AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (2013 MEASURES NO. 2) REGULATION 2013

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 Parliamentary Secretary for Agriculture, Fisheries and Forestry
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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 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 (Amendment Act) provides for prescribed reviews for section 5 of the Amendment Act. Item 57 of Schedule 6 of the provide that the Governor-General may make regulations prescribing matters required or permitted by Part 2 of Schedule 6 of the Amendment Act to be prescribed or necessary or convenient to be prescribed for carrying out or giving effect to that part 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 (2013 Measures No. 2) Regulation 2013 (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 Amendment Act conferring power fully effective on 1 July 2014. In addition, the provisions in the Amendment Regulation do not commence until the 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.

<table>
<thead>
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<th>Abbreviation</th>
<th>Definition</th>
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<tr>
<td>Amendment Act</td>
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<tr>
<td>APVMA</td>
<td>Australian Pesticides and Veterinary Medicines Authority</td>
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<td>Administration Act</td>
<td><em>Agricultural and Veterinary Chemicals (Administration) Act 1992</em></td>
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<td>agvet chemical</td>
<td>agricultural chemical and veterinary medicine</td>
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<td>Agvet Code</td>
<td>Schedule to the Code Act (see below)</td>
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<td>CEO</td>
<td>Chief Executive Officer of the APVMA</td>
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<td>Code Act</td>
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<td>Gazette</td>
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<td>EC Regulation 1272/2008</td>
<td>Table 3.1 of Annex VI of European Community Regulation Number 1272/2008</td>
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<td>LI Act</td>
<td><em>Legislative Instruments Act 2003</em></td>
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<td>Minister</td>
<td>Minister for Agriculture, Fisheries and Forestry</td>
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<td>NRS</td>
<td>National Registration Scheme for Agricultural and Veterinary Chemicals</td>
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<td>Principal Administration Regulations</td>
<td>Agricultural and Veterinary Chemicals (Administration) Regulations 1995</td>
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<td>Principal Code Regulations</td>
<td>Agricultural and Veterinary Chemicals Code Regulations 1995</td>
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<tr>
<td>Principal Levy Regulations</td>
<td>Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995</td>
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<tr>
<td>reconsideration</td>
<td>A reconsideration of an active constituent or label approval or chemical product registration, known widely as a chemical review</td>
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<td>Record</td>
<td>Record of Approved Active Constituents for Chemical Products</td>
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<td>Register</td>
<td>Register of Agricultural and Veterinary Chemical Products</td>
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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 Amendment (2013 Measures No.2) Regulation 2013 (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)

Purpose of amendments

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

- support changes made to agvet chemical legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013 (Amendment Act), which implement the ‘better regulation’ of agricultural and veterinary chemicals reforms
- implement further reforms to the regulation of agvet chemicals that do not require amendments to agvet chemical legislation
- update fees and levies consistent with an approved cost recovery impact statement
- address other minor issues that have been identified with the regulations, including removing redundant provisions and addressing some errors.

The Amendment Regulation includes:

- remade regulations for the new authorities in the Agvet Code, as a result of the simplification and modernisation of the Agvet Code (regulations 8AA to 8AT)
- timeframes for assessments that include the total time elapsed, including the time taken to provide more information, as well as timeframes and work plans for reconsiderations (regulations 20, 21, 65A, 76, 76A, 76B, 78, 78A and 78B)
- prescribing information that must be given in electronic form to streamline administrative processes (regulation 65)
- prescribing foreign regulators for which the decisions in two or more countries would trigger re-approval or re-registration applications (regulation 22D)
- the method for determining end dates and last renewal dates for the mandatory re-approval and re-registration scheme (regulations 17A and 17B)
- measures for infringement notices and conditions of registration and approval to improve the ability of the APVMA to enforce compliance with its regulatory decisions in a graduated manner (regulations 3A.01 (Administration Regulations) and 64 (Code Regulations))
- measures that simplify the data protection provisions consistent with the Agvet Code (as amended by the Amendment Act)(regulations 8A to 8E and 19AA to 19AD)
amendments to allow alternative levy collection arrangements to be implemented (regulation 8 (Levy Regulations) and 73 (Code Regulations))

amendments to increase application and other related fees and reduce levies (regulations 6A (Levy Regulations) and 69B to 71B (Code Regulations)) consistent with the approved and published cost recovery impact statement

amendments to address other minor issues that have been identified with the regulations, including removing redundant provisions and addressing some errors.

**Documents incorporated by reference**

The Amendment Regulation includes measures that incorporate documents by reference. These include:

- the European Community Regulation 1272/2008, which is readily available on the internet and a reputable source of information about the aquatic acute and chronic toxicity of Agvet chemicals
- Food and Agriculture Organization (FAO) and World Health Organization standards for specifications for pesticides and plant protection products (recognising that FAO standards are already incorporated into the Principal Code Regulations).

**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.
**Better regulation reforms**

The ‘better regulation’ reforms incorporate work undertaken via the Better Regulation Ministerial Partnership (the partnership) between the Minister for Agriculture, Fisheries and Forestry and the Minister for Finance and Deregulation, as announced at the ABARE Outlook conference in March 2010. The reforms also deliver on several election commitments made by the Australian Labor Party for the 2010 election to deliver on reforms to the regulation of agricultural and veterinary chemicals in Australia.

**Amendment Act amendments**

The Amendment Act implements the better regulation reforms to the approval, registration and reconsideration of agvet chemicals to improve the effectiveness of the current regulatory arrangements and provide greater certainty to the community that chemicals approved for use in Australia can be used safely. The amendments:

- enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations by publishing principles and processes for APVMA regulatory action, by implementing these principles and processes to better align regulatory effort with chemical risk and by providing legislated guidance to the regulator about its application of discretion
- simplify and reorganise the Agvet Code to reduce uncertainty and complexity and improve the operation and understanding of agvet chemicals legislation and simplify and modernise the legislation to improve the efficiency and effectiveness of assessment processes for agvet chemical applications for approvals, registrations, permits and licences and for reconsiderations (reviews) of chemical approvals and registration
- improve the effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improve the timeliness of agvet chemical approvals, registrations and reconsiderations
- ensure the ongoing safety of agvet chemicals and improve the effectiveness of current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration scheme, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses
- improve the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals
- improve consistency in data protection provisions and remove disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals
- address perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so
- include other amendments to remove redundant provisions and amend out of date provisions.

**PUBLIC CONSULTATION**

The Explanatory Memorandum for the Amendment Act outlines the consultation undertaken for the reforms. The consultation on the Amendment Act has also informed the development of the Amendment Regulation.

The details of the regulation (including some draft regulations) were released for public consultation from 25 September 2012 to 21 December 2012. Comments from submitters have been taken into account in preparing these regulations. These comments have resulted in the Amendment Regulation:

- providing for more flexibility for applicants and the APVMA in managing more complex applications through the use of ‘timeshift applications’
prescribing application information to be provided electronically or in electronic form

specifically authorising the APVMA to ensure adequate instructions to manage trade impacts associated with the use of chemical products, including for example the need for export slaughter intervals

refining the method for determining the period between successive re-approval and re-registration applications to align with more appropriate references for human and environmental health (for example, current Poisons Standard and the EC regulation 1272/2008)

including the New Zealand Environmental Protection Authority as an additional agency whose decisions would contribute to the trigger for re-approval and re-registration applications to be made

refining the formula for calculating when a reconsideration is to be concluded to include an additional component of three months to deal with data-compensation negotiations currently provided for in Part 3 of the Agvet Code. This addresses the need for more flexibility in the formula to deal with access to protected information

prescribing additional matters for reconsideration work plans to include matters to be considered, timeframes, who is likely to be consulted and anticipated data requirements

providing that some permits cannot be extended, including permits relating to contraventions of provisions relating to good manufacturing practice requirements and where chemical product registrations have ended.

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 AND COST RECOVERY IMPACT STATEMENT

A Regulation Impact Statement (RIS) was completed for the reforms which led to the Amendment Act. The RIS is at <http://ris.finance.gov.au/2011/11/29/better-regulation-of-agricultural-and-veterinary-chemicals-%e2%80%93-regulation-impact-statement-%e2%80%93-department-of-agriculture-fisheries-and-forestry/>. The RIS was prepared by the Department of Agriculture, Fisheries and Forestry and has been assessed as adequate by the Office of Best Practice Regulation (OBPR reference 11523). The RIS was published on 29 November 2011.

The Amendment Regulation includes measures that are in addition to those needed to give effect to the Amendment Act. The Office of Best Practice Regulation was consulted about these additional measures and has advised that no further analysis (in the form of a further RIS) is required (ID 15131).


HUMAN RIGHTS COMPATIBILITY ASSESSMENT

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

The Agricultural and Veterinary Chemicals Amendment (2013 Measures No.2) Regulation 2013 (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)

These regulations require amendment to:

- support changes to agvet chemical legislation made by the Agricultural and Veterinary Chemicals Legislation Amendment Act 2013 (Amendment Act), which in turn implement reforms to the approval, registration and reconsideration of agricultural and veterinary chemicals (agvet chemicals) that improve the efficiency and effectiveness of the current regulatory arrangements, and provide greater certainty to the community that chemicals approved for use in Australia are safe;
- update fees and levies consistent with an approved cost recovery impact statement; and
- address other minor issues that have been identified with the regulations, including removing redundant provisions and addressing 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) and fair trial and fair hearing rights including the right to the presumption of innocence in Article 14 of the International Covenant on Civil and Political Rights (ICCPR).

Right to health and a healthy environment

The Amendment Regulation engages and promotes the right to health in Article 12 of the ICESCR by supporting the provisions in the Agvet Code (as amended by the Amendment Act) that provide that the first priority of the system for regulating agvet chemicals is the health and safety of human beings, animals and the environment. 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 a fair trial and fair hearing rights, including the right to the presumption of innocence

Article 14 of the ICCPR ensures that everyone shall be entitled to a fair and public hearing by a competent, independent and impartial tribunal established by law. The Amendment Regulation may limit the right to a fair and public hearing through prescribing civil penalty provisions for which infringement notices may be issued. The Amendment Regulation also provides for a scale of penalties in infringement notices depending on the amount of the active constituent or chemical product involved in the alleged contravention.

An infringement notice can be issued by an APVMA inspector for contraventions of a civil penalty provision that is enforceable under agvet chemical legislation. The Administration Act and the Agvet Code ensure against arbitrariness or abuses of power through limitations as to who can issue an infringement notice. These notices can only be issued by an APVMA inspector.

The right of a person to a fair and public hearing by a competent, independent and impartial tribunal is preserved by the Administration Act and the Agvet Code as their provisions allow a person to elect to have the matter heard by a court rather than pay the amount specified in the notice. Additionally, the Administration Act and the Agvet Code outline that this right must be stated in an infringement notice.

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notice issued to a person, ensuring that a person issued with an infringement notice is aware of their right to have the matter heard by a court.

These powers are reasonable, necessary and proportionate. The Administration Act and the Agvet Code ensure that relevant courts have sufficient authority to ensure against arbitrariness or abuses of power. Regulatory functions and powers in the issuing of infringement notices are limited to authorised officers and a person can elect to have the matter heard by a court.

**Other provisions**

The Amendment Regulation includes amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation. 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 to the extent that it may limit human rights, those limitations are reasonable, necessary and proportionate. In addition, the limitations on human rights have adequate safeguards in place and are appropriate in the context of protecting the community and the environment from the risks of unacceptable agvet chemical products.
AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT (2013 MEASURES NO.2) REGULATION 2013

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 Amendment (2013 Measures No.2) Regulation 2013 (Amendment Regulation).

Section 2 – Commencement

This section provides that the measures in Schedule 1 commence on 1 July 2014 when the Amendment Act commences.

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

This section provides for the amendment of 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)

Section 4 – Schedules

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

- items 1 to 5 amend the Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Principal Levy Regulations);
- items 6 to 10 amend the Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Principal Administration Regulations);
- items 11 to 17 amend the Agricultural and Veterinary Chemicals Code Regulations 1995 (Principal Code Regulations).

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

Reductions in levy rates

Items 1 to 3 – Subregulations 6A(3) and (4)

For the authority in section 12C of the Collection Act and consistent with the approved cost recovery impact statement, these items amend subregulation 6A(3) and insert new subregulation 6A(4) into the Principal Levy Regulations to reduce the rates of the levies payable for chemical products in the 2014-2015 financial year and subsequent financial years. The reduction in these levy rates is a consequence of changes to application fees.
Compliance and enforcement matters

Items 4 and 5 – Regulations 7 and 8 and Schedule 2

Item 4 repeals regulation 7 of the Principal Levy Regulations and inserts new regulation 8 to allow the APVMA to provide a collection agency with such information that is necessary for it to carry out its collection agency functions. Item 5 repeals Schedule 2 of the Principal Levy Regulations.

