Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015

Select Legislative Instrument No. 219, 2015

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 10 December 2015

Peter Cosgrove
Governor-General

By His Excellency's Command

Barnaby Joyce
Minister for Agriculture and Water Resources

OPC61090 - B

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1 Name

This is the *Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	17 December 2015
2. Schedule 1	The day after this instrument is registered.	17 December 2015
3. Schedule 2	1 March 2016.	1 March 2016
4. Schedule 3	1 July 2016.	1 July 2016

Note: This table relates only to the provisions of this instrument as originally made.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

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

3 Authority

This instrument is made under the following Acts:

(a) the *Agricultural and Veterinary Chemicals (Administration) Act 1992*;

(b) the *Agricultural and Veterinary Chemicals Code Act 1994*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments commencing day after registration

Agricultural and Veterinary Chemicals (Administration) Regulations 1995

1 Paragraphs 1A.1(a) and (b)

Omit "year", substitute "period".

2 Regulation 1A.3

Omit "subparagraph 61(2)(c)(ii)", substitute "subparagraph 61(b)(ii)".

3 Regulation 1A.3

Omit "year" (wherever occurring), substitute "period".

Agricultural and Veterinary Chemicals Code Regulations 1995

4 Subregulation 70A(3)

Omit all the words after "in relation to an application,", substitute "is the fee (if any) mentioned for the item in column 3 of Schedule 7".

5 Subregulation 77(1)

Omit "Column 3", substitute "Column 2".

6 Schedule 4 (after table item 1)

Insert:

2	A chemical product containing 4-aminopropiophenone (also known as PAPP)

7 Schedule 7 (table)

Repeal the table, substitute:

Table of fees and periods for completion of modules, levels and types of assessments			
Item	**Column 1** **Module, level or type**	**Column 2** **Period for completion**	**Column 3** **Fee ($)**
1	**Preliminary assessment**		710
2	**Chemistry**		
2.1	Chemistry—level 1	13 months	9 220
2.2	Chemistry—level 2	9 months	3 075
2.3	Chemistry—level 3	6 months	1 580
2.4	Chemistry—timeshift application	As set out in the project plan	9 220
3	**Toxicology** (not requiring poison schedule classification)		
3.1	Toxicology—level 1	13 months	27 920
3.2	Toxicology—level 2	9 months	15 795
3.3	Toxicology—level 3	5 months	4 050
3.4	Toxicology—timeshift application	As set out in the project plan	27 920
4	**Toxicology** (requiring poison schedule classification)		
4.1	Toxicology requiring poison schedule classification	13 months	2 435
4.2	Toxicology requiring poison schedule classification—timeshift application	As set out in the project plan	2 435
5	**Residues**		
5.1	Residues—level 1	13 months	18 170
5.2	Residues—level 2	8 months	10 525
5.3	Residues—level 3	8 months	8 200
5.4	Residues—level 4	4 months	7 465
5.5	Residues—level 5	4 months	2 000
5.6	Residues—timeshift application	As set out in the project plan	18 170
6	**Work health and safety**		
6.1	Work health and safety—level 1	13 months	4 410
6.2	Work health and safety—level 2	7 months	3 185

Table of fees and periods for completion of modules, levels and types of assessments			
Item	**Column 1** **Module, level or type**	**Column 2** **Period for completion**	**Column 3** **Fee ($)**
6.3	Work health and safety—level 3	4 months	2 910
6.4	Work health and safety—timeshift application	As set out in the project plan	4 410
7	**Environment**		
7.1	Environment—level 1	13 months	26 390
7.2	Environment—level 2	7 months	7 315
7.3	Environment—level 3	4 months	1 720
7.4	Environment—timeshift application	As set out in the project plan	26 390
8	**Efficacy and safety**		
8.1	Efficacy and safety—level 1	6 months	2 370
8.2	Efficacy and safety—level 2	4 months	975
8.3	Efficacy and safety—level 3	3 months	580
8.4	Efficacy and safety—timeshift application	As set out in the project plan	2 370
9	**Non-food trade**	6 months	1 175
10	**Special data**		
10.1	Special data—level 1	13 months	nil
10.2	Special data—level 2	7 months	nil
10.3	Special data—level 3	7 months	nil
10.4	Special data—timeshift application	As set out in the project plan	nil
11	**Finalisation**		
11.1	Finalisation—type 1	3 months	4 055
11.2	Finalisation—type 2	2 months	1 545
11.3	Finalisation—type 3	2 months	865
12	**Limits on use of information**		460

Schedule 2—Amendments commencing 1 March 2016

Part 1—Amendments relating to chemical product registration renewals

Agricultural and Veterinary Chemicals Code Regulations 1995

1 Before regulation 8AG

Insert:

8AFA Application requirements—chemical product registration renewal applications

For subparagraph 8A(a)(v) of the Code, an application for the renewal of the registration of a chemical product must nominate whether the application is for a 5 year or 12 month renewal period.

