**EXPLANATORY STATEMENT**

**SELECT LEGISLATIVE INSTRUMENT No. 219, 2015**

# AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (SIMPLIFIED FORMULATION VARIATIONS AND OTHER MEASURES) REGULATION 2015

Issued by the authority of the Minister for Agriculture and Water Resources

*Agricultural and Veterinary Chemicals Code Act 1994*

*Agricultural and Veterinary Chemicals (Administration) Act 1992*

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## LEGISLATIVE AUTHORITY FOR REGULATION

Subsection 6(1) of the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) provides, in part, that the Governor-General may make regulations prescribing matters: required or permitted by the Schedule to the Code Act (the Agvet Code) to be prescribed by regulations within the meaning of the Agvet Code; or necessary or convenient to be prescribed by such regulations for carrying out or giving effect to the Agvet Code. The Agvet Code includes provision for certain matters to be prescribed in regulations. These provisions are described for each of the relevant amending items in the 'details of the amendment regulation' part of this explanatory statement.

Paragraph 61(b) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) provides for regulations to prescribe performance indicators for inclusion in the Australian Pesticides and Veterinary Medicines Authority's annual report.

### Disallowance of Regulation

The Amendment Regulation is a disallowable legislative instrument for the purposes of the *Legislative Instruments Act 2003* (LI Act). Section 54 of the LI Act means that the Amendment Regulation is not subject to sunsetting as the amendments to regulations in the Amendment Regulation are enabled by legislation that facilitates the establishment and operation of a scheme involving the Commonwealth and one or more states.

## GLOSSARY

The following abbreviations and acronyms are used throughout this explanatory statement.

| Abbreviation | Definition |
|---|---|
| Administration Act | *Agricultural and Veterinary Chemicals (Administration) Act 1992* |
| Administration Regulations | Agricultural and Veterinary Chemicals (Administration) Regulations 1995 |
| agvet chemicals | agricultural chemicals and veterinary medicines |
| Agvet Code | Schedule to the Code Act (see below) |
| Amendment Regulation | Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015 |
| APVMA | Australian Pesticides and Veterinary Medicines Authority |
| Code Act | *Agricultural and Veterinary Chemicals Code Act 1994* |
| LI Act | *Legislative Instruments Act 2003* |
| NRS | National Registration Scheme for Agricultural and Veterinary Chemicals |
| OBPR | Office of Best Practice Regulation |
| Principal Code Regulations | Agricultural and Veterinary Chemicals Code Regulations 1995 |

# OUTLINE

## Amendments made

The Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015 (Amendment Regulation) amends the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations) and the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Administration Regulations).

## Purpose, impact and effect of amendments

The Australian Government has committed to improve the efficiency of agricultural chemicals and veterinary medicines (agvet chemicals) regulation.

The Amendment Regulation amends the Principal Code Regulations and the Administration Regulations to:

- simplify the process for varying the formulation of a registered agvet chemical product
- improve efficiency by simplifying the process for registering, or varying a suite of chemical products
- simplify the process for varying the name of an overseas veterinary chemical product manufacturer
- include another international list of animal feed ingredients to improve efficiencies in the regulation of some animal feed products
- specify that bulk feed that incorporates an excluded animal feed product is not a veterinary chemical product to reduce the regulatory burden for these kinds of products
- declare chemical products containing 4-aminopropiophenone (or para-aminopropiophenone, PAPP) to be restricted chemical products to reflect recent safety assessments for the poison scheduling of these products
- reduce red tape by providing the option for renewing chemical product registration for five years instead of only for one year
- remove spent provisions and correct some errors.

### *Documents incorporated by reference*

The Amendment Regulation includes measures that incorporate documents by reference. The incorporated documents are referred to in new Division 3.2 of Part 3 of Schedule 3AA of the Principal Code Regulations. These provisions incorporate the standards and specifications in the *Feed Regulations 1983* of Canada to improve efficiencies in the regulation of animal feed products.