Regulation 7 and Schedule 2 deal with the form of a search warrant. Regulation 7 and Schedule 2 are no longer necessary as the form of a monitoring warrant and investigation warrant is dealt with in the Administration Act.

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

Prescribed annual report and annual operational plan matters

Item 6 – Part 1A

This item inserts new regulations 1A.1, 1A.2 and 1A.3. These regulations specify information for inclusion in the APVMA annual report, the annual operational plan and performance indicators for the annual report. Collectively these measures improve transparency about the APVMA’s performance.

Part 6 of the Administration Act provides for the APVMA to develop and release corporate and annual operational plans. Section 55 of the Administration Act provides that the APVMA must develop an annual operational plan which includes particulars of actions that the APVMA intends to undertake to further the goals set out in the corporate plan, as well as performance indicators against which the performance of the APVMA can be assessed. Section 61 of the Administration Act requires the APVMA to prepare and provide an annual report on the APVMA’s operations during a year.

For the authority in paragraph 73(b) of the Administration Act, new regulation 1A.1 specifies that the APVMA must include details about standards that the APVMA has made or varied during the year to which the annual report relates. These are the standards that the APVMA makes under section 6E of the Agvet Code.

For the authority in paragraph 55(2)(c) of the Administration Act, new regulation 1A.2 specifies that the APVMA annual operational plan must include information about reconsiderations commenced, completed or progressed during the period to which the plan relates. The information would set out the timeframe that is to apply to the reconsideration and include anticipated steps in the reconsideration, including future consultation opportunities. For the authority in subparagraph 61(2)(c)(ii) of the Administration Act, new regulation 1A.3 specifies performance indicators for inclusion in the annual report. These performance indicators include information on reconsiderations, applications determined within prescribed timeframes and information about adverse experience reports. The Adverse Experience Reporting Program (AERP) is a post-registration quality assurance program established by the APVMA to help facilitate the management of veterinary medicines and agricultural chemicals throughout their lifecycle. For reconsiderations, the purpose of the information in the annual report is to set out the progress that the APVMA has made on reconsiderations during the year, as well as reconsiderations that have concluded or commenced.
Infringement notices

Items 7 and 9 – Part 3A and Schedule 5

Item 7 includes a new Part and regulation 3A.01 that prescribes the civil penalty provisions for which infringement notices may be issued. Item 9 inserts a new Schedule 5 that specifies the civil penalty provisions in the Administration Act and the Collection Act for which a infringement notice may be given and specifies the amount of the penalty that may be included in a infringement notice.

The authority to prescribe civil penalty provisions is set out in section 4 of the Administration Act. The term ‘prescribed civil penalty provision’ is defined to mean a civil penalty provision that is prescribed by the regulations. The term ‘civil penalty provision’ is defined in the Administration Act to mean a provision declared by this Act or the Collection Act to be a civil penalty provision. Collection Act civil penalty provisions are therefore included in the table as the authority to make them prescribed civil penalty provisions is in section 4 of the Administration Act and the power to set penalty amounts is also in the Administration Act (see section 73 and subsection 69EKA(3)).

Subsection 69EKA(2) of the Administration Act provides that the penalty for an infringement notice must be no greater than one-fifth of the maximum penalty that a court could impose for that contravention. The highest penalty in Schedule 5 is one tenth of the maximum penalty that a court could impose for that contravention. This allows for penalties to be increased in the future if this is considered necessary and appropriate.

Consistent with the authority in subsection 69EKA(3), Schedule 5 provides for a scale of penalties for some infringement notices. This scale is based on the amount of an active constituent or chemical product or the number of containers of a chemical product to which the contravention relates.

Compliance and enforcement matters

Items 8 and 10 – Regulation 4.15 and Schedule 6

These items replace regulation 4.15 and delete Schedule 6 which dealt with the form of a search warrant. New regulation 4.15 specifies the method for securing samples and refers to the new monitoring and investigation powers in the Administration Act. The method aligns with the method for securing samples in the Principal Code Regulations (Regulation 63). As the form of a monitoring warrant and investigation warrant is dealt with in the Administration Act (as amended by the Amendment Act), old regulation 4.15 and Schedule 6 are no longer necessary.

Schedule 1 – Agricultural and Veterinary Chemicals Code Regulations 1995

Definitions

Items 11 and 12 – Regulations 1 and 2

These items insert new headings in the Principal Code Regulations.

Items 13 to 22 – Subregulation 3(1)

Item 13 inserts a new definition of ‘application information details’ to simplify the subsequent requirements in the regulations that deal with information contained in or accompanying an application. So that information can be efficiently located, the definition specifies that information must include a unique identifier that indicates where the item of information is located in the application such as the volume and page number. This assists the APVMA to locate information and to identify it for regulatory purposes (for example, data protection) and is also consistent with the purpose of these requirements, which is to provide greater transparency between the APVMA, holders of approval and registration and the general public.
Item 14 repeals the definition of ‘approved active constituent’ as this has been included in the Agvet Code (as amended by the Amendment Act). Item 15 inserts a new definition of ‘APVMA CEO’ to be used throughout the Principal Code Regulations. Item 16 inserts a new definition of ‘collecting agency’ to be used throughout the Principal Code Regulations and incorporates the definition in the Collection Act. Item 17 corrects a typographical error in the spelling of ‘organisation’ in the definition of ‘CSIRO’. Items 19 and 20 insert a new definition of ‘FAO and WHO Specifications for Pesticides’ to include relevant standards made by the World Health Organization. Item 22 replaces the old term of ‘interested person’ with the new term of ‘holder’ that is used throughout the Agvet Code.

Item 18 amends the definition of ‘emergency use’ to extend the circumstances under which an emergency use permit may be issued to include circumstances where the need for use is for some future time because of an impending or manifest emergency. This amendment is intended to provide the APVMA with more flexibility to issue permits on a contingency basis for emergencies that may not yet have occurred but that are likely to occur in the future. For example, a permit for an emergency use could be issued in anticipation of diseases infestations that are likely after an unusual major rain event. This would enable users to be prepared for emergencies with permits for the use of products which would allow these products to be used once the emergency occurs.

However, as part of determining an emergency use permit application the APVMA must, among other things, be satisfied that there are reasonable grounds for an application not having been made to vary the registration of the product to accommodate the emergency use.

Item 21 inserts a new definition of formulation type. This definition is necessary because of the new relevant particular about formulation type prescribed for chemical product registrations (see item 47). This item also inserts a definition of ‘GMP audit’ and ‘identifying information’ so that these terms can be used consistently throughout the Principal Code Regulations.

Item 21 also includes a definition of a ‘timeshift application’ that is intended to provide more flexibility for applicants for approval or registration of innovative new active constituents and chemical products. A timeshift application is limited to applications for new active constituents and new chemical products containing new active constituents and 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, see item 156). Provision for timeshift applications recognises the flexibility needed for determining assessment periods for applications for new active constituents and new products containing new active constituents. Timeshift applications are relevant also for the APVMA’s part of a coordinated international assessment of a new chemical, known as a global joint review.

Item 23 inserts a new regulation 5A that prescribes the meaning of ‘lodged’ for section 3 of the Agvet Code. For applications under sections 10 or 27 of the Agvet Code, the APVMA must complete a preliminary assessment within 1 month after it is lodged. Subregulation 5A(1) provides that an application is lodged when the application form is given and all information that is specified for the application is provided to the APVMA. Subregulation 5A(2) effectively sets a time limit of 7 days after the application form is given for applicants to give any other information specified for the application to the APVMA for that information to accompany the application. Section 8C of the Agvet Code provides that in determining the application the APVMA must not take into account information given by or on behalf of an applicant that does not accompany the application.
Definition of ‘protection period’

Item 24 – Regulation 6

This item removes the definition of ‘protection period’ from the Principal Code Regulations as the definition and protection period of eight years is now specified in the Agvet Code.

Safety criteria, efficacy criteria, trade criteria and labelling criteria

Item 25 – New regulations 8AA to 8AQ

Prescribed matters – ‘meets the safety criteria’ – active constituents

This item inserts a new regulation 8AA to replace old regulation 13. As for old regulation 13, the purpose of new regulation 8AA is to prescribe the method of analysis of the chemical composition of an active constituent as a matter that the APVMA must have regard to for the purposes of being satisfied as to whether an active constituent meets the safety criteria. This amendment is necessary to remake old regulation 13 for the new authority in subparagraph 5A(2)(a)(vii) of the Agvet Code.

Prescribed matters – ‘meets the safety criteria’ – chemical products

Item 25 also inserts a new regulation 8AB to replace old regulations 9 and 14. The purpose is to prescribe particular requirements for chemical products that the APVMA must have regard to in determining whether the chemical product meets the safety criteria. This amendment is necessary to remake old regulations 9 and 14 for the new authority in subparagraph 5A(3)(a)(vii) of the Agvet Code (as amended by the Amendment Act).

Paragraphs 8AB(1)(d) to(f) replace regulation 9 but are now matters that the APVMA must have regard to in determining its satisfaction about whether a chemical product meets the safety criteria. This approach is consistent with the other criteria in paragraph 5A(3)(a) of the Agvet Code which deal with safety matters the APVMA must have regard to. Old subregulations 9(2), (3) and (4) have been recast as matters that the APVMA must have regard to. For example, the APVMA must have regard to whether a molluscicide in the form of a bait and for which the active constituent is metaldehyde, contains sufficient green pigment or dye to colour the bait a distinctive green colour and does not contain any bone meal or other product of animal origin.

As provided for by old regulation 14, paragraph 8AB(1)(a) prescribes the method of analysis of the chemical composition and form of the constituents in a chemical product as a matter that the APVMA must have regard to for the purposes of being satisfied as to whether a chemical product meets the safety criteria.

New paragraphs 8AB(1)(b) and (c) align with old regulation 14A and prescribe matters that the APVMA must have regard to for the manufacture of veterinary chemical products. They require the APVMA to have regard to whether the veterinary chemical product complies or will comply with the manufacturing principles and the Australian GMP Code or in the case of a product manufactured outside Australia, a standard of manufacture that the APVMA has determined is comparable to the manufacturing principles and the Australian GMP Code. The requirements in new paragraphs 8AB(1)(b) and (c) do not apply for chemical products, which are exempt from the manufacturing licence provisions in Part 8 of the Agvet Code. These exempt products are listed chemical products, reserved chemical products and the products described in regulation 59 (including all agricultural chemical products).

The manufacturing principles are the Agricultural and Veterinary Chemicals Instrument No. 1 (Manufacturing Principles) 2007 (a legislative instrument available on the Federal Register of Legislative Instruments). The Australian Code of Good Manufacturing Practice for Veterinary Chemical Products is currently defined in subregulation 3(1), was published on 29 March 2007 and

**Prescribed matters – ‘meets the trade criteria’**

Item 25 inserts new regulation 8AD to require the APVMA to have regard to specified matters for determining whether the use of a product meets the trade criteria. The purpose is to require the APVMA to continue to have regard to prejudice to international trade where products of a treated crop or animal might be exported, or for treated crops that will be fed to animals and where products derived from these animals might be exported.

Regulation 8AD applies whenever the APVMA is required to determine its satisfaction about whether the use of a chemical product meets the trade criteria, including for permit applications and for reconsiderations (section 110 and Division 4 of Part 2 of the Agvet Code respectively). This regulation also applies for other applications when it appears to the APVMA that there are reasonable grounds to believe that the use of the chemical product does not meet the trade criteria (for example, for section 29F applications for re-approval or re-registration), as well as when it appears to the APVMA that the use of the chemical product may not meet the trade criteria (for example, for section 41 suspensions and cancellations).

The authority for this regulation is subsection 5C(3) of the Agvet Code.

Regulation 8AC has been reserved to allow for the future addition of a regulation for the efficacy criteria authorities in subsection 5B(3) of the Agvet Code.

**Prescribed matters – ‘meets the labelling criteria’**

Item 25 also inserts new regulation 8AE to replace old regulation 12. For the authority in 5D(1)(j) of the Agvet Code, the purpose of regulation 8AE is to prescribe matters that may be appropriate for adequate instructions for a label for containers for a chemical product.

Paragraph 8AE(1)(b) includes the matter about the prevention of undue prejudice to trade or commerce between Australia or places outside of Australia as a matter that may be appropriate for adequate instructions for a label. The purpose of this amendment is to specifically authorise the APVMA to ensure adequate instructions in product labels manage trade impacts associated with the use of chemical products, including, for example, the need for export slaughter intervals.

