out in the Schedule

Repeal the subsection.

21 Paragraph 15(2)(b) of the Code set out in the Schedule

Omit all the words after "listed chemical product".

22 Subsection 19(1) of the Code set out in the Schedule

Omit "(1)".

23 Paragraph 19(1)(d) of the Code set out in the Schedule

Omit "APVMA;", substitute "APVMA.".

24 Paragraph 19(1)(e) of the Code set out in the Schedule

Repeal the paragraph.

25 Subsections 19(2), (3) and (4) of the Code set out in the Schedule

Repeal the subsections.

26 Paragraphs 20(1)(f) and (g) of the Code set out in the Schedule

Repeal the paragraphs, substitute:

(f) the date the registration ends.

27 Subsections 20(2), (3) and (4) of the Code set out in the Schedule

Repeal the subsections, substitute:

(2) The date the registration ends must:

(a) be the last day of a calendar month not more than 7 years after the registration takes place; and

(b) be worked out in accordance with the method prescribed by the regulations.

(3) However, if the regulations do not prescribe a method for the purposes of paragraph (2)(b), the date the registration ends must be the next 30 June after the registration takes place.

28 Subsections 26D(2) and (3) of the Code set out in the Schedule

Repeal the subsections, substitute:

(2) If the relevant particulars of a listed chemical product are varied in such a way that the product or any approved label for the product does not comply with the established standard for the product, the APVMA must amend the Register so that the product is no longer noted as a listed chemical product.

29 Subsections 29B(2) and (3) of the Code set out in the Schedule

Repeal the subsections, substitute:

(2) If the relevant particulars or conditions of a listed chemical product are varied in such a way that the product or any approved label for the product does not comply with the established standard for the product, the APVMA must amend the Register so that the product is no longer noted as a listed chemical product.

30 Division 3A of Part 2 of the Code set out in the Schedule

Repeal the Division.

31 Subsection 29L(10) of the Code set out in the Schedule

Repeal the subsection, substitute:

(10) If the APVMA affirms the approval or registration, it must notify the holder and publish a notice in the Gazette (section 34AC).

32 Subsections 34A(5) and (6) of the Code set out in the Schedule

Repeal the subsections.

33 Paragraphs 34AC(2)(c), (d) and (e) of the Code set out in the Schedule

Repeal the paragraphs, substitute:

(c) state the date the registration ends; and

(d) include any information prescribed by the regulations.

34 Sections 34AD and 34AE of the Code set out in the Schedule

Repeal the sections.

35 Subsection 34AF(4) of the Code set out in the Schedule

Omit "34AE", substitute "34AC".

36 Subsection 34G(1A) of the Code set out in the Schedule

Omit ", 29A or 29G", substitute "or 29A".

37 Subsection 43(2) of the Code set out in the Schedule

Omit "29D,".

38 Subsections 46A(3) to (6) of the Code set out in the Schedule

Repeal the subsections, substitute:

(3) The APVMA must publish notice of the end of a registration as soon as practicable after the registration has ended (section 47C).

(4) If the APVMA publishes notice of the end of the registration of a product under section 47C, then:

(a) certain persons are taken to have a permit to possess, have custody of or use of the product for a limited period (section 47D); and

(b) persons may only supply the product in accordance with instructions contained in the notice (section 47E).

39 Subsection 47(1) of the Code set out in the Schedule

Repeal the subsection, substitute:

(1) The approval of an active constituent continues in force unless it is cancelled.

40 Subsection 47(3) of the Code set out in the Schedule

Repeal the subsection.

41 Subsection 47(6) of the Code set out in the Schedule

Repeal the subsection.

42 Section 47A of the Code set out in the Schedule

Repeal the section.

43 Subdivision C of Division 6 of Part 2 of the Code set out in the Schedule (heading)

Repeal the heading, substitute:

Subdivision C—Notifying the end of registrations

44 Section 47B of the Code set out in the Schedule

Repeal the section.

