

2010-2011-2012

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT
BILL 2012**

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Agriculture, Fisheries and Forestry,
Senator the Hon. Joe Ludwig)

TABLE OF CONTENTS

Glossary	iv
GENERAL OUTLINE	1
Objectives of the Bill.....	1
Overview of amendments	2
<i>Approvals, registrations, permits and licences</i>	2
Simplification, reorganisation and modernisation of the Agvet Code	2
Enhanced consistency and transparency of assessments	2
Improving assessment efficiency and effectiveness	3
<i>Re-approval and re-registration</i>	3
<i>Enforcement</i>	3
New offences and civil penalty provisions	4
Penalty increases	5
Abrogation of privilege against self-incrimination for certain notices	5
Suspension or cancellation to prevent imminent risk to persons of death, serious injury or serious illness	5
Powers for persons assisting APVMA inspectors	6
Costs of investigation	6
Infringement notices	6
<i>Data protection</i>	6
<i>Levy collection</i>	7
Retrospective application	7
<i>Other amendments</i>	7
Legislative instruments	7
Retrospective application	7
Public Consultation.....	8
Policy context	8
<i>Agricultural chemicals and veterinary medicines</i>	8
<i>National Registration Scheme</i>	8
<i>Roles and responsibilities of the APVMA</i>	9
<i>Reform context</i>	9
<i>Election commitment</i>	9
FINANCIAL IMPACT STATEMENT	9
REGULATION IMPACT STATEMENT	10
STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS	10
NOTES ON ITEMS	17
SCHEDULE 1 – Approvals, registrations, permits and licences	18
Summary	18
Detailed Explanation	18
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	18
General provisions about applications	24
General provisions about notices	25
Holders and nominated agents	26
Notice of certain proposed decisions	27
Established standards	28
Preliminary assessment	29
Approvals and registrations	30
Conditions for approvals or registrations	32
Incorrect particulars or conditions	32
Varying prescribed relevant particulars	32
Varying relevant particulars and conditions	33
Reconsideration	36
Permits	40
Preliminary assessment	40
Issuing permits	41
Permits issued on the APVMA’s initiative	42

SCHEDULE 2 – Re-approvals and re-registrations.....	50
Summary.....	50
Detailed Explanation	50
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	50
Preliminary Assessment	51
Re-approval and re-registration	51
Reconsideration	52
How re-approval or re-registration take place	52
Decisions of foreign regulators	53
Notices of approval or registration	53
Permit taken to have been issued	54
SCHEDULE 3 – Enforcement	56
Summary.....	56
Detailed Explanation	56
<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>	56
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>	58
Monitoring and investigation powers	60
Rights and responsibilities of occupiers	62
Seizure	62
Warrants	62
Civil penalty orders	63
Civil penalty provisions - evidential burden	64
Civil penalty provisions - liability for executive officers of body corporate	65
Infringement notices	65
Enforceable undertakings	66
Injunctions	66
Substantiation notices	67
Warnings	67
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	68
Notices to produce or attend	76
Monitoring and investigation powers	77
Rights and responsibilities of occupiers	80
Seizure	80
Warrants	81
Civil penalty provisions and orders	82
Enforceable undertakings	85
Injunctions	86
Substantiation notices	86
Enforceable directions	87
Warnings	87
SCHEDULE 4 – Data Protection.....	90
Summary.....	90
Detailed Explanation	90
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	90
SCHEDULE 5 – Arrangements for collecting levy.....	97
Summary.....	97
Detailed Explanation	97
<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>	97
SCHEDULE 6 – Miscellaneous.....	99
Summary.....	99
Detailed Explanation	99
Part 1 – Miscellaneous amendments	99
<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>	99
<i>Agricultural and Veterinary Chemicals Act 1994</i>	99
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>	100
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	101
Part 2 – Transitional, application and savings provisions	102

