

EXPOSURE DRAFT

2016-2017-2018

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

EXPOSURE DRAFT

Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018

No. , 2018

(Agriculture and Water Resources)

**A Bill for an Act to amend the law relating to
agricultural and veterinary chemicals, and for
related purposes**

EXPOSURE DRAFT

EXPOSURE DRAFT

Contents

1	Short title.....	1
2	Commencement.....	1
3	Schedules.....	3
Schedule 1—Main amendments		4
Part 1—Provisional registration of chemical products		4
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		4
Part 2—Accreditation of assessors		13
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>		13
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		17
Part 3—Approval and registration for prescribed active constituents, chemical products or labels		18
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		18
Part 4—Limits on use of information		25
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		25
Part 5—Information to be taken into account in determining applications		29
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		29
Part 6—Computerised decision-making		30
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		30
Part 7—Voluntary recalls		32
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		32
Part 8—Notification of new information		34
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		34
Part 9—Definition of registered chemical product		36
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>		36
Part 10—Suspension or cancellation of approval or registration for provision of false or misleading information		39

EXPOSURE DRAFT

<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	39
Part 11—Supply of registered chemical products with unapproved label	40
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	40
Part 12—Variation of approval or registration during suspension	42
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	42
Part 13—Safety, efficacy, trade and labelling criteria	44
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	44
Part 14—Annual operational plans	45
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>	45
Part 15—Other amendments	47
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>	47
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	48
<i>Agricultural and Veterinary Chemicals Legislation Amendment Act 2013</i>	52
Schedule 2—Other amendments	53
Part 1—Amendments	53
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	53
Part 2—Repeals	54
<i>Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014</i>	54

EXPOSURE DRAFT

1 **A Bill for an Act to amend the law relating to**
2 **agricultural and veterinary chemicals, and for**
3 **related purposes**

4 The Parliament of Australia enacts:

5 **1 Short title**

6 This Act is the *Agricultural and Veterinary Chemicals Legislation*
7 *(Streamlining Regulation) Act 2018.*

8 **2 Commencement**

9 (1) Each provision of this Act specified in column 1 of the table
10 commences, or is taken to have commenced, in accordance with

EXPOSURE DRAFT

1 column 2 of the table. Any other statement in column 2 has effect
2 according to its terms.

3

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.	
2. Schedule 1, Parts 1 and 2	The day after the end of the period of 12 months beginning on the day this Act receives the Royal Assent.	
3. Schedule 1, Parts 3 to 5	The day after the end of the period of 6 months beginning on the day this Act receives the Royal Assent.	
4. Schedule 1, Part 6	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.	
5. Schedule 1, Parts 7 and 8	The day after the end of the period of 3 months beginning on the day this Act receives the Royal Assent.	
6. Schedule 1, Parts 9 to 13	The day after this Act receives the Royal Assent.	
7. Schedule 1, Part 14	1 January 2020.	1 January 2020
8. Schedule 1, Part 15	The day after this Act receives the Royal Assent.	
9. Schedule 2	The day after this Act receives the Royal Assent.	
4 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.	

5

6

2 *Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018* No. , 2018

EXPOSURE DRAFT

EXPOSURE DRAFT

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

4 **3 Schedules**

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 1 Provisional registration of chemical products

1 **Schedule 1—Main amendments**

2 **Part 1—Provisional registration of chemical products**

3 *Agricultural and Veterinary Chemicals Code Act 1994*

4 **1 Section 3 of the Code set out in the Schedule (definition of**
5 **relevant particulars)**

6 After “29,”, insert “29AA,”.

7 **2 Section 3 of the Code set out in the Schedule (at the end of**
8 **the definition of relevant particulars)**

9 Add “(as affected by any determination under subsection 29C(1))”.

10 **3 Paragraph 14(1)(d) of the Code set out in the Schedule**

11 After “a label”, insert “for containers”.

12 **4 After subsection 14(1) of the Code set out in the Schedule**

13 Insert:

14 *Provisional registration of chemical product—efficacy criteria not*
15 *met*

16 (1A) The APVMA may register the chemical product if:

- 17 (a) the chemical product is of a kind prescribed by the
18 regulations for the purposes of this paragraph; and
19 (b) the APVMA is satisfied that the application meets the
20 application requirements; and
21 (c) the APVMA is satisfied that the chemical product meets the
22 safety criteria and the trade criteria; and
23 (d) the APVMA is not satisfied that the chemical product meets
24 the efficacy criteria; and
25 (e) the APVMA has given the applicant a written notice
26 specifying:

EXPOSURE DRAFT

Main amendments **Schedule 1**
Provisional registration of chemical products **Part 1**

- 1 (i) information relating to whether the chemical product
2 meets the efficacy criteria that is sought by the
3 APVMA; and
4 (ii) the period within which the applicant must provide that
5 information (which must be no more than the 3 years
6 that would start on the day that, if the APVMA were to
7 register the chemical product, the registration would
8 commence); and
9 (f) the applicant has given the APVMA a written undertaking to
10 provide that information within that period; and
11 (g) the criteria prescribed by the regulations for the purposes of
12 this paragraph are satisfied.

13 Note: For notice of registration, see section 8F.

14 *Refusal of application*

15 **5 Subsection 14(2) of the Code set out in the Schedule**

16 Omit “Otherwise”, substitute “If the APVMA does not approve the
17 active constituent or label, or register the chemical product, under this
18 section”.

19 **6 At the end of section 23 of the Code set out in the Schedule**

20 Add:

21 *Provisional registration of chemical product—efficacy criteria not*
22 *met*

- 23 (4) If, under subsection 14(1A), the APVMA registers a chemical
24 product, the registration of the chemical product is on the condition
25 that:
26 (a) the holder makes an application under subsection 27(2A) for
27 assessment of the information that is specified under
28 paragraph 14(1A)(e) and that the holder provides with the
29 application; and
30 (b) the holder makes the application:
31 (i) before the end of the period specified under
32 paragraph 14(1A)(e); or

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 1 Provisional registration of chemical products

- 1 (ii) if the APVMA extends that period by no more than 2
2 years because the APVMA is satisfied that
3 circumstances beyond the control of the holder, or that
4 exceptional circumstances, will prevent the holder
5 providing that information before the end of that
6 period—before the end of the extended period.

