



Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021

No. 125, 2021

**An Act to amend the law relating to agricultural
and veterinary chemicals, and for related purposes**

Note: An electronic version of this Act is available on the Federal Register of Legislation
(<https://www.legislation.gov.au/>)

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Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021

No. 125, 2021

**An Act to amend the law relating to agricultural
and veterinary chemicals, and for related purposes**

[Assented to 7 December 2021]

The Parliament of Australia enacts:

No. 125, 2021 Agricultural and Veterinary Chemicals Legislation Amendment 1
(Australian Pesticides and Veterinary Medicines Authority Board and
Other Improvements) Act 2021

1 Short title

This Act is the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021*.

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
Provisions	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.	7 December 2021
2. Schedule 1, Parts 1 and 2	The day after the end of the period of 6 months beginning on the day this Act receives the Royal Assent.	7 June 2022
3. Schedule 1, Part 3	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 3 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	7 March 2022
4. Schedule 1, Part 4	The day after this Act receives the Royal Assent.	8 December 2021
5. Schedule 1, Part 5	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 6 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	7 June 2022

2 *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021* No. 125, 2021

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
6. Schedule 1, Part 6	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	7 December 2022
7. Schedule 1, Parts 7 to 12	The day after the end of the period of 3 months beginning on the day this Act receives the Royal Assent.	7 March 2022
8. Schedule 1, Part 13	The first 1 January to occur after the day this Act receives the Royal Assent.	1 January 2022
9. Schedule 1, Parts 14 to 20	The day after this Act receives the Royal Assent.	8 December 2021
10. Schedule 2	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 12 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	4 March 2022 (F2022N00042)

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 Schedules

Legislation 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—Main improvements

Part 1—Information to be taken into account in determining applications

Agricultural and Veterinary Chemicals Code Act 1994

1 Subsection 8C(2) of the Code set out in the Schedule

Omit “However”, substitute “Subject to subsection (2A)”.

2 After subsection 8C(2) of the Code set out in the Schedule

Insert:

- (2A) Subsection (2) does not apply to information that is prescribed by the regulations, and that is provided in the circumstances prescribed by the regulations, for the purposes of this subsection.

3 Application provision

The amendments of section 8C of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to the following:

- (a) applications lodged on or after the commencement of this item;
- (b) applications lodged before the commencement of this item but not determined by the APVMA before that commencement.

Part 2—Approval and registration for prescribed active constituents, chemical products or labels

Agricultural and Veterinary Chemicals Code Act 1994

4 Section 3 of the Code set out in the Schedule

Insert:

prescribed active constituent has the meaning given by subsection 14C(4).

prescribed chemical product has the meaning given by subsection 14D(4).

prescribed label for containers for a chemical product has the meaning given by subsection 14E(4).

5 Before section 9A of the Code set out in the Schedule

Insert:

Subdivision A—Explanation of Division

6 Subsections 9A(2) to (5) of the Code set out in the Schedule

Repeal the subsections, substitute:

Approval and registration for active constituents, chemical products or labels after assessment

- (2) Subdivision B provides for approval and registration for active constituents, chemical products or labels after assessment against certain criteria. Section 10 provides for applications to be made and applications must meet the application requirements in section 8A.
- (3) The APVMA must complete a preliminary assessment of an application. If the application passes preliminary assessment, the

Schedule 1 Main improvements

Part 2 Approval and registration for prescribed active constituents, chemical products or labels

APVMA must notify the applicant and publish a summary of the application (section 11).

- (4) Before determining certain applications that have passed preliminary assessment, the APVMA must publish a notice inviting public submissions (sections 12 and 13).
- (5) The APVMA must approve an active constituent or label, or register a chemical product, if specified criteria are met (section 14).

Approval and registration for prescribed active constituents, chemical products or labels

- (5A) Subdivision C provides for approval and registration for a prescribed active constituent, prescribed chemical product or prescribed label for containers for a chemical product. Sections 14C, 14D and 14E provide for applications to be made and applications must meet the application requirements in section 8A.
- (5B) If an application meets the application requirements, the APVMA must approve the active constituent or label, or register the chemical product, if no disqualifying circumstances exist in relation to the applicant.

Common provisions

7 After section 9A of the Code set out in the Schedule

Insert:

Subdivision B—Approval and registration for active constituents, chemical products or labels after assessment

8 After section 14B of the Code set out in the Schedule

Insert:

Subdivision C—Approval and registration for prescribed active constituents, chemical products or labels

14C Applications for approval of prescribed active constituents

- (1) A person may apply to the APVMA for approval of a prescribed active constituent.

Note: For *prescribed active constituent*, see subsection (4).

- (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 active constituent* is an active constituent that:

(a) is for a proposed or existing chemical product; and

(b) is of a kind:

(i) prescribed by the regulations for the purposes of this subparagraph; or

(ii) determined by the APVMA under subsection (6).

- (5) The APVMA must not determine a kind of active constituent under subsection (6) unless it is satisfied that the kind of active constituent would meet the safety criteria.

- (6) The APVMA may, by legislative instrument, determine a kind of active constituent for the purposes of subparagraph (4)(b)(ii).

Decision on application

- (7) The APVMA must approve the active constituent that is the subject of the application if it is satisfied that:

(a) the application meets the application requirements; and

(b) the active constituent is a prescribed active constituent; and

(c) none of the circumstances determined in an instrument under subsection (9) apply in relation to the applicant.

Note: For notice of approval, see section 8F.

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Part 2 Approval and registration for prescribed active constituents, chemical products or labels

- (8) Otherwise, the APVMA must refuse the application.

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

Disqualifying circumstances

- (9) The APVMA may, by legislative instrument, determine circumstances for the purposes of paragraph (7)(c).

14D Applications for registration of prescribed chemical products

- (1) A person may apply to the APVMA for registration of a prescribed chemical product.

Note: For *prescribed chemical product*, see subsection (4).

- (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 chemical product* is a chemical product that is of a kind:

- (a) prescribed by the regulations for the purposes of this paragraph; or
- (b) determined by the APVMA under subsection (6).

- (5) The APVMA must not determine a kind of chemical product under subsection (6) unless it is satisfied that the kind of chemical product would:

- (a) meet the safety criteria, the trade criteria and the efficacy criteria; or
- (b) comply with the established standard for the kind of chemical product.

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

Decision on application

- (7) The APVMA must register the chemical product that is the subject of the application if it is satisfied that:
- (a) the application meets the application requirements; and
 - (b) the chemical product is a prescribed chemical product; and
 - (c) none of the circumstances determined in an instrument under subsection (9) apply in relation to the applicant.

Note: For notice of approval, see section 8F.

- (8) Otherwise, the APVMA must refuse the application.

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

Disqualifying circumstances

- (9) The APVMA may, by legislative instrument, determine circumstances for the purposes of paragraph (7)(c).

14E Applications for approval of prescribed labels for containers for chemical products

- (1) A person may apply to the APVMA for approval of a prescribed label for containers for a chemical product.

Note: For *prescribed label for containers for a chemical product*, see subsection (4).

- (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 label for containers for a chemical product* is a label:

- (a) for containers for a chemical product; and
- (b) that is of a kind:
 - (i) prescribed by the regulations for the purposes of this subparagraph; or
 - (ii) determined by the APVMA under subsection (6).

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- (5) The APVMA must not determine a kind of label under subsection (6) unless it is satisfied that the kind of label would:
 - (a) meet the labelling criteria; or
 - (b) comply with the established standard for the chemical product.
- (6) The APVMA may, by legislative instrument, determine a kind of label for the purposes of subparagraph (4)(b)(ii).
- (7) Without limiting subsection (6), a kind of label may be described by reference to a kind of chemical product.

Decision on application

- (8) The APVMA must approve the label that is the subject of the application if it is satisfied that:
 - (a) the application meets the application requirements; and
 - (b) the label that is the subject of the application is a prescribed label for containers for a chemical product; and
 - (c) none of the circumstances determined in an instrument under subsection (10) apply in relation to the applicant.

Note: For notice of approval, see section 8F.

- (9) Otherwise, the APVMA must refuse the application.

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

Disqualifying circumstances

- (10) The APVMA may, by legislative instrument, determine circumstances for the purposes of paragraph (8)(c).