2 Paragraph 23(1)(b)

Repeal the paragraph, substitute:

(b) if:

(i) after the end of the period for making an application referred to in subsection 48(2) of the Code and before the registration of the product ends, the applicant requests in writing that the APVMA accept a late application; and

(ii) the APVMA agrees to that request.

3 At the end of Part 2

Add:

Division 2.7—Renewal of registration

23A When renewed registration ends

For paragraph 50(2)(b) of the Code, the method for working out the date the registration of a chemical product (as renewed) ends is:

(a) if the holder applies for the registration of the product to be renewed, or further renewed, as the case may be, for a period of 5 years—add 5 years to the date on which the registration would otherwise end; or

(b) if the holder applies for the registration of the product to be renewed, or further renewed, as the case may be, for a period of 12 months—add 12 months to the date on which the registration would otherwise end.

4 Regulation 71A (heading)

Repeal the heading, substitute:

71A Fees for continued registration of chemical product

5 Subregulation 71A(1)

Repeal the subregulation, substitute:

(1) For section 164 of the Code, the fee payable for an application for the renewal of the registration of a chemical product is:

(a) if the application is for the renewal, or further renewal, of the product for a period of 5 years—$2 150; or

(b) if the application is for the renewal, or further renewal, of the product for a period for 12 months—$430.

6 Subregulation 71A(5)

Repeal the subregulation, substitute:

(5) The overseas GMP compliance assessment fee for a financial year is payable on or before the last day for payment of the fee shown on an invoice issued for the fee by the APVMA for the financial year.

(6) A fee payable under this regulation is not refundable if the registration of the chemical product is subsequently suspended or cancelled.

7 At the end of Part 10

Add:

Division 10.5—Amendments made by the Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015

90 Operation of amendments to applications for the renewal of the registration of a chemical product

The amendments of these Regulations made by items 1 to 6 of Part 1 of Schedule 2 to the *Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015* apply to an application for the renewal, or further renewal, of the registration of a chemical product, if the registration of the product is to end on or after 30 June 2017.

91 Repeal of this Division

This Division is repealed on 1 July 2017.

Part 2—Other amendments

Agricultural and Veterinary Chemicals Code Regulations 1995

8 Regulation 19AF (at the end of the table)

Add:

2	A variation of the name of a manufacturer of a chemical product, if the manufacturer is outside Australia	any registration of a chemical product other than a chemical product that is prescribed under subregulation 59(1)

9 After subregulation 76(1A)

Insert:

(1B) If:

(a) an application is of the kind mentioned in section 10 or 27 of the Code (the ***primary application***); and

(b) the applicant makes another application of the same kind as the primary application (the ***secondary application***); and

(c) the secondary application is made at the same time as the primary application; and

(d) the applicant nominates the secondary application as an application related to the primary application; and

(e) the chemical products to which the primary and secondary applications relate would have, if the applications were approved:

(i) the same identifying information for the holder of the registration of the chemical products; and

(ii) the same manufacturer; and

(iii) the same address at which the chemical products are manufactured; and

(iv) the same active constituent on the label of the chemical products;

then, the period mentioned in subregulation (1) or (1A) and applicable to the primary application also applies to the secondary application.

10 Clause 3 of Part 3 of Schedule 3AA (before table item 2)

Insert:

1	Animal feed products that incorporate an excluded nutritional or digestive product, if: (a) the container for the animal feed product is labelled in accordance with the instructions on the label for the container for the excluded nutritional or digestive product; and (b) the excluded nutritional or digestive product is incorporated at a rate of use in accordance with the label for the container for the excluded nutritional or digestive product; and (c) the claims made for the animal feed product do not exceed the claims made for the incorporated nutritional or digestive product.

11 Subclause 5(3) of Part 3 of Schedule 3AA (at the end of the table)

Add:

9	Part 1 of Schedules IV and V to the *Feeds Regulations 1983* of Canada, as existing at the time of the supply

Schedule 3—Amendments commencing 1 July 2016

Agricultural and Veterinary Chemicals Code Regulations 1995

1 Subregulation 3(1)

Insert:

interchangeable constituent determination means a determination under regulation 19AEA.

