SELECT LEGISLATIVE INSTRUMENT No. 118, 2014

AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT (REMOVAL OF RE-APPROVALS AND RE-REGISTRATIONS) REGULATION 2014

Agricultural and Veterinary Chemicals Code Act 1994

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. 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.

Sections 26AB and 26B of the Agvet Code, as amended by the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-registration Act), provide for variations of approval and registration to be made by notification to the APVMA and for additional prescribed variations to which simplified procedures apply.

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*
agvet chemical	agricultural chemical and veterinary medicine
Agvet Code	Schedule to the Code Act (see below)
Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
LI Act	*Legislative Instruments Act 2003*
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
Principal Code Regulations	Agricultural and Veterinary Chemicals Code Regulations 1995
Record	Record of Approved Active Constituents for Chemical Products
Register	Register of Agricultural and Veterinary Chemical Products
Removing Re-registration Act	*Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*

OUTLINE

Amendments made

The Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014 (Amendment Regulation) amends the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations).

Purpose of amendments

The Amendment Regulation amends the Principal Code Regulations to:

- give effect to the measures in the Removing Re-registration Act, including implementing the election commitment to remove the need for re-approval of active constituents and the re-registration of chemical products by removing regulations related to the re-approval and re-registration of agvet chemicals
- amend regulations to improve the APVMA's ability to secure information about the safety of chemicals supplied to the market, and address concerns about chemical product quality
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it
- introduce further simple reforms to agvet chemicals regulation to reduce red tape and improve efficiency
- make other amendments consequential to other reforms.

Documents incorporated by reference

The Amendment Regulation includes measures that incorporate documents by reference. The documents are incorporated in new regulation 55A and are:

- Commonwealth legislative instruments, including the established standards for listed chemical products, which are already incorporated in regulation 42 of the Principal Code Regulations; and
- Food and Agriculture Organization (FAO) and World Health Organization standards for specifications for pesticides and plant protection products, which are already incorporated into the Principal Code Regulations in regulation 42.

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.

Amendment Act amendments

The Removing Re-registration Act implements the election commitment to remove the need for re-approval of active constituents and the re-registration of chemical products and makes other improvements to agvet legislation, including to reduce red tape and improve the APVMA's ability to secure information about the safety of chemicals supplied to the market.

PUBLIC CONSULTATION

The Explanatory Memorandum for the Removing Re-registration Act outlines the consultation undertaken for the reforms. The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Removing Re-registration Act and the Amendment Regulation.

Submissions were sought between 18 December 2013 to 7 March 2014 about an exposure draft of the legislation and particulars for the Amendment Regulation. This was undertaken as part of an associated consultation paper, *Proposed Agricultural and Veterinary Chemicals Legislation Amendments: Consultation Paper*. Forty-two submissions were received and considered. Teleconferences and face to face meetings with interested stakeholders occurred over January and February 2014.

Comments from stakeholders resulted in the inclusion in the Removing Re-registration Act and Amendment Regulation of amendments to provide for simplified prescribed variation applications and notifiable variations (items 14, 41 and 53). Also, some additional amendments to the Principal Code Regulations were considered necessary to address some inconsistent expressions used in the regulations and to:

- provide that a test approved in writing by the APVMA may be used so results can be compared with any applicable standards (item 25)
- provide that the name for a product on the approved label for containers of the product may differ from the distinguishing name of the chemical product detailed in the Register (items 9 and 10).

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

These amendments are related to the measures in the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*. The Office of Best Practice Regulation was consulted about these measures and has advised that the regulatory changes are machinery in nature and a regulation impact statement is not required (ID number 16147).

HUMAN RIGHTS COMPATIBILITY ASSESSMENT

Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014

The Agricultural and Veterinary Chemicals Code Amendment (Removal of Re-approvals and Re-registration) 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 Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations) to:

- give final effect to the measures in the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-registration Act), including implementing the election commitment to remove the need for re-approval of active constituents and the re-registration of chemical products by removing regulations related to the re-approval and re-registration of agvet chemicals
- amend regulations to improve the APVMA's ability to secure information about the safety of chemicals supplied to the market, and address concerns about chemical product quality
- oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it
- introduce further simple reforms to agvet chemicals regulation to reduce red tape and improve efficiency
- make other amendments consequential to other reforms.