Paragraph 8AE(1)(c) includes the appropriate signal words required by the current Poisons Standard as a matter that may be appropriate for adequate instructions for a label.

The additional matter of the storage of containers of the product is also prescribed in paragraph 8AE(1)(d). This only applies for all veterinary chemical products and for agricultural chemical products that are date controlled chemical products (see section 3 of the Agvet Code for a definition of ‘date-controlled chemical product’). The storage of containers of a product is critical to the efficacy and safety of the product. If a product is not stored as instructed it may degrade and not be effective or not be safe. The APVMA already requires storage conditions in a label and the inclusion of instructions for the storage of containers of the product as a prescribed matter does not have any regulatory impact. However, its inclusion in the regulations improves the transparency about this label requirement for prospective applicants.

**Standards for active constituents, products and labels**

**Standards made by the APVMA**

For the authority in paragraph 6(2)(a) of the Code Act, new regulation 8AF specifies how the APVMA is to make or vary a standard under section 6E of the Agvet Code. Paragraph 8AF(1)(a) requires the APVMA to consider whether the standard or variation is necessary given other standards.
that may already apply and section 1A(2)(c). Paragraphs 8AF(2)(b) and (d) require the publication of a notice about a standard that the APVMA is proposing to make or vary, including a draft of a standard, reasons for why it is necessary and how people can get more information about it.

Subregulation 8AF(2) provides for a public comment period on a standard of not less than 28 days, unless the standard is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA must consider any public comment and must publish a notice about any standard it has made or varied, or alternatively, publish a notice about any standard that it has decided to abandon; including the reasons for the making, variation or abandonment of the standard. In this context, the reasons for making, varying or abandoning a standard would include a response to each issue raised in written submissions on the standard.

The APVMA is not prevented from forming expert committees to assist the APVMA in the development of a standard.

Regulation 1A.1 of the Principal Administration Regulations specifies that the APVMA annual report must include a list of the standards made or varied by the APVMA in that year.

Prescribed application requirements

Application requirements – timeshift applications

For the authority in 8A(d) of the Agvet Code, new regulation 8AG specifies that it is an application requirement for a timeshift application (see item 21) that the application include a project plan with timeframes for submitting information and assessment periods. The project plan must be included in the application to ensure that this plan forms part of the application. The project plan can be varied where the applicant and the APVMA agree on the variation.

Application requirements – copies of applications

For the authority in 8A(d) of the Agvet Code, new regulation 8AH specifies that it is an application requirement for copies of an application to be provided to the APVMA within 28 days of the notice in regulations 8AO, 8AP or 8AQ. Regulations 8AO, 8AP and 8AQ are notices to the applicant that will specify the copies of an application that are required and that these must be provided with 28 days of the notice. If these copies are not provided within 28 days then the application does not meet the application requirements in section 8A of the Agvet Code and the APVMA must refuse the application. (Regulation 72 provides that the APVMA may remit the whole or part of the application fee if an application is refused because the specified copies or form of an application were not provided within 28 days.)

Notices and publication requirements

Notices for holder - approval or registration or variation

For the authority in paragraph 8F(2)(e) of the Agvet Code, new regulation 8AK specifies the requirements that must be included in a notice to a holder of an approval, registration or variation. It ensures that the holder is provided with the same information that is published publicly (for sections 8H and 8J of the Agvet Code, see new regulations 8AM and 8AN below) as well as information about the date of approval and registration, the distinguishing name of the chemical product and the distinguishing number of the approved label for containers for a chemical product. Regulation 8AK also provides for the APVMA to provide other information to the holder that it thinks appropriate.

Notices for applicants – refusal

For the authority in paragraph 8G(2)(c) of the Agvet Code, new regulation 8AL provides for the same notice to be provided to a holder as was provided in old subsection 26A(5) of the Agvet Code.
The regulation provides for a holder to be made aware that they may apply for a variation under Division 3 of Part 2 (variation of conditions or relevant particulars) of the Agvet Code instead of Division 2A of Part 2 (variation of a relevant particular as provided for in a legislative instrument). This would apply, for example, where an application under Division 2A of Part 2 was refused because the relevant particular was not of a kind set out in the legislative instrument made by the APVMA for the purposes of section 26B of the Agvet Code.

**Publication requirements - approval or registration or variation**

New regulation 8AM specifies the matters that must be in notices published in the Gazette and on the APVMA’s website for approvals and variations of approvals for active constituents. New regulation 8AN specifies the matters that must be in notices published in the Gazette and on the APVMA’s website for approvals and variations of approvals of labels for containers of chemical products, and registrations and variation of registration of chemical products.

New regulations 8AM and 8AN align with the previous requirements in old regulations 22B and 22C with one exception. New regulations 8AM and 8AN do not require the APVMA to publish a summary of advice it has received and instead require the APVMA to publish on its website a list of information it has relied on to approve an active constituent or register a chemical product and brief details of the APVMA’s decision. This represents an efficiency measure to reduce the volume of information the APVMA must publish in the Gazette and on its website while still informing the public of the information that it has relied on in making its decision. This measure does not prevent the APVMA from continuing to publish the advice it receives, provided that this advice does not include confidential commercial information.

Information to be published in the Gazette or on the APVMA website includes:

- the name of the applicant (Gazette and website)
- the application number (Gazette and website)
- the name of the active constituent or chemical product (Gazette and website)
- the distinguishing number that the APVMA gave to the active constituent, chemical product or label when the APVMA approved or registered it (Gazette and website)
- a short description of the application and its purpose, including the way in which the active constituent or chemical product is intended to be used (Gazette and website)
- brief details about the APVMA’s decision to approve or vary the approval of the active constituent or label, or to register or vary the registration of a chemical product (website only)
- details of the items of information given in connection with an application that the APVMA relied on to approve the active constituent or label or register the chemical product (website only)
- where relevant, details of other items of information that the APVMA relied on to approve the active constituent or label or register the chemical product (website only)

**Notices for applicants – after preliminary assessment**

New regulation 8AO specifies the matters that must be in notices to applicants that the APVMA issues after preliminary assessment of applications. These notices are provided for by paragraphs 29E(2)(b) and 110A(2)(b) and subparagraphs 11(2)(a)(ii) and 28(2)(a)(ii) of the Agvet Code. Similarly, new regulation 8AP specifies the matters that must be in notices to applicants that the APVMA must issue one month after receiving an application under regulation 8AS (technical assessment). New regulation 8AQ specifies the matters that must be in notices to applicants that the APVMA must issue one month after receiving an application under section 115 of the Agvet Code.

The matters in these notices ensure that applicants are aware of how their application will be progressed, that fees are payable within 28 days and the basis for these fees, and that copies of the application in the appropriate form must be provided within 28 days. The obligation to provide fees and copies of the application within a certain time is made in subregulation 70(7) and regulation
8AH respectively. The matters in the notices also include information about the obligation of applicants in relation to new information relevant to their application that they become aware of, imposed by section 160A of the Agvet Code.

The matters include the opportunities for applicants in relation to the progress of their application, including that they may notify the APVMA to treat the application as having been refused if the application is not determined within the assessment period so that they may seek review or that they may withdraw the application. The purpose of these measures is to inform applicants of how their application will be progressed and their obligations in ensuring the efficient determination of their application.

Listed chemical products

New regulation 8AR replaces old regulation 23A and specifies that chemical products which are listed chemical products are set out in Schedule 3B. The authority for this regulation is subsection 8T(1) of the Agvet Code. This replacement of old regulation 23A is necessary to reflect the new authority in the Agvet Code.

Applications for technical assessments and pre-application assistance

Item 26 – new Division 2.1A

This item inserts a new Division 2.1A that deals with applications for technical assessments and pre-application assistance that the APVMA may provide.

New regulation 8AS clarifies the status of applications for technical assessments described at item 25 in Part 2 of Schedule 6 (known as ‘category 25’ applications) and specifies that these applications are a function that the APVMA may undertake under the Agvet Code. Regulation 8AS improves transparency about these applications and provides that the APVMA may charge a fee for them. Applications under regulation 8AS may include, for example, assessments of trial protocols so that a prospective applicant may have some certainty about whether a proposed experimental methodology is adequate to generate information suitable for regulatory assessment purposes.

New regulation 8AT clarifies that the APVMA function of providing assistance to prospective applicants in preparing their application is a function that the APVMA undertakes under the Agvet Code. This ensures that the APVMA may apply a fee for this assistance. Fees and associated reductions for pre-application assistance are detailed elsewhere in the regulations (see regulations 69B and 70).

Publication of application summaries

Items 27 to 38 – Regulations 8A to 8D

The Agvet Code now provides for companion animal active constituents and chemical products to be eligible for data protection in the same way as for other active constituents and chemical products. As a result, regulations 8A and 8C may be omitted from the Principal Code Regulations. There is no longer any need to maintain specific regulations that deal with the publication of summaries of applications for approval of active constituents for companion animal products. All requirements for publication of application summaries can now be specified in regulations 8B and 8D. Items 30 and 36 are amendments to refer to the new authority in paragraph 11(2)(b) of the Agvet Code (as amended by the Amendment Act). Items 31, 32, 37 and 38 simplify the regulation by instead referring to ‘application information details’ as defined in subregulation 3(1).
Item 39 – Regulation 8E

Item 39 amends the heading of regulation 8E to more correctly refer to products that are the same as a registered chemical product instead of using the undefined term ‘repacks’.

Item 40 – Subdivision 2.1.2

This item repeals this subdivision as the old regulations in this subdivision have been relocated to new Divisions 1.1 or 1.2.

Prescribed particulars for approvals, registrations and labels

Items 41 to 44 – Regulation 15

These items update regulation 15 which prescribes the particulars of approved active constituents that must be recorded in the Record. Item 41 amends the authority for the regulation to reflect the Agvet Code (as amended by the Amendment Act). Item 42 simplifies the particular of the name of the active constituent.

Items 43 and 44 remove particulars that are now required to be recorded by the Agvet Code and inserts the new particulars of the identifying information of the holder and any nominated agent. For Division 4 of Part 1 of the Agvet Code, a holder that is overseas must have a nominated agent that is a resident of Australia and a holder in Australia may have a nominated agent. Holders of an approval and their nominated agents must advise the APVMA of changes in their identifying details. This information is essential for the APVMA as it ensures that they can contact a person responsible for the active constituent in an emergency. It is therefore appropriate that the prescribed particulars for an approval of an active constituent include the identifying information of the holder and any nominated agent.

Items 45 to 49 – Regulation 16

These items update regulation 16 which prescribes the particulars of registered chemical products that must be recorded in the Register. Item 45 amends the authority for the regulation to reflect the Agvet Code (as amended by the Amendment Act). Item 46 simplifies the particular of the name of the chemical product. Items 48 and 49 remove particulars that are now required to be recorded by the Agvet Code and inserts new particulars of the identifying information of the holder and any nominated agent (see discussion about items 43 and 44, above).

Item 47 inserts new prescribed particulars for a registered chemical product. The new particulars are the formulation type and net contents of the chemical product. These are essential characteristics of a chemical product. The purpose of this item is to require the APVMA to record formulation type and net contents for a chemical product in the Register of Chemical Products. The prescription of these particulars will also mean that compliance with these particulars can be imposed as part of the conditions of registration of a chemical product.

In many cases the formulation type is already part of the distinguishing name of a chemical product. Formulation types for chemical products are used internationally and a list of these formulation types is published by the APVMA as part of its guidelines for applicants (that the APVMA makes for section 6A of the Agvet Code).

Net contents is integral to the risk assessment, not only for occupational health and safety but also as a control in terms of the likely market segment the product may be sold to. Having the net contents recorded as a particular provides an efficient mechanism for controlling the supply of a chemical product. The APVMA currently has records of net contents for all registered products in its records.
**Items 50 to 56 – Regulation 17**

These items update regulation 17 which prescribes the particulars for an approved label of containers for a chemical product that must be recorded in the relevant APVMA file. Item 50 amends the authority for the regulation to reflect the Agvet Code (as amended by the Amendment Act). Item 51 updates the particular of the distinguishing name of the chemical product to align with other prescribed particulars.

Item 52 removes the particular about the distinguishing number as that is now required to be recorded by the Agvet Code. Item 54 removes an unnecessary and superseded note. Item 52 also omits regulation paragraph 17(1)(g), as the requirement for the label to bear the ‘name and address of the person who is primarily responsible for marketing the product’ can be enforced more efficiently with regulation 18D and the Labelling Standard. This is a current requirement. Administering the requirement through the Labelling Standard would allow holders to update the contact details as necessary (within the rules set out in the Standard) without the need to make an application to the APVMA.

