AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT REGULATION 2014

Select Legislative Instrument No. 67, 2014

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994
Agricultural and Veterinary Chemicals Code Act 1994
Agricultural and Veterinary Chemicals (Administration) Act 1992
Agricultural and Veterinary Chemicals Legislation Amendment Act 2013

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Agriculture

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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 Agvet Code (a Schedule to the Code Act) 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.

Subsection 39(1) of the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) provides that the Governor-General may make regulations prescribing matters required or permitted by this Act to be prescribed; or necessary or convenient to be prescribed for carrying out or giving effect to this Act; and, in particular, prescribing the way in which notices may be given by or to the Australian Pesticides and Veterinary Medicines Authority (APVMA) (a Commonwealth authority) under the Collection Act. Section 12C of the Collection Act provides specific authority to prescribe rates of levy in regulations.

Section 73 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* provides that the Governor-General may make regulations prescribing all matters required or permitted by this Act to be prescribed; or necessary or convenient to be prescribed for carrying out or giving effect to this Act. Section 6 of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (2013 Amendment Act) provides for prescribed reviews for section 5 of the Amendment Act.

The legislation above also includes other provisions that provide specific authorities for matters to be prescribed in regulations. These authorities are specified in the particular regulation amendment in this explanatory statement.

Section 4 of the *Acts Interpretation Act 1901* applies to some provisions in the Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014 (Amendment Regulation). However, exercising the power to make regulations does not confer a power or right or impose an obligation on a person before 1 July 2014, except in so far as is necessary or convenient to bring the Amendment Regulation into effect or to make the 2013 Amendment Act conferring power fully effective on 1 July 2014. In addition, the provisions in the Amendment Regulation do not commence until after the 2013 Amendment Act commences on 1 July 2014.

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
2013 Amendment Act	*Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*
2013 Amendment Regulation	Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013
agvet chemical	agricultural chemical and veterinary medicine
Agvet Code	Schedule to the Code Act (see below)
CEO	Chief Executive Officer of the APVMA
Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Gazette	APVMA Gazette
Collection Act	*Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*
LI Act	*Legislative Instruments Act 2003*
Minister	Minister for Agriculture
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
Principal Administration Regulations	Agricultural and Veterinary Chemicals (Administration) Regulations 1995
Principal Code Regulations	Agricultural and Veterinary Chemicals Code Regulations 1995
Principal Levy Regulations	Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995
reconsideration	A reconsideration of an active constituent or label approval or chemical product registration, known widely as a chemical review

OUTLINE

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act), *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) are collectively referred to as 'agvet chemical legislation' throughout this explanatory statement.

Amendments made

The Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014 (Amendment Regulation) amends the following regulations that may be made under agvet chemical legislation:

- Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations)
- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Principal Administration Regulations)
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations)
- Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013 (2013 Amendment Regulation).

Purpose of amendments

The Amendment Regulation amends regulations made under agvet chemical legislation to:

- clarify that reduced levy rates apply to levies payable in respect of leviable disposals in the 2013-2014 financial year and that goods and services taxation applies to fees for pre-application assistance and technical assessments
- reduce red tape by removing annual returns about active constituents not made into products
- specify the information to be lodged with the Australian Pesticides and Veterinary Medicines Authority (APVMA) in electronic form
- make minor technical amendments to improve implementation of existing measures
- address minor issues that have been identified with the regulations, including removing redundant provisions, clarifying existing requirements and addressing some errors.

Documents incorporated by reference

The Amendment Regulation does not include any measures that incorporate new documents by reference.

Background

National Registration Scheme

Agricultural chemicals and veterinary medicines (together, agvet chemicals) are regulated through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals (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 authority). Control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The Code Act contains as a schedule to it, the Agvet Code. Under the NRS, the Agvet Code operates, with the Agvet Code of each participating territory (that is, each State and the Northern Territory) to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agricultural and veterinary 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 government agencies, the APVMA approves active constituents and registers chemical products, undertakes reconsiderations (reviews) of existing approvals and registrations and monitors the compliance of approvals and registration 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 Code Act, together with its scheduled Agvet Code, which provides detailed operational procedures on the registration and management of agvet chemicals.

PUBLIC CONSULTATION

The details of the regulations in the Amendment Regulation were released for public consultation from December 2013 to 7 March 2014. Comments from submitters have been taken into account in preparing these regulations. These comments have resulted in the definition of 'timeshift application' being extended to provide for more flexibility for complex applications and to support innovation in product development.