Human rights implications

The Amendment Regulation engages the the right to health and a healthy environment (Article 12) in the *International Covenant on Economic, Social and Cultural Rights* (ICESCR).

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 improving the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying. 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 previous section 99 of the Agvet Code and its associated regulation 55 in the Principal Code Regulations allowed the APVMA to require a person who had possession or custody of a substance intended for supply as a chemical product to provide an analysis of the substance's composition and quality. However, these provisions were not effective as they applied only if the APVMA had a reasonable suspicion that the product did not meet APVMA requirements.

The Removing Re-registration Act amended section 99 of the Agvet Code to provide that the APVMA may, by written notice, require a person to provide information about substances supplied or intended for supply as a chemical product (or an active constituent for a chemical product) if they have, will have, or have had possession of the substance. The information that may be required includes details of the composition of the substance, manufacturing details, packaging, labeling and advertising information and about conformance of the substance with any relevant standard. New regulation 55A in the Amendment Regulation supports this by prescribing the standards that apply when section 99 is used by the APVMA. The prescribed standards are the same standards that constituents and products must conform to as part of other obligations under the Agvet Code (regulation 42).

The APVMA is to be able to require a chemical analysis of the product to provide the required information about conformance to prescribed standards and for the results of the analysis to be provided to the APVMA. The power is to apply only if the APVMA considers the information is necessary to protect human, animal and environmental health and safety or protect trade. As a transparency measure, the APVMA must report in its annual report a summary of the occasions that it uses its authority under section 99.

In addition, the APVMA is bound by the *Privacy Act 1988* (Cwlth) in collecting, handling and disclosing personal information and this Act confers rights designed to protect privacy. These rights and obligations are set out in 13 Australian Privacy Principles (APPs) contained within the Privacy Act.

The amendments to include new regulation 55A therefore promote the protection of the right to heath and a healthy environment (through the confirmation of information about substances which may include chemical analysis).

Other provisions

The Amendment Regulation includes amendments to specifically oblige the APVMA to provide access to information in its files to persons eligible to receive it and removes redundant provisions. These provisions do not make any substantive change to the law and 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 amendments to section 99.

The Hon. Barnaby Joyce MP, Minister for Agriculture

AGRICULTURAL AND VETERINARY CHEMICALS CODE AMENDMENT (REMOVAL OF RE-APPROVALS AND RE-REGISTRATIONS) REGULATION 2014

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 Code Amendment (Removal of Re-approvals and Re-registrations) Regulation 2014 (Amendment Regulation).

Section 2 – Commencement

This section provides that Sections 1 to 4 commence the day after this regulation is registered.

This section would also provide that the measures in Schedule 1 commence the day after this regulation is registered, except for items 9, 10, 14 and 52 which commence on 1 January 2015.

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

This section specifies the legislation that authorises the amendment of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations).

Section 4 – Schedules

This section specifies how the amendments in Schedule 1 are to apply to the instruments specified for amendment.

Schedule 1 – Agricultural and Veterinary Chemicals Code Regulations 1995

Implementing the election commitment to remove re-registration

Items 4 to 7, 11, 15, 17, 21, 22, 40, 47 to 51, 55 – Regulation 8AO, Subdivision 2.1.3A of Division 2.1 and Division 2.2A of Part 2, regulations 22, 42, 65A, 76, 76A, 78, 78AA, 81 and Part 2 of Schedule 6.

These items remove those regulations that relate to re-registration and re-approval. These amendments are consequential to the removal of the authorities in the Agvet Code made by the Removing Re-registration Act. The purpose of items 4, 5 and 6 is to remove references to paragraph 29E(2)(b), subsection 29E(2) and section 29D from the applicant notice requirements as these provisions have been removed from the Agvet Code. Item 7 removes reference to applications for re-approval or re-registration from the applicant notice requirements regulation paragraph 8AO(2)(j). The variations referred to in items 6 and 7 of Regulation 19AE are only notifiable variations if the label, as varied, would not include information about the use, safety, environmental impact or efficacy of the chemical product that is misleading or deceptive.