GLOSSARY

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

Abbreviation	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority
Admin Act	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
agvet chemical	agricultural chemical and veterinary medicine
Agvet Act	<i>Agricultural and Veterinary Chemicals Act 1994</i>
Agvet Code	Schedule to the Code Act (see below)
Bill	Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
CEO	Chief Executive Officer of the APVMA
COAG	Council of Australian Governments
Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Collection Act	<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>
FSANZ	Food Standards Australia New Zealand
<i>Gazette</i>	APVMA Gazette
the <i>Guide</i>	<i>A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers</i> , published the Attorney General's Department.
LI Act	<i>Legislative Instruments Act 2003</i>
Minister	Minister for Agriculture, Fisheries and Forestry
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
penalty unit	Defined by reference to section 4AA of the <i>Crimes Act 1914</i> . At the time of writing a penalty unit is \$110.
policy discussion paper	<i>Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper</i> , released November 2010
reconsideration	A reconsideration of an active constituent or label approval or chemical product registration, known widely as a chemical review
Record	Record of Approved Active Constituents for Chemical Products
Register	Register of Agricultural and Veterinary Chemical Products
therapeutic goods legislation	<i>Therapeutic Goods Act 1989</i>

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

GENERAL OUTLINE

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill) amends the *Agricultural and Veterinary Chemicals Act 1994* (Agvet Act), *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act), the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act).

Objectives of the Bill

The Bill implements reforms to the approval, registration and reconsideration of agvet chemicals to 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. The Bill makes it clear that the health and safety of human beings, animals and the environment is the first priority of the regulatory system.

The reforms aim to encourage the development of newer and safer chemicals by providing more flexible and streamlined regulatory processes with higher levels of transparency and predictability for business seeking approval for agvet chemicals to enter the market. The reforms should result in a more straightforward assessment process that is easier to understand and more cost effective to administer. In many cases, particularly for products of low regulatory concern, the reformed system as established by these amendments should be faster, deliver more predictable outcomes and result in improved health and environmental protection for the broader community.

The reforms also seek to provide greater assurance for all stakeholders about the safety of new and existing agvet chemicals. This is achieved by implementing a systematic approach to regular review of approvals and registrations, which is tailored to the Australian agricultural and veterinary chemicals market. The amendments in the Bill enhance the Australian Pesticides and Veterinary Medicines Authority's (APVMA) ability to ensure compliance with its decisions and to manage issues of non-compliance.

Benefits to human health and the environment flow particularly from improved access to newer and safer chemistry, increased scrutiny of currently available chemicals for their human and environmental health and safety impacts, and from improved mechanisms to ensure compliance with regulatory decisions. Business benefits through increased certainty over regulatory requirements and timeliness, reduced application requirements where permitted by appropriate risk management, improved data protection provisions and increased community confidence in regulatory outcomes.

The amendments:

- Enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, which the APVMA must have regard to and legislative amendments to align regulatory effort with chemical risk
- Ensure the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration regime, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses

- Improve the efficiency and effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations
- 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.

The Bill also includes other amendments to remove redundant provisions and amend out of date provisions.

Overview of amendments

Approvals, registrations, permits and licences

Simplification, reorganisation and modernisation of the Agvet Code

The Bill simplifies, reorganises and modernises the Agvet Code to reduce uncertainty and complexity in the legislation, and improve the operation and understanding of the legislation. The Bill also includes other amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation.

The Office of Parliamentary Counsel has made extensive technical revisions to the Agvet Code, amending provisions around applications, reconsiderations, re-approval and re-registration, suspensions and cancellations, notices and data protection. These amendments provide a streamlined and simplified way of achieving the existing objectives of the Agvet Code.

The existing Agvet Code largely reflects legislative drafting standards of the early 1990s. These revisions bring these areas of the Agvet Code up to contemporary standards for legislative drafting. The improvements in comprehension and utility delivered by these changes are significant, with benefits particularly for improved efficiency in complying with and administering the Agvet Code.