Following consultation, further amendments were necessary to clarify that an application for pre-application assistance or a technical assessment attracts goods and services tax (GST) (items 68, 99 and 100), and to promote transparency about reconsiderations of label approvals (item 54).

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 Amendment Regulation clarifies reductions in the rates of levies payable consistent with an approved Cost Recovery Impact Statement (CRIS) that is accessible at <http://www.apvma.gov.au/about/work/cost_recovery.php>.

The other amendments provide for red tape reduction and provision of information to the APVMA in electronic form. Additional amendments address typographical errors, make minor technical amendments to improve the readability and interpretation of provisions, and clarify existing measures without substantially altering the existing regulatory arrangements. The Office of Best Practice Regulation was consulted and advised that the measures were machinery in nature and that no further regulatory impact analysis was required (ID 16147).

HUMAN RIGHTS COMPATIBILITY ASSESSMENT

Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014

The Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014 (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 following regulations that may be made under agvet chemical legislation:

- Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations)
- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Principal Administration Regulations)
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations)
- Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013 (2013 Amendment Regulation).

These regulations require amendment to:

- clarify that reduced levy rates apply to levies payable in respect of leviable disposals in the 2013-2014 financial year
- specify that information is to be lodged with the Australian Pesticides and Veterinary Medicines Authority (APVMA) in electronic form
- make minor technical amendments to give full effect to earlier reform measures
- address minor issues that have been identified with the regulations, including removing redundant provisions, clarifying existing requirements and addressing some errors.

Human rights implications

This Legislative Instrument does not engage any of the applicable rights or freedoms.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT REGULATION 2014

DETAILS OF THE AMENDMENT REGULATION

Section 1 – Name of Regulation

This section provides that the name of the Amendment Regulation is the Agricultural and Veterinary Chemicals Legislation Amendment Regulation 2014 (Amendment Regulation).

Section 2 – Commencement

This section provides that Sections 1 to 4 commence the day after this regulation is registered. The measures in Schedule 1 commence immediately after the Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013 (2013 Amendment Regulation) commences on 1 July 2014. The measures in Schedule 2 commence immediately before the 2013 Amendment Regulation commences.

Section 3 – Amendment of regulations for agricultural and veterinary chemicals legislation

This section specifies the agvet legislation that authorises the amendments done by this instrument to the following regulations:

- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations)
- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Principal Administration Regulations)
- Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations).
- 2013 Amendment Regulation

Section 4 – Schedules

This section specifies that the amendments in Schedules 1 and 2 apply to the items in the Schedule according to the items. In Schedule 1:

- items 1 to 5 amend the Principal Levy Regulations
- items 6 to 10 amend the Principal Administration Regulations
- items 10 to 103 amend the Principal Code Regulations

In Schedule 2, item 1 amends the 2013 Amendment Regulation to correct a typographical error.

Schedule 1 – Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995

Removing redundant provisions

Items 1 and 5 – Regulation 3 and Schedule 1

These items remove redundant regulation 3 and Schedule 1 of the Principal Levy Regulations, which, for the purposes of levies, specified the laws that chemical products were registered under prior to commencement of the Schedule to the *Agricultural and Veterinary Chemical Code Act 1994* (Agvet Code). These provisions are no longer necessary as all chemical products are now registered chemical products under the Agvet Code.

Reductions in levy rates

Items 2 to 4 – Subregulations 6A(3) and (4)

The *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) defines a 'leviable disposal'. For the authority in section 12C of the Collection Act and consistent with the approved cost recovery impact statement, these items clarify that reduced levy rates apply to levies payable in respect of leviable disposals in the 2013-2014 financial year. This ensures clarity as to the original intention of the amendments made to the Principal Levy Regulations on 1 July 2013 by the Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No.1) Regulation 2013, which inserted subregulations 6A(3) and (4).

Item 2 amends subregulation 6A(3) to specify that the rates of the levy in this subregulation only apply to leviable disposals in the 2012-2013 financial year.

Items 3 and 4 specify that the lower rates of the levy in subregulation 6A(4) apply to leviable disposals in the 2013-2014 financial year. Until any variation of these rates in the future, the rates of the levies in subregulation 6A(4) also apply to leviable disposals in succeeding financial years. The reduction in these levy rates is a consequence of changes to application fees that were made in 2013.