7 Note: See subsection 36(3) for the consequences of a breach of this
8 condition.

9 *Varying registration of chemical product—efficacy criteria not met*

- 10 (5) If, under subsection 29(1B), the APVMA varies the relevant
11 particulars or conditions of the registration of a chemical product,
12 the registration of the chemical product becomes subject to the
13 condition that:
14 (a) the holder makes an application under subsection 27(2A) for
15 assessment of the information that is specified under
16 paragraph 29(1B)(e) and that the holder provides with the
17 application; and
18 (b) the holder makes the application:
19 (i) before the end of the period specified under
20 paragraph 29(1B)(e); or
21 (ii) if the APVMA extends that period by no more than 2
22 years because the APVMA is satisfied that
23 circumstances beyond the control of the holder, or that
24 exceptional circumstances, will prevent the holder
25 providing that information before the end of that
26 period—before the end of the extended period.

27 Note: See section 29C for the consequences of a breach of this condition.

28 *No limit on subsections (1) to (3)*

- 29 (6) Subsections (4) and (5) do not limit subsections (1) to (3).

30 **7 After subsection 26E(5) of the Code set out in the Schedule**

31 Insert:

EXPOSURE DRAFT

Main amendments **Schedule 1**
Provisional registration of chemical products **Part 1**

1 (5A) For an application under subsection 27(2A), the APVMA may vary
2 the relevant particulars or conditions if satisfied that the chemical
3 product meets the efficacy criteria (section 29AA).

4 **8 At the end of section 26E of the Code set out in the**
5 **Schedule**

6 Add:

7 (8) Section 29C deals with the APVMA determining that a variation
8 under subsection 29(1B) ceases to have effect if there is a
9 contravention of the condition under subsection 23(5).

10 **9 After subsection 27(2) of the Code set out in the Schedule**

11 Insert:

12 (2A) In relation to the registration of a chemical product, the holder may
13 apply to the APVMA for assessment of the information referred to
14 in paragraph 14(1A)(e) or 29(1B)(e) that the holder provides with
15 the application.

16 **10 Subsection 27(3) of the Code set out in the Schedule**

17 Omit “or (2)”, substitute “, (2) or (2A)”.

18 **11 Subparagraph 28(2)(a)(i) of the Code set out in the**
19 **Schedule**

20 After “section 29”, insert “or 29AA”.

21 **12 Section 29 of the Code set out in the Schedule (heading)**

22 Repeal the heading, substitute:

23 **29 Varying relevant particulars and conditions—applications under**
24 **subsection 27(1) or (2)**

25 **13 Before subsection 29(1) of the Code set out in the**
26 **Schedule**

27 Insert:

28 (1A) This section applies to an application under subsection 27(1) or (2).

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 1 Provisional registration of chemical products

14 After subsection 29(1) of the Code set out in the Schedule

Insert:

Varying registration of chemical product—efficacy criteria not met

(1B) The APVMA may vary the relevant particulars or conditions of the registration of a chemical product if:

- (a) the chemical product is of a kind prescribed by the regulations for the purposes of this paragraph; and
- (b) the APVMA is satisfied that the application meets the application requirements; and
- (c) the APVMA is satisfied that, if those particulars or conditions were varied in accordance with the application, the chemical product would meet the safety criteria and the trade criteria; and
- (d) the APVMA is not satisfied that, if those particulars or conditions were varied in accordance with the application, the chemical product would meet the efficacy criteria; and
- (e) the APVMA has given the holder a written notice specifying:
 - (i) information relating to whether the chemical product meets the efficacy criteria that is sought by the APVMA; and
 - (ii) the period within which the holder must provide that information (which must be no more than the 3 years that would start on the day that, if the APVMA were to make the variation, the variation would take place); and
- (f) the holder has given the APVMA a written undertaking to provide that information within that period; and
- (g) the criteria prescribed by the regulations for the purposes of this paragraph are satisfied.

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

Refusal of application

15 Subsection 29(2) of the Code set out in the Schedule

Omit “Otherwise”, substitute “If the APVMA does not vary the relevant particulars or conditions under this section”.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Provisional registration of chemical products **Part 1**

1 **16 After section 29 of the Code set out in the Schedule**

2 Insert:

3 **29AA Varying relevant particulars and conditions—applications**
4 **under subsection 27(2A)**

- 5 (1) This section applies to an application under subsection 27(2A).
- 6 (2) The APVMA may vary the relevant particulars or conditions of the
7 registration of the chemical product if, after assessment of the
8 information referred to in that subsection, the APVMA is satisfied
9 that the chemical product meets the efficacy criteria.

10 **17 At the end of Division 3 of Part 2 of the Code set out in the**
11 **Schedule**

12 Add:

13 **29C When variation under subsection 29(1B) ceases to have effect**

- 14 (1) The APVMA must, in writing, determine that a variation under
15 subsection 29(1B) of the relevant particulars or conditions of the
16 registration of a chemical product ceases to have effect if there is a
17 contravention of the condition under subsection 23(5) of the
18 registration of the chemical product.
- 19 (2) The APVMA must, within 14 days of making the determination
20 under subsection (1), give written notice of the determination to the
21 holder. The notice must set out the relevant particulars and
22 conditions that will apply after the APVMA updates the Register to
23 reflect the cessation.
- 24 (3) At least 14 days after giving the notice under subsection (2), the
25 APVMA must update the Register to reflect the cessation and to
26 record the date on which the determination under subsection (1) is
27 made.
- 28 (4) The variation ceases to have effect when that update takes place.
29 The APVMA must, on the day of the update, give written notice of
30 the update to the holder.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 1 Provisional registration of chemical products

1 **18 Subsection 34M(1) of the Code set out in the Schedule**
2 **(table items 5 and 6)**

3 Omit “section 27”, substitute “subsection 27(1) or (2)”.

4 **19 Subsection 34M(1) of the Code set out in the Schedule (at**
5 **the end of the table)**

6 Add:

7	information:	5 years	the relevant particulars or conditions are varied.
	(a) given in connection with an application made under subsection 27(2A) in relation to the registration of an agricultural chemical product; and		
	(b) relied on to vary the relevant particulars or conditions of the registration of the agricultural chemical product		

8	information:	3 years	the relevant particulars or conditions are varied.
	(a) given in connection with an application made under subsection 27(2A) in relation to the registration of a veterinary chemical product; and		
	(b) relied on to vary the relevant particulars or conditions of the registration of the veterinary chemical product		

7 **20 Subsection 34MA(5) of the Code set out in the Schedule**

8 Omit “or 6”, substitute “, 6, 7 or 8”.

9 **21 After subsection 34N(4) of the Code set out in the**
10 **Schedule**

11 Insert:

12 (4A) The APVMA must cancel a registration if there is a contravention
13 of the condition under subsection 23(4) (subsection 36(3)).