Item 11 omits Subdivision 2.1.3A of Part 2 which specified the method for working out when an approval ends or a registration cannot be renewed. Item 15 removes Division 2.2A of Part 2 which specified fees and arrangements for late re-approval or re-registration applications. These provisions are redundant.

Item 17 is a consequential amendment to the Principal Code Regulations to reflect the omission of references to re-approval and re-registration.

Items 21 and 22 amend regulation 42 to remove all references to the redundant expression 'last renewal date'.

Item 40 removes redundant subregulation 65A(4) which dealt with periods for giving information for re-approval and re-registration applications. Items 47 to 49 remove references to re-approval and re-registration applications from subregulations 76, 76A(3) and 78(3). Respectively, these redundant subregulations dealt with extended assessment periods and the commencement of assessment periods for re-approval and re-registration applications.

For the authority in subsection 165(1) of the Agvet Code, item 50 inserts new regulation 78AA to provide that the timeframe for the APVMA to determine a renewal application is one month. This regulation is necessary as the Removing Re-registration Act removed the specific timeframe of one month for these applications from the Agvet Code and instead provided for regulations to prescribe the timeframe.

Item 51 removes redundant regulation 81 which specified when approvals end and when registrations cannot be renewed for active constituents that the APVMA has already approved and chemical products that the APVMA has already registered.

Item 55 removes redundant item 26 from part 2 of Schedule 6. This item dealt with the timeframe and fees for re-approval and re-registration applications.

These measures, in part, implement the election commitment to remove re-approval and re-registration. The Agvet Code contains comprehensive powers for the APVMA to ensure any newly identified risks about the safety, efficacy or trade impact of a chemical are examined. The APVMA also has powers to recall unsafe chemical products or suspend or cancel the registration of a chemical product if they may no longer meet criteria for registration. These provisions were recently strengthened and streamlined by the 2013 Amendment Act with further improvements provided for in the Removing Re-registration Act.

Reducing red tape by allowing for simpler variations to approvals and registrations

Items 3, 14, 36 to 39, 41, 46 and 54 – Regulation 8AL, Subdivisions 2.2.2 and 2.2.3 of Division 2.2 of Part 2, regulations 65, 69AA, 76 and Part 2 of Schedule 6

Notifiable variations

Division 2AA of the Agvet Code provides for variations of approval and registration to be made by notification to the APVMA. Item 14 inserts Subdivision 2.2.2 (including new regulation 19AE) which specifies those variations that are notifiable variations for the authority in subparagraph 26AB(3)(a)(ii) of Division 2AA of the Agvet Code.

Regulation 19AE prescribes these simple variations to the relevant particulars of approvals and registrations that are notifiable variations and which can be made through simple notification to the APVMA. The notifiable variations in regulation 19AE include simple changes to the name of a manufacturer of an active constituent (item 1), the name or address of a manufacturer of a product not prescribed under subregulation 59(1) (item 5), the distinguishing name of a chemical product (item 2), the name of the chemical product that appears on an approved label (item 7), as well as variations to the net contents of containers of chemical products (item 3) and to reduce the use of a product by amending instructions for the product where these changes do not affect other instructions (item 4). Item 6 of regulation 19AE sets out a notifiable variation of a label approval as a consequence of another notifiable variation in item 3 or 4 of regulation 19AE.

Item 41 provides that the fee charged for these notifications under subparagraph 26AD(1)(c) is $50, unless the notification is for a consequential notifiable variation to a label approval under item 6 of regulation 19AE. There is no fee for a notification under item 6.

Prescribed variations

Division 2A of the Agvet Code provides for applications for simple variations of registrations or approvals. Item 14 of the Amendment Regulation also inserts new Subdivision 2.2.3 (including regulation 19AF) which specifies those variations that are prescribed variations for the authority in paragraph 26B(4)(b) of the Agvet Code.