Schedule 1 – Agricultural and Veterinary Chemicals (Administration) Regulations 1995

Requirements to improve implementation of existing measures

Item 6 – Regulation 1A.3

For the authority in subparagraph 61(2)(c)(ii) of the Administration Act, item 6 inserts a new paragraph in regulation 1A.3 that specifies an additional performance indicator for inclusion in the APVMA annual report. These performance indicators currently include information on reconsiderations, applications determined within prescribed timeframes and information about adverse experience reports. As a transparency measure, the new paragraph inserted by item 6 requires the APVMA to report a summary of any action that it takes under section 99 of the Agvet Code. Section 99 of the Agvet Code provides for the APVMA to require a person to have a substance or mixture of substances analysed for compliance with prescribed standards or requirements.

Reducing red tape

Item 7 – Regulation 4.10

This amendment reduces the regulatory burden on importers, exporters and manufacturers of agvet chemical products by reducing annual reporting requirements for certain active constituents. For the authorities in subsection 69E(2) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act), the amendment replaces the existing regulation to exempt active constituents from annual reporting requirements if these active constituents are not made into or included in chemical products. This information is not necessary for the national scheme for regulating agvet chemical products and removing the obligation reduces the regulatory burden on importers, exporters and manufacturers. Annual returns will still be required on the quantities of active constituents made into chemical products that are imported, exported or manufactured in Australia.

Removing redundant or incorrect provisions

Items 8 to 10 – Part 2 of Schedule 1

Item 9 amends the entry for mirex in item 39 of Part 2 of Schedule 1so that prohibitions and conditions on its use are the same as for other organochlorine substances. Subsection 69C(1) of the Administration Act provides for regulations to prescribe international agreements. The Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention) and Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (Rotterdam Convention) are currently prescribed. Section 69C(2) of the Administration Act provides for regulations to prohibit certain activities for a controlled chemical under these international conventions. Part 3 and Schedule 1 of the Administration Regulations prescribe the conditions and restrictions that apply for each controlled chemical.

Item 9 amends the out of date entry for 'mirex' as the use of this substance as a termiticide in accordance with Australia's use-specific exemption under Article 4 of the Stockholm Convention is no longer applicable. The amendment provides that mirex is subject to the same conditions and restrictions as other organochlorine substances in Part 2 of Schedule 1 (for example, hexachlorobenzene, aldrin, chlordane etc), including prohibitions on manufacture and use.

Section 69C specifies that before regulations are prescribed for controlled chemicals a notice must be published in the *Gazette* identifying the arrangement and listing the constituent or product. As required by section 69C, a notice was published in the *APVMA Gazette No.* 9 on 5 September 2006, advising the removal of Australia's exemption for mirex under the Stockholm Convention. The Australian Pesticides and Veterinary Medicines Authority cancelled the registration of mirex effective as of 31 January 2007 (published in the *Commonwealth of Australia Special Gazette No. S27* on 5 February 2007) following the Northern Territory government's decision to cease the use of mirex as there was no longer a need for it.

Items 8 and 10 amend items 31 (methazole) and 70 (tribufos) in Part 2 of Schedule 1 to remove the reference to "Subject to notification of final regulatory action by Australia". This reference is unnecessary given that Australia has determined and notified its final regulatory action for these substances. The amendment is an administrative correction as the final regulatory action for methazole undertaken by Australia came into force on 31 March 1996, and for tribufos the final regulatory action undertaken by Australia came into force on 30 June 1997. A notice under section 69C of the Act was published in the *Commonwealth of Australia Gazette no. APVMA 6* on 1 June 2004, for the list of chemicals subject to the Rotterdam Convention including methazole and tribufos. No further gazettal notice is required for the amendments for methazole and tribufos in the Amendment Regulation because the amendments only serve as an administrative correction to remove a condition that is not applicable for these two substances.

Schedule 1 – Agricultural and Veterinary Chemicals Code Regulations 1995

Improving efficiency by requiring electronic lodgement of information and fees

Items 59 to 63, 66, 73 and 74 – Regulations 65 and 74 and new regulations 69A and 73A

Items 59 to 63 amend regulation 65 and items 66, 73 and 74 insert new regulations 69A and 73A and omit regulation 74. These amendments provide for the electronic lodgement of information and fees to the APVMA. For the authority in subsection 156A(2) of the Agvet Code, regulation 65 specifies the information that must be given to the APVMA in electronic form. For the authority in subsection 164(1) of the Agvet Code, new regulation 73A specifies the fees for converting information into electronic form. For the authority in subsection 164(2) of the Agvet Code, new regulation 69A specifies the form in which fees are to be provided to the APVMA.