Subdivision D—Common provisions

9 Paragraphs 17(3)(a) and (b) of the Code set out in the Schedule

After “section 14”, insert “or 14C”.

10 After subsection 34G(1) of the Code set out in the Schedule

Insert:

- (1AA) The APVMA must not use the following information to assess or make a decision on an application made under section 14C, 14D or 14E:
- (a) information given to the APVMA in connection with an application made under section 10 or 27 by the applicant for that application;
 - (b) information given under section 161.

11 Subsection 34G(1B) of the Code set out in the Schedule

After “subsections (1)”, insert “, (1AA)”.

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

After “subsection 14(2)”, insert “, 14C(8), 14D(8) or 14E(9)”.

13 Paragraph 167(1)(a) of the Code set out in the Schedule

After “subsection 14(1)”, insert “, 14C(7), 14D(7) or 14E(8)”.

14 Paragraph 167(1)(b) of the Code set out in the Schedule

After “subsection 14(2)”, insert “, 14C(8), 14D(8) or 14E(9)”.

Part 3—Limits on use of information

Agricultural and Veterinary Chemicals Code Act 1994

15 Section 3 of the Code set out in the Schedule (at the end of the definition of *limitation period*)

Add:

Note: See also section 34MA (which deals with extensions of limitation periods).

16 Section 3 of the Code set out in the Schedule (paragraph (b) of the definition of *protected active constituent*)

Repeal the paragraph, substitute:

- (b) the term of the letters patent (including any extension of that term):
 - (i) has ended; or
 - (ii) will end during the protection period (including that period as extended) that applies to protected information about that constituent;

17 Section 3 of the Code set out in the Schedule (paragraph (b) of the definition of *protected chemical product*)

Repeal the paragraph, substitute:

- (b) the term of the letters patent (including any extension of that term):
 - (i) has ended; or
 - (ii) will end during the protection period (including that period as extended) that applies to protected information about that product;

18 Section 3 of the Code set out in the Schedule (at the end of the definition of *protection period*)

Add:

Note: See also section 34KA (which deals with extensions of the protection period).

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

After “34K”, insert “, 34KA”.

20 Subsection 34F(5) of the Code set out in the Schedule

Omit “Section 34M sets”, substitute “Sections 34M and 34MA set”.

21 Subsection 34J(5A) of the Code set out in the Schedule

Repeal the subsection, substitute:

Protected information whose protection period has expired

- (5A) Another condition is that the information is protected information and either:
- (a) the protection period in relation to that information has ended; or
 - (b) if the protection period in relation to that information is extended in accordance with regulations made for the purposes of section 34KA—the protection period, as extended, has ended.

Note: For *protected information* and *protection period*, see section 3 and Part 3.

22 After section 34K of the Code set out in the Schedule

Insert:

34KA Extension of protection periods

- (1) The regulations may make provision for and in relation to either or both of the following:
 - (a) extending the protection period in relation to protected information;
 - (b) ending such an extension.
- (2) An application for an extension is not required.

- (3) Instead, an extension of a protection period must not occur unless, at least 3 years before that protection period (including that period as previously extended) will end, an application that satisfies the following is lodged:
- (a) the application is under a provision of this Part prescribed by the regulations for the purposes of this paragraph;
 - (b) the application satisfies the requirements prescribed by the regulations for the purposes of this paragraph.

Maximum extension

- (4) The total length of all extensions of a protection period, in relation to particular protected information, must not be more than 5 years.

Powers may be conferred on the APVMA

- (5) In relation to an extension of a protection period, or ending such an extension, the regulations may confer a power to make a decision of an administrative character on the APVMA.

23 Subsection 34M(1) of the Code set out in the Schedule

Omit “The table”, substitute “Subject to section 34MA, the table”.

24 At the end of subsection 34M(1) of the Code set out in the Schedule

Add:

Note: Section 34MA deals with extensions of the limitation period.

25 At the end of Division 4A of Part 2 of the Code set out in the Schedule

Add:

34MA Extension of limitation periods

- (1) The regulations may make provision for and in relation to either or both of the following:
- (a) extending the limitation period for information covered by an item of the table in subsection 34M(1);

- (b) ending such an extension.
- (2) An application for an extension is not required.
- (3) One of the circumstances in which there may be an extension of a limitation period under the regulations is if, at least 3 years before that limitation period (including that period as previously extended) will end, an application that satisfies the following is lodged:
 - (a) the application is under a provision of this Part prescribed by the regulations for the purposes of this paragraph;
 - (b) the application satisfies the requirements prescribed by the regulations for the purposes of this paragraph.

Maximum extension

- (4) The total length of all extensions of a limitation period, for particular information covered by an item of the table in subsection 34M(1), must not be more than 5 years.

Powers may be conferred on the APVMA

- (5) In relation to an extension of a limitation period, or ending such an extension, the regulations may confer a power to make a decision of an administrative character on the APVMA.

26 Paragraph 59(2)(c) of the Code set out in the Schedule

After “protection period”, insert “(including that period as extended)”.

27 Application provisions

- (1) Section 34KA of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, as inserted by this Part, applies in relation to a protection period beginning before, on or after the day this item commences.
- (2) Section 34MA of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, as added by this Part, applies in relation to a limitation period beginning before, on or after the day this item commences.

Part 4—Annual returns and record-keeping

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

28 Subsection 3(1)

Insert:

active constituent has the same meaning as in the Agricultural and Veterinary Chemicals Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

29 After section 34

Insert:

35 Annual returns by interested persons

- (1) The interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of the product that took place anywhere in Australia at any time during a financial year must give the APVMA, before 30 November in the next financial year, a return setting out the total quantity of the chemical product covered by those leviable disposals.

Note: See also sections 37A and 37B.

- (2) Subsection (1) does not apply:
 - (a) to that interested person in relation to that chemical product and to a financial year if the total quantity of that product covered by those leviable disposals in that year is not more than the quantity prescribed by the regulations for the purposes of this paragraph; or
 - (b) to a chemical product prescribed by the regulations for the purposes of this paragraph.

Strict liability offence

- (3) A person commits an offence of strict liability if the person contravenes subsection (1).

Penalty: 50 penalty units.

Civil penalty

- (4) Subsection (1) is a civil penalty provision.

Note 1: For monitoring and investigation powers of inspectors in relation to this Act, see Part 7AA of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Note 2: Division 1 of Part 7AB of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides for pecuniary penalties for contraventions of civil penalty provisions.

Note 3: For infringement notices, enforceable undertakings and formal warnings in relation to contraventions of subsection (1), see Divisions 2, 3 and 6 of Part 7AB of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Statement to Department

- (5) From the returns given to the APVMA in relation to a financial year, the APVMA must give the Secretary of the Department, before the end of the next financial year, a statement setting out the total quantities of each active constituent for each chemical product covered by those returns.

30 After section 36

Insert:

37 Records to be kept by interested persons

- (1) The interested person in relation to a chemical product who is liable to pay levy in respect of leviable disposals of the product that took place anywhere in Australia at any time during a financial year must:
- (a) keep any records relating to those disposals that are reasonably necessary to enable the APVMA to find out whether section 35 has been complied with; and

Schedule 1 Main improvements

Part 4 Annual returns and record-keeping

(b) retain those records for 6 years.

Note: See also sections 37A and 37B.

Strict liability offence

(2) A person commits an offence of strict liability if the person contravenes subsection (1).

Penalty: 50 penalty units.

Civil penalty

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

Note 1: For monitoring and investigation powers of inspectors in relation to this Act, see Part 7AA of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

Note 2: Division 1 of Part 7AB of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides for pecuniary penalties for contraventions of civil penalty provisions.

Note 3: For infringement notices, enforceable undertakings and formal warnings in relation to contraventions of subsection (1), see Divisions 2, 3 and 6 of Part 7AB of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

37A Main constitutional basis of sections 35 and 37

Sections 35 and 37 rely on the Commonwealth's legislative powers under paragraphs 51(xi) (census and statistics) and (xxxix) (incidental matters) of the Constitution.

37B Other constitutional bases of sections 35 and 37

(1) Independently of section 37A, sections 35 and 37 also have effect as provided by this section.