45 Section 47C of the Code set out in the Schedule (heading)

Repeal the heading, substitute:

47C Notice of end of registration

46 Subsection 47C(1) of the Code set out in the Schedule

Repeal the subsection, substitute:

(1) If the registration of a chemical product ends without being renewed, the APVMA must publish in the Gazette, and in any other manner that it thinks appropriate, notice of the end of the registration.

47 Paragraphs 47C(2)(a), (b) and (c) of the Code set out in the Schedule

Omit "approval or".

48 Paragraphs 47C(2)(d), (e) and (f) of the Code set out in the Schedule

Omit "constituent or" (wherever occurring).

49 Subsection 47C(3) of the Code set out in the Schedule

Omit all the words after "not apply", substitute:

if:

(a) the APVMA thinks that, in the circumstances, it is unnecessary to publish the notice; or

(b) the registration of the chemical product ends because it is cancelled.

Note: For notice of the cancellation of the registration of a chemical product, see section 45A.

50 Paragraph 47C(4)(a) of the Code set out in the Schedule

Omit "the holder", substitute "the person who was the holder of the registration".

51 Paragraph 47C(4)(b) of the Code set out in the Schedule

Omit "approval or".

52 Section 47D of the Code set out in the Schedule

Repeal the section, substitute:

47D Permit taken to have been issued

(1) This section applies if notice of the end of the registration of a chemical product is published under section 47C.

(2) A person who possesses, has custody of or uses the product in accordance with the instructions contained in the notice is taken to have been issued with a permit to do so until:

(a) 1 year after the day on which the registration ended; or

(b) the APVMA, by notice published in the Gazette, declares that this subsection ceases to apply in respect of the product;

whichever first occurs.

(3) A permit that is taken to have been issued to a person under subsection (1) does not authorise the person to manufacture or import the product.

53 Subsection 47E(1) of the Code set out in the Schedule

Repeal the subsection, substitute:

(1) This section applies if, after notice of the end of the registration of a chemical product is published under section 47C, a person has possession or custody of the product with the intention of supplying it.

54 Subsection 47E(2) of the Code set out in the Schedule

Omit "constituent or".

55 Subsection 47E(3) of the Code set out in the Schedule

Omit "constituent or product was approved or", substitute "product was".

56 Subsection 47E(3) of the Code set out in the Schedule

Omit "been approved or", substitute "been".

57 Subsection 47E(3) of the Code set out in the Schedule

Omit "approval or".

58 Subsection 48(2) of the Code set out in the Schedule

Repeal the subsection, substitute:

(2) Subject to subsection (3), the application must not be made:
  (a) earlier than 3 months before the registration ends; or
  (b) later than one month (or such shorter period as the APVMA allows) before the registration ends.

59 Subsection 48(4) of the Code set out in the Schedule

Repeal the subsection.

60 Subsection 48(5) of the Code set out in the Schedule

Omit "renewal".

61 Subsection 49(1) of the Code set out in the Schedule

Repeal the subsection (not including the note), substitute:

(1) If the APVMA is satisfied that an application for the renewal of a registration meets the application requirements, the APVMA must renew the registration.

62 Section 50 of the Code set out in the Schedule

Before "Renewal", insert "(1)".

63 Section 50 of the Code set out in the Schedule

Omit all the words after "registration (as renewed)", substitute "ends".

64 At the end of section 50 of the Code set out in the Schedule

Add:

(2) The date the registration (as renewed) ends must:

(a) be the last day of a calendar month not less than 12 months and not more than 7 years after the renewal takes place; and

(b) be worked out in accordance with the method prescribed by the regulations.

(3) However, if the regulations do not prescribe a method for the purposes of paragraph (2)(b), the date the registration (as renewed) ends must be the next 30 June after the renewal takes place.

65 Subsection 59(1) of the Code set out in the Schedule (note)

Repeal the note.

66 Paragraph 59(2)(e) of the Code set out in the Schedule

Omit all the words after "information and", substitute "Division 4A of Part 2 does not limit the use of the information; or".