14 **22 At the end of subsection 34P(4) of the Code set out in the**
15 **Schedule**

16 Add “or subsection 36(3)”.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Provisional registration of chemical products **Part 1**

1 **23 Section 36 of the Code set out in the Schedule**

2 Before “If”, insert “(1)”.

3 **24 At the end of section 36 of the Code set out in the**
4 **Schedule**

5 Add:

6 (2) Subsection (1) does not apply to a contravention of the condition
7 under subsection 23(4) or (5) of the registration of a chemical
8 product.

9 (3) If there is a contravention of the condition under subsection 23(4)
10 of the registration of a chemical product, the APVMA must cancel
11 the registration.

12 Note: For a contravention of the condition under subsection 23(5), see
13 section 29C.

14 **25 After paragraph 43(4)(c) of the Code set out in the**
15 **Schedule**

16 Insert:

17 (ca) an application being made under subsection 27(2A) for
18 assessment of the information referred to in
19 paragraph 14(1A)(e) or 29(1B)(e) that the holder provides
20 with the application; or

21 **26 Subsection 43(5) of the Code set out in the Schedule**

22 Omit “or (c)”, substitute “, (c) or (ca)”.

23 **27 After paragraph 167(1)(a) of the Code set out in the**
24 **Schedule**

25 Insert:

26 (aa) a decision under subsection 14(1A) to register a product;

27 **28 Before paragraph 167(1)(d) of the Code set out in the**
28 **Schedule**

29 Insert:

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 1 Provisional registration of chemical products

- 1 (cb) a decision under subsection 29(1B) to vary the relevant
2 particulars or conditions of the registration of a chemical
3 product;

4 **29 After paragraph 167(1)(d) of the Code set out in the** 5 **Schedule**

6 Insert:

- 7 (da) a decision under subsection 29AA(2) to vary the relevant
8 particulars or conditions of the registration of a chemical
9 product;
- 10 (db) a decision under subsection 29C(1) to determine that a
11 variation under subsection 29(1B) of the relevant particulars
12 or conditions of the registration of a chemical product ceases
13 to have effect;

14 **30 Application provisions**

- 15 (1) Subsection 14(1A) of the Code set out in the Schedule to the
16 *Agricultural and Veterinary Chemicals Code Act 1994*, as inserted by
17 this Part, applies in relation to an application made under section 10 of
18 that Code on or after the commencement of this item.
- 19 (2) Subsection 29(1B) of the Code set out in the Schedule to the
20 *Agricultural and Veterinary Chemicals Code Act 1994*, as inserted by
21 this Part, applies in relation to an application made under section 27 of
22 that Code on or after the commencement of this item (whether the
23 chemical product was registered before, on or after that
24 commencement).

EXPOSURE DRAFT

Main amendments **Schedule 1**
Accreditation of assessors **Part 2**

1 **Part 2—Accreditation of assessors**

2 *Agricultural and Veterinary Chemicals (Administration) Act*
3 *1992*

4 **31 Section 4**

5 Insert:

6 *accredited person* means a person who is accredited in accordance
7 with an instrument made under section 69GA.

8 **32 Paragraph 58(1)(b)**

9 Omit “or the Agvet Regulations”, substitute “, the Agvet Regulations or
10 an instrument under section 69GA”.

11 **33 Paragraph 69ES(3)(c)**

12 After “inspector”, insert “or accredited person”.

13 **34 After section 69G**

14 Insert:

15 **69GA Accreditation of persons**

16 (1) The APVMA may, by legislative instrument, prescribe matters
17 relating to:

- 18 (a) the accreditation of persons (whether or not Australian
19 citizens or Australian residents) by the APVMA for the
20 purposes of the Agvet Codes; and
21 (b) such persons performing roles prescribed in the instrument
22 (which may include the assessing of information of a kind
23 prescribed in the instrument).

24 (2) Examples of matters that the instrument may deal with are the
25 following:

- 26 (a) the making of applications for accreditation;

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 2 Accreditation of assessors

- 1 (b) the criteria that are to be met by persons who seek to be
2 accredited;
- 3 (c) how accreditation is to be recognised (for example, by
4 establishment of a register or the issue of a certificate of
5 accreditation);
- 6 (d) whether accreditation is for a specified period or continues
7 until it is revoked;
- 8 (e) if accreditation is for a specified period—the renewal of
9 accreditation, including the making of applications for
10 renewal;
- 11 (f) the certificates, assessments or reports that accredited persons
12 may or must provide and the circumstances in which those
13 certificates, assessments or reports may or must be provided;
- 14 (g) the making of standards by the APVMA to be complied with
15 by accredited persons in providing those certificates,
16 assessments or reports;
- 17 (h) the standards and other obligations that persons must
18 continue to meet to remain accredited;
- 19 (i) the conditions of accreditation and the variation or revocation
20 of those conditions;
- 21 (j) the consequences of accredited persons failing to comply
22 with conditions of accreditation or other requirements in the
23 instrument;
- 24 (k) the APVMA’s monitoring of compliance with conditions of
25 accreditation or other requirements in the instrument;
- 26 (l) the obligations of accredited persons in relation to the
27 APVMA’s monitoring of such compliance;
- 28 (m) the circumstances in which an accredited person may have
29 the person’s accreditation varied, suspended or revoked;
- 30 (n) the review of decisions to refuse, vary, suspend or revoke
31 accreditation;
- 32 (o) the process for handling complaints involving accredited
33 persons;
- 34 (p) who may deliver training to accredited persons;
- 35 (q) auditing accredited persons.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Accreditation of assessors **Part 2**

1

Fees

2

(3) An instrument under subsection (1) may make provision for the following:

3

4

(a) the payment of fees to the Commonwealth in respect of matters prescribed in the instrument;

5

6

(b) the APVMA, on behalf of the Commonwealth, waiving or refunding fees.

7

8

(4) Without limiting subsection (3), the instrument may make provision for the following:

9

10

(a) the payment of an application fee for an application for accreditation;

11

12

(b) if the instrument provides for the renewal of accreditation—the payment of an application fee for an application for renewal of accreditation.

13

14

15

(5) A fee must not be such as to amount to taxation.

16

Instrument to be disallowable

17

(6) Despite subsection 44(1) of the *Legislation Act 2003*, section 42 (disallowance) of that Act applies to an instrument made under subsection (1) of this section.

18

19

20

Incorporation of other instruments

21

(7) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument under subsection (1) of this section may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

22

23

24

25

26

69GB Offences and civil penalties for contravening a condition of accreditation

27

28

(1) An accredited person commits an offence if:

29

(a) the person does an act or omits to do an act; and

30

(b) the act or omission contravenes a condition of the person's accreditation; and

31

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 2 Accreditation of assessors

- 1 (c) either:
2 (i) the act or omission has caused, will cause, or is likely to
3 cause, significant damage to the health and safety of
4 human beings, to animals, plants or things or to the
5 environment; or
6 (ii) the act or omission has significantly prejudiced, will
7 significantly prejudice, or is likely to significantly
8 prejudice, trade or commerce between Australia and
9 places outside Australia.