Trade and commerce

(2) Sections 35 and 37 also have the effect they would have if a reference to a leviable disposal were expressly confined to a leviable disposal that occurs in the course of:

- (a) trade or commerce between Australia and places outside Australia; or
- (b) trade or commerce among the States; or
- (c) trade or commerce within a Territory, between a State and a Territory or between 2 Territories.

Corporations

- (3) Sections 35 and 37 also have the effect they would have if a reference to a leviable disposal were expressly confined to a leviable disposal by a corporation to which paragraph 51(xx) of the Constitution applies.

Territories

- (4) Sections 35 and 37 also have the effect they would have if a reference to a leviable disposal were expressly confined to a leviable disposal that occurs in a Territory.

31 Application provisions

- (1) Section 35 of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, as inserted by this Part, applies in relation to leviable disposals that take place in the financial year in which this item commences or in a later financial year.
- (2) Section 37 of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, as inserted by this Part, applies in relation to leviable disposals that take place on or after the commencement of this item.

Agricultural and Veterinary Chemicals (Administration) Act 1992

32 Section 69E

Repeal the section.

33 Subsection 69EA(1) (heading)

Repeal the heading, substitute:

Records relating to compliance with sections 69B and 69C

34 Paragraph 69EA(1)(a)

Omit “69B, 69C and 69E”, substitute “69B and 69C”.

35 Saving provisions

- (1) Despite the repeal of section 69E of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Part, that section, as in force immediately before the commencement of this item, continues to apply on and after that commencement in respect of the following:
- (a) the import, manufacture or export of active constituents referred to in paragraph 69E(1)(a) of that Act that occurred in a financial year that ended before the commencement of this item;
 - (b) the import, manufacture or export of chemical products referred to in paragraph 69E(1)(b) of that Act that occurred in a financial year that ended before the commencement of this item.
- (2) Despite the amendments of section 69EA of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Part, that section, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to the keeping and retaining of records in respect of the matters covered by paragraphs (1)(a) and (b) of this item.

Part 5—Computerised decision-making

Agricultural and Veterinary Chemicals Code Act 1994

36 Before section 6 of the Code set out in the Schedule

Insert:

5F APVMA may arrange for use of computer programs to make decisions

- (1) The APVMA may arrange for the use, under the APVMA's control, of computer programs for any purposes for which the APVMA may, or must, under this Code:
- (a) make a decision of a kind determined in an instrument under subsection (1A); or
 - (b) exercise any power, or comply with any obligation, related to making a decision to which paragraph (a) applies; or
 - (c) do anything else related to making a decision to which paragraph (a) applies or related to exercising a power, or complying with an obligation, to which paragraph (b) applies.

(1A) The APVMA may, by legislative instrument, determine kinds of decisions for the purposes of paragraph (1)(a). The APVMA may, in that instrument, also determine conditions of use of a computer program as mentioned in subsection (1).

(1B) The APVMA must take all reasonable steps to ensure that decisions made by the operation of a computer program under an arrangement made under subsection (1) are correct.

Note: In addition, subsection 1A(2) of this Code sets out how this Code is to be implemented (which covers the making of an arrangement under subsection (1) of this section).

- (2) For the purposes of this Code, the APVMA is taken to have:
- (a) made a decision; or
 - (b) exercised a power or complied with an obligation; or

(c) done something else related to the making of a decision or the exercise of a power or the compliance with an obligation; that was made, exercised, complied with or done by the operation of a computer program under an arrangement made under subsection (1).

Substituted decisions

- (3) The APVMA may substitute a decision for a decision (the **initial decision**) the APVMA is taken, under paragraph (2)(a), to have made if the APVMA is satisfied that the initial decision is incorrect.
- (4) However, the substituted decision may only be made before the end of the period of 60 days beginning on the day the initial decision is made.

37 Paragraph 166(1)(a) of the Code set out in the Schedule

Repeal the paragraph, substitute:

- (a) a decision (the **reviewable decision**) on a particular matter (the **relevant matter**):
- (i) has been made under this Code on behalf of the APVMA by a member of the staff of the APVMA; or
 - (ii) is taken, under paragraph 5F(2)(a), to have been made by the APVMA for the purposes of this Code; and

38 Paragraph 166(1)(b) of the Code set out in the Schedule

Omit “original decision”, substitute “reviewable decision”.

39 Paragraph 166(1A)(a) of the Code set out in the Schedule

Repeal the paragraph, substitute:

- (a) a decision (the **reviewable decision**) on a particular matter (the **relevant matter**):
- (i) has been made under this Code on behalf of the APVMA by a member of the staff of the APVMA; or
 - (ii) is taken, under paragraph 5F(2)(a), to have been made by the APVMA for the purposes of this Code; and

40 Paragraphs 166(1A)(b) and (c) of the Code set out in the Schedule

Omit “original decision” (wherever occurring), substitute “reviewable decision”.

41 After subsection 166(1A) of the Code set out in the Schedule

Insert:

- (1B) This section also applies if:
- (a) the APVMA is taken, under paragraph 5F(2)(a), to have made a decision (the *initial decision*) for the purposes of this Code; and
 - (b) under this section, a person may request the APVMA to reconsider the initial decision; and
 - (c) the APVMA, under subsection 5F(3), substitutes a decision (the *reviewable decision*) for the initial decision.

42 Subsections 166(2) to (4A) and (5) to (7) of the Code set out in the Schedule

Omit “original decision” (wherever occurring), substitute “reviewable decision”.

43 After subsection 167(2A) of the Code set out in the Schedule

Insert:

- (2B) If:
- (a) the APVMA is taken, under paragraph 5F(2)(a), to have made a decision (the *initial decision*) for the purposes of this Code; and
 - (b) under subsection (1) of this section, an application may be made to the Administrative Appeals Tribunal for review of the initial decision; and
 - (c) the APVMA, under subsection 5F(3), substitutes a decision for the initial decision;

an application may be made to the Administrative Appeals Tribunal for review of the substituted decision.

44 Application and saving provisions

- (1) The amendments of section 166 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to reviewable decisions made on or after the commencement of this item.
- (2) Section 166 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to original decisions made before that commencement.

Part 6—Preliminary assessments

Agricultural and Veterinary Chemicals Code Act 1994

45 Subsection 11(2) of the Code set out in the Schedule

Omit “from the preliminary assessment”, substitute “to the APVMA, after completing a preliminary assessment of the application or after defects in the application have been rectified in response to a notice under subsection (3)”.

46 Subsection 11(3) of the Code set out in the Schedule

Repeal the subsection, substitute:

- (3) If it appears to the APVMA, after completing a preliminary assessment of the application, that the application does not meet the application requirements but that the defects in the application can reasonably be rectified, the APVMA must, within 14 days, give written notice to the applicant:
 - (a) stating that the application does not meet the application requirements; and
 - (b) giving particulars of the defects in the application; and
 - (c) requiring the defects to be rectified within 1 month.
- (3A) The APVMA must refuse the application if:
 - (a) the APVMA is not satisfied that defects in the application can reasonably be rectified; or
 - (b) the defects are not rectified to the satisfaction of the APVMA within the period mentioned in paragraph (3)(c).

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

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

Omit “from the preliminary assessment”, substitute “to the APVMA, after completing a preliminary assessment of the application or after defects in the application have been rectified in response to a notice under subsection (3)”.

48 Subsection 28(3) of the Code set out in the Schedule

Repeal the subsection, substitute:

- (3) If it appears to the APVMA, after completing a preliminary assessment of the application, that the application does not meet the application requirements but that the defects in the application can reasonably be rectified, the APVMA must, within 14 days, give written notice to the applicant:
- (a) stating that the application does not meet the application requirements; and
 - (b) giving particulars of the defects in the application; and
 - (c) requiring the defects to be rectified within 1 month.
- (3A) The APVMA must refuse the application if:
- (a) the APVMA is not satisfied that defects in the application can reasonably be rectified; or
 - (b) the defects are not rectified to the satisfaction of the APVMA within the period mentioned in paragraph (3)(c).

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

49 Subsection 110A(2) of the Code set out in the Schedule

Omit “from the preliminary assessment”, substitute “to the APVMA, after completing a preliminary assessment of the application or after defects in the application have been rectified in response to a notice under subsection (3)”.

50 Subsection 110A(3) of the Code set out in the Schedule

Omit “from the preliminary assessment”, substitute “to the APVMA, after completing a preliminary assessment of the application”.