## Background

### *National Registration Scheme*

Agricultural chemicals and veterinary medicines (together, agvet chemicals) are regulated through a cooperative National Registration Scheme (the NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities up to the point of retail sale, is undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) (a Commonwealth statutory authority). The control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The Code Act contains, as a schedule, the Agvet Code. The Agvet Code operates in each State, the Northern Territory and each participating territory (the Australian Capital Territory) to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agvet chemical products (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products; and ensure compliance with and enforcement of the Agvet Code.

***Roles and responsibilities of the APVMA***

The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale. With input from other Commonwealth agencies, the APVMA approves active constituents and registers chemical products, undertakes reconsiderations (reviews) of existing approvals and registrations and monitors compliance with legislative requirements for agvet chemicals up to and including the point of retail sale. The APVMA's regulatory functions are defined by the Administration Act which establishes the APVMA and the Agvet Code.

## PUBLIC CONSULTATION

The Amendment Regulation implement reforms that have been informed by stakeholder consultation that has occurred through industry consultation forums, as well as various discussion papers that the department released during 2014 and 2015. A number of the reforms were suggested by stakeholders to improve the efficiency agvet chemical legislation.

The prospective holder of registration for chemical products containing 4-aminopropiophenone was consulted about the declaration of these products as restricted chemical products.

An exposure draft of the Amendment Regulation was made available for public consultation from 23 October to 5 November 2015. Four submissions were received on the exposure draft of the Amendment Regulation. These submitters supported the measures in the Amendment Regulation, although one submitter requested more flexibility for one of the measures. This additional flexibility could not be provided at this time because of the APVMA's existing system and business processes. This will be reviewed in the next three years to resolve the system and business processes that will provide the additional flexibility.

The APVMA was consulted closely over the requirements for and content of the Amendment Regulation. Relevant state and territory agencies were also consulted on the regulations as part of the public consultation and comments provided were taken into account in preparing these regulations.

## REGULATORY IMPACT ANALYSIS

The Office of Best Practice Regulation (OBPR) was consulted about the measures in the Amendment Regulation and has advised that a Regulation Impact Statement is not required (ID number 18523, 18614, 19403, 19624, 19656, 19697 and 19747).

# HUMAN RIGHTS COMPATIBILITY ASSESSMENT

Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015 (Amendment Regulation) is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### *Overview of the Legislative Instrument*

The Amendment Regulation amends the Principal Code Regulations and the Administration Regulations to:

- simplify the process for varying the formulation of a registered agvet chemical product
- improve efficiency by simplifying the process for registering, or varying, a suite of chemical products
- simplify the process for varying the name of an overseas veterinary chemical product manufacturer
- include another international list of animal feed ingredients to improve efficiencies in the regulation of some animal feed products
- specify that bulk feed that incorporates an excluded animal feed product is not a veterinary chemical product to reduce the regulatory burden for these kinds of products
- declare chemical products containing 4-aminopropiophenone (or para-aminopropiophenone, PAPP) to be restricted chemical products to reflect recent safety assessments for the poison scheduling of these products
- reduce red tape by providing the option for renewing chemical product registration for five years instead of only for one year
- remove spent provisions and correct some errors.

### *Human rights implications*

The Amendment Regulation engages the right to health and a healthy environment (Article 12) in the *International Covenant on Economic, Social and Cultural Rights* (ICESCR). The United Nations Committee on Economic, Social and Cultural Rights has interpreted Article 12 to extend to the underlying determinants of health, including a healthy environment.

#### The right to health and a healthy environment

The Amendment Regulation engages and promotes the right to health in Article 12 of the ICESCR by restricting the substances that may be included as constituents of chemical products. The restrictions limit the constituents to those that are appropriate, having regard to the likelihood that the constituents may impact human health.

#### Other provisions

The Amendment Regulation includes other provisions, including measures about registration renewal but these provisions do not engage any rights.

### *Conclusion*

The Amendment Regulation is compatible with human rights because it is promoting the right to health and a healthy environment through controlling constituents of agvet chemical products.