10 Penalty: 300 penalty units.

- 11 (2) An accredited person contravenes this subsection if:
12 (a) the person does an act or omits to do an act; and
13 (b) the act or omission contravenes a condition of the person's
14 accreditation; and
15 (c) either:
16 (i) the act or omission has caused, will cause, or is likely to
17 cause, significant damage to the health and safety of
18 human beings, to animals, plants or things or to the
19 environment; or
20 (ii) the act or omission has significantly prejudiced, will
21 significantly prejudice, or is likely to significantly
22 prejudice, trade or commerce between Australia and
23 places outside Australia.

24 (3) Subsection (2) is a civil penalty provision.

25 Note: Part 7AB provides for pecuniary penalties for contraventions of civil
26 penalty provisions.

- 27 (4) An accredited person commits an offence of strict liability if:
28 (a) the person does an act or omits to do an act; and
29 (b) the act or omission contravenes a condition of the person's
30 accreditation.

31 Penalty: 50 penalty units.

- 32 (5) An accredited person contravenes this subsection if:
33 (a) the person does an act or omits to do an act; and

EXPOSURE DRAFT

Main amendments **Schedule 1**
Accreditation of assessors **Part 2**

1 (b) the act or omission contravenes a condition of the person’s
2 accreditation.

3 (6) Subsection (5) is a civil penalty provision.

4 Note: Part 7AB provides for pecuniary penalties for contraventions of civil
5 penalty provisions.

6 (7) Section 15.3 of the *Criminal Code* (Extended geographical
7 jurisdiction—category C) applies to an offence against
8 subsection (1) or (4) of this section.

9 *Agricultural and Veterinary Chemicals Code Act 1994*

10 **35 Section 3 of the Code set out in the Schedule**

11 Insert:

12 *accredited person* means a person who is accredited in accordance
13 with an instrument made under section 69GA of the *Agricultural*
14 *and Veterinary Chemicals (Administration) Act 1992*.

15 **36 Subsections 162(1) and (9) of the Code set out in the** 16 **Schedule**

17 After “consultant to the APVMA,”, insert “an accredited person,”.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 3 Approval and registration for prescribed active constituents, chemical products or labels

1 **Part 3—Approval and registration for prescribed**
2 **active constituents, chemical products or**
3 **labels**

4 *Agricultural and Veterinary Chemicals Code Act 1994*

5 **37 Section 3 of the Code set out in the Schedule**

6 Insert:

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

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

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

13 **38 Before section 9A of the Code set out in the Schedule**

14 Insert:

15 **Subdivision A—Explanation of Division**

16 **39 Subsections 9A(2) to (5) of the Code set out in the**
17 **Schedule**

18 Repeal the subsections, substitute:

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

21 (2) Subdivision B provides for approval and registration for active
22 constituents, chemical products or labels after assessment against
23 certain criteria. Section 10 provides for applications to be made
24 and applications must meet the application requirements in
25 section 8A.

26 (3) The APVMA must complete a preliminary assessment of an
27 application. If the application passes preliminary assessment, the

EXPOSURE DRAFT

Main amendments **Schedule 1**

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

Part 3

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

3 (4) Before determining certain applications that have passed
4 preliminary assessment, the APVMA must publish a notice
5 inviting public submissions (sections 12 and 13).

6 (5) The APVMA must approve an active constituent or label, or
7 register a chemical product, if specified criteria are met
8 (section 14).

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

11 (5A) Subdivision C provides for approval and registration for a
12 prescribed active constituent, prescribed chemical product or
13 prescribed label for containers for a chemical product.
14 Sections 14C, 14D and 14E provide for applications to be made
15 and applications must meet the application requirements in
16 section 8A.

17 (5B) If an application meets the application requirements, the APVMA
18 must approve the active constituent or label, or register the
19 chemical product, if no disqualifying circumstances exist in
20 relation to the applicant.

21 *Common provisions*

22 **40 After section 9A of the Code set out in the Schedule**

23 Insert:

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

27 **41 After section 14B of the Code set out in the Schedule**

28 Insert:

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 3 Approval and registration for prescribed active constituents, chemical products or labels

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.

EXPOSURE DRAFT

Main amendments **Schedule 1**

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

Part 3

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

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

3 *Disqualifying circumstances*

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

6 **14D Applications for registration of prescribed chemical products**

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

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

10 (2) The application must meet the application requirements.

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

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

14 (4) A *prescribed chemical product* is a chemical product that is of a
15 kind:

16 (a) prescribed by the regulations for the purposes of this
17 paragraph; or

18 (b) determined by the APVMA under subsection (6).

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

22 (a) meet the safety criteria, the trade criteria and the efficacy
23 criteria; or

24 (b) comply with the established standard for the kind of chemical
25 product.

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 3 Approval and registration for prescribed active constituents, chemical products or labels

1

Decision on application

2

(7) The APVMA must register the chemical product that is the subject of the application if it is satisfied that:

3

4

(a) the application meets the application requirements; and

5

(b) the chemical product is a prescribed chemical product; and

6

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

7

8

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

9

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

10

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

11

Disqualifying circumstances

12

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

13

14

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

15

16

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

17

18

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

19

20

(2) The application must meet the application requirements.

21

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

22

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

23

24

(4) A *prescribed label for containers for a chemical product* is a label:

25

26

(a) for containers for a chemical product; and

27

(b) that is of a kind:

28

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

29

30

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

22

Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018

No. , 2018

EXPOSURE DRAFT

EXPOSURE DRAFT

Main amendments **Schedule 1**

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

Part 3

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

10 *Decision on application*

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

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

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

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

21 *Disqualifying circumstances*

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

24 **Subdivision D—Common provisions**

25 **42 Paragraphs 17(3)(a) and (b) of the Code set out in the** 26 **Schedule**

27 After “section 14”, insert “or 14C”.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 3 Approval and registration for prescribed active constituents, chemical products or labels

1 **43 After subsection 34G(1) of the Code set out in the**
2 **Schedule**

3 Insert:

4 (1AA) The APVMA must not use the following information to assess or
5 make a decision on an application made under section 14C, 14D or
6 14E:

- 7 (a) information given to the APVMA in connection with an
8 application made under section 10 or 27 by the applicant for
9 that application;
10 (b) information given under section 161.

