Agricultural and Veterinary Chemicals Code Amendment Bill 2010

No. , 2010

A Bill for an Act to amend the Agricultural and Veterinary Chemicals Code Act 1994, and for related purposes
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A Bill for an Act to amend the *Agricultural and Veterinary Chemicals Code Act 1994*, and for related purposes

The Parliament of Australia enacts:

1 **Short title**

This Act may be cited as the *Agricultural and Veterinary Chemicals Code Amendment Act 2010*.

2 **Commencement**

This Act commences on the day after this Act receives the Royal Assent.
3 Schedule(s)

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.
Schedule 1—Amendments

Agricultural and Veterinary Chemicals Code Act 1994

1 Section 3 of the Schedule
Before “In this Code”, insert “(1)”.

2 Section 3 of the Schedule (at the end of the definition of adequate)
Add:
; and (d) would not unduly prejudice trade or commerce between Australia and places outside Australia.

2A Section 3 of the Schedule ( subparagraph (a)(ii) of the definition of approved person)
Omit “notified the APVMA in writing is”.

2B Section 3 of the Schedule (paragraph (b) of the definition of approved person)
Omit “has notified the APVMA in writing is authorised by that person”, substitute “has authorised”.

3 Section 3 of the Schedule (at the end of the definition of confidential commercial information)
Add:
; but does not include:
(d) the making of an application for a permit for the use of an active constituent for a proposed or existing chemical product or for the use of a chemical product, if the use of the product proposed in the application is:
(i) a minor use; or
(ii) an emergency use; or
(e) any prescribed information relating to the making of an application for a permit, as mentioned in paragraph (d).

4 Section 3 of the Schedule
Insert:
emergency use has the same meaning as in the regulations.

4A Section 3 of the Schedule
Insert:

file includes a file of information stored or recorded by means of a computer.

5 Section 3 of the Schedule
Insert:

minor use has the same meaning as in the regulations.

5A Section 3 of the Schedule (paragraph (d) of the definition of relevant particulars)
Repeal the paragraph, substitute:
(d) in relation to the approval of a label for containers for a chemical product—the information required to be recorded in the relevant APVMA file by paragraph 21(2)(c);

5B Section 3 of the Schedule (definition of relevant particulars)
Before “29(1)(h)”, insert “26A(4)(a) or”.

6 At the end of section 3 of the Schedule
Add:

(2) A regulation that prescribes information for the purposes of paragraph (e) of the definition of confidential commercial information is a legislative instrument.

6A After subsection 9(2) of the Schedule
Insert:

(2A) Division 2A deals with applications to vary a relevant particular if the relevant particular is of a kind set out in a legislative instrument made by the APVMA for the purposes of section 26A.

6B Subsection 21(1) of the Schedule
Omit “section 23”, substitute “section 23A”.

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4 Agricultural and Veterinary Chemicals Code Amendment Bill 2010 No. , 2010
6C Subsection 21(2) of the Schedule

Repeal the subsection, substitute:

(2) Approval of a label takes place by:
   (a) determining the particulars, prescribed by the regulations, that are appropriate to be contained on the label; and
   (b) giving a distinguishing number to the label; and
   (c) recording the following information in the relevant APVMA file:
      (i) the distinguishing number;
      (ii) the adequate instructions and any particulars that are to be contained on the label; and
      (d) recording any conditions imposed on the approval by the APVMA under subsection 23A(2) in the relevant APVMA file.

6D Subsection 23(1) of the Schedule

Omit “, the registration of a chemical product or the approval of a label for containers for a chemical product”, substitute “or the registration of a chemical product”.

Note: The heading to section 23 is amended by adding “—active constituents and chemical products”.

6E Subsection 23(3) of the Schedule

Omit “, registration of a chemical product or approval of a label for containers for a chemical product”, substitute “or the registration of a chemical product”.

6F After section 23 of the Schedule

Insert:

23A Conditions of approval—labels

(1) The approval of a label for containers for a chemical product is subject to:
   (a) the conditions prescribed by the regulations (whether or not the conditions are prescribed at the time the label is approved); and
   (b) any conditions imposed on the approval by the APVMA under subsection (2).
(2) At the time of approving a label for containers for a chemical product, the APVMA may impose conditions, as the APVMA considers appropriate, on the approval.

(3) The conditions prescribed by the regulations may be expressed to apply in relation to:
   (a) a label for containers for a particular chemical product; or
   (b) a label for containers for a class of chemical products; or
   (c) a label for containers for all chemical products.