**The Hon. Barnaby Joyce MP, Minister for Agriculture and Water Resources**

# AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (SIMPLIFIED FORMULATION VARIATIONS AND OTHER MEASURES) REGULATION 2015

## DETAILS OF THE AMENDMENT REGULATION

### Section 1 – Name of Regulation

This section provides that the name of the regulation is the *Agricultural and Veterinary Chemicals Legislation Amendment (Simplified Formulation Variations and Other Measures) Regulation 2015* (Amendment Regulation).

### Section 2 – Commencement

This section provides that Sections 1 to 4 and Schedule 1 commence the day after the Amendment Regulation is registered. This section also provides that the measures in Schedule 2 commence on 1 March 2016 and the measures in Schedule 3 commence on 1 July 2016.

### Section 3 – Authority

This section specifies that the Amendment Regulation is made under the authorities in the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) and the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act).

### Section 4 – Schedules

This section provides that each instrument in a Schedule to the Amendment Regulation is amended as described in the Schedule.

## Schedule 1 – Amendments commencing the day after registration

### *Agricultural and Veterinary Chemicals (Administration) Regulations 1995*

### Items 1 and 3 – Regulations 1A.1 and 1A.3

Items 1 and 3 amend regulations 1A.1 and 1A.3 to replace the term ‘year’ with ‘period’ to reflect the terms used in section 61 of the Administration Act (the authorising section). Section 61 of the Administration Act specifies the annual reporting requirements for the APVMA.

### Item 2 – Regulation 1A.3

Item 2 replaces the incorrect reference to subparagraph 61(2)(c)(ii) of the Administration Act with the correct reference of subparagraph 61(b)(ii). This is a consequential amendment arising from the *Public Governance, Performance and Accountability (Consequential and Transitional Provisions) Act 2014*.

### *Agricultural and Veterinary Chemicals Code Regulations 1995*

### Items 4, 5 and 7 – Subregulations 70A(3) and 77(1) and Schedule 7

Item 7 replaces Schedule 7 to remove the spent 1 July 2014 fee provisions and correct errors in the fees for items 5.6 and 6.3. The fee in item 5.6 has been reduced so that it is the same as the fee in item 5.1. The fee in item 6.3 has been reduced to correct an error. Item 4 is a consequential

amendment arising from the removal of the spent fee provisions in Schedule 7 and item 5 amends subregulation 77(1) so it refers to the correct column in Schedule 7. Section 164 of the Agvet Code provides specific authority for fees to be prescribed in regulations, including the manner and the time in which they are due and payable.

**Item 6 – Schedule 4**

For the authority in section 93 of the Agvet Code, item 6 amends Schedule 4 of the Principal Code Regulations to provide that 4-aminopropiophenone (also known as para-aminopropiophenone or PAPP) is a restricted chemical product. PAPP is an active constituent intended to act as a lethal agent for vertebrates such as foxes and wild dogs. Due to the acute toxicity to humans and non-target species and as specified by subsection 93(2) of the Agvet Code, the APVMA has certified that it is in the public interest to declare products incorporating PAPP as restricted chemical products. This is based on the decision to list PAPP as a Schedule 7 Poison in the current Poisons Standard (another Commonwealth legislative instrument). This amendment means that chemical products containing PAPP must only be supplied by authorised persons and that these products must meet certain labelling requirements (as specified in Division 4 of Part 4 of the Agvet Code).

## Schedule 2 – Amendments commencing 1 March 2016

### Part 1 – Amendments relating to chemical product registration renewals

***Agricultural and Veterinary Chemicals Code Regulations 1995***

**Items 1 to 7 – New regulation 8AFA, subregulation 23(1), new regulation 23A, regulation 71A, new division 10.5.**

Together items 1 to 7 amend the Principal Code Regulations to reduce red tape by providing the option for renewing chemical product registrations for five years instead of only for one year.