Items 53 and 55 amend regulation 17 to refer to the Chief Executive Officer (CEO) of the APVMA. This amendment is required because regulation 17(2) is made under the authority provided by paragraph 6(2)(c) of the Code Act which refers to authorising any matter or thing to be from time to time determined, applied or regulated by a particular person. The regulation should therefore refer to a person (the APVMA CEO) rather than an organisation (APVMA).

Item 56 inserts new particulars of the identifying information of the holder and any nominated agent for the label approval. This information is essential for the APVMA as it ensures that they can contact a person responsible for the product in an emergency. It is therefore appropriate that the prescribed particulars for a label approval include the identifying information of the holder and any nominated agent. However, this only applies where this information has not already been recorded for the label approval as part of the registration of the chemical product to reduce the need for double recording of these particulars.

**Method for determining end dates and last renewal dates**

**Item 57 – New subdivision 2.1.3A – Regulations 17A and 17B**

The re-approval and re-registration scheme in Division 3A of the Agvet Code provides for the periodic review (every seven to 15 years) of active constituents and products to ensure that they do not pose unacceptable risks to human or environmental health and safety. The re-approval and re-registration scheme is based on the principle that re-approval and re-registration should occur unless it appears to the APVMA that there are reasonable grounds to believe that an active constituent or chemical product does not meet any of the safety criteria, trade criteria or efficacy criteria. The APVMA is not prevented from commencing a reconsideration at any time, irrespective of any actions taken under the re-approval and re-registration scheme.

The scheme provides that approvals will end on, and chemical product registrations cannot be renewed after, specified dates and holders will be required to apply beforehand for re-approval or re-registration. Chemical product registrations are subject to annual renewal and so the equivalent to an approval end date for a chemical product registration is the last renewal date. Following assessment of applications from approval and registration holders and if there are no reasonable grounds to believe the chemical does not meet the relevant criteria, the APVMA is to re-approve the active constituent or re-register the chemical product for a period of between seven and 15 years.

Irrespective of the prescribed method, the Agvet Code provides for the APVMA to determine end dates for active constituent approvals and last renewal dates for chemical products so that these dates align with the end dates and last renewal dates of certain other approvals and registrations. This allows the APVMA to re-approve an active constituent or re-register a chemical product for a period
less than seven years to allow the approval or registration to end at the same time as another approval for the active constituent or registration of a chemical product containing the same active constituent. Allowing the APVMA to set these dates for a period of less than seven years if it is convenient to do so improves efficiency by aligning future applications for re-approval or re-registration for a particular chemical.

This item inserts new regulations 17A and 17B that, respectively, prescribe the method for working out the date an approval of an active constituent ends, and the date after which the registration of a chemical product cannot be renewed, under Division 6 of Part 2 of the Agvet Code.

**End dates and last renewal dates**

The method in regulations 17A and 17B must be used by the APVMA to:

- determine end dates for approvals of new active constituents and last renewal dates for new chemical products for sections 19 and 20 of the Agvet Code
- determine end dates for active constituent approvals and last renewal dates for chemical products for sections 29J and 29K (following re-approval or re-registration)
- determine end dates for active constituent approvals and last renewal dates for chemical products for section 34AE (following affirmation after reconsideration)

Section 20 of the Agvet Code also applies where, under subsections 26D(2) or 29B(2), the APVMA must include a last renewal date for a chemical product in the Register where it has varied relevant particulars or conditions of a registration. The method in regulation 17B must be used to determine the last renewal dates of chemical products in these situations.

The method in regulations 17A and 17B provides for the determination of the end dates of active constituent approvals and last renewal dates for chemical product registrations for periods of between seven and 15 years. Regulations 17A and 17B provide for ranges where the APVMA determines that an approval be aligned with another approval or a registration aligned with another registration (Column 2 of the tables), as well as a different range (Column 3 of the tables) where approval or registration is not aligned with another approval or registration. While ranges are provided for, the end date and last renewal dates must be the last day of a calendar month (see subregulations 17A(3) and 17B(4)).

The transitional measures in the Amendment Act provide that the APVMA will determine end dates and last renewal dates for the existing inventory of active constituent approvals and chemical product registrations. Despite this, the transitional regulations also include end dates and last renewal dates for specified active constituents and the chemical products containing them (see new regulation 81). The method in regulations 17A and 17B does not apply to these existing approved active constituents and registered chemical products containing them until an application for re-approval or re-registration is to be determined.

**The basis for the method**

The method in regulations 17A and 17B is based on using information that is publicly and readily available, and consistent with criteria used internationally or in Australia for classifying agvet chemicals. As the scheme is based on active constituents, the hazard aspects of active constituents are an important factor in determining the end date for active constituent approvals and chemical product last renewal dates. This approach reflects the Regulation Impact Statement in that the periods between re-registration and re-approval are based on the hazard of the active constituent and risk of its use in the product.
The method is based on the current Poisons Standard; Table 3.1 of Annex VI of European Community (EC) Regulation Number 1272/2008 on the classification of mixtures and substances; the substances listed in the Stockholm and Rotterdam Conventions as set out in Schedule 1 of the Agricultural and Veterinary Chemicals (Administration) Regulations 1995; and the substances subject to the Montreal Protocol. As provided for in paragraph 6(3)(a) of the Code Act and regulation 3(2) of the Principal Code Regulations, these references in the method apply as amended from time to time so that the most up to date references are used to determine end dates and last renewal dates.

The EC Regulation has been incorporated into the method because it is a comprehensive and reputable source of information about the aquatic acute and chronic toxicity of agvet chemicals, and there is no equivalent source of this type of information in Australia. This regulation is readily available and is published on the EC legislation website at this link <http://echa.europa.eu/regulations/clp/legislation>.

Where approval or registration is aligned with another approval or registration

Paragraphs 17A(2)(a) and 17B(2)(a) provide that the APVMA may align the approval end date or chemical product last renewal date with the end date of another approval for the same active constituent or last renewal date of another registration of a chemical product containing the same active constituent. This improves efficiency by aligning future applications for re-approval or re-registration for a particular chemical. Separate ranges are applied in this circumstance (See Column 2 of the tables to regulations 17A and 17B). These separate ranges ensure that the end dates and last renewal dates cannot be earlier than seven years (to be consistent with the authority in the Agvet Code) or later than those that could be determined where no alignment occurs (see Column 3 of the tables to regulations 17A and 17B).

Where approval or registration is not aligned with another approval or registration

Regulation 17A provides that active constituents in Schedule 1 of the Administration Regulations or Schedule 9 or Appendix C of the current Poisons Standard (as well as the active constituent methyl bromide because of the Montreal protocol) will have end dates in the range of seven years to less than eight years after approval or re-approval (items 1 to 3 of the tables). Regulation 17B provides that products containing these active constituents will have last renewal dates in the range of seven years to less than eight years after registration or re-registration.

Regulation 17A provides that active constituents listed in Schedule 8 of the current Poisons Standard or active constituents in restricted chemical products in Schedule 4 of the Principal Code Regulation will have end dates of eight to less than 10 years after approval or re-approval (items 4 and 5 of the tables). Regulation 17B provides that products containing these active constituents will have last renewal dates of eight to less than 10 years after registration or re-registration. This approach reflects that both restricted chemical products and Schedule 8 products have specific restrictions on access and use and it is therefore consistent for them to have the same frequency of re-approval or re-registration.

1 To clarify, the reference to Table 3.1 of Annex VI of European Community Regulation Number 1272/2008 means a reference to the ‘Hazard Class and Category Code(s)’ column in Table 3.1 of Annex VI of European Community Regulation Number 1272/2008 as amended from time to time.

2 Schedule 1 of the Principal Administration Regulations includes active constituents and severely hazardous pesticide formulations listed in the Stockholm and Rotterdam Conventions that Australia has ratified and their reference in the method in its entirety is for simplicity. This does not mean that active constituents listed in the Stockholm Convention that Australia has ratified can be used, approved, re-approved, registered or re-registered. The provisions of the Administration Act and the Administration Regulations already prevent the use of these active constituents in Australia unless this use is authorised under that Act or those regulations.
Regulation 17A provides that active constituents listed in both Schedule 7 of the current Poisons Standard and described as either ‘aquatic acute’ or ‘aquatic chronic’ in Table 3.1 of Annex VI of the EC Regulation will have end dates of eight to less than 10 years after approval or re-approval (item 6 of the tables). Regulation 17B provides that products containing these active constituents will have last renewal dates of eight to less than 10 years after registration or re-registration.

Regulation 17A also provides that active constituents listed in either Schedule 7 of the current Poisons Standard, or described as either ‘aquatic acute’ or aquatic chronic’ in Table 3.1 of Annex VI of the EC Regulation will have end dates of 10 to less than 13 years after approval or re-approval (items 7 and 8 of the tables). Regulation 17B provides that products containing these active constituents will have last renewal dates of 10 to less than 13 years after registration or re-registration.

Regulations 17A and 17B provide that other active constituents and products containing them will have end dates of between 13 and 15 years (item 9 of the tables).

Holders of approval and registration will need to apply for re-approval or re-registration of these active constituents or chemical products when they end or cannot be renewed. Re-approval or re-registration applications may be required earlier than this if prescribed regulators in two or more countries prohibit the use of the active constituent or chemical products containing the active constituent in the previous seven years (section 47A of the Agvet Code). Regulation 22D specifies these prescribed regulators. APVMA is not prevented from commencing a reconsideration at any time, irrespective of any actions taken under the re-approval and re-registration scheme.

Ranges in the method

The method also includes ranges for end dates and last renewal dates to allow the APVMA some discretion in determining these dates. The purpose of this provision is to require the APVMA to determine end dates and last renewal dates within the ranges provided for in the regulations in such a manner as to ensure the most efficient allocation of its resources for determining re-approval and re-registration applications in future years. This requires the APVMA to determine end dates and last renewal dates in the ranges so that the numbers of re-approval and re-registration applications in any given year in the future are as manageable as the APVMA can achieve given the ranges prescribed in the regulations. This might, for example, mean that the APVMA would use the longer periods in the ranges unless the number of applications in that subsequent year were unmanageable or greater than preceding years, and therefore the APVMA could determine a shorter re-approval or re-registration period so that application numbers across the years were as consistent as possible.

The ranges also provide for the APVMA to determine end dates and last renewal dates that align with a particular date in a year (for example, 30 June). This is necessary to recognise that the APVMA may re-approve an active constituent or re-register a chemical product at any time after the application passes preliminary assessment and that re-approval and re-registration applications have a 12 month timeframe. The range provides for the APVMA to apply the same end date for an approval or last renewal date for a registration, irrespective of when in the twelve month timeframe the application is determined. For example, a re-approval application determined in August and another application for the same active constituent determined in June of the following year could have the same end date determined for the active constituent approval.

Multiple active constituent products

As some chemical products contain multiple active constituents, it is possible that these active constituents will have different periods between when re-approval applications are required. Subregulation 17B(3) makes provision for setting last renewal dates for chemical products with multiple active constituents. The intention is that holders of registration of chemical products with multiple active constituents would only be required to apply to re-register chemical products on the

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basis of the active constituent with the lowest number of years in Column 3 of the table in regulation 17B.

**Conditions of approval and registration**

**Item 58 – New Regulation 17C**

This item inserts conditions of approval for active constituents and conditions of registration of chemical products. Paragraph 23(1)(a) of the Agvet Code (as amended by the Amendment Act) provides for the regulations to include conditions of approval and registration. The conditions include that holders of approval and registration must not supply active constituents or chemical products unless the identifying information for a holder or any nominated agent in the Record or Register, respectively, is current (item 4 of the table to subregulation 17C(1) and item 7 of the table to subregulation 17C(2)). This approach ensures that the APVMA always has accurate records of holders of approval and registration and their nominated agents and can contact them if and when necessary.

The conditions also require an active constituent and a chemical product to be manufactured in compliance with particulars recorded in the Record and the Register, respectively. These conditions apply to all approved active constituents and registered chemical products. While the APVMA can already apply these conditions to individual approvals or registrations, the incorporation of these conditions in the regulations promotes transparency and consistency in relation to active constituent approvals and chemical product registrations. It also promotes efficiency as incorporating the conditions in regulations will mean that the APVMA will not need to apply these conditions to each individual approval or registration.

For all chemical products, it is a condition of registration that the products not be supplied unless they comply with the new prescribed particulars of net contents and formulation type. These are essential characteristics of a chemical product. The purpose of these conditions is to prevent the supply of products of a formulation type or net contents that is not recorded by the APVMA in the Register of Chemical Products. This is necessary to ensure that the risks associated with the formulation of chemical products and their supply in suitably sized containers are adequately managed to protect human health and the environment.