67 Paragraph 59(6)(a) of the Code set out in the Schedule

Omit ", other than under Division 3A of Part 2 (re-approving and re-registering)".

68 Paragraph 165(2)(a) of the Code set out in the Schedule

Repeal the paragraph.

69 Subparagraph 166(1A)(b)(i) of the Code set out in the Schedule

Omit ", 29E(3)".

70 Paragraphs 167(1)(da) and (db) of the Code set out in the Schedule

Repeal the paragraphs.

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71 Item 51 of Schedule 6

Repeal the item.

Part 2—Transitional provisions

72 End dates

(1) This item applies if, before the commencement of this Schedule, the APVMA has entered:

(a) the date an approval ends in the Record; or

(b) the date after which a registration cannot be renewed in the Register.

(2) The APVMA must remove the date.

Schedule 2—Miscellaneous amendments

Part 1—Amendments

Agricultural and Veterinary Chemicals Code Act 1994

1 Section 3 of the Code set out in the Schedule (paragraph (a) of the definition of *agvet law*)

After "Agvet Code", insert "or the Agvet Regulations".

2 Section 3 of the Code set out in the Schedule (paragraph (a) of the definition of *agvet penalty provision*)

After "Agvet Code", insert "or the Agvet Regulations".

3 Section 3 of the Code set out in the Schedule (definition of *approved active constituent*)

Repeal the definition, substitute:

> ***approved active constituent*** means an active constituent that is approved and complies with the relevant particulars entered in the Record for the constituent.

4 Section 3 of the Code set out in the Schedule (definition of *approved label*)

Repeal the definition, substitute:

> ***approved label*** means a label that is approved and complies with the relevant particulars recorded in the relevant APVMA file for the label.

5 Section 3 of the Code set out in the Schedule (definition of *continue*)

After "***continue***,", insert "in relation to".

6 Section 3 of the Code set out in the Schedule (second definition of *limitation period*)

Repeal the definition.

7 Section 3 of the Code set out in the Schedule (definition of *lodged*)

After "this Code", insert "or a notice under Division 2AA of Part 2".

8 Section 3 of the Code set out in the Schedule

Insert:

meets the notice requirements has the meaning given by subsection 26AD(1).

9 Section 3 of the Code set out in the Schedule

Insert:

notifiable variation, of the relevant particulars of an approval or registration, has the meaning given by subsection 26AB(3).

10 Section 3 of the Code set out in the Schedule

Insert:

prescribed variation, of the relevant particulars of an approval or registration, has the meaning given by subsection 26B(4).

11 Section 3 of the Code set out in the Schedule (definition of *registered chemical product*)

Repeal the definition, substitute:

registered chemical product means a chemical product that is registered and complies with the relevant particulars entered in the Register for the product.

12 Section 3 of the Code set out in the Schedule (definition of *relevant particulars*)

After "26,", insert "26AC,".

13 Section 3 of the Code set out in the Schedule (first and second definitions of *secondary applicant*)

Repeal the definitions.

14 Section 6B of the Code set out in the Schedule

Repeal the section, substitute:

6B Varying relevant particulars and conditions

To avoid doubt, a power under this Code to vary relevant particulars or conditions:

(a) includes the power to add or remove relevant particulars or conditions; but

(b) does not authorise the APVMA to vary or remove relevant particulars that were not determined, or conditions that were not imposed, by the APVMA.

15 Subparagraph 8A(a)(v) of the Code set out in the Schedule

Repeal the subparagraph, substitute:

(v) contains, or is accompanied by, any information specified for the application by the APVMA under section 8B or prescribed for the application by the regulations for the purposes of this subparagraph.

16 Paragraph 8A(e) of the Code set out in the Schedule

Omit "payable", substitute "due and payable".

17 Paragraph 8F(1)(e)

Omit "whether on application or on the initiative of the APVMA", substitute "whether on notice under Division 2AA of Part 2, on application or on the initiative of the APVMA".