The Agvet Code provides that the date a chemical product registration ends is to be worked out in accordance with the method prescribed by the regulations (paragraph 50(2)(b)). Previously, only a one-year period of registration applied because a method had not been prescribed (see subsection 50(3) of the Agvet Code). The amendments provide for holders of chemical product registration to be able to nominate either a one-year or a five-year registration renewal period. This option does not apply to a registration that is subject to the condition mentioned in subsection 23(2) of the Agvet Code (where a registration is for a one-year period).

For the authority in subparagraph 8A(a)(v) of the Agvet Code, item 1 inserts new regulation 8AFA to require an applicant for renewal of registration to nominate whether the renewal is for a period of one year or five years.

Item 2 amends regulation paragraph 23(1)(b) to clarify the circumstance where the fee for a late application for renewal of registration in subregulation 23(2) applies. The fee applies to a late application where the applicant requests the APVMA to accept a late application after the end of the period for making an application referred to in subsection 48(2) of the Code, and before the registration ends, and if the APVMA agrees to that request.

For the authority in paragraph 50(2)(b) of the Agvet Code, item 3 inserts new regulation 23A that specifies the method for working out when renewed registration ends. Depending on what renewal

period the applicant has nominated in the application for renewal of registration, the method provides for the registration to end either five years or 12 months after the date on which the registration would otherwise end.

For the authority in subsection 164(1) of the Agvet Code, item 5 amends subregulation 71A(1) to provide that the fee for an application for renewal of registration is $430 where the applicant nominates a one-year renewal period and $2150 where the applicant nominates a five-year renewal period. The fee for a one-year renewal period is unchanged and the fee for the five-year renewal period is five times the fee payable for a one-year renewal. Item 4 amends the heading for regulation 71A because the fees in the regulation for renewal are not necessarily 'annual' fees.

For the authority in subsection 164(1) of the Agvet Code, item 6 substitutes subregulation 71A(5) to provide that the overseas GMP compliance assessment fee 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. This approach is administratively simple and is consistent with the licence fee approach in subregulation 72A(7). The amendment is necessary to allow the overseas GMP compliance fee to continue to be paid annually, even though renewal of registration may be for a period of either one year or five years. The amount of the overseas GMP compliance assessment fee is unchanged. The overseas GMP compliance assessment fee continues to be payable for each site outside of Australia at which the registered veterinary chemical product is manufactured or each site outside of Australia at which a step in the manufacture of the registered veterinary chemical product occurs.

Item 6 also inserts a new provision (subregulation 71A(6)) to clarify that holders of registrations that are suspended or cancelled (on the initiative of either the APVMA or the holder of registration) are not eligible for any rebate of any renewal application fee.

Item 7 inserts new Division 10.5 (and new regulations 90 and 91) to specify that the amendments in items 1 to 6 apply to renewal, or further renewal of, a product registration where the registration of the product is to end on, or after, 30 June 2017. This new division is no longer required after 30 June 2017 and regulation 91 repeals the division on 1 July 2017.

**Part 2 – Other amendments**

***Agricultural and Veterinary Chemicals Code Regulations 1995***

**Item 8 – Regulation 19AF**

Item 8 amends the table to regulation 19AF to add a new kind of prescribed variation that will simplify the process for varying the name of a chemical product manufacturer. For the authority in paragraph 26B(4)(b) of the Agvet Code, regulation 19AF specifies the prescribed variations for which Division 2A of the Agvet Code applies. Division 2A of the Agvet Code is a simplified process for holders to apply to vary prescribed relevant particulars of approval and registration.

The amendment provides that the variation to the particulars of the name of a manufacturer of a chemical product is a prescribed variation if the address of the manufacturer is located outside of Australia. This does not apply to a chemical product prescribed under subregulation 59(1) as variations to the name of the manufacturer for these products are already provided for as notifiable variations in regulation 19AE. This additional prescribed variation for chemical products, which are not prescribed under subregulation 59(1), is similar to existing prescribed variations of the name of each Australian manufacturer for the same chemical products.