Some highlights of this are revision of the explanation sections; consolidation of existing ‘legislative tests’ for approval and registration, variation, reconsideration and elsewhere into four ‘*meets the X criteria*’ tests; a single set of general provisions relating to all applications except those for licences and consolidated notice provisions. The Bill also substantially simplifies provisions around ‘interested persons’ and ‘approved persons’ to address some inconsistencies in the Agvet Code.

The Bill also simplifies provisions related to listed registration, ‘mainstreaming’ these registrations with other registrations of chemical products and approvals of labels, but with simpler criteria for registration.

Enhanced consistency and transparency of assessments

The Bill includes amendments that improve the efficiency and effectiveness of agvet chemical regulation through increased transparency and predictability of decision-making. The amendments provide for the APVMA to make, publish and have regard to guidelines. These are to form part of an overarching risk-based compendium that would be developed, maintained and published by the APVMA. The compendium will improve transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions.

The compendium assists in communicating the APVMA's acceptable level of risk and regulatory posture in regulating agricultural and veterinary chemicals. The compendium also allows the APVMA and its regulatory partners to determine the scale of an assessment appropriate to the decision by better matching regulatory effort to risk. Providing a comprehensive reference to the risk assessment process improves the predictability of regulatory decisions, and therefore increases certainty and consistency for applicants and the community.

Improving assessment efficiency and effectiveness

The Bill also includes amendments to address concerns about the time taken by the APVMA to complete applications and reconsiderations. The current assessment timeframes do not take into account the total time elapsed for considering an application or finalising a reconsideration (known as chemical review). This does not provide for certainty and predictability in assessment timeframes for applicants or the APVMA. In addition, applicants may provide data for the APVMA's consideration at any time. These existing arrangements unnecessarily frustrate the finalisation of assessments for applications and reconsiderations.

The amendments require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The reforms also 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 reforms introduce timeframes for reconsiderations (also known to the community as chemical reviews). Along with other reforms to reconsiderations, this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes.

The reforms would ensure that there is no undue impediment to the use of overseas data and assessments by the APVMA, where conducted by comparable agencies and while recognising differences in national approaches. The reforms enable the APVMA to require electronic communication between it and applicants. This electronic communication would also streamline the APVMA's internal administrative processes.

Re-approval and re-registration

Australia currently has no requirement for existing agricultural and veterinary chemicals to be regularly reviewed. Australia has an ad hoc reconsideration system whereby chemicals of concern are brought to the regulator's attention by the community, by industry itself or on the regulator's own initiative. This existing approach is not consistent with international best practice.

Consistent with international practice and coupled with Commonwealth funding to mitigate start-up costs, the Bill provides for a mandatory scheme for re-approval and re-registration. Re-approval and re-registration will increase the scrutiny of chemical constituents and products through a scheme that minimises impacts on industry. The scheme provides a greater level of assurance that existing chemicals and products do not pose an undue risk to human health or the environment, and further promotes public confidence in agvet chemical regulation.

Enforcement

The APVMA currently lacks a modern graduated compliance regime. The current legislation provides no intermediate measures between the extremes of warning letters and criminal prosecution. In addition, some provisions limit the APVMA's ability to respond when new information becomes available during the course of an investigation.

The Bill modernises agvet chemical regulation by introducing provisions that allow for a graduated and contemporary approach to compliance and enforcement. These improve the ability of the APVMA to efficiently administer its regulatory decisions, and protect public health and safety and the environment. The measures are comparable to those available to other regulators under other Commonwealth laws.

New offences and civil penalty provisions

The Bill includes a number of new offence provisions. The new offences either align with existing or previous offences or are consistent with the *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers* (published by the Attorney-General's Department) (the *Guide*) and include:

- offences (30 penalty units) for not complying with the directions of APVMA inspectors, which align with the 30 penalty unit offence in the previous section 131 of the Agvet Code (sections 69EAC, 69EBA and 69EBC of the Admin Act and sections 131A, 132A and 132C of the Agvet Code)
- offences (30 penalty units) for not complying with a notice to produce or attend (section 130B)
- new offences (30 penalty units) for failing to provide assistance to APVMA inspectors (section 69EFA of the Admin Act and section 138D of the Agvet Code)
- offences for not complying with enforceable directions (section 145H of the Agvet Code (30 or 120 penalty units) consistent with the 30 penalty unit offence in the previous section 131
- offences (50 penalty units) for not complying with substantiation notices (sections 69ENB of the Admin Act and section 145GB of the Agvet Code), which is consistent with existing and previous penalties in agvet chemical legislation
- offences (50 penalty units) for not complying with a requirement to answer questions or produce documents to an APVMA inspector executing a warrant (sections 69EAH and 69EC of the Admin Act and sections 131F and 132G of the Agvet Code), which is consistent with other penalties in agvet chemical legislation.

The offence in section 99 has been amended to address an inconsistency and provide that this section applies in relation to active constituents as well as to chemical products, with no change in the penalty amount. A new offence has also been included in section 116 to deal with non-compliance with permit conditions with a penalty that is consistent with other offences in the Agvet Code that deal with non-compliance with conditions. New offences have also been included in sections 143D of the Agvet Code and section 69EHD of the Admin Act, which apply to APVMA inspectors and warrants.

The Bill also provides for existing offence provisions to also be civil penalty provisions, and to allow the APVMA to apply to the court for a civil penalty order against a person who has contravened a civil penalty provision. The financial disincentives to misconduct provided by civil penalties are a more proportionate and effective enforcement tool, reflecting the practice of other areas of (particularly, corporate) regulation under Commonwealth legislation.

A number of current offences in agvet chemical legislation place an evidential or legal burden on a defendant in certain circumstances. The new civil penalty provisions within the Bill place the same evidential or legal burden on a defendant in the same circumstances as the existing offences. With two exceptions, the amendments in the Bill ensure minimal changes to existing offences so as not to disturb the existing provisions dealing with the evidential burden and legal burden. The exceptions are new section 45C of the Agvet Code (Schedule 3 of the Bill) and to a lesser degree new section 47E (Schedule 2 of the Bill).

Section 47E mirrors old section 54. New section 47E contains the same defence as in old section 54 with the same evidential burden for the defence. The old (pre-amendment) sections 45A and 55 have been amalgamated into new sections 45A, 45B and 45C. Just as is provided for in old sections 45A and 55, new section 45C provides for a strict liability offence for possessing, having custody of, or other dealing with a suspended active constituent or chemical product in contravention of the instructions in the notices provided to persons or notices which have been published. The defences in the old subsections 55(5) and (6) have been retained as subsections 45C(3) and (4). The defence and the reversal of the onus of proof in subsection 45C(4) mirrors the current defence and onus of proof in old subsection 55(6).

The approach of aligning the defences and burdens of proof in the new provisions with those in the old provisions results in the least impact on all parties to which the old and new offence provisions relate (see the Statement of Compatibility with Human Rights below for more detail on this measure).

Penalty increases

The penalties for some offences have been increased in the Admin Act (sections 69E, 69EA and 69EP), the Collection Act (sections 15, 20 and 36) and the Agvet Code (sections 88, 89 and 170A) to ensure that the penalty remains proportionate to the potential gain from non-compliance and to align with the penalties for other similar offences. The penalties for these offences have been increased from either 20 or 30 penalty units to 50 penalty units.

Abrogation of privilege against self-incrimination for certain notices

Consistent with the *Guide*, the Bill includes a new Division 2 in Part 9 that deals with notices requiring people to attend, give information and produce documents or things. This new division provides for the more efficient collation of information to provide a response that is complete and allows persons to consider their rights and obligations and seek appropriate legal advice before providing information, documents or answers to questions. The new division aligns with old section 144 but includes a new section 130C that abrogates the privilege against self-incrimination for the purposes of a notice under section 130 (see the Statement of Compatibility with Human Rights below for more detail on this measure).

Suspension or cancellation to prevent imminent risk to persons of death, serious injury or serious illness

New sections 35A and 119A allow the APVMA to suspend or cancel, respectively, a registration or a permit where it considers this is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA may exercise this authority whether or not the product is being used in accordance with its instructions for use or conditions of the permit.