Items 3 and 4 of subregulation 17C(2) provide that it is a condition that relevant products not be supplied unless they comply with the manufacturing principles (a disallowable legislative instrument the APVMA makes) and the Australian GMP Code, or a standard of manufacture that the APVMA has determined is comparable to these requirements. This condition provides that it is an offence or contravention of a civil penalty provision to supply chemical products that have not been manufactured to meet the requirements.

**Container and label requirements**

**Items 59 and 60 – Regulation 18**

These items update the heading for regulation 18 to more accurately describe its purpose and remake the regulation for the new authority in paragraph 23(1)(a) of the Agvet Code (as amended by the Amendment Act). While the previous authority provided for regulation 18 matters to be imposed on a discretionary basis by the APVMA, the new authority in the Agvet Code provides for the matters in regulation 18 to be imposed on a mandatory basis. This change does not alter existing regulatory impacts as the container requirements in regulation 18 have historically been imposed for all chemical products by the APVMA. In addition, the detail of the container requirements has not changed. On this basis, the remaking of the regulation as a mandatory requirement for the new authority in paragraph 23(1)(a) of the Agvet Code does not result in any change in the regulatory burden imposed on holders.
Items 61 to 66 – Regulations 18B to 18I

Item 61 remakes regulation 18B for the new authority in paragraph 23(1)(a) of the Agvet Code (as amended by the Amendment Act). Item 62 inserts the name and address of the person primarily responsible for marketing the product into regulation 18D as this enables this matter to be more efficiently enforced through the Labelling Standard made by legislative instrument under regulation 18A. Items 63 and 65 replace the term ‘interested person’ with ‘holder’ to reflect the terminology in the Agvet Code. Item 64 updates regulation 18G to reflect that section 55 has been omitted from the Agvet Code and these matters are now in paragraph 45A(1)(b) of the Agvet Code. Item 66 updates Regulation 18I to use the terms in the Agvet Code of ‘imminent risk to persons of death, serious illness or serious injury’.

Item 67 – Regulation 18J

Similar to conditions of approval for active constituents and registrations of chemical products, this item inserts a condition of approval of a label for containers for a chemical product that the identifying information for a holder or any nominated agent are current. This approach will ensure that the APVMA always has accurate records of holders of approval and their nominated agents and can contact them if and when necessary.

Amending incorrect particulars and conditions

Item 68 – New regulation 18K

This item inserts a new regulation 18K to specify those particulars and conditions that the APVMA must vary if these particulars or conditions are incorrect in the Record or Register. It specifies that the signal words required by the current Poisons Standard are prescribed and this authorises the APVMA to amend these particulars or conditions in the Record or Register if the APVMA is satisfied that they are incorrect.

The definitions of approved active constituent and registered chemical product in the Agvet Code require active constituents and chemical products to comply with the particulars which includes details of holders and nominated agents in the Record or Register. Regulation 18K authorises the APVMA to update the Record or Register to amend the street address and postal address of a holder or nominated agent. No fee would apply for this change and this provides a no-cost means of ensuring holders and nominated agents keep their details up to date in the Record or register.

However, any change to the entity that is the holder or nominated agent would require an application under section 8L, 8M or 8P of the Agvet Code. Under the Agvet Code a holder will be able to apply under section 8L to change the holder or section 8P to change the nominated agent.

Item 69 – Subdivision 2.1.7 and Regulation 19

This item repeals subdivision 2.1.7 and regulation 19 as that regulation has been remade under section 8F of the Agvet Code in regulation 8AK.

Publication of advice summaries

Items 70 to 75 – Regulations 19AA to 19AD

Item 70 repeals regulations 19AA, 19AB and 19AC from the Principal Code Regulations and items 71 to 75 amend the heading and content of regulation 19AD. The Agvet Code (as amended by the Amendment Act) provides for companion animal related active constituents and chemical products to be eligible for data protection in the same way as for other active constituents and chemical products. For this reason, there is no longer any need to maintain specific regulations that deal with the publication of summaries of applications for variation of approvals for active constituents for companion animal products.
In addition, regulation 19AB is repealed because it is unnecessary as no summary is required for variations of approval of active constituents. Item 73 is an amendment to give effect to the new authority for regulation 19AD in paragraph 28(2)(b) of the Agvet Code. Items 74 and 75 simplify the regulation by instead referring to ‘application information details’ as defined in subregulation 3(1).

**Late re-approval and re-registration applications**

**Items 76 and 77 – Regulation 19A**

Item 76 omits the old regulation 19A as these requirements are now dealt with in new regulation 8AB.

Item 77 inserts a new regulation 19A to provide for late re-approval and re-registration applications, including the fees payable for these applications. Subsection 29D(3) of the Agvet Code specifies that the APVMA may accept late applications for re-approval of an active constituent or re-registration of a chemical product. New regulation 19A provides that the APVMA may accept these late applications up until the approval or registration ends. New regulation 19A also provides that the fee for a late re-approval or re-registration application is $500. This fee is in addition to the usual re-approval or re-registration application fee and is intended to encourage applicants to provide re-approval and re-registration applications in a timely manner.

To mitigate the potential for late applications, section 47B of the Agvet Code also requires the APVMA to notify holders 12 months in advance of an approval ending or when a chemical product cannot be renewed. However, the APVMA may provide less than 12 months notice if the date the approval or registration ends or the date after which the registration cannot be renewed is varied under section 47A because of decisions by two more foreign regulators. Potential applicants will always therefore be provided with adequate notice to enable them to make an application and avoid having to pay a fee for a late application.

**Reconsiderations**

**Item 78 – Regulation 20**

This item omits regulations 20 to 22AA as these are no longer necessary because the safety criteria, trade criteria, efficacy criteria and labelling criteria already include these matters and these criteria are considered when the APVMA reconsiders an approval of an active constituent, a registration of a chemical products or the approval of a label for containers for a chemical product. This item also repeals regulation 22A which dealt with prescribed uses that extended the period that the APVMA could not use information for another application under section 34F of the Agvet Code. Section 34F was repealed by the Amendment Act and so regulation 22A is no longer required.

**Reconsideration work plan**

This item also inserts new regulation 20. For the authority in subsection 31(2) of the Agvet Code, regulation 20 specifies the matters that a reconsideration work plan must include. Some measures for the work plan cannot be known at the time that the work plan is first developed and therefore for the authority in paragraph 31(3)(a) of the Agvet Code, subregulation 20(2) specifies that the work plan must be updated at least once a year or whenever specified notices are issued or decisions made.

**Period for providing information, reports, results or samples**

The Agvet Code (as amended by the Amendment Act) provides for reconsiderations (Division 4 of Part 2) to be concluded within a period stated in or determined in accordance with the regulations (section 165A). For a reconsideration, section 33 of the Agvet Code authorises the APVMA to require a holder to conduct or cause to be conducted trials or laboratory experiments and to give the results to the APVMA. Section 33 also authorises the APVMA to require a holder to provide
samples, information, reports or results of trials or experiments to the APVMA. By virtue of paragraph 165A(3)(b), the period required to comply with this notice is not included in the period in which a reconsideration must be concluded.

For the authority in subsection 33(1A), new regulation 21 prescribes limits on the time period for responding to a notice under section 33. The purpose of this amendment is to retain predictability about when reconsidersations will be concluded, while providing holders the opportunity to provide information to support ongoing uses of chemical products. The maximum period that may be stated in a subsection 33(1) notice for responding to the notice is half the period of that in which the APVMA is required to conclude a reconsideration. This maximum period does not apply where an extraordinary event or circumstance beyond the control of the notice recipient prevents the notice recipient from fulfilling their obligations in the notice (i.e. force majeure). The maximum period for providing a response to section 33 notice is to be calculated on the basis of the reconsideration timeframe at the time the notice is issued. This recognises that the time to comply with a section 33 notice varies according to the complexity of the reconsideration and that reconsideration timeframes may change depending on how the reconsideration progresses.

In effect, where trials and experimental data are required by section 33, the maximum period for completing a reconsideration could be extended by a maximum of half that reconsideration period (i.e. a total time of one and a half times the initial reconsideration period). While a shorter period could be applied by the APVMA, aligning the maximum period with the reconsideration timeframe recognises that different reconsiderations will have different timeframes, and more complex reconsiderations are likely to require more time to generate experimental data.

**Notice of decision – reconsideration**

Item 78 also inserts a new regulation 22 that specifies the information that the APVMA must give to a holder when the APVMA affirms an approval or registration following a reconsideration. This ensures that the holder is provided with the same information as that which the APVMA publishes and other information the APVMA thinks the holder should have from the Record, Register or relevant APVMA file. The authority for the notice is provided in paragraph 34AC(2)(e) of the Agvet Code and it aligns with the information provided to a holder following approval, registration or variation (Regulation 8AK).

**Reconsideration of approval of a label without notice**

This item also replaces the old regulation 22AA and amends the prescribed matters which the APVMA can reconsider for the approval of a label for containers of a chemical product without notice. The purpose is to allow the APVMA to efficiently reconsider a label approval to ensure adequate instructions relating to the disposal of the product when it is no longer required, the disposal of the containers of the product, the safe handling of the product and first aid in the event of an accident caused by the handling of the product.

**Prescribed regulators**

**Items 79 and 80 – New Division 2.5**

Item 80 inserts new regulation 22D to specify those prescribed foreign regulators by which decisions made in two or more countries would trigger re-approval or re-registration applications. These regulators are those which the APVMA liaises with now as part of international work-share arrangements, including regulators in Canada, United States of America, United Kingdom and New Zealand. The Agvet Code (as amended by the Amendment Act) includes a new section 47A which details when the APVMA must vary the day an approval ends or a registration cannot be renewed because of actions taken by foreign regulators. The purpose of this section is to provide for an automatic ‘trigger’ for re-approval and re-registration applications. The trigger applies where
prescribed regulators in two or more foreign countries have prohibited all the uses of an active constituent or chemical product to prevent harm to humans or prevent unintended harm to animals, plants, things or to the environment (that is, grounds related to the safety criteria in section 5A of the Agvet Code). Item 79 is an editorial amendment to repeal an unnecessary division heading.

**Item 81 – Part 2A**

This item repeals Part 2A of the Principal Code Regulations as the matters for listed chemical products are now dealt with in regulations for all registered chemical products.

**Items 82 to 106 – Regulations 24 to 38**

These items update Part 3 of the Principal Code Regulations to replace terms in this Part with the new terms used in the Agvet Code (as amended by the Amendment Act). These include replacing ‘applicant’ with ‘holder’ and ‘a primary applicant’ with ‘each primary holder’. Item 95 replaces ‘a reasonable period’ with ‘14 days’ in subregulation 27(2) to remove uncertainty about when notices will be issued about the appointment of an arbitrator.

**Items 107 to 114 – Regulations 40A, 40 and 41**

Item 107 inserts a new division heading. Item 108 removes the redundant regulation 40A which dealt with the possession and supply of active constituents at the time of commencement of the Agvet Code. Regulation 40A ceased to have effect 12 months after the Agvet Code commenced in 1995.

Item 109 is a consequential amendment to regulation 40 to reflect changes to the parts in the Agvet Code that deal with investigative powers and enforcement. Items 110 to 114 are consequential amendments to regulation 41 to reflect that section 83A has been omitted from the Agvet Code and registration of listed chemical products is now dealt under the Part 2 process for registration of chemical products.

**Prescribed standards**

**Items 115 to 117 – Regulation 42**

Item 115 remakes subregulation 42(1) for the more specific authority in subparagraph 87(1)(b)(ii) of the Agvet Code. Item 116 replaces subregulation 42(3) to provide for a new hierarchy of standards that apply to chemical products and their constituents. Section 87(1)(a) of the Agvet Code provides this authority and section 6E of the Agvet Code and paragraphs 6(2)(a), (c) and 6(3)(b) authorise the APVMA to make standards. Section 87 of the Agvet Code provides that products must not be supplied unless they conform to any prescribed standards and that non-compliance is an offence and a contravention of a civil penalty provision.

Standards made under section 6E on or after 1 July 2014 are disallowable legislative instruments. However standards approved before then are not. For this reason, standards made under section 6E (paragraph 42(3)(b)) are second in the hierarchy of standards after Orders made by the Minister (which are also disallowable legislative instruments).