Where the only particular to be changed is the name of the manufacturer, it is possible to establish continued quality assurance through a review of international regulatory material that accompanies the application. This is controlled by the APVMA under subparagraph 8A(a)(v) of the Agvet Code (application requirements), and the related instrument for section 8B of the Agvet Code (information to be provided with applications). Prescribing this kind of variation improves efficiency by simplifying the processes for varying this particular.

**Item 9 – new subregulation 76(1B)**

For the authority in subsection 165(1) of the Agvet Code, item 9 inserts a new subregulation 76(1B) to improve efficiency by simplifying the process for registering, or varying the particulars of, a suite of chemical products. This reform provides applicants with the ability to link applications and decision dates on those applications to concurrent decisions on registration, or variations of particulars, of a suite of products.

Industry may make several applications for a suite of products containing the same chemical in different concentrations. Examples of suites of agvet chemical products are products with the same active constituent but different formulation types (granule, powder and concentrate) or a product range for large, medium and small dogs. For efficiency, the data for these applications are assessed once with the primary application and not reassessed for the related applications (secondary applications).

APVMA application timeframes and fees are proportionate to the assessment effort required. In circumstances where a secondary application relied on data contained in a primary application, and where satisfaction about the secondary application was being drawn from the primary application, then the determination timeframe was less for the related secondary application. However, this process meant that the APVMA must either exceed a statutory timeframe or refuse the second application as it could not be satisfied of the statutory criteria until the assessment of the primary application was complete.

The new measure in subregulation 76(1B) addresses this problem by providing for applicants to nominate an application (a secondary application) as a related application to another application (the primary application) and so to align the period within which the secondary application is to be determined with the timeframe for the primary application. The amendment means that the period for determining the secondary applications is coupled to that of the primary application, nullifying the period that would otherwise apply to those secondary applications if they stood alone. Both applications can then be determined by the same date. The date for determining secondary applications remains coupled to that of the primary application if an extended assessment period is applied to the primary application. An applicant may only nominate an application as a related application if both the related and primary applications have the same particulars recorded in the Register of Chemical Products as set in paragraph 76(1B)(e). In addition, the primary application and the related application must be the same kind of application, that is, made under the same section of the Agvet Code. For example, this provision does not apply if a person makes a primary application mentioned under section 27 and a related application under section 10.

**Items 10 and 11 – Part 3 of Schedule 3AA**

Item 10 inserts a new item 1 in the table to clause 3 of Part 3 of Schedule 3AA. Paragraph 5(4)(b) of the Agvet Code provides for a substance or mixture of substances to be declared by the regulations

not to be a veterinary chemical product. For this authority and as specified by subregulation 8(2), the substances listed in Division 3.1 of Part 3 of Schedule 3AA are substances declared not to be veterinary chemical products. These 'excluded substances' are not subject to the requirements in the Agvet Code.

The new table item inserted by item 10 relates to an animal feed product that incorporates a nutritional or digestive product that is an excluded nutritional or digestive substance (see Division 3.2 of Part 3 of Schedule 3AA). This new measure means that animal feed products that incorporate these excluded nutritional or digestive substances are also excluded substances and therefore not subject to the Agvet Code. This measure ensures that the regulatory burden experienced for these products is proportional to their risk. Where a substance is excluded then subsequent products are also excluded if they incorporate that substance and have claims consistent with that substance. This exclusion only applies if:

- the animal feed product is labelled in accordance with the instructions on the label for the container for the nutritional or digestive product; and
- the nutritional or digestive product has been incorporated at a rate of use in accordance with the label for the container for the nutritional or digestive product; and
- the claims for the animal feed product do not exceed those made for the incorporated nutritional or digestive product.

Item 11 inserts a new entry in the table to subclause 5(3) of Part 3 of Schedule 3AA to include an additional reference for ingredients that are permitted in excluded nutritional or digestive substances. These 'excluded substances' are not subject to the requirements in the Agvet Code. This reference is in addition to the eight prescribed lists of ingredients that are currently permitted in excluded nutritional or digestive substances. The new reference is for the substances listed in Part 1 of Schedules IV and V to the Feeds Regulations of Canada, as at the time of the supply of the substance. The effect of this amendment is to specify additional ingredients (those in Part 1 of Schedules IV and V to the Feeds Regulations of Canada) that may be present in these excluded nutritional and digestive substances, so that substances containing only these ingredients are not subject to the Agvet Code. As authorised by subsection 6(3) of the *Agricultural and Veterinary Chemicals Code Act 1994*, and as specified in subregulation 3(2), the reference to ingredients in Part 1 of Schedules IV and V to the Feeds Regulations of Canada applies as modified or amended from time to time.