This measure provides for the APVMA to only take action in those situations where action is strictly necessary to protect people. For example, where the APVMA needs to take action as part of a whole of government response to an emergency or major public health incident, where other agencies are taking commensurate and parallel action. There must be an imminent risk of death or serious illness or serious injury to a human that relates to use of a registered agvet chemical product or to a permit. The imminent risk must be able to be addressed (even in part) by cancelling or suspending the registration or permit. Suspension or cancellation of the registration/permit must be necessary (and thus proportionate to the risk and the most appropriate course of action to take) to address the imminent risk.

Powers for persons assisting APVMA inspectors

Persons assisting can exercise powers while inspectors are exercising powers but they cannot exercise these powers once an APVMA inspector has completed the execution of the warrant. A guard can be placed to guard evidence but can only act in accordance with the directions of an inspector. However, other laws generally provide for police to attend premises to support APVMA inspectors. Police would act independently of APVMA inspectors and may choose to take action in respect to relevant Commonwealth, state or territory laws.

Costs of investigation

A new section 149A has been included to allow the APVMA to apply to a court to have a person pay certain costs incurred in investigation of the offence or civil penalty provision. While this provision is not consistent with the *Guide*, a provision to allow for offsetting costs in particular situations avoids inappropriate drains on the APVMA's resources (which are almost fully cost recovered from industry). The measure minimises the impact on compliant industry participants by providing for convicted industry participants to be responsible for reasonable costs and expenses. Safeguards have been included by limiting a court order to reasonable costs and expenses that the court considers just and equitable.

Infringement notices

Section 69EK of the Admin Act and section 145DA of the Agvet Code provide for infringement notices to be issued where there are reasonable grounds to believe a civil penalty provision has been contravened. Sections 69EKA and 145DB provide for a scale of infringement notice penalty amounts to apply for alleged contraventions and for this scale to be detailed in the regulations. While the provision for a scale of amounts is not consistent with the *Guide*, this scale is intended to provide for a proportionate response to contraventions based, for example, on the amount of substance concerned or the number of containers implicated in an alleged contravention. These provisions also specify that the infringement notice penalty must be less than one-fifth of the maximum that a court could impose, which provides a safeguard as to the maximum amount that could be imposed.

Data protection

Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. As investment in regulatory data can require significant resources and because the time taken to collect such data and have it assessed by the regulator diminishes its value, the protection of these data encourages innovation in agricultural and veterinary chemicals. In the case of new chemical products this means that the APVMA cannot rely on data it holds to register a product without the data owner's permission and before the protection period has elapsed.

The current data protection provisions are overly complex and do not provide meaningful access to data protection for information provided to a reconsideration. By enhancing data protection provisions, the Bill removes disincentives to invest in innovative product development and to improve the productivity of Australia's agri-food industries.

The Bill includes amendments to improve data protection provisions by making them simpler and more consistent, and therefore easier for industry and the APVMA to interpret and for the APVMA to administer. The reforms also reduce the disincentives to generating and providing data by extending data protection eligibility to a greater range of data. In the case of reconsiderations, some amendments have been made to improve the system whereby the data owners and other registrants can share the costs of any data required.

The Bill includes amendments to improve the mechanism by which data owners can obtain compensation for information submitted in relation to a reconsideration. These reforms would more closely align the data protection for new products and reconsiderations, and reduce the disincentive to providing data as part of these reconsiderations.

Levy collection

The Bill amends the current levy collection provisions to allow alternative arrangements to be implemented. The APVMA is one of a number of Australian Government regulators funded by fees, charges and levies imposed on the industry it regulates. Chemical companies pay fees for the APVMA to, for example, evaluate product registration proposals and pay a levy based on the value of wholesale sales of chemical products.

Amendments in the Bill provide for any Commonwealth agency to be able to issue notices regarding levy assessments and receive levy payments, should it be cost effective to do so. Such a change would allow the government to respond to perceptions of a conflict of interest arising from the current arrangements for collection of this levy. No change to the levy structure or rate is proposed by the Bill.