51 Application provision

The amendments made by this Part apply in relation to applications lodged under section 10, 27 or 110 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* on or after the commencement of this item.

Part 7—Variation of relevant particulars and conditions

Agricultural and Veterinary Chemicals Code Act 1994

52 At the end of subsection 8S(1) of the Code set out in the Schedule (before the note)

Add:

; or (c) varies, under section 29, relevant particulars or conditions in a way other than set out in the application.

53 After paragraph 8S(2)(a) of the Code set out in the Schedule

Insert:

(b) for notice under paragraph (1)(c)—set out the proposed variation; and

54 Paragraphs 29(1)(b), (c) and (d) of the Code set out in the Schedule

Omit “in accordance with the application”, substitute “in a particular way (which may not be the same way as set out in the application)”.

55 After paragraph 167(1)(c) of the Code set out in the Schedule

Insert:

(ca) a decision under subsection 29(1) to vary relevant particulars or conditions in a way other than set out in the application for variation;

56 Application provision

The amendments made by this Part apply in relation to an application lodged under section 27 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* on or after the commencement of this item.

Part 8—Variation of approval or registration during suspension

Agricultural and Veterinary Chemicals Code Act 1994

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

Repeal the heading, substitute:

42 Suspension or cancellation of approval or registration at request of holder

58 Subparagraph 42(1)(a)(i) of the Code set out in the Schedule

After “to”, insert “suspend or”.

59 Subsection 42(1) of the Code set out in the Schedule

Omit “the APVMA must cancel the approval or registration”, substitute “the APVMA must suspend or cancel the approval or registration (as the case may be)”.

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

Omit “An”, substitute “Subject to this section, an”.

61 At the end of section 43 of the Code set out in the Schedule

Add:

- (4) A suspension of an approval or registration does not prevent:
 - (a) the lodging of a notice under section 26AB of one or more notifiable variations of the relevant particulars of the approval or registration or the dealing with the notice; or
 - (b) an application being made under section 26B for one or more prescribed variations of the relevant particulars of the approval or registration or the dealing with the application; or

- (c) an application being made under subsection 27(1) for variation of the relevant particulars or conditions of the approval or registration or the dealing with the application; or
 - (d) a variation under section 29A of the relevant particulars or conditions of the approval or registration.
- (5) A notice referred to in paragraph (4)(a), an application referred to in paragraph (4)(b) or (c) or a variation referred to in paragraph (4)(d) must be in relation to the reasons for the suspension of the approval or registration.

62 Subsection 45A(2) of the Code set out in the Schedule

Omit “subsection (1)”, substitute “paragraph (1)(a)”.

63 Paragraph 45A(2)(b) of the Code set out in the Schedule

Omit “in respect of a suspension or cancellation of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product—”.

64 Subsection 45A(4) of the Code set out in the Schedule

After “notice of the”, insert “suspension or”.

65 Subsection 45A(4) of the Code set out in the Schedule

After “requested the”, insert “suspension or”.

66 Application provisions

- (1) The amendments of section 42 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to requests made on or after the commencement of this item.
- (2) The amendments of section 43 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to:
 - (a) a suspension made on or after the commencement of this item; and
 - (b) a suspension made before the commencement of this item that was in effect immediately before that commencement.

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Part 8 Variation of approval or registration during suspension

- (3) The amendments of section 45A of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to a suspension or cancellation made on or after the commencement of this item.

Part 9—False and misleading information

Agricultural and Veterinary Chemicals (Administration) Act 1992

67 Before subsection 69ER(1)

Insert:

Offences

68 At the end of section 69ER

Add:

Civil penalties

- (3) A person must not, for the purposes of, or in connection with, the making of a decision by the APVMA as to whether it should give a consent under section 69B:
- (a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or
 - (b) produce a document that the person knows to be false or misleading in a material particular without:
 - (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
 - (ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.
- (4) A person must not, in compliance or purported compliance with a requirement made by an inspector under Part 7A, Part 7AA or this Part or for the purposes of, or in connection with, any provision of Part 7A (other than section 69B), Part 7AA or this Part:
- (a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or

- (b) produce a document that the person knows to be false or misleading in a material particular without:
 - (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
 - (ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.
- (5) Subsections (3) and (4) are civil penalty provisions.

Note: Division 1 provides for pecuniary penalties for contraventions of civil penalty provisions.

Agricultural and Veterinary Chemicals Code Act 1994

69 Before subsection 146(1) of the Code set out in the Schedule

Insert:

Offences

70 At the end of section 146 of the Code set out in the Schedule

Add:

Civil penalties

- (3) A person must not, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under this Code, of any matters referred to in section 5A, 5B, 5C or 5D or subsection 123(1):
 - (a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or
 - (b) produce a document that the person knows to be false or misleading in a material particular without:

- (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
 - (ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.
- (4) A person must not, for the purposes of, or in connection with, the consideration by the APVMA, in the course of the performance of any of its functions or the exercise of any of its powers under this Code, of any matters other than matters referred to in subsection (3):
- (a) give information (whether orally or in writing) that the person knows to be false or misleading in a material particular; or
 - (b) produce a document that the person knows to be false or misleading in a material particular without:
 - (i) indicating to the person to whom the document is produced that it is false or misleading and the respect in which it is false or misleading; and
 - (ii) providing correct information to that person if the person producing the document is in possession of, or can reasonably acquire, the correct information.
- (5) Subsections (3) and (4) are civil penalty provisions.

Note: Division 2 provides for pecuniary penalties for contraventions of civil penalty provisions.

71 Application provision

The amendments made by this Part apply in relation to information given, or a document produced, on or after the commencement of this item.

Part 10—Suspension or cancellation of approval or registration for provision of false or misleading information

Agricultural and Veterinary Chemicals Code Act 1994

72 Paragraph 34N(4)(d) of the Code set out in the Schedule

Omit “the holder”, substitute “a person”.

73 Section 38A of the Code set out in the Schedule

Repeal the section, substitute:

38A Suspension or cancellation of approval or registration for provision of false or misleading information

The APVMA may suspend or cancel an approval or registration if:

- (a) a person has given information:
 - (i) in, or in connection with, the application for the approval or registration; or
 - (ii) in connection with a variation of the approval or registration; or
 - (iii) in response to a notice under subsection 32(1) or section 33 or 159; or
 - (iv) as required by section 160A or 161; and
- (b) the information was false or misleading in a material particular.

74 Application provision

Section 38A of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, as substituted by this Part, applies in relation to information given on or after the commencement of this item.

Part 11—Voluntary recalls

Agricultural and Veterinary Chemicals Code Act 1994

75 Section 100 of the Code set out in the Schedule

Before “This Part”, insert “(1)”.

76 At the end of section 100 of the Code set out in the Schedule

Add:

- (2) This Part also provides for voluntary recalls of chemical products (see section 106).

77 Section 106 of the Code set out in the Schedule

Repeal the section, substitute:

106 Notification to APVMA of voluntary recalls

- (1) This section applies if a person voluntarily takes action to recall a chemical product because it appears to the person that:
 - (a) either or both of the following apply:
 - (i) the chemical product may not meet the safety criteria, the trade criteria or the efficacy criteria;
 - (ii) a label for containers for the chemical product may not meet the labelling criteria; or
 - (b) the chemical product is not a registered chemical product.
- (2) The person must, within 2 days after taking the action, give the APVMA a notice that:
 - (a) is in writing in the approved form; and
 - (b) contains the information required by the approved form.
- (3) Subsection (2) does not apply in the circumstances prescribed by the regulations for the purposes of this subsection.

Offence

- (4) A person commits an offence of strict liability if:
- (a) the person is required by subsection (2) to give a notice to the APVMA; and
 - (b) the person refuses or fails to give the notice as required by that subsection.

Penalty: 60 penalty units.

Civil penalty

- (5) Subsection (2) is a civil penalty provision.

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

APVMA to publish notice of recall

- (6) If a notice is given to the APVMA under subsection (2), the APVMA:
- (a) must, within 3 working days, publish a copy of the notice on its website; and
 - (b) must, within 14 days, publish a copy of the notice in the Gazette.

The APVMA may also make available a copy of the notice in any other manner that it thinks appropriate.

- (7) Subsection (6) does not apply in the circumstances prescribed by the regulations for the purposes of this subsection.