## Schedule 3 – Amendments commencing 1 July 2016

Chemical manufacturers have advised that significant effort is expended in making routine applications to the APVMA to amend mundane information about the constituents of products. Often changes are made only to respond to changes in supply arrangements for chemical manufacturers and have no effect on the safety or efficacy of the product. The measures in this Schedule provide a streamlined mechanism to allow substitution of non-active constituents in the formulation of a registered chemical product in limited circumstances. This is achieved through prescribing an additional 'notifiable variation' and a new kind of 'prescribed variation', so that the simplified processes in Division 2AA and Division 2A of the Agvet Code apply to these variations.

*Agricultural and Veterinary Chemicals Code Regulations 1995*

**Items 1, 3, 4, 6, 7 – Subregulation 3(1), subregulation 19AE, new regulations 19AEA, 19AEB, 19AEC, paragraph 78C(c), Part 2 of Schedule 6**

Items 1, 3, 4, 6 and 7 insert new measures into the Principal Code Regulations to provide for simplified formulation variations. For the authority in paragraph 26AB(3)(a)(ii) of the Agvet Code, this is achieved by introducing a new kind of 'notifiable variation' for some particulars of a chemical product registration. Division 2AA of the Agvet Code specifies how notifiable variations of relevant particulars are made and is a simplified process for varying the particulars of an approval or registration. The prescribed notifiable variations allow for formulation changes to be made to a chemical product where these changes do not require an assessment by APVMA. The permitted formulation changes relate to the substitution of certain non-active constituents only and only for a certain number of constituents.

The variations are implemented through the APVMA maintaining a list of interchangeable constituents – interchangeable constituent determinations – which allows holders of registration to substitute constituents according to this list and notify the APVMA of the change through a notifiable variation under the simplified processes for variation in Division 2AA of the Agvet Code.

Item 1 inserts a new definition of 'interchangeable constituent determination'. Item 3 inserts a new kind of notifiable variation in the table to regulation 19AE to allow the variation of one or more constituents of a chemical product. The constituents to be varied must be listed in an interchangeable constituent determination made by the APVMA. In addition, the number of constituents that can be varied is limited to two in the case of products containing less than nine constituents, or a number that is no more than 25 per cent of the number of constituents in the case of products containing nine or more constituents. This restriction is to prevent a large number of constituents being varied and to ensure that these notifiable variations do not affect the APVMA's satisfaction about whether the product continues to meet the safety criteria, trade criteria, efficacy criteria and labelling criteria.

Item 4 inserts new regulations 19AEA, 19AEB and 19AEC into the Principal Code Regulations. Collectively, these new regulations provide for the making, varying and revoking of interchangeable constituent determinations, including on application from any person, as well as limits on the information used for interchangeable constituent determinations. These determinations are relevant for the new prescribed kind of notifiable variation that streamline formulation changes (item 3 above).

Regulation 19AEA provides that the APVMA may determine, by legislative instrument, that one or more constituents of a chemical product or class of chemical products may be interchanged with another constituent. Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. Regulation 19AEA therefore provides for the APVMA to make, vary or revoke interchangeable constituent determinations, including requirements that apply where a constituent is being interchanged.

In an interchangeable constituent determination, the APVMA may specify conditions on the interchange of the constituents (for example, to restrict the interchange to constituents fulfilling a particular purpose in the product) if that is reasonably necessary to ensure the chemical product continues to meet the safety, efficacy, trade and labelling criteria. The APVMA must be satisfied of

certain matters before making or varying an interchangeable determination and these are specified in subregulation 19AEA(5). Where the APVMA proposes to vary or revoke an interchangeable constituent determination, the APVMA must publish a notice about the variation or revocation, and seek and consider any submissions. Regulation 19AEA specifies the publication requirements when the APVMA makes, varies or revokes an interchangeable constituent determination.