(4) Approval of a label for containers for a chemical product may be granted on the condition that the approval remains in force for a particular period. The period may not be more than one year.

(5) If:
   (a) the approval is subject to a condition referred to in subsection (4); and
   (b) the conditions of approval have not been varied before the end of the period referred to in the condition, or the end of that period as previously extended under this subsection, so as to remove the condition;

the APVMA may vary the condition so as to extend the period for a further period of not more than one year or for further periods each of which is not more than one year.

6G After Division 2 of Part 2 of the Schedule

Insert:

Division 2A—Changes in certain relevant particulars

26A Applying for a change in certain relevant particulars

(1) An interested person in relation to:
   (a) an approved active constituent for a proposed or existing chemical product; or
   (b) a registered chemical product; or
   (c) an approved label for containers;

may apply to the APVMA for variation of a relevant particular of the approval or registration if the relevant particular is of a kind set out in a legislative instrument made by the APVMA for the purposes of this section.
(2) An application must:
   (a) be signed by an approved person; and
   (b) be accompanied by the prescribed fee (if any); and
   (c) be lodged with the APVMA.

(3) Subsection (4) applies if:
   (a) in the case of an application that relates to an active constituent or registration of a chemical product—the APVMA is satisfied that, if those particulars were varied in accordance with the application, the continued use of, or any other dealing with, the constituent or product in accordance with the instructions for its use or for such a dealing:
      (i) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
      (ii) would not be likely to have an effect that is harmful to human beings; and
      (iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
      (iv) would not unduly prejudice trade or commerce between Australia and places outside Australia; or
   (b) in the case of an application that relates to a label for containers for a chemical product—the APVMA is satisfied that, if those particulars were varied in accordance with the application, the use of the product in accordance with the instructions for its use would be effective according to criteria determined by the APVMA for the product.

(4) If the APVMA is satisfied, as mentioned in subsection (3), the APVMA must:
   (a) both:
      (i) vary the relevant particulars; and
      (ii) record in the relevant APVMA file the relevant particulars as varied and the date on which the record is made; and
   (b) give the interested person a written notice that states that the relevant particulars have been varied.

(5) If the APVMA is not satisfied, as mentioned in subsection (3), the APVMA must give the interested person a written notice that:
(a) states that the relevant particulars have not been varied; and
(b) sets out the reasons why the relevant particulars have not
been varied; and
(c) states that the interested person may apply to have the
relevant particulars varied under Division 3 of this Part.

6H Paragraph 28(1)(ba) of the Schedule

Repeal the paragraph.

6J After subsection 28(1) of the Schedule

Insert:

(1A) If an application is made under this Division and an application has
previously been made for the same variation under Division 2A,
the APVMA must set off the fee paid for the previous application
against the fee payable (if any) under paragraph (1)(d).

6K Subparagraph 29(1)(h)(ii) of the Schedule

Repeal the subparagraph, substitute:

(ii) if the application was for a variation of the relevant
particulars of the approval of a label—by recording in
the relevant APVMA file the relevant particulars as
varied and the date on which the record is made; or

6L Subparagraph 34(5)(a)(ii) of the Schedule

Repeal the subparagraph, substitute:

(ii) if the variation relates to the relevant particulars of the
approval of a label—by recording in the relevant
APVMA file the relevant particulars as varied and the
date on which the record is made; or

6M Subsection 34(5A) of the Schedule

Repeal the subsection, substitute:

(5A) The APVMA may only vary a condition of the approval of a label
that was imposed under subsection 23A(2).

6N Paragraph 34A(3)(a) of the Schedule

Repeal the paragraph, substitute:

(a) both:
(i) vary the relevant particulars; and
(ii) record in the relevant APVMA file the relevant particulars as varied and the date on which the record is made; and

6P Subsection 34A(4) of the Schedule

Repeal the subsection.

6Q Paragraph 40(2)(b) of the Schedule

Repeal the paragraph, substitute:
(b) the interested person does not satisfy the APVMA that a label, including the particulars as proposed to be varied by the APVMA, will be attached to the containers for the chemical product;

6R Paragraph 41(4)(b) of the Schedule

Repeal the paragraph, substitute:
(b) the interested person does not satisfy the APVMA that a label, including the particulars as proposed to be varied by the APVMA, will be attached to the containers for the chemical product;

6S Paragraph 47(5)(a) of the Schedule

Repeal the paragraph, substitute:
(a) any condition of a kind referred to in:
(i) subsection 23(3) to which an approval or registration is subject; or
(ii) subsection 23A(4) to which an approval of a label for containers for a chemical product is subject; and

6T Paragraph 81(1)(a) of the Schedule

Repeal the paragraph, substitute:
(a) the label attached to the container:
(i) states the relevant particulars; and
(ii) does not contain information that is contrary to the relevant particulars; or

6U Subsection 81(2) of the Schedule
Omit “that the label attached to the container was not identical to an approved label for the container for the product”, substitute “that the label attached to the container:

(a) did not state the relevant particulars; or
(b) contained information contrary to the relevant particulars”.