No limit on the Competition and Consumer Act 2010

- (8) This section does not limit section 128 of Schedule 2 to the *Competition and Consumer Act 2010* (about voluntary recall of consumer goods).

78 Application provision

Section 106 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*, as substituted by this Part, applies in relation to action taken on or after the commencement of this item.

Part 12—Notification of new information

Agricultural and Veterinary Chemicals Code Act 1994

79 Subparagraph 160A(1)(a)(v) of the Code set out in the Schedule

Omit “and”, substitute “or”.

80 At the end of paragraph 160A(1)(a) of the Code set out in the Schedule

Add:

- (vi) approval of a label for containers for a chemical product; or
- (vii) variation of the relevant particulars or conditions of the approval of an active constituent, of the registration of a chemical product or of the approval of a label for containers for a chemical product; and

81 Paragraph 160A(1)(c) of the Code set out in the Schedule

Omit “or in relation to the product or any of its constituents”, substitute “in relation to the product or any of its constituents or in relation to the label”.

82 Subparagraph 160A(4)(a)(ii) of the Code set out in the Schedule

After “or 20(1)(c)”, insert “or relates to the matters covered by subparagraph 21(c)(iv) or (iva)”.

83 At the end of paragraph 160A(4)(b) of the Code set out in the Schedule

Add “or that the label may not meet the labelling criteria”.

84 After paragraph 161(1)(b) of the Code set out in the Schedule

Insert:

or (c) the holder of the approval of a label for containers for a chemical product;

85 Subsection 161(1) of the Code set out in the Schedule

Omit “or in relation to the product or of any of its constituents”, substitute “, in relation to the product or of any of its constituents or in relation to the label”.

86 Subsection 161(2) of the Code set out in the Schedule

Omit “relevant information”, substitute “*relevant information*”.

87 Paragraph 161(2)(a) of the Code set out in the Schedule

After “product”, insert “or in the relevant APVMA file for the label”.

88 At the end of paragraph 161(2)(b) of the Code set out in the Schedule

Add “or that the label may not meet the labelling criteria”.

89 Application provisions

- (1) The amendments of section 160A of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to applications lodged on or after the commencement of this item.
- (2) The amendments of section 161 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to information a holder becomes aware of on or after the commencement of this item (whether the approval of the label was given before, on or after that commencement).

Part 13—Annual operational plans

Agricultural and Veterinary Chemicals (Administration) Act 1992

90 Part 6 (heading)

Repeal the heading, substitute:

Part 6—Corporate plan

91 Sections 55, 56 and 57

Repeal the sections.

92 Paragraph 61(a)

Repeal the paragraph.

93 Paragraph 61(b)

Repeal the paragraph, substitute:

- (b) an evaluation of the APVMA's overall performance during that period against the performance indicators (if any) prescribed by the regulations for the purposes of this paragraph; and

94 Paragraph 61(d)

Repeal the paragraph.

95 Application and transitional provisions

- (1) The amendments made by this Part apply in relation to the calendar year beginning on the day this item commences and each later calendar year.
- (2) Despite the amendments made by this Part, sections 55 to 57 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to an annual

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operational plan relating to the period of 12 months beginning on 1 July of the financial year in which this item commences.

- (3) Despite the amendments made by this Part, section 61 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to the period of 12 months beginning on 1 July of the financial year in which this item commences.
- (4) Regulations in force for the purposes of subparagraph 61(b)(ii) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* immediately before the commencement of this item continue in force, on and after that commencement, for the purposes of paragraph 61(b) of that Act.

Part 14—Definition of registered chemical product

Agricultural and Veterinary Chemicals Code Act 1994

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

Repeal the definition, substitute:

registered chemical product has the meaning given by section 5AA.

97 After section 5 of the Code set out in the Schedule

Insert:

5AA Definition of *registered chemical product*

- (1) A ***registered chemical product*** is a chemical product:
- (a) that is registered; and
 - (b) that complies with the relevant particulars entered in the Register for the product.

Constituents of the chemical product

- (2) If:
- (a) a chemical product is registered; and
 - (b) under regulations made for the purposes of paragraph 20(1)(c), a relevant particular (the ***subject particular***) required to be entered in the Register in relation to the chemical product is the constituents of the chemical product; and
 - (c) there are regulations in force for the purposes of paragraph 83(1)(a) in relation to the chemical product; and
 - (d) the constituents of the chemical product do not differ by more than the extent prescribed for the purposes of paragraph 83(1)(a);

then, for the purposes of paragraph (1)(b) of this section, the chemical product is taken to comply with the subject particular.

Concentration of constituents of the chemical product

- (3) If:
- (a) a chemical product is registered; and
 - (b) under regulations made for the purposes of paragraph 20(1)(c), a relevant particular (the ***subject particular***) required to be entered in the Register in relation to the chemical product is the concentration of one or more constituents of the chemical product; and
 - (c) there are regulations in force for the purposes of paragraph 83(1)(b) in relation to the chemical product; and
 - (d) the concentration of the constituents of the chemical product does not differ by more than the extent prescribed for the purposes of paragraph 83(1)(b);
- then, for the purposes of paragraph (1)(b) of this section, the chemical product is taken to comply with the subject particular.

Composition of constituents of the chemical product

- (4) If:
- (a) a chemical product is registered; and
 - (b) under regulations made for the purposes of paragraph 20(1)(c), a relevant particular (the ***subject particular***) required to be entered in the Register in relation to the chemical product is the composition of a constituent of the chemical product; and
 - (c) there are regulations in force for the purposes of paragraph 83(1)(c) in relation to the composition of that constituent of the chemical product; and
 - (d) the composition of that constituent of the chemical product does not differ by more than the extent prescribed for the purposes of paragraph 83(1)(c);
- then, for the purposes of paragraph (1)(b) of this section, the chemical product is taken to comply with the subject particular.

Purity of constituents of the chemical product

- (5) If:
- (a) a chemical product is registered; and
-

- (b) under regulations made for the purposes of paragraph 20(1)(c), a relevant particular (the ***subject particular***) required to be entered in the Register in relation to the chemical product is the purity of a constituent of the chemical product; and
 - (c) there are regulations in force for the purposes of paragraph 83(1)(c) in relation to the purity of that constituent of the chemical product; and
 - (d) the purity of that constituent of the chemical product does not differ by more than the extent prescribed for the purposes of paragraph 83(1)(c);
- then, for the purposes of paragraph (1)(b) of this section, the chemical product is taken to comply with the subject particular.

Part 15—Supply of registered chemical products with unapproved label

Agricultural and Veterinary Chemicals Code Act 1994

98 Subparagraph 81(1)(a)(i) of the Code set out in the Schedule

Omit “relevant particulars”, substitute “minimum information (see subsection (5))”.

99 Subparagraph 81(1)(a)(ii) of the Code set out in the Schedule

Omit “the relevant particulars”, substitute “the minimum information”.

100 Paragraph 81(2)(a) of the Code set out in the Schedule

Omit “relevant particulars”, substitute “minimum information (see subsection (5))”.

101 Paragraph 81(2)(b) of the Code set out in the Schedule

Omit “the relevant particulars”, substitute “the minimum information”.

102 Paragraphs 81(3)(a), (b) and (c) of the Code set out in the Schedule

Repeal the paragraphs, substitute:

- (a) the label attached to the container states the minimum information (the *earlier information*) that was required to be stated on a label for containers for the product at a time before the supply takes place; and
- (b) the earlier information is different from the minimum information that is required to be stated on a label for containers for the product at the time the supply takes place; and
- (c) the APVMA has determined that this subsection applies in respect of the earlier information; and

- (d) the supply takes place not later than 2 years (or such shorter or longer period as the APVMA allows) after the earlier information ceased to be the minimum information that was required be stated on a label for containers for the product.

103 At the end of section 81 of the Code set out in the Schedule

Add:

- (5) For the purposes of this section, the *minimum information* is the information covered by subparagraphs 21(c)(iii) and (iv) (including that information as varied under Part 2).

104 Application provision

The amendments of section 81 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to supplies occurring on or after the commencement of this item.

Part 16—Safety, efficacy, trade and labelling criteria

Agricultural and Veterinary Chemicals Code Act 1994

105 At the end of subsection 5D(2) of the Code set out in the Schedule

Add:

; (d) any matters prescribed by the regulations.