11 **44 Subsection 34G(1B) of the Code set out in the Schedule**

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

13 **45 Subparagraph 166(1A)(b)(i) of the Code set out in the**
14 **Schedule**

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

16 **46 Paragraph 167(1)(a) of the Code set out in the Schedule**

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

18 **47 Paragraph 167(1)(b) of the Code set out in the Schedule**

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Limits on use of information **Part 4**

1 **Part 4—Limits on use of information**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **48 Section 3 of the Code set out in the Schedule (at the end**
4 **of the definition of *limitation period*)**

5 Add:

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

8 **49 Section 3 of the Code set out in the Schedule**
9 **(paragraph (b) of the definition of *protected active***
10 ***constituent*)**

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

12 **50 Section 3 of the Code set out in the Schedule**
13 **(paragraph (b) of the definition of *protected chemical***
14 ***product*)**

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

16 **51 Section 3 of the Code set out in the Schedule (at the end**
17 **of the definition of *protection period*)**

18 Add:

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

21 **52 Subsection 34F(4) of the Code set out in the Schedule**

22 After “34K”, insert “, 34KA”.

23 **53 Subsection 34F(5) of the Code set out in the Schedule**

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

25 **54 Subsection 34J(5A) of the Code set out in the Schedule**

26 Repeal the subsection, substitute:

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 4 Limits on use of information

- 1 *Protected information whose protection period has expired*
- 2 (5A) Another condition is that the information is protected information
3 and either:
- 4 (a) the protection period in relation to that information has
5 ended; or
- 6 (b) if the protection period in relation to that information is
7 extended in accordance with regulations made for the
8 purposes of section 34KA—the protection period, as
9 extended, has ended.
- 10 Note: For *protected information* and *protection period*, see section 3 and
11 Part 3.

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

12 Insert:

14 34KA Extension of protection periods

- 15 (1) The regulations may make provision for and in relation to
16 extending, on application, the protection period in relation to
17 protected information.
- 18 *Timing of extension*
- 19 (2) An extension of a protection period must not be given on
20 application unless that protection period (including that period as
21 previously extended) will end after 3 years beginning on the day
22 that the application was lodged.
- 23 *Maximum extension*
- 24 (3) The total length of all extensions of a protection period, in relation
25 to particular protected information, must not be more than 5 years.
- 26 *Kinds of active constituent*
- 27 (4) If the protected information relates to an active constituent that has
28 been approved, the protection period, in relation to that
29 information, may be extended only if the active constituent is of a

EXPOSURE DRAFT

Main amendments **Schedule 1**
Limits on use of information **Part 4**

1 kind prescribed by the regulations for the purposes of this
2 subsection.

3 *Relevant uses of chemical product*

4 (5) If the protected information relates to a chemical product that has
5 been registered, the protection period, in relation to that
6 information, may be extended only if one or more of the uses of the
7 product, being uses covered by entries in the Register, are uses of a
8 kind prescribed by the regulations for the purposes of this
9 subsection.

10 **56 Subsection 34M(1) of the Code set out in the Schedule**

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

12 **57 At the end of subsection 34M(1) of the Code set out in the** 13 **Schedule**

14 Add:

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

16 **58 At the end of Division 4A of Part 2 of the Code set out in** 17 **the Schedule**

18 Add:

19 **34MA Extension of limitation periods**

20 (1) The regulations may make provision for and in relation to
21 extending, on application, the limitation period for information
22 covered by an item of the table in subsection 34M(1).

23 *Timing of extension*

24 (2) An extension of a limitation period must not be given on
25 application unless that limitation period (including that period as
26 previously extended) will end after 3 years beginning on the day
27 that the application was lodged.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 4 Limits on use of information

1 *Maximum extension*

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

5 *Kinds of active constituent*

- 6 (4) A limitation period, for particular information covered by item 1 of
7 the table in subsection 34M(1), may be extended only if the active
8 constituent covered by that item is of a kind prescribed by the
9 regulations for the purposes of this subsection.

10 *Relevant uses of chemical product*

- 11 (5) A limitation period, for particular information covered by item 2,
12 3, 4, 5 or 6 of the table in subsection 34M(1), may be extended
13 only if one or more of the uses of the chemical product covered by
14 that item, being uses covered by entries in the Register, are uses of
15 a kind prescribed by the regulations for the purposes of this
16 subsection.

17 **59 Paragraph 59(2)(c) of the Code set out in the Schedule**

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

19 **60 Application provisions**

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Information to be taken into account in determining applications **Part 5**

1 **Part 5—Information to be taken into account in**
2 **determining applications**

3 *Agricultural and Veterinary Chemicals Code Act 1994*

4 **61 Subsection 8C(2) of the Code set out in the Schedule**

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

6 **62 After subsection 8C(2) of the Code set out in the Schedule**

7 Insert:

8 (2A) Subsection (2) does not apply to information that is prescribed by
9 the regulations, and that is provided in the circumstances
10 prescribed by the regulations, for the purposes of this subsection.

11 **63 Application provision**

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

- 15 (a) applications made on or after the commencement of this
16 item;
- 17 (b) applications made before the commencement of this item but
18 not determined by the APVMA before that commencement.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 6 Computerised decision-making

1 **Part 6—Computerised decision-making**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **64 Before section 6 of the Code set out in the Schedule**

4 Insert:

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

- 7 (1) The APVMA may arrange for the use, under the APVMA's
8 control, of computer programs for any purposes for which the
9 APVMA may, or must, under this Code:
- 10 (a) make a decision; or
11 (b) exercise any power or comply with any obligation; or
12 (c) do anything else related to making a decision to which
13 paragraph (a) applies or related to exercising a power, or
14 complying with an obligation, to which paragraph (b)
15 applies.
- 16 (2) For the purposes of this Code, the APVMA is taken to have:
- 17 (a) made a decision; or
18 (b) exercised a power or complied with an obligation; or
19 (c) done something else related to the making of a decision or
20 the exercise of a power or the compliance with an obligation;
21 that was made, exercised, complied with or done by the operation
22 of a computer program under an arrangement made under
23 subsection (1).

24 *Substituted decisions*

- 25 (3) The APVMA may substitute a decision for a decision (the *initial*
26 *decision*) the APVMA is taken, under paragraph (2)(a), to have
27 made if the APVMA is satisfied that the initial decision is
28 incorrect.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Computerised decision-making **Part 6**

- 1 (4) However, the substituted decision may only be made before the
2 end of the period of 60 days beginning on the day the initial
3 decision is made.