6V Paragraph 81(3)(a) of the Schedule

Repeal the paragraph, substitute:

(a) the label attached to the container states the relevant particulars that were required to be stated on a label (the earlier approved label) that was an approved label for containers for the product at a time before the supply takes place; and

6W Section 86 of the Schedule

Repeal the section, substitute:

86 Labels not to be detached etc.

(1) A person commits an offence if:

(a) either:

(i) a label attached to a container of a chemical product contains any relevant particular identical to any relevant particular contained on an approved label for containers for the product; or
(ii) a label attached to a container of a chemical product contains any relevant particular identical to any matter required by an established standard for the product to be included on a label for containers for the product; and

(b) the person:

(i) detaches or otherwise removes the label; or
(ii) alters, defaces, obliterates or destroys the relevant particular; or
(iii) attaches another label to, or endorses anything upon, the container that in either case has the effect of expressly or impliedly negating, varying, or in any way detracting from, qualifying or minimising the purport or effect of, the relevant particular.

Penalty: 300 penalty units.
(2) A person commits an offence if:
   
   (a) either:
       
       (i) a label attached to a container of a chemical product contains any relevant particular identical to any relevant particular contained on an approved label for containers for the product; or
       
       (ii) a label attached to a container of a chemical product contains any relevant particular identical to any matter required by an established standard for the product to be included on a label for containers for the product; and
       
   (b) the person causes or permits:
       
       (i) the label to be detached or otherwise removed; or
       
       (ii) the relevant particular contained on the label to be altered, defaced, obliterated or destroyed; or
       
       (iii) another label to be attached to the container that has the effect of expressly or impliedly negating, varying, or in any way detracting from, qualifying or minimising the purport or effect of, the relevant particular; or
       
       (iv) anything to be endorsed upon the container that has the effect of expressly or impliedly negating, varying, or in any way detracting from, qualifying or minimising the purport or effect of, the relevant particular.

   Penalty: 300 penalty units.

   (3) Subparagraphs (1)(b)(ii) and (2)(b)(ii) do not apply to an alteration, defacing, obliteration or destruction of a relevant particular that is done by the destruction or disposal of the chemical product without otherwise contravening this Code.

   (4) Subsections (1) and (2) do not apply if the person has a reasonable excuse.

   Note: The defendant bears an evidential burden in relation to the matter in subsection (4). See subsection 13.3(3) of the Criminal Code.

6X  Paragraph 103(1)(a) of the Schedule

   Omit “kept in, or in conjunction with, the relevant APVMA file in relation to the product”, substitute “for the product”.

6Y  Paragraph 103(2)(c) of the Schedule
Omit “kept in, or in conjunction with, the relevant APVMA file”,
substitute “for the product”.

6Z Section 158 of the Schedule

Repeal the section.

7 Subsection 162(13) of the Schedule

Repeal the subsection, substitute:

(13) A reference in this section to information about an active
constituent for a proposed or existing chemical product, or about a
chemical product, includes a reference to the fact that:
(a) an application has been made for approval of the constituent
or registration of the product; or
(b) an application has been made for a permit in respect of the
constituent or product, if the making of the application is
confidential commercial information.

7A After paragraph 167(1)(b) of the Schedule

Insert:
(baa) a decision under section 26A to refuse to vary:
(i) relevant particulars of the approval of an active
constituent for a proposed or existing chemical product;
or
(ii) relevant particulars of the registration of a chemical
product; or
(iii) relevant particulars of the approval of a label for
containers for a chemical product;

7B Labels approved under existing law

(1) If a label was, immediately before commencement, an approved label
within the meaning of the old law, then:
(a) the label is taken, from commencement, to be an approved
label within the meaning of the new law; and
(b) any particulars determined under paragraph 21(2)(c) of the
old law are taken, from commencement, to be recorded on
the relevant APVMA file; and
(c) any condition on the approval of the label imposed under
section 23 of the old law is taken, from commencement, to be
a condition imposed on the approval of the label under
subsection 23A(2) of the new law; and
(d) any condition prescribed by regulations made under
paragraph 23A(1)(a) of the new law is taken to be a condition
imposed on the approval of the label.