The standards for the listed chemical products in paragraphs 42(3)(c) and (d) are also disallowable legislative instruments. Some listed chemical products do not need to comply with these established standards and paragraphs 42(3)(c) and (d) make it clear that it is only those listed chemical products without a last renewal date in the Register that must comply with these standards. A last renewal date is not included in the Register if the chemical product is a listed chemical product and the product and each label for the chemical product comply with the established standard for the listed chemical product. Item 117 inserts a definition of ‘last renewal date’ for the purposes of regulation 42 to clarify that it is the date after which the registration of a chemical product cannot be renewed under Division 6 of Part 2.
Paragraphs 42(3)(e) and (f) align with the previous prescribed standards in regulation 42 but have been updated to refer to the specifications of pesticides that the World Health Organization develops in addition to those that the Food and Agriculture Organization (FAO) develops. These jointly developed standards are now the contemporary approach used for developing these international standards but the standards include those previously developed by FAO.

Paragraph 42(3)(g) provides for the existing APVMA approved standards to apply and also provides that these standards (not disallowable legislative instruments) apply only if the preceding standards do not. Item 49 of Schedule 6 of the Amendment Act saves ‘approvals’ made before commencement of the Amendment Act and so the approved standards in regulation 42(3)(g) will continue to apply after 30 June 2014.

**Items 118 to 120 – Regulation 44**

Items 118 and 120 amend subregulation 44(1) to correct typographical errors. Item 119 amends subparagraph 44(1)(a)(ii) to reflect changes to the Agvet Code (as made by the Amendment Act) in that old Part 9 of the Agvet Code is now Part 9A and Part 9 now deals with investigative powers.

**Item 121 – Subregulations 46(1A), (1B) and (1C)**

This item removes redundant subregulations 46(1A), (1B) and (1C). These subregulations dealt with the supply of chemical products at the time of commencement of the Agvet Code and ceased to have effect on 30 April 1998.

**Items 122 to 125 – Regulations 46, 52 and 54**

Items 122 and 124 amend regulation 46 and 52 to reflect changes to the Agvet Code (as made by the Amendment Act) in that old Part 9 of the Agvet Code is now Part 9A and Part 9 now deals with investigative powers. Item 123 inserts a new division heading and item 125 corrects an incorrect reference in subregulation 54(2).

**Permits**

**Item 126 – Regulations 57 and 57A**

Item 126 replaces regulation 57 and inserts new regulations 57A and 57B that deal with requirements for the issue of permits. The replaced regulation 57 now refers to the new authority in paragraph 112(2)(e) of the Agvet Code (as amended by the Amendment Act).

*Limits on issue of permits for offences against an ‘eligible law of this jurisdiction’*

Subregulation 57(2) authorises the APVMA to issue permits for offences described at paragraph 109(b) of the Agvet Code in certain situations only. Paragraph 109(b) relates to offences against an ‘eligible law of this jurisdiction’ (defined in section 3) and these eligible laws control use of active constituents or chemical products in the states and territories. Subregulations 57(1) and (2) provide that the APVMA may only issue permits for offences against an eligible law of this jurisdiction if the permits are for minor use, emergency use or research purposes.

**Permits relating to offences and contraventions of section 121 of the Agvet Code**

Subregulation 57(3) and regulation 57A specify the requirements for permits (issued on application or on the APVMA’s own initiative) relating to manufacture of chemical products that would otherwise be an offence or contravention of section 121 of the Agvet Code. These permits are only to be issued in exceptional circumstances and provision for them in the regulations aligns with the measures in the Agvet Code (as amended by the Amendment Act). These new regulations restrict these permits to an in-force period of 90 days. This is to ensure that these permits are not used to circumvent the good manufacturing practice requirements that apply to registered products. Most of
these permits are expected to be issued to address matters about packaging or labelling of chemical products. However, permits may also be issued for formulating chemical products where this is relevant and appropriate in the circumstances. As this restriction relates to the issue of permits, the authority in paragraph 112(2)(e) is considered the most appropriate authority. These permits cannot be extended (see new regulation 57B below).

New regulation 57B specifies the requirements for the extension of the duration of a permit for a further period under section 115 of the Agvet Code. It specifies that the requirements for an extension mirror those for issuing a permit. It also provides that a permit relating to manufacture of chemical products that would otherwise be an offence or contravention of section 121 (paragraph 112(2)(g) of the Agvet Code) cannot be extended. It also provides that permits taken to have been issued for sections 45B or 47D cannot be extended. This is to ensure that permits cannot be used to circumvent good manufacturing practice requirements or to extend the availability of an active constituent or chemical product where the approval of that active constituent or the registration of that chemical product has ended.

The requirements for the extension of a permit require the APVMA to determine whether there are reasonable grounds as to why an application for variation of an approval or registration (including by a third party), as provided for by section 27 of the Agvet Code has not been made (paragraph 57B(g)). The requirements in sections 112(2)((c) and (d) of the Agvet Code are also prescribed as matters that the APVMA must be satisfied about before extending the permit. However these only apply where it appears to the APVMA that its previous assessment of these matters when the permit was issued or previously extended is no longer valid.

**Item 127 – Regulation 58**

This item removes the redundant regulation 58. Regulation 58 dealt with the commencement of provisions relating to manufacturing licences and prescribed that they commenced with the commencement of the Agvet Code and is no longer necessary.

**Items 128 and 129 - Regulations 59C and 59D**

These items amend regulations 59C and 59D which deal with exempt persons for the manufacture of chemical products. The amendments update the regulations to refer to the relevant authority in paragraph 121(4)(a) of the Agvet Code.

**Item 130 – Regulation 59E**

This item amends regulation 59E to update the authority for the regulation in the Agvet Code (as amended by the Amendment Act). The regulation prescribes a requirement for the issue of a licence to manufacture a veterinary chemical product under Part 8 of the Agvet Code. The regulation prescribes that the APVMA must be satisfied that a manufacturer will comply with licence conditions, including any conditions that are to be imposed by the APVMA. These are the conditions specified or imposed under sections 126(1) and (4) of the Agvet Code. The requirements in regulation 59E mirror those licence conditions that the APVMA already imposes when it issues a licence to manufacture a chemical product.

**Item 131 – Regulation 63**

This item is a consequential update to regulation 63 which deals with the method for securing samples. The amendments refer to the new monitoring and investigation powers in the Agvet Code (as amended by the Amendment Act).
Compliance and enforcement matters and infringement notices

**Items 132 and 170 – Regulation 64 and Schedule 5A**

Item 132 removes the old regulation 64 which dealt with the form of a search warrant. The form of a monitoring warrant or investigation warrant is now provided for in the Agvet Code (as amended by the Amendment Act).

Item 132 also includes a new regulation 64 that prescribes the civil penalty provisions for which infringement notices may be issued. Item 170 inserts new Schedule 5A that specifies the civil penalty provisions in the Agvet Code for which an infringement notice may be issued and the amount of the penalty.

The authority for issuing infringement notices by an APVMA inspector is in section 145DA of the Agvet Code. Sections 145DA to 145DF of the Agvet Code include safeguards relating to the issue of infringement notices. These include that notices must be issued within 12 months of the alleged contraventions, that the timeframe to pay the penalty may be extended and the effect of the payment (discharge of any liability).

Subsection 145DB(2) of the Agvet Code provides that the penalty for an infringement notice must be no greater than one-fifth of the maximum penalty that a court could impose for that contravention. The highest penalty in Schedule 5A is one-tenth of the maximum penalty that a court could impose for that contravention. Consistent with the authority in subsection 145DB(3) of the Agvet Code, Schedule 5A provides for a scale of penalties for some infringement notices. This scale is based on the amount of an active constituent or chemical product or the number of containers of a chemical product to which the contravention relates.

**Information that must be given electronically**

**Item 133 – Regulations 65 and 65A**

This item removes old regulation 65 which dealt with those authorities, other than the APVMA, that may require information, reports or samples from an interested person or approved person. This regulation is unnecessary as these requests are made through the APVMA. For the authority in subsection 156A(2) of the Agvet Code, this item also inserts new regulation 65 that prescribes the information that must be given electronically. The information that must be provided in electronic form includes the label container information and short descriptions of information provided in applications. Requiring this information to be provided electronically will improve the APVMA’s ability to more efficiently process applications and reduce the potential for errors in applications.

**Time to respond to a section 159 notice**

Item 133 also inserts new regulation 65A to specify the time in which additional information must be provided to the APVMA by an applicant. The regulation is made for the authority in subsection 159(1AA) and sets limits on the maximum period the APVMA may specify for an applicant to respond to a notice issued under section 159. Should the applicant not respond in the period specified then the application is to be refused (as per the requirements of subsection 8A(c) of the Agvet Code).

Section 159 of the Agvet Code provides that the APVMA may request information from an applicant in order to further consider an application. The Agvet Code currently excludes the time taken for an applicant to provide this information from the application timeframe (‘stop the clock’ mechanism).

The reforms and the Amendment Regulation introduce timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised. The Agvet Code (as amended by the Amendment Act) removes the stop the clock mechanism and institutes a total elapsed time model. Under this new
model the regulations will include the assessment period for an application and an extended assessment period where a section 159 notice is issued. For clarity, the ‘assessment period’ is the time for considering an application where a section 159 request is not made. The ‘extended assessment period’ is the period that replaces the assessment period when the APVMA makes a section 159 request of the applicant. If a section 159 notice is issued then the extended assessment period applies instead of the original assessment period and no further extensions apply.

Regulation 65A prescribes the maximum time that the APVMA may specify in a notice for subsection 159(1) for an applicant to provide additional information and complements regulations 76 and 76A that specify the extended assessment period for an application when a section 159 notice is issued. It is based on a formula approach because different applications have different timeframes. The formula is based on the difference between the assessment period and extended assessment period for the application, less one month to allow the APVMA time to assess additional information.

This regulation does not apply to a section 159 notice for timeshift applications (including global joint reviews) because the timeframe for these applications are agreed with the applicant. The regulation does not prevent the APVMA from issuing more than one section 159 notice for the same application. However, as provided for in regulation 76A, additional notices do not further extend the assessment period. Regulation 65A(4) specifies that the time for responding to a section 159 notice for a re-approval or re-registration application is 28 days. For clarity, for those circumstances not mentioned in 65A the APVMA would determine a reasonable period on a case by case basis.

For the purposes of subsection 159(1AB), subregulation 65A(5) provides that the APVMA may allow a further period if an extraordinary event or circumstance beyond the control of the notice recipient prevents the notice recipient from fulfilling the obligations in the notice (i.e. force majeure). However, this does not increase the extended assessment period.

**Items 134 and 135 – Subregulations 66(2) and 69(5)**

Item 134 replaces the old term of ‘interested person’ with ‘holder’ to align with the new terminology in the Agvet Code. Item 135 omits subregulation 69(5) as there is no need to define ‘Minister’ as section 19A of the *Acts Interpretation Act 1901* already provides that the Minister responsible for administering the Act is the Minister responsible under the Administrative Arrangements Orders.

**Pre-application assistance fees**

**Item 136 – New Regulation 69B**

Item 136 inserts a new regulation 69B which specifies the fees for pre-application assistance. Pre-application assistance may take many forms depending on the nature of the prospective application. For this reason, the regulation provides for the APVMA to make a legislative instrument setting out what is meant by a unit of pre-application assistance for the different kinds of assistance that may be provided. As an example, it is anticipated that the legislative instrument would set out the amount of time for an evaluator or range of evaluators to assist a prospective applicant or whether the unit of pre-application assistance is based on meeting with people in person or for meeting preparation. Section 163A of the Agvet Code provides that the legislative instrument is subject to disallowance.

Subregulation 69B(3) specifies that the fee for each unit or part of a unit of pre-application assistance is $175 and subregulation 69B(4) further specifies that the minimum number of pre-application assistance units that can be purchased is two units. The fees for pre-application assistance in subregulation 69B(4) must be provided at the time of applying for pre-application assistance. Any additional fees for the purposes of paragraph 69B(5) would be payable when an invoice is issued for
these fees. Some pre-application assistance fees may reduce the application fee and this is provided for in new regulation 70.

Application fees and assessment periods

**Items 137 and 138 – Regulation 70**

Item 137 inserts subregulation 70(1) to include reference to applications made under the regulations. This amendment allows for fees to be charged for applications, for example, for pre-application assistance or technical assessments, which are now specifically provided for in the regulations.

Item 137 also inserts new subregulations 70(2) to (7) that specify the fees for an application of a kind specified in Part 2 of Schedule 6. The increases in these fees are in accordance with the approved cost recovery impact statement. The authority for these fees is section 164 of the Agvet Code.