106 After section 5D of the Code set out in the Schedule

Insert:

5E Overseas trials and experiments

Without limiting subparagraph 5A(2)(a)(vii) or (3)(a)(vii) or paragraph 5B(2)(d), 5C(2)(c) or 5D(2)(d) and despite section 160, the matters prescribed by regulations made for the purposes of that subparagraph or paragraph may relate to matters covered by paragraph 160(2)(a), (b) or (c).

107 Application provision

The amendment of section 5D of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part applies in relation to deciding, on or after the commencement of this item, whether a label for containers for a chemical product meets the labelling criteria.

Part 17—Maximum Residue Limits Standard

Agricultural and Veterinary Chemicals (Administration) Act 1992

108 Section 7A (heading)

Omit “**Annual publication**”, substitute “**Approval**”.

109 Subsection 7A(1)

Repeal the subsection, substitute:

- (1) The APVMA must, by legislative instrument, approve standards for residues of chemical products in protected commodities.

Agricultural and Veterinary Chemicals Code Act 1994

110 Subparagraph 8E(2)(b)(i) of the Code set out in the Schedule

Repeal the subparagraph, substitute:

- (i) the names, or proposed names, of the active constituents concerned; and

111 Paragraph 8E(2)(c) of the Code set out in the Schedule

Repeal the paragraph, substitute:

- (c) be given to Food Standards Australia New Zealand before the approval, registration, variation or permit is given, made or issued.

112 Application provision

The amendments of section 8E of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to notices given on or after the commencement of this item.

Part 18—Expiry date

Agricultural and Veterinary Chemicals Code Act 1994

113 Section 3 of the Code set out in the Schedule (definition of expiry date)

Omit “should”, substitute “must”.

114 Application provision

The amendment made by this Part applies in relation to a supply referred to in subsection 85(1) or 91(1) or (2) of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* that occurs on or after the commencement of this item.

Part 19—Other amendments

Agricultural and Veterinary Chemicals (Administration) Act 1992

115 Paragraph 7(1A)(a)

Omit “sale”, substitute “supply”.

116 Paragraphs 8A(2)(a) and (b)

Omit “whether to grant”.

117 Subsection 58(7)

Repeal the subsection.

118 Subsection 69D(1)

After “fee (if any)”, insert “to the Commonwealth”.

119 After subsection 69D(1A)

Insert:

(1AA) The APVMA may, on its own initiative, reconsider a decision of the APVMA to refuse to give a certificate under subsection (1).

(1AB) If the APVMA reconsiders the decision, it must:

- (a) confirm the decision; or
- (b) set aside the decision and give the certificate.

(1AC) The APVMA must give notice of a thing done under subsection (1AB) to the person who applied for the certificate.

120 Part 7B

Repeal the Part.

121 Subsection 72(5)

Repeal the subsection, substitute:

- (5) The Minister must cause a copy of the report of the review to be tabled in each House of the Parliament within 15 sitting days of that House after the Minister receives the report.

122 Sections 78, 79 and 80

Repeal the sections.

123 Application and saving provisions

- (1) Subsections 69D(1AA) to (1AC) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as inserted by this Part, apply in relation to decisions made on or after the commencement of this item.
- (2) Despite the repeal of Part 7B of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Part, section 69EZ of that Act, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to an approval referred to in that section that was given before that commencement.

Agricultural and Veterinary Chemicals Code Act 1994

124 After section 6E of the Code set out in the Schedule

Insert:

6F Specification by class

To avoid doubt, a reference in this Code to a class or kind of matter or thing does not, by implication, affect the application of:

- (a) subsection 13(3) of the *Legislation Act 2003*; or
(b) subsection 33(3AB) of the *Acts Interpretation Act 1901*.

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

Omit “subparagraph.”, substitute “subparagraph; and”.

126 Subparagraph 14A(1)(a)(ii) of the Code set out in the Schedule

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

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

Omit “relevant file”, substitute “relevant APVMA file”.

128 Paragraph 51(c) of the Code set out in the Schedule

Omit “relevant file”, substitute “relevant APVMA file”.

129 Paragraph 74(1)(c) of the Code set out in the Schedule

Omit “permit; or”, substitute “permit.”.

130 Paragraph 74(1)(d) of the Code set out in the Schedule

Repeal the paragraph.

131 Subsection 74(2) of the Code set out in the Schedule

Repeal the subsection.

132 Subsection 74(2A) of the Code set out in the Schedule (note)

Omit “(d)”, substitute “(c)”.

133 Subsection 74(3A) of the Code set out in the Schedule (note 2)

Omit “(d)”, substitute “(c)”.

134 Subsection 74(4) of the Code set out in the Schedule

Repeal the subsection.

135 Paragraph 75(1)(b) of the Code set out in the Schedule

Omit “section; or”, substitute “section.”.

136 Paragraph 75(1)(c) of the Code set out in the Schedule

Repeal the paragraph.

137 Subsection 75(2) of the Code set out in the Schedule

Repeal the subsection.

138 Subsection 75(2A) of the Code set out in the Schedule (note)

Omit “to (c)”, substitute “and (b)”.

139 Subsection 75(3A) of the Code set out in the Schedule (note 2)

Omit “to (c)”, substitute “and (b)”.

140 Subsection 75(4) of the Code set out in the Schedule

Repeal the subsection.

141 Paragraph 76(1)(b) of the Code set out in the Schedule

Omit “permit; or”, substitute “permit.”.

142 Paragraph 76(1)(c) of the Code set out in the Schedule

Repeal the paragraph.

143 Subsection 76(2) of the Code set out in the Schedule

Repeal the subsection.

144 Subsection 76(2A) of the Code set out in the Schedule (note)

Omit “to (c)”, substitute “and (b)”.

145 Subsection 76(3A) of the Code set out in the Schedule (note 2)

Omit “to (c)”, substitute “and (b)”.

146 Subsection 76(4) of the Code set out in the Schedule

Repeal the subsection.

147 Paragraph 78(1)(b) of the Code set out in the Schedule

Omit “section; or”, substitute “section.”.

148 Paragraph 78(1)(c) of the Code set out in the Schedule

Repeal the paragraph.

149 Subsection 78(2) of the Code set out in the Schedule

Repeal the subsection.

**150 Subsection 78(2A) of the Code set out in the Schedule
(note)**

Omit “to (c)”, substitute “and (b)”.

**151 Subsection 78(3A) of the Code set out in the Schedule
(note 2)**

Omit “to (c)”, substitute “and (b)”.

152 Subsection 78(4) of the Code set out in the Schedule

Repeal the subsection.

153 Paragraph 117A(1)(a) of the Code set out in the Schedule

Omit “suspend or cancel the approval, or suspend or cancel the registration, as the case may be”, substitute “suspend or cancel the permit”.

**154 Subsections 166(3) and (4) of the Code set out in the
Schedule**

Repeal the subsections, substitute:

- (3) If a request is so made, the APVMA must reconsider the original decision having regard only to the information used to make it.
- (4) The APVMA may, on its own initiative, reconsider the original decision having regard only to the information used to make it.
- (4A) If, under subsection (3) or (4), the APVMA reconsiders the original decision, the APVMA must:
 - (a) confirm the original decision; or
 - (b) vary the original decision; or
 - (c) set aside the original decision; or

- (d) set aside the original decision and make a new decision in substitution for the original decision.
- (4B) The APVMA must, as soon as practicable, give written notice setting out the APVMA's decision on the reconsideration to:
 - (a) for a reconsideration under subsection (3)—the person who made the request; or
 - (b) for a reconsideration under subsection (4)—each person whose interests are affected by that decision of whom the APVMA is aware.

155 Subsection 166(6) of the Code set out in the Schedule

Omit “If the APVMA has not given notice under subsection (4)”, substitute “For a reconsideration under subsection (3), if the APVMA has not given notice under subsection (4B)”.

156 Paragraph 167(1)(i) of the Code set out in the Schedule

Repeal the paragraph.

157 Sections 180, 183 and 184 of the Code set out in the Schedule

Repeal the sections.

158 Application provision

The amendments of section 166 of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* made by this Part apply in relation to original decisions made on or after the commencement of this item.

Part 20—Repeals

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

159 The whole of the Act

Repeal the Act.