Item 63 inserts new subregulation 65(2) which specifies that all approved forms for applications must be given to the APVMA in electronic form. Requiring these application forms to be provided in an online electronic form assists applicants by ensuring that all application form information is included in the application when it is given to the APVMA. In addition to reducing the potential for mistakes and errors in applications, this measure also improves the APVMA's efficiency in managing applications.

APVMA approved forms for applications are all accessible forms. Persons with special needs (for example, vision impairment) can use these forms to make an application to the APVMA. Items 60 to 62 are editorial amendments to align the descriptions of information in regulation 65 with those in regulation paragraphs 8B(2)(g), 8D(2)(i) and 19AD(2)(i). Item 59 is an editorial amendment.

Item 73 inserts regulation 73A that applies from 1 July 2015. New regulation 73A provides for the application information, other than approved forms, to be provided to the APVMA in a form other than electronic form and for this to be converted into electronic form for a fee. This provides flexibility for applicants who may wish to use the APVMA's information technology hardware or software to convert their own information into a suitable electronic format. The fee is the same as the fee for copies and extracts in regulation 73. Fees must be provided within 14 days so the APVMA can deal with applications in the prescribed timeframes.

Item 66 inserts new regulation 69A that requires all fees to be paid by electronic means, for example, electronic funds transfer, billpay or credit card. This is intended to provide for a more secure and convenient means of transferring funds. This also delivers increased efficiency in the management of applications. Item 74 omits regulation 74 as the matters dealt with by this regulation are now in new regulation 69A which is more appropriately located at the beginning of the division in the Principal Code Regulations that deals with fees.

Requirements to improve implementation of existing measures

Items 19, 52 to 54, 56 to 57, 64 to 65, 78 to 81, 91 and 92 – Regulations 3, 22AA, 65, 74, 81, 80E to 80F and new regulation 65B

Item 19 amends the definition of a 'timeshift application' to extend the scope for these applications by including a third type of application. This type of application would be an application for registration of a chemical product containing a previously endorsed active constituent but for which a full assessment of the chemical product is required. The purpose of this amendment is to provide for a more flexible approach for applications which relate to new products and innovative ways of using existing active constituents (that is, previously endorsed active constituents). A timeshift application requires agreement between the APVMA and the applicant about a project plan for the application. This ensures that timeshift applications are still efficiently progressed but that flexibility may be provided about how these applications are assessed and determined (for example, flexibility about the timeframes that apply to assessing these applications). Item 91 is a consequential amendment to Part 2 of Schedule 6, as a result of the amendment to the definition of 'timeshift application'.

For the authority in subsection 34AF(1) of the Agvet Code, items 52 and 53 amend regulation 22AA to clarify that the matters in regulation paragraphs 22AA(a) and 22AA(b) are separate prescribed matters for the purposes of subsection 34AF(1) of the Agvet Code. This ensures that, as originally intended, the APVMA is able to reconsider a label approval for any of the matters in paragraphs (a) or (b) of regulation 22AA without going through the reconsideration process set out in Division 4 of Part 2 of the Agvet Code.

Item 54 amends regulation 22AA to limit the matters that the APVMA is able to reconsider for a label approval without notification. As a transparency measure, the amendment removes the labelling criteria matter that has been determined by the APVMA CEO under subregulation 8AE(2) so that the matters are limited to those in regulation paragraphs 8AE(1)(a), (b), (c) and (d). This means that

where a labelling criteria matter was determined by the APVMA (in regulation paragraph 8AE(1)(e)) then the APVMA will not be able to reconsider the label approval without going through the reconsideration process described in Division 4 of Part 2 of the Agvet Code.

Items 56 and 57 replace the specific names of established standards for listed chemical products with generic reference to the 'established standard' for these products. The term 'established standard' is defined in the Agvet Code and can therefore be used to define the standards applicable to these products. These amendments mean that the regulations do not need to be updated each time the name of the established standard changes.

For the authority in subsection 159(1AA), item 65 inserts a new regulation 65B which deals with the period to respond to a notice under section 159 to provide information, reports or samples where the APVMA is considering suspension or cancellation of an approval, registration or permit. A period of 28 days is prescribed. The APVMA need not issue a section 159 notice when considering suspension or cancellation but if it does then prescribing this period ensures that any response must be provided within a limited period. The APVMA may require a response in a shorter period where circumstances dictate (for example, where a health concern has been identified). Item 64 includes a heading for the existing regulation 65A.