(2) In this item:

commencement means the day this item commences.
new law means the *Agricultural and Veterinary Chemicals Code Act 1994*, as in force immediately after commencement.
old law means the *Agricultural and Veterinary Chemicals Code Act 1994*, as in force immediately before commencement.

8 Application

(1) The amendment made by item 2 of this Schedule applies in relation to:

(a) an application for approval of a label for containers for a
chemical product under section 10 of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994* that is
made on or after the day this item commences; and

(aa) an application for variation of the relevant particulars of the
approval for a label for containers for a chemical product
under section 26A of the Schedule to the *Agricultural and
Veterinary Chemicals Code Act 1994*, as inserted by this
Schedule, that is made on or after the day this item
commences; and

(b) an application for variation of the relevant particulars or
conditions of the approval for a label for containers for a
chemical product under section 27 of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994* that is
made on or after the day this item commences; and

(c) a reconsideration of the approval of a label for containers for
a chemical product under section 34 of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994*, as
amended by this Schedule, if:

(i) the APVMA has published a notice in respect of the
label for containers for the chemical product under
subsection 32(1) of the Schedule to that Act before, on
or after the day this item commences; or
(ii) the APVMA had given written notice in respect of the label for containers for the chemical product under subsection 32(2) of the Schedule to that Act to an interested person or an approved person before the day this item commences and, on the day this item commences, the period stated in the notice has not expired; or

(iii) the APVMA gives written notice in respect of the label for containers for the chemical product under subsection 32(2) of the Schedule to that Act to an interested person or an approved person on or after the day this item commences; and

(d) a reconsideration of the approval of a label for containers for a chemical product under section 34A of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994, as amended by this Schedule, that began before, or begins on or after, the day this item commences; and

(e) a standard for a chemical product that is submitted to the Minister for approval under section 56D of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994 on or after the day this item commences.

(2) The amendments made by items 3, 4, 5, 6 and 7 of this Schedule apply in respect of an application for a permit that is made on or after the day this item commences.

(2A) The amendments made by items 4A, 5A, 6B, 6C, 6D, 6E, 6F, 6H, 6K, 6L, 6M, 6N, 6P, 6Q, 6R, 6S, 6T, 6U, 6V, 6W, 6X, 6Y, 6Z and 7B of this Schedule apply in relation to:

(a) an application for approval of a label for containers for a chemical product under section 10 of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994 that is made on or after the day this item commences; and

(b) an application for variation of the relevant particulars of the approval for a label for containers for a chemical product under section 26A of the Schedule to the Agricultural and Veterinary Chemicals Code Act 1994, as inserted by this Schedule, that is made on or after the day this item commences; and

(c) an application for variation of the relevant particulars or conditions of the approval for a label for containers for a...
chemical product under section 27 of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994* that is
made on or after the day this item commences; and

(d) a reconsideration of the approval of a label for containers for
a chemical product under section 34 of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994*, as
amended by this Schedule, if:

(i) the APVMA has published a notice in respect of the
label for containers for the chemical product under
subsection 32(1) of the Schedule to that Act before, on
or after the day this item commences; or

(ii) the APVMA had given written notice in respect of the
label for containers for the chemical product under
subsection 32(2) of the Schedule to that Act to an
interested person or an approved person before the day
this item commences and, on the day this item
commences, the period stated in the notice has not
expired; or

(iii) the APVMA gives written notice in respect of the label
for containers for the chemical product under subsection
32(2) of the Schedule to that Act to an interested person
or an approved person on or after the day this item
commences; and

(e) a reconsideration of the approval of a label for containers for
a chemical product under section 34A of the Schedule to the
*Agricultural and Veterinary Chemicals Code Act 1994*, as
amended by this Schedule, that begins on or after the day this
item commences; and

(f) a standard for a chemical product that is submitted to the
Minister for approval under section 56D of the Schedule to
the *Agricultural and Veterinary Chemicals Code Act 1994* on
or after the day this item commences.

(2B) The amendments made by items 5B, 6A, 6G, 6J and 7A of this
Schedule apply in respect of an application for a variation that is made
on or after the day this item commences.

(3) In this item:

*approval* has the same meaning as in the *Agricultural and Veterinary
Schedule 1 Amendments

approved person has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994, as amended by this Schedule.

chemical product has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.

container has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.

interested person has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.

label has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.

permit has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.

relevant particulars has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994, as amended by this Schedule.

variations has the same meaning as in the Agricultural and Veterinary Chemicals Code Act 1994.