<i>No. 125, 2021</i>	<i>Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Act 2021</i>	<i>55</i>
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Schedule 2—Australian Pesticides and Veterinary Medicines Authority Board

Agricultural and Veterinary Chemicals (Administration) Act 1992

1 Section 4 (definition of *Advisory Board*)

Repeal the definition.

2 Section 4

Insert:

appointed Board member means a Board member other than the Chief Executive Officer.

Board means the Board of the APVMA established by section 14.

3 Section 4 (definition of *Board member*)

Repeal the definition, substitute:

Board member means a member of the Board.

4 Section 4 (definition of *Chair*)

Repeal the definition, substitute:

Chair means the Chair of the Board.

5 Section 4

Insert:

paid work means work for financial gain or reward (whether as an employee, a self-employed person or otherwise).

6 Subsection 8(3)

Repeal the subsection.

7 Paragraph 10(2)(c)

Omit “Chief Executive Officer”, substitute “Board”.

8 Section 10A

Repeal the section.

9 Part 3 (heading)

Repeal the heading, substitute:

Part 3—Constitution of APVMA, the Board and committees

10 Section 13

Repeal the section.

11 Divisions 2, 3 and 4 of Part 3

Repeal the Divisions, substitute:

Division 2—Board of the APVMA

Subdivision A—Establishment and functions of the Board

14 Establishment of the Board

The Board of the APVMA is established by this section.

15 Functions and powers of the Board

- (1) The functions of the Board are:
- (a) to ensure the proper, efficient and effective performance of the APVMA’s functions; and
 - (b) to determine objectives, strategies and policies to be followed by the APVMA; and
 - (c) to do anything incidental to or conducive to the performance of the functions referred to in paragraph (a) or (b).

- (2) In determining objectives, strategies and policies to be followed by the APVMA, the Board must have regard to section 1A of the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.
- (3) The Board has power to do all things necessary or convenient to be done for or in connection with the performance of its functions.

16 Limitation on functions and powers of the Board

To avoid doubt, the functions and powers of the Board do not include making decisions under any of the following:

- (a) Part 7A, 7AA, 7AB or 8 of this Act;
- (b) the Code set out in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*;
- (c) regulations made under the *Agricultural and Veterinary Chemicals Code Act 1994*;
- (d) the *Agricultural and Veterinary Chemicals Act 1994*;
- (e) the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*.

Subdivision B—Board members

17 Membership of the Board

The Board consists of the following members:

- (a) the Chair;
- (b) the Chief Executive Officer;
- (c) 3 other members.

18 Appointment of appointed Board members

- (1) The appointed Board members are to be appointed by the Minister by written instrument, on a part-time basis.

Note: An appointed Board member may be reappointed: see section 33AA of the *Acts Interpretation Act 1901*.

- (2) A person must not be appointed as an appointed Board member unless the Minister is satisfied that the person has appropriate

qualifications, skills or experience in one or more of the following fields:

- (a) financial management;
 - (b) law;
 - (c) risk management;
 - (d) public sector governance;
 - (e) science (including agricultural science and veterinary science);
 - (f) public health or occupational health and safety.
- (3) In appointing the appointed Board members, the Minister must ensure, to the extent practicable, that the appointed Board members are an appropriate mix of persons with the qualifications, skills or experience referred to in subsection (2).

19 Term of appointment

- (1) An appointed Board member holds office for the period specified in the instrument of appointment. The period must not exceed 4 years.
- (2) The appointed Board member is eligible to be reappointed on one occasion after the appointed Board member's first appointment.

20 Acting Board members

Acting as the Chair

- (1) The Minister may, by written instrument, appoint an appointed Board member to act as the Chair:
 - (a) during a vacancy in the office of Chair, whether or not an appointment has previously been made to the office; or
 - (b) during any period, or during all periods, when the Chair:
 - (i) is absent from duty or from Australia; or
 - (ii) is, for any reason, unable to perform the duties of the office.

Note: For rules that apply to acting appointments, see sections 33AB and 33A of the *Acts Interpretation Act 1901*.

Acting as an appointed Board member (except the Chair)

- (2) The Minister may, by written instrument, appoint a person to act as an appointed Board member (except the Chair):
- (a) during a vacancy in the office of an appointed Board member (except the Chair), whether or not an appointment has previously been made to the office; or
 - (b) during any period, or during all periods, when an appointed Board member (except the Chair):
 - (i) is absent from duty or from Australia; or
 - (ii) is, for any reason, unable to perform the duties of the office.

Note: For rules that apply to acting appointments, see sections 33AB and 33A of the *Acts Interpretation Act 1901*.

- (3) A person is not eligible for appointment under subsection (2) unless the Minister is satisfied that the person has appropriate qualifications, skills or experience in one or more of the fields referred to in subsection 18(2).

21 Remuneration

- (1) An appointed Board member is to be paid the remuneration that is determined by the Remuneration Tribunal. If no determination of that remuneration by the Tribunal is in operation, the member is to be paid the remuneration that is prescribed by the regulations.
- (2) An appointed Board member is to be paid the allowances that are prescribed by the regulations.
- (3) This section has effect subject to the *Remuneration Tribunal Act 1973*.

22 Paid work

An appointed Board member must not engage in any paid work that, in the Minister's opinion, conflicts or could conflict with the proper performance of the member's duties.

23 Leave of absence

- (1) The Minister may grant leave of absence to the Chair on the terms and conditions that the Minister determines.
- (2) The Chair may grant leave of absence to any other appointed Board member on the terms and conditions that the Chair determines.

24 Resignation of appointment

- (1) An appointed Board member may resign the member's appointment by giving the Minister a written resignation.
- (2) The resignation takes effect on the day it is received by the Minister or, if a later day is specified in the resignation, on that later day.

25 Termination of appointment

The Minister may terminate the appointment of an appointed Board member:

- (a) for misbehaviour; or
- (b) if the appointed Board member is unable to perform the duties of the member's office because of physical or mental incapacity; or
- (c) if the appointed Board member:
 - (i) becomes bankrupt; or
 - (ii) applies to take the benefit of any law for the relief of bankrupt or insolvent debtors; or
 - (iii) compounds with the member's creditors; or
 - (iv) makes an assignment of the member's remuneration for the benefit of the member's creditors; or
- (d) if the appointed Board member is absent, except on leave of absence, from 3 consecutive meetings of the Board; or
- (e) if the appointed Board member engages in paid work that, in the Minister's opinion, conflicts or could conflict with the proper performance of the member's duties (see section 22); or

- (f) if the Minister is satisfied that the appointed Board member's performance has been unsatisfactory.

Note: The appointment of an appointed Board member may also be terminated under section 30 of the *Public Governance, Performance and Accountability Act 2013* (which deals with terminating the appointment of an accountable authority, or a member of an accountable authority, for contravening general duties of officials).

26 Other terms and conditions

An appointed Board member holds office on the terms and conditions (if any) in relation to matters not covered by this Act that are determined by the Minister.

Subdivision C—Meetings of the Board

27 Convening meetings

- (1) The Board must hold such meetings as are necessary for the efficient performance of its functions.
- (2) The Chair:
 - (a) may convene a meeting at any time; and
 - (b) must convene at least 4 meetings each calendar year; and
 - (c) must convene a meeting within 30 days after receiving a written request to do so from another Board member.

27A Presiding at meetings

- (1) The Chair must preside at all meetings at which the Chair is present.
- (2) If the Chair is not present at a meeting, the other Board members present must appoint one of themselves to preside.

27B Quorum

- (1) At a meeting of the Board, a quorum is constituted by a majority of Board members.
 - (2) However, if:
-

- (a) a Board member is required by rules made for the purposes of section 29 of the *Public Governance, Performance and Accountability Act 2013* not to be present during the deliberations, or to take part in any decision, of the Board with respect to a particular matter; and
 - (b) when the Board member leaves the meeting concerned there is no longer a quorum present;
- the remaining Board members at the meeting constitute a quorum for the purpose of any deliberation or decision at that meeting with respect to that matter.

27C Voting at meetings

- (1) A question arising at a meeting of the Board is to be determined by a majority of the votes of the Board members present and voting.
- (2) The person presiding at the meeting of the Board has a deliberative vote and, if the votes are equal, a casting vote.

27D Conduct of meetings

The Board may, subject to this Subdivision, regulate proceedings at its meetings as it considers appropriate.