Prescribed Reviews

Items 78 to 80 amend the reviews prescribed to be undertaken by the regulations on specific matters. Item 78 amends the review prescribed for reconsideration participation (regulation 80D) to move the reporting date back to 30 June 2017 and to allow more time for this review to be conducted. Item 79 amends the review prescribed for work health and safety duplication (regulation 80E) to move the reporting date back to 30 September 2016 and to allow more time for this review to be conducted. Item 80 omits regulation 80F which dealt with the review prescribed for minor use because this is no longer necessary.

Re-registration Scheme Notice Periods

For the authority in subitem 58(1) of Part 2 of Schedule 6 of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (2013 Amendment Act), item 81 modifies the requirements in section 47B of the Agvet Code for approvals that end on 30 June 2015 and registrations with last renewal dates of 30 June 2015 (in regulation 81). The purpose of these modifications is to provide for an orderly introduction of the re-registration scheme. The modifications provide for shorter notice periods for holders and submitters for section 47B of the Agvet Code. This is to allow the APVMA more time to issue notices for the end of approvals and last renewal dates for registrations.

The approvals that end on 30 June 2015 and the last renewal dates of 30 June 2015 for registrations are already prescribed in regulation 81. There is therefore no detriment to the community or holders of approval and registration with the shorter notice period because the end dates and last renewal dates for these active constituents and products containing them are already public knowledge.

The modifications are that the notice in the *Gazette* for subsection 47B(1) about the end of an approval or last renewal date for a registration must be published before 1 January 2015. This amendment means that a minimum of six months notice will be provided to the community and holders of approval and registration, instead of 12 months notice. The modifications also include that the invitation for public submissions in subsection 47B(2) of the Agvet Code must specify that submissions must be provided no later than 1 April 2015, instead of six months before approvals end. This ensures that the APVMA has sufficient time to consider the issues in submissions before determining applications from 1 July 2015. To align with the *Gazette* notice modifications for subsection 47B(1), an additional modification is to the operation of subsection 47B(3), where the APVMA must give the holder of approval or registration six months notice of the end of an approval or date after which the registration cannot be renewed, instead of providing 12 months notice.

New Application Category

Item 92 inserts a new category of application to account for applications for approval of a label for containers for a registered chemical product. It has the same modular assessment fees as would have applied if such an application had been part of a registration of a chemical product. This new category specifically provides for these applications to assist potential applicants.

Clarifying existing requirements

Items 14 to 16, 23, 25, 27, 29 to 38, 42 to 45, 47, 48, 51, 55, 67 to 72, 85, 86, 99 to 103 – Regulations 3, 3A, 3B, 8AF, 8AN, 8AO, 8AQ, 8AP, 18B, 18D, 18F, 18J, 20, 42, 69B, 70, 70A, Schedules 6 and 7 and new regulation 8AHA

Item 14 amends the definition of 'identifying information' so that the person's name is only required if the person is an individual. If the person is a body corporate the APVMA would only need to know the trading name.

Items 15 and 16 insert a new definition of 'labelling standard' and a signpost for 'lodged' to assist in interpreting the Principal Code Regulations.

Items 23 and 25 clarify that regulations 3A and 3B extend to constituents and products that have been approved or registered.

Item 27 amends regulation 8AF to clarify that the standards referred to in the regulation are those authorised by section 6E of the Agvet Code.

Items 29 and 42 consolidate the labelling standards matters into regulation 8AF by omitting regulation 18A in subdivision 2.1.5 and including the requirements for a labelling standard in previous regulation 18A in subregulation 8AF(4).

Notices for Label Approvals

Items 30 and 31 insert new regulation 8AHA and amend regulation 8AN to more appropriately provide for the APVMA to publish notices about approvals of a label for containers for a chemical product and variations to these approvals. For the authority in paragraph 6(2)(h) of the Code Act, new regulation 8AHA provides for the APVMA to publish notices about approvals and variations for labels in the same way as sections 8H and 8J of the Agvet Code provide the authority in relation to notices about active constituent approvals and chemical product registrations. Including this regulation then allows regulation 8AN to specify the matters that these required notices must contain.

Other Clarifications

Items 32, 43, 55 and 72 amend regulations 8AO, 18B, 42 and 73 to use the more appropriate wording of 'prescribes' or 'prescribed' in the regulations.

Items 33 and 38 insert references to section 161 of the Agvet Code in regulations 8AO and 8AQ so that notices to applicants include information about an applicant's ongoing obligations under section 161.

Items 34 and 36 are editorial amendments to align the formats of regulations 8AP and 8AQ with the format in regulation 8AO.