Regulation 19AF prescribes the simple variations that can be made by application to the APVMA and which are taken to have been made after a set period where the application meets the application requirements. The prescribed variation in item 1 of regulation 19AF allows changes to details about the manufacturer of chemical products prescribed under subregulation 59(1). The requirements in Part 8 of the Agvet Code for the manufacture of chemical products mean that it is not appropriate for prescribed variations to include variations to the name of the manufacturer or site of manufacture for all chemical products. The prescribed variations cannot apply where the manufacturer or site of manufacture is outside of Australia because it is not possible to deal with the necessary product manufacturing requirements in the one month timeframe provided for prescribed variations.

Item 54 amends the previous entry for item 13A in Part 2 of Schedule 6 to provide that the set period is a period of one month and the fee is $175.

Item 14 does not commence until 1 January 2015 (see section 2 of the Amendment Regulation) to allow the APVMA time to develop the necessary approved forms and information technology systems for these notifications and applications.

The provisions relating to the fees for these variations commence on registration. This is because the Agvet Code provides that the APVMA may make a legislative instrument about notifiable variations and prescribed variations before this time. The fees for these variations therefore need to be in place should the APVMA make a legislative instrument about notifiable variations and prescribed variations before 1 January 2015.

The simplified notification and application processes will greatly reduce the supporting information required and industry time taken to make a variation to a registration or approval. Without these amendments to the Agvet Code the APVMA would have to complete a more onerous technical assessment of these variations with no real benefit to improving chemical safety.

As a consequence of providing for notifiable variations, items 36 to 39 amends regulation 65 to provide that approved forms for notifiable variations must be provided to the APVMA in electronic form.

Items 3 and 46 amend regulations 8AL and 76 respectively as a consequence of the introduction of defined prescribed variations.

Addressing concerns with chemical product quality

Items 18 to 20 and 24 to 27 – Regulations 41, 55 and 55A

Items 18 to 20 are amendments to regulation 41 to remove references to section 99 of the Agvet Code, as the prescribed requirements for section 99 are now in new regulation 55A.

Items 24 and 25 amend regulation 55 which deals with tests that are to apply when active constituents and chemical products are tested. The amendment is to allow for the use of a test for determining impurities that were not known at the time of registration. The test may include a test that the APVMA has approved in writing. The purpose of this amendment is to ensure that where an analysis is to be required then the test that is approved by the APVMA can be used to ensure that the results of that analysis can be compared to applicable standards. This will enable the APVMA to confirm that chemical products supplied to the market are the same as those assessed and registered

by the APVMA. The authority for this regulation is in paragraphs 6(2)(c) and 6(3)(b) of the Code Act.

Item 26 inserts new regulation 55A that prescribes the standards that apply when section 99 of the Agvet Code is used by the APVMA. These standards are the same standards that constituents and products must conform to as part of other obligations under the Agvet Code (that is, regulation 42).

Item 27 is a consequential amendment to regulation 56 to reflect the new authority in section 99 of the Agvet Code.

The APVMA is to be able to require a chemical analysis of the product to provide the required information about conformance to prescribed standards and for the results of the analysis to be provided to the APVMA. As provided for by section 99 of the Agvet Code, the power is to apply only if the APVMA reasonably believes it necessary to protect human, animal and environmental health and safety or protect trade. As a transparency measure, the APVMA must report a summary of the occasions that it uses its authority under section 99 in its annual report.

These measures improve the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying.

Obliging access to information about chemicals that the APVMA holds

Item 45 – Regulations 73

For the authority in subsection 8W(2) of the Agvet Code, item 45 amends regulation 73 to provide for a fee for a person to request a copy or extract of certain documents that the APVMA has in its possession or custody. This does not apply to information that the APVMA has in its Record or Register as other provisions provide for information from these sources to be provided for a fee. The fees for these requests are the same as for the other fees for information that persons may request of the APVMA.

Currently, the APVMA is often asked by companies to provide information relating to their own registered chemical products (including about the formulation and details of manufacturing). This information is then provided under the *Freedom of Information Act 1982* (FOI Act). These requests often occur because companies do not keep adequate records about applications they make to the APVMA, or because records are not transferred between companies when responsibility for a chemical changes hands. Payments for information sought under the FOI Act are not recovering the costs of providing the information. As a result, companies that maintain accurate records are subsidising the records costs of those that do not.