18 At the end of subsection 8F(2) of the Code set out in the Schedule

Add:

Note: This subsection does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162: see section 8X.

19 Section 8K of the Code set out in the Schedule

Repeal the section.

20 Paragraph 8S(1)(b) of the Code set out in the Schedule

Omit "application; or", substitute "application.".

21 Paragraph 8S(1)(c) of the Code set out in the Schedule

Repeal the paragraph.

22 Paragraph 8S(2)(b) of the Code set out in the Schedule

Repeal the paragraph.

23 At the end of subsection 8S(2) of the Code set out in the Schedule

Add:

Note: This subsection does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162: see section 8X.

24 At the end of Part 1 of the Code set out in the Schedule

Add:

Division 7—Access to certain documents and information

8W Access to certain documents in the possession or custody of the APVMA

(1) A person may, in writing, apply to the APVMA 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.

(2) The APVMA must provide the copy or extract to the person if the person pays the prescribed fee (if any).

Note 1: See subsections 17(4) and (5) and 18(4) and (5) for access to the Record and Register.

Note 2: This subsection does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162: see section 8X.

8X Confidential commercial information must not be disclosed under certain provisions

(1) Engaging in conduct in the performance of functions or duties, or the exercise of powers, under any of the following provisions does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162:

(a) subsection 8F(2);
(b) subsection 8S(2);
(c) subsection 8W(2);
(d) subsection 17(4) or (5);
(e) subsection 18(4) or (5);
(f) subsection 34AB(2);
(g) subsection 34AC(2).

(2) Subsection (1) has effect despite subsection 162(1A).

25 After subsection 9(2) of the Code set out in the Schedule

Insert:

(2A) Division 2AA provides for notifiable variations of relevant particulars of approvals and registrations if the variations are of a kind determined by the APVMA or prescribed by the regulations and are not prescribed variations under Division 2A. Only holders of approvals or registrations may notify variations under Division 2AA.

26 Subsection 9(3) of the Code set out in the Schedule

Omit "if the relevant particulars are of a kind set out in a legislative instrument made under section 26B", substitute "if the variations are of a kind determined by the APVMA or prescribed by the regulations".

27 Subsections 17(4) and (5) and 18(4) and (5) of the Code set out in the Schedule (note)

Omit "8K", substitute "8X".

28 Subsection 23(2) of the Code set out in the Schedule

Omit "remains", substitute "is taken to remain".

29 Before Division 2A of Part 2 of the Code set out in the Schedule

Insert:

Division 2AA—Notified variations of relevant particulars

26AA Explanation of Division

(1) This Division provides for some kinds of variations of relevant particulars of approvals and registrations (called notifiable variations) to be made on notice by the holders of approvals or registrations.

(2) A notifiable variation is a variation of a kind:

(a) determined by the APVMA; or

(b) prescribed by the regulations.

A prescribed variation under Division 2A cannot be a notifiable variation.

(3) Only holders of approvals or registrations may notify variations under this Division (section 26AB). The notice must meet the notice requirements specified in subsection 26AD(1).

(4) Section 26AC sets out how the APVMA varies the relevant particulars on notice under this Division.

26AB Notice of notifiable variations

(1) The holder may, in writing, lodge notice with the APVMA of one or more notifiable variations of the relevant particulars of an approval or registration.

(2) The notice must meet the notice requirements.

Note: For ***meets the notice requirements***, see subsection 26AD(1).

(3) A ***notifiable variation*** is a variation of a kind that:

(a) either:

(i) is determined by the APVMA under subsection (5); or

(ii) is prescribed by the regulations; and

(b) is not a prescribed variation under Division 2A.

(4) The APVMA must not determine a kind of variation under subsection (5) unless it is satisfied that, with the relevant particulars so varied:

(a) for an active constituent—the constituent would meet the safety criteria; and

(b) for a chemical product—the product would:

(i) meet the safety criteria, the trade criteria and the efficacy criteria; or

(ii) comply with the established standard for the product; and

(c) for a label for a chemical product—the label would:

(i) meet the labelling criteria; or

(ii) comply with the established standard for the product.