4 **65 Paragraphs 166(1)(a) and (1A)(a) of the Code set out in the** 5 **Schedule**

6 Repeal the paragraphs, substitute:

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

13 **66 After subsection 167(2A) of the Code set out in the** 14 **Schedule**

15 Insert:

16 (2B) If:

- 17 (a) the APVMA is taken, under paragraph 5F(2)(a), to have
18 made a decision (the *initial decision*); and
19 (b) under subsection (1) of this section, an application may be
20 made to the Administrative Appeals Tribunal for review of
21 the initial decision; and
22 (c) the APVMA, under subsection 5F(3), substitutes a decision
23 for the initial decision;
24 an application may be made to the Administrative Appeals
25 Tribunal for review of the substituted decision.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 7 Voluntary recalls

1 **Part 7—Voluntary recalls**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **67 Section 100 of the Code set out in the Schedule**

4 Before “This Part”, insert “(1)”.

5 **68 At the end of section 100 of the Code set out in the**
6 **Schedule**

7 Add:

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

10 **69 After section 106 of the Code set out in the Schedule**

11 Insert:

12 **106A Other voluntary recalls**

13 (1) This section applies if a person voluntarily proposes to take action
14 to recall a chemical product because it appears to the person that:

15 (a) either or both of the following apply:

16 (i) the chemical product may not meet the safety criteria,
17 the trade criteria or the efficacy criteria;

18 (ii) a label for containers for the chemical product may not
19 meet the labelling criteria; or

20 (b) the chemical product is not a registered chemical product.

21 (2) The person must, before taking any such action, give the APVMA
22 a notice that:

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

24 (b) contains the information required by the approved form.

25 (3) Subsection (2) does not apply in the circumstances prescribed by
26 the regulations for the purposes of this subsection.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Voluntary recalls **Part 7**

1

Offence

2

(4) A person commits an offence of strict liability if:

3

(a) the person is required by subsection (2) to give a notice to the APVMA; and

4

5

(b) the person refuses or fails to give the notice as required by that subsection.

6

7

Penalty: 60 penalty units.

8

Civil penalty

9

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

10

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

11

12

APVMA to publish notice of recall

13

(6) If a notice is given to the APVMA under subsection (2), the APVMA:

14

15

(a) must, within 3 working days, publish a copy of the notice on its website; and

16

17

(b) must, within 14 days, publish a copy of the notice in the Gazette.

18

19

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

20

21

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

22

23

70 Application provision

24

Section 106A 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 action proposed to be taken on or after the commencement of this item.

25

26

27

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 8 Notification of new information

1 **Part 8—Notification of new information**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **71 Subparagraph 160A(1)(a)(v) of the Code set out in the**
4 **Schedule**

5 Omit “and”, substitute “or”.

6 **72 At the end of paragraph 160A(1)(a) of the Code set out in**
7 **the Schedule**

8 Add:

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

15 **73 Paragraph 160A(1)(c) of the Code set out in the Schedule**

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

19 **74 Subparagraph 160A(4)(a)(ii) of the Code set out in the**
20 **Schedule**

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

23 **75 At the end of paragraph 160A(4)(b) of the Code set out in**
24 **the Schedule**

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

26 **76 After paragraph 161(1)(b) of the Code set out in the**
27 **Schedule**

28 Insert:

EXPOSURE DRAFT

Main amendments **Schedule 1**
Notification of new information **Part 8**

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

3 **77 Subsection 161(1) of the Code set out in the Schedule**

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

7 **78 Subsection 161(2) of the Code set out in the Schedule**

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

9 **79 Paragraph 161(2)(a) of the Code set out in the Schedule**

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

11 **80 At the end of paragraph 161(2)(b) of the Code set out in
12 the Schedule**

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

14 **81 Application provisions**

15 (1) The amendments of section 160A of the Code set out in the Schedule to
16 the *Agricultural and Veterinary Chemicals Code Act 1994* made by this
17 Part apply in relation to applications lodged on or after the
18 commencement of this item.

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 9 Definition of registered chemical product

1 **Part 9—Definition of registered chemical product**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **82 Section 3 of the Code set out in the Schedule (definition of**
4 ***registered chemical product*)**

5 Repeal the definition, substitute:

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

8 **83 After section 5 of the Code set out in the Schedule**

9 Insert:

10 **5AA Definition of *registered chemical product***

11 (1) A *registered chemical product* is a chemical product:

- 12 (a) that is registered; and
13 (b) that complies with the relevant particulars entered in the
14 Register for the product.

15 *Constituents of the chemical product*

16 (2) If:

- 17 (a) a chemical product is registered; and
18 (b) under regulations made for the purposes of
19 paragraph 20(1)(c), a relevant particular (the *subject*
20 *particular*) required to be entered in the Register in relation
21 to the chemical product is the constituents of the chemical
22 product; and
23 (c) there are regulations in force for the purposes of
24 paragraph 83(1)(a) in relation to the chemical product; and
25 (d) the constituents of the chemical product do not differ by
26 more than the extent prescribed for the purposes of
27 paragraph 83(1)(a);

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Definition of registered chemical product **Part 9**

1 *Concentration of constituents of the chemical product*

2 (3) If:

- 3 (a) a chemical product is registered; and
4 (b) under regulations made for the purposes of
5 paragraph 20(1)(c), a relevant particular (the *subject*
6 *particular*) required to be entered in the Register in relation
7 to the chemical product is the concentration of one or more
8 constituents of the chemical product; and
9 (c) there are regulations in force for the purposes of
10 paragraph 83(1)(b) in relation to the chemical product; and
11 (d) the concentration of the constituents of the chemical product
12 does not differ by more than the extent prescribed for the
13 purposes of paragraph 83(1)(b);

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

16 *Composition of constituents of the chemical product*

17 (4) If:

- 18 (a) a chemical product is registered; and
19 (b) under regulations made for the purposes of
20 paragraph 20(1)(c), a relevant particular (the *subject*
21 *particular*) required to be entered in the Register in relation
22 to the chemical product is the composition of a constituent of
23 the chemical product; and
24 (c) there are regulations in force for the purposes of
25 paragraph 83(1)(c) in relation to the composition of that
26 constituent of the chemical product; and
27 (d) the composition of that constituent of the chemical product
28 does not differ by more than the extent prescribed for the
29 purposes of paragraph 83(1)(c);

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

32 *Purity of constituents of the chemical product*

33 (5) If:

- 34 (a) a chemical product is registered; and
-

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 9 Definition of registered chemical product

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Suspension or cancellation of approval or registration for provision of false or
misleading information **Part 10**

1 **Part 10—Suspension or cancellation of approval or**
2 **registration for provision of false or**
3 **misleading information**