Retrospective application

Schedule 5 includes provisions that validate past actions in relation to signing notices of assessment for levies payable under the Collection Act, that is, under subsection 16(12). Together with a new section 38E, these provisions correct an anomaly in the Collection Act for delegations and provide for limited delegations that were understood to apply because of section 44 of the Admin Act (which provides that the Chief Executive Officer may delegate all or any of his or her powers). The new provisions specify that notices issued under the old law by purported delegates are valid and effective, irrespective of whether these notices were issued by a person with the authority to sign these notices. Further provisions have been included to ensure that rights and liabilities of parties are not affected where a court has heard and determined proceedings between parties.

Other amendments

Legislative instruments

The Bill also updates the Agvet Act and the Code Act to specifically provide for legislative instruments made under the Agvet Act or the Code Act, including orders, to remain subject to disallowance with two exceptions (Part 1 of Schedule 6). These provisions override subsection 44(1) of the *Legislative Instruments Act 2003* which provides that the disallowance provisions don't apply if the enabling legislation for the instrument facilitates the establishment or operation of an intergovernmental body or scheme involving the Commonwealth and one or more States; and the enabling legislation authorises the instrument to be made by the body or for the purposes of the body or scheme (such as it does in this case).

All the legislative instruments are enabled by legislation which facilitate the establishment and operation of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), established in 1994 between the Commonwealth and the states, and which provides for the APVMA (a Commonwealth agency) to regulate chemicals on the states' behalf. The legislation exists for the NRS. This measure is intended to preserve Parliamentary oversight of legislative instruments made for the NRS.

Retrospective application

Schedule 6 includes provisions that deal with transitional, application and savings measures for amendments made by the Act. To ensure a comprehensive transitional approach can be adopted the

Bill provides for regulations to take effect before they are registered and this may have some retrospective application of certain measures. A safeguard measure has been included to ensure that a court must not convict a person of an offence, or order the person to pay a pecuniary penalty, in relation to the conduct on the grounds that the person contravened a provision because of a retrospective effect of the regulations.

Public Consultation

The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Bill.

Three rounds of public consultation were conducted on the reforms and associated Bill. The first round of public consultation occurred from mid November 2010 to early February 2011 about the policy discussion paper, *Better Regulation of Agricultural and Veterinary Chemicals*. Ninety two submissions were received on the discussion paper. Further public consultation with an exposure draft of the legislation occurred from 15 November 2011 to 29 February 2012. Over 70 submissions on the exposure draft legislation were received and considered.

The Bill was revised and released again as a revised exposure draft in September 2012. The revised Bill included amendments to address issues raised during the previous round of consultation. A further 23 submissions were received by the close of the consultation period to inform final amendments to the Bill.

Policy context

Agricultural chemicals and veterinary medicines

Agricultural chemicals (also known as pesticides) include a wide range of products that protect crops from a wide range of weeds, insects and pathogens. These chemicals are used in agricultural and forestry industries to ensure pest control is effective and so to aid industry productivity. In other contexts, agricultural chemicals are important in the protection of buildings, parks and infrastructure, as well as in households for the control of a range of pests.

Agricultural chemicals are also used in human health for protecting against disease vectors such as mosquitoes and rodents. Agricultural chemicals also play a role in protecting the environment from pests such as locusts, foxes and weeds.

Veterinary medicines, such as vaccines, antibiotics, worm treatments, lice treatments and some vitamins and minerals are important for the protection of livestock from pests and to treat a wide range of diseases and illnesses. These products are also essential for maintaining the health and wellbeing of companion animals, including domestic pets and service animals.

National Registration Scheme

Agricultural chemicals and veterinary medicines (together, agvet chemicals) are regulated through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals. The NRS was agreed on by the Australian Agriculture Council (now the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.

The NRS is a partnership between the Commonwealth and the states and territories, with a shared 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 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, together 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 agvet chemical products, undertakes 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 processes provide assurance, through rigorous science based risk assessments, that agvet chemical use is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9900 separate agvet chemical products registered, each of which contains one or more of around 1900 approved active constituents, of which around 780 are unique.