(5) The APVMA may, by legislative instrument, determine a kind of variation for the purposes of subparagraph (3)(a)(i).

(6) If the notice does not meet the notice requirements, the APVMA must:

(a) notify the holder in writing of that fact; and

(b) include in the notice the reasons why the holder's notice does not meet the notice requirements.

26AC Variation of relevant particulars

(1) If a notice is lodged under section 26AB, the APVMA must vary the relevant particulars of the approval or registration as proposed in the notice.

(2) The variation is taken to have effect on the day the notice is lodged.

(3) The APVMA must, within 14 days after the notice is lodged:

(a) record in the Record, Register or relevant APVMA file, as required, the relevant particulars as varied and the day the notice was lodged; and

(b) if the relevant particulars of a listed chemical product are varied in such a way that the product or any approved label for the product does not comply with the established standard

for the product—amend the Register so that the product is no longer noted as a listed chemical product.

Note 1: For notice of variation, see section 8F.

Note 2: For publication of the variation, see section 8J.

26AD Notice requirements

(1) For the purposes of this Division, a notice ***meets the notice requirements*** if the notice:

(a) is in writing in the approved form; and

(b) is signed by the holder of the approval or registration to which the notice relates; and

(c) is accompanied by the prescribed fee; and

(d) is lodged with the APVMA; and

(e) contains, or is accompanied by, any information:

(i) specified by the APVMA under subsection (2); or

(ii) prescribed by the regulations.

(2) For the purposes of subparagraph (1)(e)(i), the APVMA may, by legislative instrument, specify the information that must be contained in, or accompany, the notice.

(3) The APVMA may specify information under subsection (2) only if the information is relevant to a notifiable variation.

30 Division 2A of Part 2 of the Code set out in the Schedule (heading)

Repeal the heading, substitute:

Division 2A—Prescribed variations of relevant particulars

31 Sections 26A to 26C of the Code set out in the Schedule

Repeal the sections, substitute:

26A Explanation of Division

(1) This Division provides for prescribed variations of relevant particulars of approvals and registrations.

(2) A prescribed variation is a variation of a kind:
  (a) determined by the APVMA; or
  (b) prescribed by the regulations.

(3) Only holders of approvals or registrations may apply under this Division (section 26B). The application must meet the application requirements specified in section 8A.

(4) Section 26D sets out how a variation takes place.

26B Applications for prescribed variations

(1) The holder may apply to the APVMA for one or more prescribed variations of the relevant particulars of an approval or registration.

(2) The application must meet the application requirements.

Note: For ***meets the application requirements***, see section 8A.

(3) The APVMA may alter the application with the written consent of the applicant.

(4) A ***prescribed variation*** is a variation of a kind:
  (a) determined by the APVMA under subsection (6); or
  (b) prescribed by the regulations.

(5) The APVMA must not determine a kind of variation under subsection (6) unless it is satisfied that, with the relevant particulars so varied:
  (a) for an active constituent—the constituent would meet the safety criteria; and
  (b) for a chemical product—the product would:
    (i) meet the safety criteria, the trade criteria and the efficacy criteria; or
    (ii) comply with the established standard for the product; and
  (c) for a label for a chemical product—the label would:
    (i) meet the labelling criteria; or
    (ii) comply with the established standard for the product.

(6) The APVMA may, by legislative instrument, determine a kind of variation for the purposes of paragraph (4)(a).

(7) If the application does not meet the application requirements, the APVMA must:

(a) notify the holder in writing of that fact; and

(b) include in the notice the reasons why the holder's application does not meet the application requirements.

26C Decision on prescribed variations

(1) The APVMA must, within the period prescribed by the regulations:

(a) if it is satisfied that the application meets the application requirements—vary the relevant particulars as proposed in the application; or

(b) otherwise—refuse the application.