Item 35 clarifies that the obligations on the APVMA in regulation 8AQ apply within one month of the application being lodged (rather than when it is received).

To ensure consistency with other notices for applications, item 37 amends regulation 8AQ to require the APVMA to advise applicants that the assessment period for the application may be extended if a request is made under section 159 of the Agvet Code for additional information, reports or samples.

Items 44, 45 and 47 amend regulations 18D and 18F to clarify that the information to be included on the label is the label information recorded in the relevant APVMA file. The amendment specifies that only the information in the relevant APVMA file for subparagraphs 21(c)(iii) and (iv) is required to be included in a label. The previous regulation 18D required all relevant particulars to be included in a label and unintentionally this included the nominated agent. The amendments refine the matters to be included in a label and clarify that the nominated agent does not need to be included in a label.

Item 48 clarifies regulation 18J to specify that it is the 'nominated agent' to which the regulation applies.

For consistency, item 51 amends regulation 20 to align the wording in the regulation with the wording used in section 31 of the Agvet Code.

Items 67 and 68 amend regulation 69B which deals with pre-application assistance, including the fees that apply for this assistance. Item 67 removes the unnecessary provision (subregulation 69B(2)) that required the APVMA to make a legislative instrument about units of pre-applications assistance, as subsection 164(1A) of the Agvet Code already authorises the APVMA to make this legislative instrument. Item 68 increases the fee for pre-application assistance to clarify that it is goods and services tax (GST) inclusive. This fee for pre-application assistance and the fee for a technical assessment under regulation 8AS (see items 99 and 100) are the only fees for which GST is applied.

As a consequence of increasing the fee to include GST for pre-application assistance in regulation 69B, item 69 amends subregulation 70(3) to ensure that the reductions in application fees for pre-application assistance provided for in subregulations 70(3) and (4) take this into account. The amendments ensure that it is the GST exclusive amount of pre-application assistance that is to be rebated (for the amounts in Column 4 of Part 2 of Schedule 6). Any reduction in application fees for pre-application assistance is applied once only and item 70 inserts new subregulation 70(4A) to provide that the reduction for pre-application assistance may, at the APVMA's discretion, be applied in respect of any subsequent application lodged by the applicant.

Item 71 omits the note to regulation 70A as it is not needed.

Items 85 and 86 insert a transitional provision that clarifies that the amendments in Schedule 1 only apply to matters and things happening after Schedule 1 commences.

Items 99 and 100 clarify that GST must be added to the fees in Part 2 of Schedule 6 for a technical assessment under regulation 8AS.

Items 101 and 102 replace the expression 'occupational health and safety' with the more contemporary expression 'work health and safety'.

Item 103 incorporates the more correct expression of 'limits on the use of information' in Schedule 7 of the Principal Code Regulations.

Correcting typographical errors

Items 11 to 13, 17 to 18, 20 to 22, 24, 26, 28, 39 to 41, 46, 49 to 50, 58, 75 to 77, 82 to 84, 86 to 90, 93 to 98 – Regulations 3, 3A, 3B, 8B, 8E, 17C, 18E, 19AD, 20, 42, 78B, 85, Schedule 3B and Schedule 6

Items 11, 12 13, 17, 18, 22, 24, 39, 40, 49 and 50 replace incorrect Agvet Code or *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) references in the Principal Code Regulations.

Items 20, 21, 28 and 86 insert the correct spelling of the United States Pharmacopeia.

Items 26, 41, 58, 75 to 77 and 82 to 84 correct typographical errors.

Item 46 is an editorial amendment to regulation 18E to include the expression 'APVMA' instead of referring to the Chief Executive Officer.

Items 87 to 90 replace ‘given in’ with the more correct expression ‘given by’ in sections of Part 1 of Schedule 6.

Items 93 to 98 are editorial amendments to Part 2 of Schedule 6 to refer to the specific authority in subregulation 76(4) (item 93), inserting a missing entry in the table (item 94), clarify the basis for nil fees for emergency use permits (items 95 to 97) and amend a typographical error (item 98).

Schedule 2 – Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No.2) Regulation 2013

Correcting typographical errors

Item 23 – Schedule 1

This item corrects a typographical error in the 2013 Amendment Regulation. The heading to the item should have referred to regulation 4 not regulation 5, as regulation 5 was omitted in an earlier amending instrument. The amendment commences on 30 June 2014 so that the error is addressed just before the 2013 Amendment Regulation commences and so that the Principal Code Regulations can be correctly amended by the 2013 Amendment Regulation.