The APVMA's regulatory functions are defined by the Admin Act which established 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.

Reform context

The proposed 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 Bill builds on earlier progress that has already been made via the partnership, with the legislative changes in the *Agricultural and Veterinary Chemicals Code Amendment Act 2010* in June 2010. This included a simplified process for applicants to make minor variations to chemical approvals or registrations (such as changing pack size); allowing companies to make minor changes to chemical labels (such as changing a logo); and removing the requirement on registrants to notify the APVMA of an approved person.

Election commitment

The Bill delivers 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.

FINANCIAL IMPACT STATEMENT

This Bill, itself, has no financial impact for the Budget.

In its 2010 mid-year economic and fiscal outlook statement, the government announced \$8.8 million funding over four years to support this reform, including enabling the APVMA to upgrade its information and communications technology infrastructure, to support ongoing activities and underpin the APVMA's financial sustainability.

REGULATION IMPACT STATEMENT

The Regulation Impact Statement, entitled *Regulation Impact Statement for Better Regulation of Agricultural and Veterinary Chemicals*, is available at <http://ris.finance.gov.au/category/primary-industries/>. A direct link to the relevant document is <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.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 will make amendments to the *Agricultural and Veterinary Chemicals Act 1994* (Agvet Act), *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act), the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act), including the Schedule to that Act (Agvet Code) and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act) (collectively called agvet chemical legislation).

The Bill implements reforms to the approval, registration and reconsideration of agricultural and veterinary (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. This will also provide better protection for both human health and the environment.

The Bill simplifies, reorganises and modernises the above legislation to reduce uncertainty and complexity in the legislation, and improve the operability and understanding of the legislation. The Bill also includes other amendments to remove redundant provisions and amend out of date provisions in all Commonwealth agricultural and veterinary chemical legislation. The amendments in the Bill also enhance the Australian Pesticides and Veterinary Medicines Authority's ability to ensure compliance with its decisions and to manage issues of non-compliance.

Human rights implications

The Bill engages the following rights:

- the right to health and a healthy environment (Article 12) in the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)
- the right to protection against arbitrary and unlawful interferences with privacy in Article 17 of the *International Covenant on Civil and Political Rights* (ICCPR)

- fair trial and fair hearing rights including the right to be free from self-incrimination and the right to presumption of innocence in Article 14 of the ICCPR.

Right to health

This Bill engages and promotes the right to health in Article 12 of the ICESCR by providing 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 protection against arbitrary and unlawful interferences with privacy

Article 17 of the ICCPR prohibits arbitrary or unlawful interferences with an individual's privacy, family, home or correspondence, and protects a person's honour and reputation from unlawful attacks. This right may be subject to permissible limitations where those limitations are provided by law and non-arbitrary. In order for limitations not to be arbitrary, they must be aimed at a legitimate objective and be reasonable, necessary and proportionate to achieving that objective.

The Bill provides for the use of extensive investigation and monitoring powers by officers of the APVMA (including entry, search and seizure) (see Part 7AA of the Admin Act and Part 9 of the Agvet Code in Schedule 3 of the Bill). These powers largely existed in the Admin Act and the Agvet Code and these amendments separate the monitoring and investigative powers, improve clarity and bring the agvet chemical legislation in line with other modern legislation of similar intent.

Under sections 69EAB and 69EB of the Admin Act and sections 131 and 132 of the Agvet Code, APVMA officers have the power to enter any premises to find out if the Admin Act, the Collection Act or the Agvet Code are being complied with. It is important to ensure compliance with these Acts in order to protect the health and safety of human beings, animals and the environment. These measures include the power to enter residences when they are also used for commercial purposes, as long as either the occupier has consented to the entry or the entry has been made under a monitoring warrant. Sections 69ED of the Admin Act and 133 of the Agvet Code provide that consent can be withdrawn at any time by the occupier. While monitoring powers will limit the right to privacy, this limitation will only occur in relation to commercial premises and residential premises where they are also being used as commercial premises for the manufacture or supply of agvet chemicals. These occupiers will be aware of their need for compliance with the agvet chemical legislation in order to protect the health and safety of human beings, animals and the environment.