Note 1: For notice of variation, see section 8F.

Note 2: For notice of refusal, see section 8G.

(2) If the APVMA does not make a decision on the application within the period prescribed, the APVMA is, immediately after the end of that period, taken to have made a decision under subsection (1) to vary the relevant particulars as proposed in the application.

32 Section 26D of the Code set out in the Schedule (heading)

Repeal the heading, substitute:

26D How prescribed variation takes place

33 Subsection 26D(1) of the Code set out in the Schedule

Repeal the subsection, substitute:

(1) Variation of relevant particulars under this Division takes place when the APVMA records in the Record, Register or relevant APVMA file, as required, the relevant particulars as varied and the date on which the variation is made.

34 Subsection 27(4) of the Code set out in the Schedule

Repeal the subsection.

35 Subsection 32(1) of the Code set out in the Schedule

After "notice to the holder", insert "of the approval or registration".

36 Subsection 33(1) of the Code set out in the Schedule

After "given to the holder", insert "of the approval or registration".

37 At the end of subsection 34AB(2) of the Code set out in the Schedule

Add:

Note: This subsection does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162: see section 8X.

38 At the end of subsection 34AC(2) of the Code set out in the Schedule

Add:

Note: This subsection does not authorise the disclosure of confidential commercial information whose disclosure would otherwise be prohibited by section 162: see section 8X.

39 Subsection 59(6) of the Code set out in the Schedule

Omit "***continue*** an approval or registration", insert "***continue***, in relation to an approval or registration,".

40 Subsection 86(4) of the Code set out in the Schedule

Omit "Subsections (1) and (2)", substitute "Subsections (1A) and (2A)".

41 Section 89A of the Code set out in the Schedule

Omit all the words after "a chemical product", substitute ", or a product included in a class of chemical products, prescribed by the regulations".

42 Section 99 of the Code set out in the Schedule (heading)

Repeal the heading, substitute:

99 Information and documents about, and analysis of, substances supplied as active constituents or chemical products

43 Subsections 99(1) to (5) of the Code set out in the Schedule

Repeal the subsections, substitute:

(1) This section applies if the APVMA reasonably believes that it is necessary to exercise powers under this section:
  (a) to protect the health and safety of human beings; or
  (b) to protect animals, plants or things, or the environment; or
  (c) to prevent significant prejudice to trade or commerce between Australia and places outside Australia.

(2) The APVMA may give written notice to a person who has, has had or will have, possession or custody of a substance or mixture of substances that is or was intended for supply by the person:
  (a) as a chemical product; or
  (b) as an active constituent for a proposed or existing chemical product;

requiring the person to give the APVMA information or documents specified in the notice or to take the steps specified in the notice.

(3) The notice may require the person to give to the APVMA, within such reasonable period as is specified in the notice, information or documents required by the notice about the following:
  (a) the constituents of the substance or mixture;
  (b) the concentration of the constituents of the substance or mixture;
  (c) the formulation type of the substance or mixture;
  (d) the composition or purity of a constituent of the substance or mixture;
  (e) the name of each manufacturer of the substance or mixture;
  (f) the address of each site at which the substance or mixture is manufactured;
  (g) the packaging or labelling of the substance or mixture;
  (h) advertising material related to the substance or mixture;
  (j) if the substance or mixture is intended to be supplied, or has been supplied, as an active constituent for a chemical product, or as a chemical product, under a particular name—the name of the constituent or product and whether:
    (i) the substance or mixture conforms to any standard prescribed in respect of the constituent or product with that name, any established standard or any other prescribed requirement; or

(ii) the supply of the substance or mixture is or was in accordance with any conditions applying to the approval or registration of the constituent or product with that name;

(k) any other prescribed information or documents.

(4) The notice may also require the person, within such reasonable period as is specified in the notice:

(a) to have the substance or mixture analysed to find out about the matters mentioned in paragraphs (3)(a) to (d) and paragraphs (3)(j) and (k); and

(b) to give the results of the analysis to the APVMA; and

(c) to give the analyst's certificate to the APVMA.