Subregulations 70(3) and (4) also specify the maximum amount of pre-application assistance that may be available to reduce an application fee for an application of a kind specified in Part 2 of Schedule 6. Some applications are not eligible for a fee reduction for pre-application assistance, for example, re-approval or re-registration applications. The reduction of the application fee would occur after the application fee is provided and before the application is determined to allow the APVMA sufficient time to confirm, and validate, the claim for the fee reduction. Subregulation 70(5) refers to regulation 70A for calculating the modular assessment fees that may be applicable for an application.

Subregulation 70(6) specifies the minimum assessment fees to be provided when an application is lodged. This does not prevent an applicant from providing the entire application fee at the time of lodgement even if the fee is higher than the minimum fee. Where the balance of the fees may be provided later, subregulation 70(7) specifies that the balance of any fees is payable 28 days after the notice is given to the applicant under regulations 8A0, 8AP and 8AQ.

Item 138 renumbers previous subregulation 70(6) to 70(8).

**Item 139 – New regulations 70A and 70B**

This item removes redundant regulation 70A which dealt with the fees for applications that were made within 6 months after the Agvet Code commenced. The Agvet Code commenced in 1995 and so this regulation is no longer necessary.

This item also inserts new regulation 70A to specify the modular assessment fees that apply to application modules in Schedule 7. The increases in these fees in Schedule 7 are in accordance with the approved cost recovery impact statement. The authority for these fees is section 164 of the Agvet Code.

Re-categorising applications

Item 139 also inserts a new regulation 70B to provide for the APVMA to re-categorise applications at any time after preliminary assessment. For the purposes of section 164 of the Agvet Code, different application categories and fees are prescribed in the regulations. On occasion an application may be received with its fees, pass preliminary assessment and during further assessment the APVMA may determine that the original application category nominated or the assessment modules necessary for the application are not appropriate. New regulation 70B ensures that any time after preliminary assessment, the APVMA may determine the appropriate category or assessment modules for an application, which may be different from the category or modules identified by the applicant before preliminary assessment. Regulation 70B also ensures that an applicant is advised of any re-categorisation and any changes to assessment periods or fees payable.
In a similar approach to that used for modular assessment fees, new regulation 70B provides that the additional fee or refund for the re-categorised application is the fee payable for the re-categorised application less the fee payable for the application at the time it passed preliminary assessment.

Paragraph 70B(3)(b) specifies that any additional fees must be provided within 28 days. If additional fees are not provided within 28 days then the APVMA must refuse the application on the basis that the application does not meet the application requirements (section 8A of the Agvet Code). Sections 10, 26B, 27 and 110 of the Agvet Code require that an application must meet the application requirements and section 8A of the Agvet Code specifies that this includes the payment of any prescribed fee. Paragraph 70B(3)(c) provides that the APVMA may waive additional amounts if an application is refused on the basis that the amount was not paid within 28 days.

Where the original application fee is more than that for the re-categorised application then paragraph 70B(4)(b) requires the APVMA to remit any difference between the application fee and the fee payable for a re-categorised application as soon as practicable.

Re-categorised applications – assessment periods

Regulation 70B also provides for amended assessment periods for re-categorised applications, that is, the time for the APVMA to determine the re-categorised application. The assessment periods for applications are currently prescribed in regulations 76, 76A and 77. The assessment period for the re-categorised application is to be the same assessment period as if the application had been categorised in the same category as the re-categorised application at the time of preliminary assessment. As provided for by regulation 76A, the extended assessment period would apply for a re-categorised application if the APVMA requires further information from the applicant under section 159.

Items 140 to 146 – Regulations 71A and 71B

Item 140 updates regulations 71A and 71B to refer to the correct authority in the Agvet Code for this fee (in section 164). There is no change to the fee for a renewal application. Items 141 to 146 update the references to ‘interested person’ and ‘listable’ to respectively replace them with the terminology of ‘holder’ and ‘listed’.

Item 147 – New regulation 71C

For the authority in section 164 of the Agvet Code, this item inserts a new regulation 71C that specifies a fee of $50 for applications to change the holder of an approval or registration or to nominate or change a nominated agent. These applications are provided for in sections 8L, 8M and 8P of the Agvet Code.

Item 148 – Regulation 72

Paragraph 164(8)(b) of the Code allows the regulations to prescribe circumstances in which the APVMA may remit fees. Consistent with this authority, regulation 72 provides that the APVMA may remit or waive fees payable under the Agvet Code in prescribed circumstances. This item updates regulation 72 to provide for the fees for an application to be remitted if the APVMA refuses an application following a preliminary assessment. The Agvet Code provides for the APVMA to have discretion whether to remit or waive the whole or a part of the fee and the regulations preserve this discretion. For a re-approval and re-registration application the application fee is not repayable if the application is refused following preliminary assessment.

Paragraph 72(2)(a) provides that the APVMA may remit an application fee where it refuses an application at preliminary assessment under subsections 11(3), 28(3) and 110A(4). Paragraph 72(2)(b) provides that the APVMA may remit an application fee where it refuses an application because an applicant failed to provide the copies of an application in the form specified in a notice.
issued under regulations 8A0, 8AP or 8AQ. These provisions allow the APVMA to remit application fees where an application is refused and assessment has not yet commenced. It is anticipated that in these circumstances the APVMA would remit the whole application fee minus the amount of the fee that is for the preliminary assessment. This fee for a preliminary assessment would be the higher of the fee specified in the preliminary assessment module in item 1 in Schedule 7 or the application fee.

New subregulations 72(3) and (4) align with old subregulation 72(1) and provide that the APVMA may remit a fee where it does not determine the application (other than a renewal application) or the assessment module in the prescribed assessment (or extended assessment) period. Subregulation 72(5) provides that the APVMA may waive the balance of an application fee where it refuses an application because an applicant failed to provide the balance of a fee specified in notices issued under regulations 8A0, 8AP or 8AQ. These provisions allow the APVMA to waive outstanding application fees where an application is refused because the balance of these outstanding fees are not paid on time.

In addition, subregulation 72(6) provides for the APVMA to waive or remit any fee where it considers it is desirable to do so. For example, this may be where the cost of recovering the fee or retaining the fee would outweigh the amount involved. Subregulation 72(7) clarifies that the term ‘application fee’ in regulation 72 has the same meaning as in regulation 70.

**Items 149 and 150 – Regulation 72A**

Item 149 omits subregulation 72A(9) as it is no longer necessary after 1 July 2014. Item 150 replaces ‘listable’ with ‘listed’ to align with the new terminology in the Agvet Code.

**Item 151 – Regulation 73**

This item amends regulation 73 to remove a fee exemption and therefore provide for the APVMA to impose a fee on holders for copies or extracts from the Record, Register or for permit information. However, regulation 73 provides that no fee is payable by either:

- an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159 (1) (a), (b) or (d) of the Code or
- the collecting agency.

**Items 152 to 155 – Regulation 76**

Item 152 inserts a new heading before regulation 76 to reflect the content of following regulations. Items 153 and 154 amend regulation 76 to provide that extended assessment periods under regulations 76A and 76B may apply for an application. Item 155 amends the note to regulation 76 to provide that it does not apply for re-approval and re-registration applications. This amendment recognises the change in the approach to managing applications where, other than for re-approval or re-registration applications, the assessment periods will reflect the total elapsed time for considering an application.

**Item 156 – Regulations 76A and 76B**

This item inserts new regulations 76A and 76B that specify the extended assessment periods that apply to applications when a notice is issued under section 159. New regulation 76B also specifies the extensions of assessment periods when additional amounts may be payable for a re-categorised application.

In the course of an assessment the APVMA may need to request information under section 159 of the Agvet Code in order for it to further its consideration of an application. For clarity, the ‘assessment period’ is the time for considering an application where a section 159 request is not made. The
‘extended assessment period’ is the period that replaces the assessment period when the APVMA makes a section 159 request of the applicant.

Regulation 76A only applies to applications in Part 2 of Schedule 6 but does not apply to section 159 notices for timeshift applications (including global joint reviews). Subregulation 65A(3) specifies that the timeframe to provide further information for timeshift applications is as agreed with the applicant. Regulation 76A does not apply to re-approval or re-registration applications and subregulation 65A(4) specifies a timeframe of 28 days to provide further information for these applications.

The Agvet Code previously excluded the time taken for an applicant to provide information requested in a section 159 notice from the application timeframe (‘stop the clock’ mechanism). The reforms and the Amendment Regulation introduce timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised.

The Agvet Code (as amended by the Amendment Act) removes the ‘stop the clock’ mechanism and institutes a total elapsed time model. Under this new mechanism, where a section 159 notice is issued, the regulations will specify an extended assessment period which will include the assessment time for the application and the time for responding to the section 159 request. The applicant must provide the required information and the APVMA must evaluate the information within the extended assessment period.

New regulation 76A specifies the extended assessment period in which an application must be determined if a section 159 notice is issued. The extended assessment period applies instead of the original assessment period and no further extensions apply. Regulation 76A specifies that these extended assessment periods for an application are in Column 3 in Part 2 of Schedule 6. In general terms, the extended assessment periods are one and one-third of the assessment period for the application. The exception to this is for minor use permits which provide for a longer extended assessment period of up to a maximum of 6 months unless a shorter period is agreed between the APVMA and the applicant.

New regulation 76B provides for an assessment period or an extended assessment period for a re-categorised application to be extended. This extension is separate from the extended assessment period that applies where a section 159 is first issued. Its purpose is to allow an applicant up to 28 days to provide the additional amount for a re-categorised application. The extension begins on the date of the notice in subregulation 70B(3) and ends when the applicant pays the additional amount. Paragraph 70B(3)(b) provides that this additional amount must be provided in 28 days and the APVMA must refuse the application if the additional amount is not provided in 28 days.

**Items 157 and 158 – Regulation 77**

Item 157 is a consequential amendment to regulation 77 to refer to assessment periods and extended assessment periods in Part 2 of Schedule 6. Item 158 removes the redundant ‘11.4’ module reference from regulation 77.

**Item 159 – Regulations 78, 78A, 78B and 78C**

This item replaces regulations 78 and 78A with new regulations 78, 78A, 78B and 78C.

**Commencement of assessment periods**

The purpose of new regulation 78 is to specify that assessment periods for applications in Part 2 of Schedule 6, other than those in items 13A and 26, start when both the required fees and copies of the application are provided to the APVMA by the applicant. These fees and application copies must be provided within 28 days of the notice provided to the applicant under regulations 8AO, 8AP or 8AQ. The assessment period for an application commences on the latter of the dates for which the required
fees and required application copies are provided. Where additional fees or application copies are not required then the application commences on the date of the notice issued under regulation 8AO, 8AP or 8AQ. Regulation 78 specifies that the assessment period for applications in item 13A (made under section 26B) commences when the application is lodged. An application under item 26 (re-approval or re-registration) commences on the day after an approval or registration ends.

Regulations 8AO, 8AP, 8AQ and 78, together with the provisions in the Agvet Code provide for applications to be progressed in specified periods, which provides certainty for applicants, the APVMA and the community about how and when applications will be progressed. In general terms, the net effect of these regulations is to provide for the APVMA to assess and determine an application as follows:

i. application lodged by the applicant
ii. APVMA has one month to complete a preliminary assessment (other than applications under 26B or regulation 8AS) and issue a notice under regulations 8AO, 8AP and 8AQ (other than for applications under section 26B of the Agvet Code)
iii. Applicant has 28 days to provide fees and applications copies as specified in notices issued under regulations 8AO, 8AP or 8AQ
iv. When fees and application copies are provided, the APVMA must assess the application in the assessment period (or extended assessment period if a section 159 notice is issued).

Sections 8L, 8M and 8P applications

New regulation 78A specifies the timeframe of one month for the APVMA to determine applications to change the name of the holder of approval or registration or the name of the nominated agent, and change the Record, Register or relevant APVMA file accordingly.

Reconsideration timeframe

Item 159 also inserts new regulation 78B that specifies a formula for determining the period in which a reconsideration of an approval or registration under Division 4 of Part 2 (also known as a chemical review) must be concluded by the APVMA.

Currently, reconsiderations do not have prescribed timeframes. The Agvet Code as amended by the Amendment Act provides for reconsiderations to be concluded within a period determined or stated in the regulations (section 165A). New regulation 78B specifies a formula that uses the modular assessment periods for registration applications as a basis for determining the period in which a reconsideration is to be concluded. Section 165A excludes certain periods of time from being included in the reconsideration period, specifically notices requiring additional information for sections 32 and 33. Along with other reforms to reconsiderations, the prescription of timeframes for reconsiderations will provide for consistent and more predictable completion of reconsiderations within appropriate timeframes.