Regulation 19AEB provides for any person to apply to the APVMA for the making of an interchangeable constituent determination, and specifies the application requirements for these applications. These application requirements are in addition to those in the Agvet Code and a note has been included at the end of subregulation 19AEB(5) to inform potential applicants of these Agvet Code application requirements. Regulation 19AEB also specifies that the applicant must be notified of the interchangeable constituent determination within 14 days of the APVMA making the determination.

Regulation 19AEC provides for limits on the use of information for the making, variation and revocation of interchangeable constituent determinations. These measures provide for the APVMA to require information to be provided so that it may determine an application under regulation 19AEB, as well as authorising the APVMA to take into account results, decisions and information in overseas trials and experiments. The measures in Regulation 19AEC also limit the APVMA to considering information given in connection with the application or a decision made on the application. These measures are similar to those that apply for other applications under the Agvet Code. In addition, the measures provide for a limitation period of three years to apply to certain information if that information is used to make, vary or revoke an interchangeable constituent determination.

For the authority in paragraph 167(1)(y) of the Agvet Code, item 6 amends regulation 78C to provide that the refusal of an application under regulation 19AEB (for an interchangeable constituent determination) is a reviewable decision (both internally by the APVMA and by the Administrative Appeals Tribunal).

For the authorities in subsections 164(1) and 165(1) of the Agvet Code, item 7 amends the table in Part 2 of Schedule 6 to specify that the assessment period for an application under regulation 19AEB is the modular assessment period, and the fee is the modular assessment fee. The amendment also provides that the extended assessment period is one and one third of the modular assessment period, rounded up to the nearest whole month, plus a month (similar to the existing item 28). There is no rebate for pre-application assistance.

**Items 2 and 5 – Regulation 19AF, new regulation 8AFB**

For the authorities in subparagraph 8(a)(v) and paragraph 26B(4)(b) of the Agvet Code, items 2 and 5 insert a new kind of ‘prescribed variation’ in regulation 19AF and specify an additional application requirement that applies to applications for these prescribed variations. For the authority in paragraph 26B(4)(b) of the Agvet Code, regulation 19AF specifies the prescribed variations for which Division 2A of the Agvet Code applies. Division 2A of the Agvet Code is a simplified process for varying relevant particulars of approval and registrations. The insertion of the new kind of prescribed variation means that a simplified process applies for varying (replacing) certain constituents in chemical products.

Item 5 amends regulation 19AF to insert a new kind of prescribed variation that allows constituents in a chemical product to be replaced if the original and replacement constituents meet certain

requirements. These requirements include that these constituents are not active constituents, have the same purpose in the product and meet certain technical or compositional requirements. In addition, the prescribed variation does not apply where the replacement of the original constituent requires the signal words required by the current Poisons Standard for the product to be varied. Furthermore, the number of constituents that can be replaced is limited to two in the case of products containing less than nine constituents, or a number that is no more than 25 per cent of the number of constituents in the case of products containing nine or more constituents. This restriction is to prevent a large number of constituents being varied and to ensure that these prescribed variations do not affect the APVMA's satisfaction about whether the product continues to meet the safety criteria, trade criteria, efficacy criteria and labelling criteria. The prescribed variation does not apply if the chemical product is an immunobiological or antibiotic product or the product is to be administered through direct injection into an animal.

For the authority in subparagraph 8A(a)(v) of the Agvet Code, item 2 inserts new regulation 8AFB to specify the additional application requirements that apply for the new kind of prescribed variation. These requirements specify that the applicant must hold certain evidence about the product, including its storage stability and physical properties. This information is relevant to managing the risks of the replacement constituent to the safety to people, animals, plants or the environment or Australia's trade or the product efficacy.