Consistent with the authority in the Agvet Code, as amended by the Removing Re-registration Act, these amendments measures allow persons to apply to the APVMA for copies of documents it holds about an active constituent or chemical product and for a copy to be provided for a fee. These amendments are intended to ‘turn off’ access under the FOI Act (by relying on an existing exemption in paragraph 12(1)(b) of that Act) for these documents while still ensuring access to the information.

These provisions do not allow release of confidential commercial information unless the recipient was entitled to the information (for example, because they were the person that provided the information).

Other amendments consequential to existing reforms

Items 1, 2, 8 to 10, 12, 13, 16, 23, 28 to 35, 42 to 44, 52 and 53 – Regulations 4, 8AB, 16, 17, 17C, 18K, 22, 43A, 59, 59B, 71A, 71B, 72A, 78A, 81 and Part 1 of Schedule 6

These items are amendments to the Principal Code Regulations consequential to amendments to the authorities in the Agvet Code made by the Removing Re-Registration Act and its intent to reduce red tape.

As provided for by section 89A of the Agvet Code, the purpose of items 1 and 23 is to amend the Principal Code Regulations to provide that listed chemical products and reserved chemical products remain exempt from the requirements for date-controlled chemical products (in Division 3 of Part 4 of the Agvet Code). This is achieved by including a new regulation 43A (item 23) to exempt these products from the requirements.

Item 8 removes the need to record in the Register the state or territory in which a chemical product is registered. Controls on the use of the product in a particular state or territory continue to be provided through the instructions for use of the product set out on the approved label for containers for the product.

Items 9 and 10 provide that the name that appears on the label of containers of a chemical product may differ from the distinguishing name of that product recorded in the Register for paragraph 20(1)(c) of the Agvet Code and as prescribed by paragraph 16(a) of the Principal Code Regulations. This allows for identical products to be supplied under a variety of names without having to apply for registration of each individual variant. This provides a reduction in cost and red tape for holders of registration (by removing the requirement for multiple registrations to be renewed) and a reduction in administrative burden to the APVMA (in maintaining multiple registrations and assessing multiple registration applications).

Item 52 is an application provision for the continuation of label approvals after 1 January 2015 as a result of amendments to the Principal Code Regulations at item 9 and 10. The item provides that the distinguishing name of a chemical product for which a label approval is in force immediately before 1 January 2015 is taken to be recorded in the relevant APVMA file as the name that appears on the label for containers of the chemical product, and that the distinguishing name and number of the chemical product is recorded in the relevant file for the label approval. As a result, the red tape reduction benefits of items 9 and 10 will be available to holders of all registrations, instead of only to registrations done after 1 January 2015.

Item 13 provides for certain particulars of an approval or registration about the identity of a holder or nominated agent to be corrected when the APVMA becomes aware that the Record or Register is incorrect in a material respect.

Item 16 corrects referencing issues with the Agvet Code in regulation 22.

Section 120A of the Agvet Code provides that regulations may prescribe those products that are exempt from the requirements in Part 8 of the Agvet Code (about manufacture of chemical products). The purpose of items 28 to 35 is to amend the Principal Code Regulations to provide that listed chemical products and reserved chemical products remain exempt from the manufacturing requirements in Part 8 of the Agvet Code. This is achieved by adding listed chemical products and reserved chemical products to those products that are already exempt in regulation 59 (item 30) and recasting regulations 59 and 59B to more generally specify that the products prescribed for the purposes of section 120A of the Agvet Code are exempt products. These amendments to the Principal Code Regulations mean that some other provisions can be simplified by referencing the exemptions in regulation 59. The purpose of items 2, 12, 42 to 44 are to simplify regulations 8AB, 17C, 71A, 71B and 72A by referring to the products prescribed in regulation 59.

Item 53 amends Part 1 of Schedule 6 to provide greater clarity on the information necessary to satisfy the APVMA that a proposed chemical product meets the safety or efficacy criteria through reference to another chemical product.