2 After regulation 8AFA

Insert:

8AFB Application requirements—application for prescribed variations

For subparagraph 8A(a)(v) of the Code, an application for a prescribed variation of the kind set out in item 3 of the table in regulation 19AF must include a statement that the applicant holds:

(a) evidence that the physical properties and storage stability of the product, as varied and relevant to the product's formulation type or dosage form, are the same as the product's existing physical properties and storage stability, when measured using the same methodology used for the product before being varied; and

(b) if the application relates to a veterinary chemical product—the following evidence about the product, as varied:

(i) a dissolution profile (if relevant) of at least 2 pilot scale batches that is comparable to the formulation of the product immediately before the application is made;

(ii) at least 3 consecutive months of data on the storage stability of the product.

3 Subregulation 19AE(1) (at the end of the table)

Add:

8	A variation of one or more constituents of a	any registration of a

chemical product if: (a) the variation is to replace one or more constituents with a constituent or constituents listed for the product in an interchangeable constituent determination; and (b) in the case of a product that has 9 or more constituents entered in the Register for the product—the variation is to no more than 25% of the number of constituents entered in the Register for the product; and (c) in the case of a product that has less than 9 constituents entered in the Register for the product—the variation is to one or 2 of the constituents entered in the Register for the product	chemical product

4 After regulation 19AE

Insert:

19AEA Interchangeable constituent determinations

APVMA may determine interchangeable constituents

(1) The APVMA may, by legislative instrument, determine that one or more constituents of a chemical product or a class of chemical products may be interchanged with another constituent.

(2) Without limiting subregulation (1), the interchangeable constituent determination may authorise a constituent being interchanged with another constituent if one or more requirements specified in the determination are met.

(3) The power under subregulation (1) may be exercised on the APVMA's own initiative or on application under regulation 19AEB.

(4) If an interchangeable constituent determination can be made in relation to a class of chemical products, or varied so that it applies to a class of chemical products, the APVMA must make or, if varying a determination, vary the determination accordingly.

APVMA to be satisfied of certain matters

(5) Before making or varying an interchangeable constituent determination, the APVMA must be satisfied that:

(a) the constituent to be interchanged is not an active constituent of the product; and

(b) the interchange of the constituents does not introduce material of human or animal origin into the product; and

(c) the interchange of the constituents would not require variation to:

(i) the signal words required by the current Poisons Standard to be contained on the label of the product; or

(ii) the formulation type of the product entered in the Register; and

(d) after the constituents are interchanged, the chemical product would continue to:

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

(ii) comply with any requirements prescribed for the purposes of paragraph 8A(b) or 41(1)(c) of the Code.

(6) For the purposes of being satisfied of the matters mentioned in subregulation (5), the APVMA must have regard to any requirements to which the interchange of a constituent is, or could be, subject.

Variation or revocation of an interchangeable constituent determination

(7) If the APVMA proposes to vary or revoke an interchangeable constituent determination, the APVMA must:

(a) publish on its website a notice setting out the proposed variation or reasons for the proposed revocation; and

(b) invite written submissions on the variation or revocation to be made on or before a specified date (the ***consultation period***).

(8) The notice must:

(a) be published at least 28 days before the interchangeable constituent determination is so varied or revoked; and

(b) remain on the APVMA's website until the determination is so varied or revoked.

(9) The APVMA must consider submissions made during the consultation period.

(10) The APVMA may make a submission public, unless the person that made the submission has requested that the submission, or a part of it, be kept confidential.

19AEB Applying for an interchangeable constituent determination

(1) A person may apply to the APVMA for the making of an interchangeable constituent determination in relation to a chemical product or a class of chemical products.

(2) The application must specify the following for each constituent covered by the application:

(a) the identity of the constituent, including:

(i) the common name of the constituent; and

(ii) if a name is given to the constituent by the International Union of Pure and Applied Chemistry—that name; and

(iii) the chemical abstract service number for the constituent;

(b) the purpose of the constituent in the chemical product;

(c) any requirements (including, for example, minimum purity or other quality specifications) for the constituent.

(3) The APVMA must make an interchangeable constituent determination if the APVMA is satisfied:

(a) that the application meets the application requirements; and

(b) of the matters mentioned in subregulation 19AEA(5).

(4) The APVMA must, within 14 days of making an interchangeable constituent determination:

(a) inform the applicant, in writing, of that fact; and

(b) provide the applicant with a copy of the determination.

Note: For notification requirements if the APVMA refuses an application, see section 8G of the Code.