Note: Section 33B of the *Acts Interpretation Act 1901* contains further information about the ways in which Board members may participate in meetings.

27E Minutes

- (1) The Board must keep minutes of its meetings.
- (2) The Board must give the Secretary of the Department a copy of the minutes, and the Board papers, from each meeting within 20 business days of the meeting.

27F Decisions without meetings

- (1) The Board is taken to have made a decision at a meeting if:

- (a) without meeting, a majority of the Board members entitled to vote on the proposed decision indicate agreement with the decision; and
 - (b) that agreement is indicated in accordance with the method determined by the Board under subsection (2); and
 - (c) all the Board members were informed of the proposed decision, or reasonable efforts were made to inform all the Board members of the proposed decision.
- (2) Subsection (1) applies only if the Board:
- (a) has determined that it may make decisions of that kind without meeting; and
 - (b) has determined the method by which Board members are to indicate agreement with proposed decisions.
- (3) For the purposes of paragraph (1)(a), a Board member is not entitled to vote on a proposed decision if the Board member would not have been entitled to vote on that proposal if the matter had been considered at a meeting of the Board.
- (4) The Board must keep a record of decisions made in accordance with this section.
- (5) The Board must give the Secretary of the Department details of each decision made in accordance with this section within 20 business days of the decision being made.

Subdivision D—Minister may give directions to the Board

27G Minister may give directions to the Board

- (1) The Minister may give written directions to the Board about the performance of its functions or the exercise of its powers.
- (2) The Board must comply with a direction under subsection (1).
- (3) Subsection (2) does not apply to the extent that the direction relates to the Board's performance of functions or exercise of powers under the *Public Governance, Performance and Accountability Act 2013* in relation to the APVMA.

- (4) The Minister must not give a direction to the Board unless:
 - (a) the Minister has given the Board a written notice stating that the Minister is considering giving the direction; and
 - (b) the Minister has given the Board an adequate opportunity to discuss with the Minister the need for the proposed direction.
- (5) A direction under subsection (1) is a notifiable instrument.
- (6) The Minister must cause a copy of a direction under subsection (1) to be laid before each House of the Parliament within 15 sitting days of giving the direction.

Subdivision E—Board to give documents to Secretary

27H Board to give documents to Secretary

The Board must give the Secretary of the Department a copy of each document requested by the Secretary of the Department within 20 business days of the request being made.

Subdivision F—Board committees

27J Board committees

- (1) The Board may establish committees to assist it in the performance of its functions or the exercise of its powers, and may abolish any such committee.
- (2) A committee is to consist of such persons (whether Board members or not) as the Board determines.
- (3) The Board may determine:
 - (a) the committee's terms of reference; and
 - (b) the terms and conditions of appointment of the members of the committee; and
 - (c) the procedures to be followed by the committee.
- (4) The members of the committee (other than Board members) are not officials for the purposes of the *Public Governance, Performance and Accountability Act 2013*.

Subdivision G—Review of the Board

27K Review of the Board

- (1) The Minister must cause a review to be conducted of the functions and operation of the Board.
- (2) The review must be completed before the end of the period of 4 years beginning on the day this section commences.
- (3) At any time after the review referred to in subsection (1) is completed, the Minister may cause a review to be conducted of the functions and operation of the Board.
- (4) The person undertaking a review under this section must give the Minister a written report of the review.
- (5) The Minister must cause a copy of the report to be tabled in each House of the Parliament within 15 sitting days of that House after the report is given to the Minister.

12 Division 5 of Part 3 (heading)

Repeal the heading, substitute:

Division 5—APVMA committees

13 Subsection 32(1)

Omit “to manage the affairs of the APVMA and in doing so”, substitute “responsible for the day-to-day management and decision making of the APVMA and, in doing this”.

14 At the end of section 32

Add:

- (4) The Chief Executive Officer is to act in accordance with the objectives, strategies and policies determined by the Board under paragraph 15(1)(b).

- (5) The Board may give written directions to the Chief Executive Officer about the performance of the Chief Executive Officer's duties.
- (6) The Chief Executive Officer must comply with a direction under subsection (5).
- (7) Subsection (6) does not apply to the extent that the direction relates to the Chief Executive Officer's performance of functions or exercise of powers under the *Public Service Act 1999* in relation to the APVMA.
- (8) The Board must not give a direction to the Chief Executive Officer unless:
 - (a) the Board has given the Chief Executive Officer a written notice stating that the Board is considering giving the direction; and
 - (b) the Board has given the Chief Executive Officer an adequate opportunity to discuss with the Board the need for the proposed direction.
- (9) A direction under subsection (5) is not a legislative instrument.

15 Section 32A

Repeal the section.

16 Subsection 33(1)

Omit "Minister", substitute "Board".

17 After subsection 33(1)

Insert:

- (1A) Before appointing the Chief Executive Officer, the Board must consult the Minister.

18 Subsection 33(2)

Omit "A Board member", substitute "An appointed Board member".

19 Section 34

Omit “Minister”, substitute “Board”.

20 Subsections 35(1) and (2)

Omit “Minister”, substitute “Board”.

21 Section 37

Omit “Minister”, substitute “Board”.

22 Section 38 (heading)

Omit “paid employment”, substitute “paid work”.

23 Section 38

Omit “paid employment”, substitute “paid work”.

24 Section 38

Omit “Minister”, substitute “Board”.

25 Sections 40 and 41

Omit “Minister” (wherever occurring), substitute “Board”.

26 Section 41A

Omit “The Minister”, substitute “(1) The Board”.

27 Paragraph 41A(a)

Repeal the paragraph, substitute:

(a) for misbehaviour; or

(aa) if the Chief Executive Officer is unable to perform the duties of the Chief Executive Officer’s office because of physical or mental incapacity; or

28 Paragraph 41A(d)

Omit “Minister’s”, substitute “Board’s”.

29 Paragraph 41A(d)

Omit “paid employment”, substitute “paid work”.

30 Paragraph 41A(f)

Omit “Minister”, substitute “Board”.

31 At the end of section 41A

Add:

- (2) Before terminating the appointment of the Chief Executive Officer, the Board must consult the Minister.

32 Subsection 42(1)

Omit “Minister”, substitute “Board”.

33 Subsection 43(1)

Omit “Minister”, substitute “Board”.

34 After subsection 43(1)

Insert:

- (2) Before appointing a person to act as Chief Executive Officer, the Board must consult the Minister.

35 Subsections 51(1) and (3)

Omit “Chief Executive Officer”, substitute “Board”.

36 Subsections 52(1), (2) and (3)

Omit “Chief Executive Officer”, substitute “Board”.

37 Section 61

Omit “Chief Executive Officer”, substitute “Board”.

38 At the end of section 61

Add:

- ; and (g) any directions given to the Board by the Minister during that period and the impact of the directions on the operations of the APVMA.

39 Paragraph 69EP(7)(a)

Omit “, or the Chief Executive Officer,”.

40 Transitional provision—meetings of the Board

Paragraph 27(2)(b) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as substituted by this Schedule, does not apply in relation to the calendar year in which this item commences.

41 Application provision—Chief Executive Officer

The amendments of sections 33 to 43 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Schedule apply in relation to each appointment (including reappointment) of the Chief Executive Officer on or after the commencement of this item.

42 Application and saving provisions—corporate plans and annual report

- (1) The amendments of section 51 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Schedule apply in relation to each calendar year that begins after the commencement of this item.
- (2) The amendments of Part 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Schedule do not affect the validity of a corporate plan, or a variation of a corporate plan, approved by the Minister before the commencement of this item.
- (3) The amendments of section 61 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* made by this Schedule apply in relation to each reporting period (within the meaning of the *Public Governance, Performance and Accountability Act 2013*) that ends after the commencement of this item.

43 Transitional provision—transfer of records and documents of Advisory Board to the APVMA

- (1) This item applies to any records or documents that were in the possession of the Advisory Board immediately before the commencement of this item.

- (2) The records and documents are to be transferred to the APVMA after the commencement of this item.

Note: The records and documents transferred are Commonwealth records for the purposes of the *Archives Act 1983*.

*[Minister's second reading speech made in—
House of Representatives on 18 September 2019
Senate on 5 December 2019]*

(173/19)

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