4 *Agricultural and Veterinary Chemicals Code Act 1994*

5 **84 Paragraph 34N(4)(d) of the Code set out in the Schedule**

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

7 **85 Section 38A of the Code set out in the Schedule**

8 Repeal the section, substitute:

9 **38A Suspension or cancellation of approval or registration for**
10 **provision of false or misleading information**

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

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

22 **86 Application provision**

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 11 Supply of registered chemical products with unapproved label

1 **Part 11—Supply of registered chemical products**
2 **with unapproved label**

3 *Agricultural and Veterinary Chemicals Code Act 1994*

4 **87 Subparagraph 81(1)(a)(i) of the Code set out in the**
5 **Schedule**

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

8 **88 Subparagraph 81(1)(a)(ii) of the Code set out in the**
9 **Schedule**

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

11 **89 Paragraph 81(2)(a) of the Code set out in the Schedule**

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

14 **90 Paragraph 81(2)(b) of the Code set out in the Schedule**

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

16 **91 Paragraphs 81(3)(a), (b) and (c) of the Code set out in the**
17 **Schedule**

18 Repeal the paragraphs, substitute:

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Supply of registered chemical products with unapproved label **Part 11**

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

5 **92 At the end of section 81 of the Code set out in the**
6 **Schedule**

7 Add:

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

11 **93 Application provision**

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 12 Variation of approval or registration during suspension

1 **Part 12—Variation of approval or registration during**
2 **suspension**

3 *Agricultural and Veterinary Chemicals Code Act 1994*

4 **94 Section 42 of the Code set out in the Schedule (heading)**

5 Repeal the heading, substitute:

6 **42 Suspension or cancellation of approval or registration at request**
7 **of holder**

8 **95 Subparagraph 42(1)(a)(i) of the Code set out in the**
9 **Schedule**

10 After “to”, insert “suspend or”.

11 **96 Subsection 42(1) of the Code set out in the Schedule**

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

15 **97 Subsection 43(4) of the Code set out in the Schedule**

16 Omit “A suspension under section 36 or subsection 41(2) or 44(2) of the
17 approval of a label for containers for a chemical product”, substitute “A
18 suspension of an approval or registration”.

19 **98 Paragraphs 43(4)(a), (b) and (c) of the Code set out in the**
20 **Schedule**

21 After “approval”, insert “or registration”.

22 **99 At the end of paragraph 43(4)(d) of the Code set out in the**
23 **Schedule**

24 Add “or registration”.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Variation of approval or registration during suspension **Part 12**

1 **100 At the end of subsection 43(5) of the Code set out in the**
2 **Schedule**

3 Add “or registration”.

4 **101 Subsection 45A(4) of the Code set out in the Schedule**

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

6 **102 Subsection 45A(4) of the Code set out in the Schedule**

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

8 **103 Application provisions**

9 (1) The amendments of section 42 of the Code set out in the Schedule to the
10 *Agricultural and Veterinary Chemicals Code Act 1994* made by this
11 Part apply in relation to requests made on or after the commencement of
12 this item.

13 (2) The amendments of section 43 of the Code set out in the Schedule to the
14 *Agricultural and Veterinary Chemicals Code Act 1994* made by this
15 Part apply in relation to:

- 16 (a) a suspension made on or after the commencement of this
17 item; and
18 (b) a suspension made before the commencement of this item
19 that was in effect immediately before that commencement.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 13 Safety, efficacy, trade and labelling criteria

1 **Part 13—Safety, efficacy, trade and labelling criteria**

2 *Agricultural and Veterinary Chemicals Code Act 1994*

3 **104 At the end of subsection 5D(2) of the Code set out in the**
4 **Schedule**

5 Add:

6 ; (d) any matters prescribed by the regulations.

7 **105 After section 5D of the Code set out in the Schedule**

8 Insert:

9 **5E Overseas trials and experiments**

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

15 **106 Application provision**

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

EXPOSURE DRAFT

Main amendments **Schedule 1**
Annual operational plans **Part 14**

1 **Part 14—Annual operational plans**

2 *Agricultural and Veterinary Chemicals (Administration) Act*
3 *1992*

4 **107 Part 6 (heading)**

5 Repeal the heading, substitute:

6 **Part 6—Corporate plan**

7 **108 Sections 55, 56 and 57**

8 Repeal the sections.

9 **109 Paragraph 61(a)**

10 Repeal the paragraph.

11 **110 Paragraph 61(b)**

12 Repeal the paragraph, substitute:

13 (b) an evaluation of the APVMA’s overall performance during
14 that period against the performance indicators (if any)
15 prescribed by the regulations for the purposes of this
16 paragraph; and

17 **111 Paragraph 61(d)**

18 Repeal the paragraph.

19 **112 Application and transitional provisions**

20 (1) The amendments made by this Part apply in relation to the calendar year
21 beginning on 1 January 2020 and each later calendar year.

22 (2) Despite the amendments made by this Part, sections 55 to 57 of the
23 *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as in
24 force immediately before the commencement of this item, continue to
25 apply on and after that commencement in relation to an annual

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 14 Annual operational plans

1 operational plan relating to the period of 12 months beginning on 1 July
2 2019.

3 (3) Despite the amendments made by this Part, section 61 of the
4 *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as in
5 force immediately before the commencement of this item, continues to
6 apply on and after that commencement in relation to the period of 12
7 months beginning on 1 July 2019.

8 (4) Regulations in force for the purposes of subparagraph 61(b)(ii) of the
9 *Agricultural and Veterinary Chemicals (Administration) Act 1992*
10 immediately before the commencement of this item continue in force,
11 on and after that commencement, for the purposes of paragraph 61(b) of
12 that Act.

EXPOSURE DRAFT

Main amendments **Schedule 1**

Other amendments **Part 15**

1 **Part 15—Other amendments**

2 *Agricultural and Veterinary Chemicals (Administration) Act*
3 *1992*

4 **113 Paragraph 7(1A)(a)**

5 Omit “sale”, substitute “supply”.

6 **114 Paragraphs 8A(2)(a) and (b)**

7 Omit “whether to grant”.

8 **115 Subsection 69D(1)**

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

10 **116 After subsection 69D(1A)**

11 Insert:

12 (1AA) The APVMA may, on its own initiative, reconsider a decision of
13 the APVMA to refuse to give a certificate under subsection (1).

14 (1AB) If the APVMA reconsiders the decision, it must:

15 (a) confirm the decision; or

16 (b) set aside the decision and give the certificate.

17 (1AC) The APVMA must give notice of a thing done under

18 subsection (1AB) to the person who applied for the certificate.