(5) The following provisions of the Code apply in relation to an application under subregulation (1) as if the application were an

application made under the Code in relation to an active constituent for a proposed or existing chemical product:

(a) section 157 (samples to be given for analysis);

(b) section 159 (requiring information to determine an application).

Note 1: A number of provisions in the Code apply automatically in relation to applications made under it (including applications made under these Regulations). See, for example, sections 8B to 8D, and sections 8G, 8S, 156A, 164 and 165, of the Code.

Note 2: Regulation 19AEC applies certain other provisions in relation to applications made under this regulation.

19AEC Limits on information that may be used for interchangeable constituent determinations

Overseas trials and experiments, consultation and information, reports or samples

(1) The following provisions apply in relation to the making, variation or revocation of an interchangeable constituent determination as if the constituent to which the determination relates were an active constituent for a proposed or existing chemical product:

(a) section 159 of the Code (requiring information to determine an application);

(b) subsections 160(2) and (3) of the Code (overseas trials and experiments);

(c) section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (consultation).

Limits on use of information

(2) The APVMA must not use information given to it in connection with an application under the Code:

(a) to assess an application made under regulation 19AEB; or

(b) to make any other decision in relation to the making, variation or revocation of an interchangeable constituent determination;

unless the information was given to it in connection with the application mentioned in paragraph (a) or the decision mentioned in paragraph (b).

(3) A person or body consulted under section 8 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, as that section applies under subregulation (1), must not, for the purposes of providing information or advice in relation to the making, variation or revocation of an interchangeable constituent determination, use information that the APVMA must not, under subregulation (2), use in relation to the interchangeable constituent determination.

(4) The following provisions of the Code apply in relation to subregulations (2) and (3) in the same way as they apply in relation to subsections 34G(1) and (3) of the Code:

(a) subsections 34G(1B) and (2);

(b) sections 34H to 34M.

(5) For subregulation (4), the condition in subsection 34J(4) of the Code is taken to be replaced by the condition that:

(a) the information relates to the making, variation or revocation of an interchangeable constituent determination in relation to a constituent; and

(b) the information shows that a matter mentioned in subregulation 19AEA(5) may not be satisfied in relation to the constituent.

(6) For subregulation (4), if the APVMA relies on information to make, vary or revoke an interchangeable constituent determination, a limitation period is taken to apply to the information under section 34M of the Code that ends 3 years after the day the determination is made, varied or revoked.

5 Regulation 19AF (at the end of the table)

Add:

3	A variation of one or more constituents of a chemical product if: (a) the constituent (the ***original constituent***) is replaced with another constituent (the ***replacement constituent***); and (b) the original constituent is not an active constituent of the product; and (c) the replacement constituent will	a registration of a chemical product, other than a chemical product that is: (a) an antibiotic product; or (b) an immunobiological product; or (c) a product that is administered through direct injection into an animal

not be an active constituent of the product; and

(d) the original and replacement constituents have the same purpose in the product; and

(e) the original and replacement constituents differ only in solvates or hydrates; and

(f) the original and replacement constituents have the same:

(i) pH; and

(ii) dissolution profile; and

(iii) hydrophilic or hydrophobic behaviour; and

(iv) hygroscopic behaviour; and

(g) neither the original nor replacement constituent are a nanomaterial; and

(h) in the case of the original and replacement constituents being a straight or branched unsaturated hydrocarbon—the change in the length of the hydrocarbon chain is not more than 33% of the length of the original constituent's hydrocarbon chain; and

(i) the replacement constituent does not introduce material of human or animal origin into the product; and

(j) the variation does not require variation to the signal words required by the current Poisons Standard to be on the label of the product; and

(k) in the case of a product that is a molluscicide in the form of a bait or a product applied to seeds to be stored before planting or sowing—the variation does not change the colour of the product;

and

(l) the variation does not require the formulation type entered in the Register for the product to be varied; and

(m) in the case of a product that has 9 or more constituents entered in the Register for the product—the variation is to no more than 25% of the number of constituents entered in the Register for the product; and

(n) in the case of a product that has less than 9 constituents entered in the Register for the product

6 After paragraph 78C(c)

Insert:

(ca) a decision to refuse an application, in whole or part, made under regulation 19AEB;

7 Part 2 of Schedule 6 (at the end of the table)

Add:

29	Application made under regulation 19AEB to make an interchangeable constituent determination	The modular assessment period	One and one third of the modular assessment period, rounded up to the nearest whole month, plus 1 month	Nil	The modular assessment fee