(4A) Without limiting subsection (4), the notice may require any one or more of the following:

(a) that samples of the substance or mixture are taken:

(i) under the supervision of an inspector; or

(ii) in the manner stated in the notice;

(b) that the analysis is carried out:

(i) under the supervision of an approved analyst; or

(ii) in the manner stated in the notice;

(c) that the analysis is carried out at a prescribed laboratory;

(d) that the analysis is carried out within a period stated in the notice;

(e) that the analysis is carried out at the expense of the person.

(4B) Information or results required to be given to the APVMA must be given in writing.

Note: For giving information electronically, see section 156A.

(5) A person to whom a notice is given under subsection (2) must not fail to comply with the notice.

44 Subsection 116(3C) of the Code set out in the Schedule (note)

Omit "provisions..", substitute "provisions.".

45 Section 120A of the Code set out in the Schedule

Omit all the words after "apply to", substitute "a chemical product, or a product included in a class of chemical products, prescribed by the regulations".

46 Paragraph 121(4)(a) of the Code set out in the Schedule

Omit "the products are exempt products or".

47 After section 146 of the Code set out in the Schedule

Insert:

146A Self-incrimination to be a reasonable excuse for non-compliance with requirement

It is a reasonable excuse for an individual to refuse or fail to give information, produce a document or do any other thing that the individual is required to do by or under this Code that the information, the production of the document or the doing of that other thing would tend to incriminate the individual.

48 At the end of subsection 159(1) of the Code set out in the Schedule

Add:

; (h) conduct, or cause to be conducted, trials or laboratory experiments and give the results of the trials or experiments to the APVMA.

49 Subsection 164(1) of the Code set out in the Schedule

After "an application to the APVMA,", insert "the lodging of a notice under Division 2AA of Part 2,".

50 Subsection 164(5) of the Code set out in the Schedule

After "an application to the APVMA,", insert "the lodging of a notice under Division 2AA of Part 2,".

51 Subsection 164(5) of the Code set out in the Schedule

After "corresponding application,", insert "the lodging of a corresponding notice,".

52 After subsection 164(7) of the Code set out in the Schedule

Insert:

(7A) If a fee has to be paid in respect of a notice under Division 2AA of Part 2, the notice is taken not to have been lodged until the fee is paid.

53 Subparagraph 166(1A)(b)(i) of the Code set out in the Schedule

Omit "26C(2),", substitute "paragraph 26C(1)(b), subsection".

54 After subparagraph 166(1A)(b)(i)

Insert:

(ia) a decision under Division 2AA of Part 2 that a notice does not meet the notice requirements; or

55 Paragraph 167(1)(j) of the Code set out in the Schedule

Repeal the paragraph, substitute:

(j) a decision under section 99 to issue a notice;

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56 Section 80

Omit "13A", substitute "8E".

57 Paragraph 81(1)(a)

Omit "13A", substitute "8E".

58 Paragraph 81(1)(b)

Omit "13A(2)(b)(i)", substitute "8E(2)(b)(i)".

59 Paragraph 81(1)(b)

Omit "section 13A", substitute "section 8E".

60 Subsection 81(2)

Omit "13A", substitute "8E".

61 Subsection 84(1)

After "without amendments),", insert "or under section 53 and 79 that the Authority has approved a draft high level health claims variation,".

62 Subsection 84(2)

After "variation,", insert "or a draft high level health claims variation,".

Part 2—Transitional provisions

63 Exempt products for the purposes of paragraph 121(4)(a) of the Code

(1) This item applies to the following as in force immediately before the commencement of this Schedule:

(a) paragraph 121(4)(a) of the Code;

(b) any regulations made for the purposes of that paragraph.

(2) Despite the amendments made by item 46 of this Schedule, that paragraph and those regulations have effect after the commencement of this Schedule until regulations are made for the purpose of section 120A of the Code.

(3) In this item:

the Code means the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.