As each reconsideration is different, a formula based approach that reflects the individual components of a reconsideration is the best means of determining a reconsideration period. However, the APVMA won’t always know which modules of the reconsideration formula will apply at the commencement of a reconsideration and so the assessment period may be adjusted as the reconsideration develops. If this occurs then the published APVMA work plan must be updated (see regulation 20).

The formula in regulation 78B is based on the following:

- a specific period for toxicology and environment assessment as these assessments are undertaken independently (period A)
• a specific period for chemistry, residues, occupational health and safety and other data to recognise that these matters depend on toxicology and environment assessments undertaken in advance (period B). NB. Trade (module 9) is dealt with as part of a residues assessment
• an increased period for consideration of efficacy data (period 2E)
• an increased period for the finalisation steps of a reconsideration to account for the multiple stakeholders that the APVMA needs to liaise with for a reconsideration (period 3C)
• a specified time to account for consultation with jurisdictions, where this is necessary (period J)
• a period to account for a draft decision on the reconsideration is also provided for in the formula (period D)
• a period to account for an arbitrator to be appointed to determine terms of compensation for the use of protected information (period X).

The formula uses a similar model that the APVMA currently uses with modular applications. For these applications, the specific assessment modules (for example, chemistry, toxicology, residues) required for an application are combined and an overall timeframe for the application determined. The same approach is used for the calculation of a timeframe for a reconsideration. This approach allows for a reconsideration timeframe to be tailored to the scope of the reconsideration with a modular method that stakeholders are familiar with.

New subregulation 78B(2) specifies when the timeframe for a reconsideration commences and new subregulation 78B(3) specifies when the timeframe for a reconsideration concludes.

**Prescribed review of decisions by the Administrative Appeals Tribunal**

**Item 159 – Regulation 78C**

For the authority in paragraph 167(1)(y) of the Agvet Code, regulation 78C prescribes that decisions to refuse applications under subsections 8L(3), 8M(3) and 8P(3) are reviewable by the Administrative Appeals Tribunal.

**Item 160 – New Division 9.4**

This item inserts a new division heading to improve readability of the Principal Code Regulations.

**Regulations for the Agricultural Chemicals Legislation Amendment Act 2013**

**Reviews of prescribed matters**

**Item 161 - Part 9A**

For the authority in sections 5 and 6 of the Amendment Act, regulations 80A to 80F prescribe reviews of some matters that relate to the functions and powers of the APVMA. These regulations specify information about the terms of reference for these reviews, how the reviews are to be conducted and the reporting arrangements for these reviews. These prescribed reviews include a review of mechanisms to encourage variations of chemical product registrations and label approvals to improve access to chemical products necessary for minor uses, for example to control pests and diseases of specialty crops and animal species.

**Transitional regulations**

Item 161 also inserts regulations 80 to 85 to provide for transitional and application measures. The authorities for these measures are items 51, 57 and 58 of Schedule 6 of the Amendment Act. The purpose of these measures is to ensure an orderly introduction of new requirements in the Agvet
Code (as amended by the Amendment Act). Regulation 80 inserts definitions of ‘Amendment Act’ and ‘old Code application’ to be used for the transitional regulations.

**End dates and last renewal dates for existing approvals and registrations**

Item 51 of Schedule 6 of the Amendment Act requires the APVMA to give an end date and last renewal date to approvals and registrations in force under the old Code or which come into force under the old Code because of item 47. Regulation 81 specifies that 30 June 2015 is the end date for the approval of the active constituents in subregulation 81(4). Regulation 81 also specifies that 30 June 2015 is the last renewal date for chemical products containing an active constituent in subregulation 81(4). These requirements do not apply if these active constituents are being reconsidered under Division 4 of Part 2 of the Agvet Code as there is no reason to require re-approval or re-registration applications for active constituents that are already under reconsideration.

The purpose of regulation 81 is to specify the active constituents (and products containing them) that are to be the first active constituents and chemical products for which applications are made for re-approval and re-registration. The active constituents specified in subregulation 81(4) are those specific active constituents that:

- are not currently being reconsidered by the APVMA and
- are not currently approved in the European Union, United States of America, Canada or New Zealand and
- have not recently been reconsidered or approved by the APVMA in the last seven years and
- are in chemical products currently registered in Australia.

The active constituents specified in subregulation 81(4) also include those active constituents (and products containing them) mentioned in Schedule 7 of the current Poisons Standard at the time of registration of the Amendment Regulation and classified as ‘aquatic chronic 1’ in Table 3.1 of Annex VI of the European Community Regulation Number 1272/2008 at the time of registration of the Amendment Regulation. These references are fixed in time to allow the APVMA sufficient time to identify and plan for those active constituents (and products containing them) which will enter the re-approval and re-registration scheme first.

For the remaining chemical product registrations and active constituent approvals (the existing inventory) the APVMA will determine the end dates and last renewal dates based on the length of time the active constituent or chemical products containing the active constituent have been available in the Australian market.

**Old Code applications**

Applications made under the old Code may still be under consideration 12 months after commencement of Schedules 1 to 6 of the Amendment Act. However, at this time the new Code will apply to these applications, including the new obligations about meeting application requirements.

For old Code applications that have not been determined 12 months after commencement, regulation 82 ensures that the application requirements under the old Code continue to apply beyond 12 months after commencement.

For old Code applications, regulation 83 specifies transitional arrangements that deal with finalising the preliminary assessment of any of these old Code applications if this is necessary 12 months after commencement. Regulation 83 provides that after 30 June 2015 the preliminary assessment is to be finalised under the preliminary assessment provisions in the new Code. However, this is not to occur until after any period in a preliminary assessment notice issued under subsection 11A(3) of the old Code has passed, or earlier if the applicant responds to the notice earlier than the period specified in the preliminary assessment notice.
For old Code applications, regulation 84 specifies transitional arrangements that deal with timeframes for old Code applications at a time 12 months after commencement. The remaining timeframe for the old Code application is to be calculated on the basis of the longer assessment periods in the new Code, taking into account any time remaining of the old Code assessment period but excluding any periods that was not part of the assessment period under subsection 165(2) of the old Code. The remaining timeframe for the old Code application commences on 1 July 2015 (12 months after commencement of Schedules 1 to 6 of the Amendment Act) unless a notice requiring additional information has been issued under section 159 of the old Code. If a notice under section 159 has been issued then the remaining assessment period does not start until the end of the notice period or when the applicant responds to the notice, whichever is earlier.

Old Code reconsiderations

Reconsiderations commenced under the old Code may not have been determined at a time 12 months after commencement of Schedules 1 to 6 of the Amendment Act. However, at this time the new Code will apply to these reconsiderations and regulation 85 specifies the timeframe and work plan requirements for these old Code reconsiderations.

Subregulation 85(2) requires the APVMA to prepare a work plan for an old Code reconsideration by 1 July 2015.

As in regulation 78B, subregulations 85(3), (4) and (5) specify the time in which a reconsideration (commenced under the old Code) must be concluded. The formula is based only on those items in the formula that the APVMA considers are necessary to carry out for the old Code reconsideration after 1 July 2015.

The timeframe for an old Code reconsideration commences on 1 July 2015 (12 months after commencement of Schedule 1 to 6 of the Amendment Act) unless a notice requiring additional information, results, reports or samples has been made under the old Code (sections 33 or 159). If a notice has been issued then the timeframe does not start until the end of the notice period or when the applicant responds to the notice, whichever is earlier.

Further regulations for the Agvet Code

Items 162 to 170 – Schedules 2, 3A, 3B, 4, 5 and 5A

Item 162 removes Schedule 2 which contained information for calculating the protection period for data as defined in regulation 6. As the protection period of 8 years is specified in the Agvet Code (as amended by the Amendment Act) and regulation 6 is being removed, there is no need for Schedule 2. Item 162 also omits Schedule 3A as it and the definition ‘major food crop’ are no longer required. Items 163 to 167 update Schedule 3B to use the terminology of ‘listed chemical product’ throughout the Schedule as provided for by the Agvet Code.

Item 168 removes two redundant entries from the restricted chemical products in Schedule 4. As products containing chlordane and heptachlor are no longer permitted to be manufactured or used in Australia, there is no longer a need to provide for the use of products containing these substances as restricted chemical products.

Item 169 removes Schedule 5 which deals with the form of a search warrant. The form of a monitoring warrant or investigation warrant is now provided for in the Agvet Code (as amended by the Amendment Act) and so this Schedule is no longer necessary. See item 132 for information about new Schedule 5A that is inserted by item 170 and that specifies the civil penalty provisions in the Agvet Code for which an infringement notice can be issued and the amount of the penalty.
**Application fees and assessment periods in Schedules 6 and 7**

### Items 171 to 173 – Part 2 of Schedule 6

Item 171 omits the definition of ‘major food crop’ as it is no longer necessary. Items 4 and 11 of Part 2 of Schedule 6 have been amended to replace reference to a ‘major food crop’ with ‘a full assessment of the chemical product is required’ to align with the terminology used in other items of Part 2 of Schedule 6.

Items 172 and 173 update the heading and replace Part 2 of Schedule 6 with a new part to prescribe assessment periods, extended assessment periods and application fees.

The assessment periods (timeframes) for application categories have not changed since 1995. They have been increased to reflect the more complex risk assessment approaches and greater transparency measures that have been introduced since 1995. Examples of increased assessment complexity include the need to conduct acute dietary exposure assessments and the publication of application and advice summaries. The extended assessment periods for the various application categories are also described in Part 2 of Schedule 6 (for new regulation 76A)(Column 3).

The application fees have also been increased in accordance with the approved cost recovery impact statement. Column 4 specifies the maximum amount of any pre-application assistance (as provided for in regulation 69B) that may reduce an application fee.

**Timeshift applications**

A new category of ‘timeshift’ application has been included in Part 2 of Schedule 6 (item 27). A timeshift application may include a global joint review and is an application that the applicant has requested be assessed and determined as a timeshift application. A timeshift application must be for either or both of the following:

- approval of an active constituent that is not a previously endorsed active constituent (section 3 of the Agvet Code includes a definition)
- registration of a chemical product if there is no registered chemical product containing the active constituent.

For a timeshift application, applicants may request the APVMA to accept an application which does not contain all the information required for the application. That is, the application would not be accompanied by all of the information that is otherwise required for the application at the time the application is lodged. If the APVMA agrees to assess and determine an application as a timeshift application it will assess the application on the understanding that the applicant will submit the outstanding information according to the agreed project plan for the application. All timeshift applications are treated as modular applications and only exist if an applicant requests such an application and the APVMA agrees to accept and consider a timeshift application.

As provided for in regulation 8AG, a timeshift application must include a project plan that the applicant has agreed with the APVMA detailing when the applicant will provide the data for the timeshift application and when the APVMA will complete assessment of that data. The agreed project plan may include multiple dates when data will be provided and may be revised after a timeshift application has been lodged but only if both the applicant and the APVMA agree. For a timeshift application the assessment period is as set out in the agreed project plan and extensions of this assessment period are not applicable as the project plan will set out the dates for providing information. The assessment fee for timeshift applications is the modular assessment fee. For a timeshift application, the maximum pre-application fee reduction is $1 400.

**Permits**

The new Part 2 of Schedule 6 mentions extensions of the duration of a permit for a further period as part of the permit application category descriptions. In addition, item 19 of the new Part 2 of
Schedule 6 clarifies that this item only deals with permits where no data of a technical nature is required. Item 19 is an application for a permit to possess or supply, other than for use in Australia. Consistent with the fee for this application the amendment provides that it only applies where no assessment of data of a technical nature is required. Where technical data assessment is required then item 23 is the most appropriate category.

Re-approval and re-registration applications

A new category for re-approval and re-registration applications has been included in Part 2 of Schedule 6 (item 26). No pre-application assistance fee reduction is available for re-approval or re-registration applications.

Listed Chemical products

Item 9 of Part 2 of Schedule 6 has been amended so that it only applies for an application for registration of a listed chemical product and approval of a product label where the product and each label for the product comply with the established standard that has been made in accordance with section 8U of the Code. For other applications for a listed chemical product, another item in Part 2 of Schedule 6 would apply depending on the application.

Editorial changes

Item 25 of Part 2 of Schedule 6 now cross-references to regulation 8AS for which applications for technical assessments are specifically now provided.

Item 174 – Schedule 7

This item inserts a new Schedule 7 to increase fees and assessment periods for assessment modules and to specifically provide for assessment modules for timeshift applications. The fees have been changed in accordance with the approved cost recovery impact statement.

The extended assessment periods are in Part 2 of Schedule 6 and are described above for new regulation 76A. Modules 2.4 and 11.4 have been deleted as they are no longer necessary.