19 **117 Subsection 72(5)**

20 Repeal the subsection, substitute:

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

24 **118 Sections 78, 79 and 80**

25 Repeal the sections.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 15 Other amendments

1 **119 Application provision**

2 Subsections 69D(1AA) to (1AC) of the *Agricultural and Veterinary*
3 *Chemicals (Administration) Act 1992*, as inserted by this Part, apply in
4 relation to decisions made on or after the commencement of this item.

5 ***Agricultural and Veterinary Chemicals Code Act 1994***

6 **120 After section 6E of the Code set out in the Schedule**

7 Insert:

8 **6F Specification by class**

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

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

13 **121 Paragraph 74(1)(c) of the Code set out in the Schedule**

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

15 **122 Paragraph 74(1)(d) of the Code set out in the Schedule**

16 Repeal the paragraph.

17 **123 Subsection 74(2) of the Code set out in the Schedule**

18 Repeal the subsection.

19 **124 Subsection 74(2A) of the Code set out in the Schedule**
20 **(note)**

21 Omit “(d)”, substitute “(c)”.

22 **125 Subsection 74(3A) of the Code set out in the Schedule**
23 **(note 2)**

24 Omit “(d)”, substitute “(c)”.

25 **126 Subsection 74(4) of the Code set out in the Schedule**

26 Repeal the subsection.

EXPOSURE DRAFT

Main amendments **Schedule 1**
Other amendments **Part 15**

1 **127 Paragraph 75(1)(b) of the Code set out in the Schedule**

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

3 **128 Paragraph 75(1)(c) of the Code set out in the Schedule**

4 Repeal the paragraph.

5 **129 Subsection 75(2) of the Code set out in the Schedule**

6 Repeal the subsection.

7 **130 Subsection 75(2A) of the Code set out in the Schedule**
8 **(note)**

9 Omit “to (c)”, substitute “and (b)”.

10 **131 Subsection 75(3A) of the Code set out in the Schedule**
11 **(note 2)**

12 Omit “to (c)”, substitute “and (b)”.

13 **132 Subsection 75(4) of the Code set out in the Schedule**

14 Repeal the subsection.

15 **133 Paragraph 76(1)(b) of the Code set out in the Schedule**

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

17 **134 Paragraph 76(1)(c) of the Code set out in the Schedule**

18 Repeal the paragraph.

19 **135 Subsection 76(2) of the Code set out in the Schedule**

20 Repeal the subsection.

21 **136 Subsection 76(2A) of the Code set out in the Schedule**
22 **(note)**

23 Omit “to (c)”, substitute “and (b)”.

24 **137 Subsection 76(3A) of the Code set out in the Schedule**
25 **(note 2)**

26 Omit “to (c)”, substitute “and (b)”.

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 15 Other amendments

1 **138 Subsection 76(4) of the Code set out in the Schedule**

2 Repeal the subsection.

3 **139 Paragraph 78(1)(b) of the Code set out in the Schedule**

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

5 **140 Paragraph 78(1)(c) of the Code set out in the Schedule**

6 Repeal the paragraph.

7 **141 Subsection 78(2) of the Code set out in the Schedule**

8 Repeal the subsection.

9 **142 Subsection 78(2A) of the Code set out in the Schedule**
10 **(note)**

11 Omit “to (c)”, substitute “and (b)”.

12 **143 Subsection 78(3A) of the Code set out in the Schedule**
13 **(note 2)**

14 Omit “to (c)”, substitute “and (b)”.

15 **144 Subsection 78(4) of the Code set out in the Schedule**

16 Repeal the subsection.

17 **145 Subsections 166(3) and (4) of the Code set out in the**
18 **Schedule**

19 Repeal the subsections, substitute:

20 (3) If a request is so made, the APVMA must reconsider the original
21 decision having regard only to the information used to make it.

22 (4) The APVMA may, on its own initiative, reconsider the original
23 decision having regard only to the information used to make it.

24 (4A) If, under subsection (3) or (4), the APVMA reconsiders the original
25 decision, the APVMA must:

26 (a) confirm the original decision; or

27 (b) vary the original decision; or

EXPOSURE DRAFT

Main amendments **Schedule 1**
Other amendments **Part 15**

- 1 (c) set aside the original decision; or
2 (d) set aside the original decision and make a new decision in
3 substitution for the original decision.
- 4 (4B) The APVMA must, as soon as practicable, give written notice
5 setting out the APVMA's decision on the reconsideration to:
6 (a) for a reconsideration under subsection (3)—the person who
7 made the request; or
8 (b) for a reconsideration under subsection (4)—each person
9 covered by paragraph (1)(b) or (1A)(c), as the case may be,
10 of whom the APVMA is aware.

11 **146 Subsection 166(6) of the Code set out in the Schedule**

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

15 **147 Paragraph 167(1)(i) of the Code set out in the Schedule**

16 Repeal the paragraph.

17 **148 Sections 180, 183 and 184 of the Code set out in the** 18 **Schedule**

19 Repeal the sections.

20 **149 Application provision**

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

EXPOSURE DRAFT

Schedule 1 Main amendments

Part 15 Other amendments

1 *Agricultural and Veterinary Chemicals Legislation*
2 *Amendment Act 2013*

3 **150 Subsection 4(4)**

4 Omit “within 15 sitting days of that House after 1 July 2019”, substitute
5 “before the end of the last day on which the report of the first review
6 under section 72 of the *Agricultural and Veterinary Chemicals*
7 *(Administration) Act 1992* can be laid before that House”.

EXPOSURE DRAFT

Other amendments **Schedule 2**
Amendments **Part 1**

1 **Schedule 2—Other amendments**

2 **Part 1—Amendments**

3 *Agricultural and Veterinary Chemicals Code Act 1994*

4 **1 Subparagraph 8E(2)(b)(i) of the Code set out in the**
5 **Schedule**

6 Repeal the subparagraph, substitute:

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

9 **2 Paragraph 117A(1)(a) of the Code set out in the Schedule**

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

13 **3 Application provision**

14 The repeal and substitution of subparagraph 8E(2)(b)(i) of the Code set
15 out in the Schedule to the *Agricultural and Veterinary Chemicals Code*
16 *Act 1994* made by this Part applies in relation to notices given under
17 section 8E of that Code on or after the commencement of this item.

EXPOSURE DRAFT

Schedule 2 Other amendments

Part 2 Repeals

1 **Part 2—Repeals**

2 *Agricultural and Veterinary Chemicals Legislation*
3 *Amendment (Removing Re-approval and*
4 *Re-registration) Act 2014*

5 **4 The whole of the Act**

6 Repeal the Act.