Section 131AA also authorises APVMA inspectors to enter premises without consent or without a warrant to prevent imminent risk to persons of death, serious injury or serious illness. In addition, new paragraph 126(4)(aa) makes it a condition of a manufacturing licence that an inspector may enter premises where chemical products are manufactured and exercise the monitoring powers. These powers are necessary as without them there is no practical way for APVMA to monitor or investigate possible offences of human health significance.

The Bill protects against arbitrary abuses of powers as the entry, monitoring, search, seizure and information gathering powers by ensuring that these powers are generally conditional upon consent being given by the occupier of the premises or prior judicial authorisation under warrant. Where entry is based on the consent of the occupier, consent must be informed and voluntary and the occupier of premises can restrict entry by authorised persons to a particular period. Additional safeguards are provided through provisions requiring authorised persons and any persons assisting them to leave the premises if the occupier withdraws their consent.

The Bill also specifies that an issuing officer of a warrant to enter premises for the purpose of monitoring or investigation must be a judicial officer. The Bill also provides limits on the issuing of

a monitoring or investigation warrant. In the case of an investigation warrant, for example, an issuing officer may issue an investigation warrant only when satisfied, by oath or affirmation, that there are reasonable grounds for suspecting that there is, or may be evidential material on the premises. An issuing officer must not issue a warrant unless the issuing officer has been provided, either orally or by affidavit, with such further information as they require concerning the grounds on which the issue of the warrant is being sought. Such constraints on this power ensure adequate safeguards against arbitrary limitations on the right to privacy in the issuing of warrants.

An authorised person cannot enter premises unless their identity card or a copy of the warrant under which they are entering is shown to the occupier of the premises. This provides for transparency and mitigates arbitrariness and risk of abuse of the investigative powers.

The Bill also provides the APVMA with powers to seek and obtain information to ensure compliance with agvet chemical legislation (see Division 2 of Part 9 for example). These powers replace the previous powers of entry, search and seizure in the Admin Act and the Agvet Code. The new powers have been included in both the Admin Act and the Agvet Code, and the powers in the Admin Act can be exercised for the purposes of the Collection Act. The exercise of these powers is also subject to warrant or consent, unless there are reasonable grounds for suspecting that it is necessary to exercise the monitoring powers to prevent an imminent risk to persons of death, serious injury or serious illness.

Overall, the investigative powers and monitoring powers are reasonable, necessary and proportionate to achieve the legitimate objective of. Adequate safeguards and limitations on the use of these powers in the Bill ensures that such lawful interferences are not arbitrary or at risk of abuse in practice. In addition, the APVMA is bound by the *Privacy Act 1988* (Cth) in collecting, handling and disclosing personal information and this Act confers rights designed to protect privacy. These rights and obligations are set out in 11 information privacy principles (IPPs) contained within the Privacy Act.

The right to a fair trial and fair hearing rights, including the privilege against self-incrimination and the right to the presumption of innocence

The Bill also engages several aspects of fair trial and fair hearing rights, including the right to be free from self-incrimination and the right to the presumption of innocence.

The obligations placed on participants provided in the Bill relate to:

- requiring people to attend, give information and produce documents or things – Division 2 of Part 9 of the Agvet Code
- civil penalty orders – Division 2 of Part 9A of the Agvet Code (and Division 1 of Part 7AB of the Admin Act)
- infringement notices – Division 3 of Part 9A of the Agvet Code (and Division 2 of Part 7AB of the Admin Act)
- enforceable undertakings – Division 4 of Part 9A of the Agvet Code (and Division 3 of Part 7AB of the Admin Act)
- restraining and performance injunctions – see Division 5 of Part 9A of the Agvet Code (and Division 4 of Part 7AB of the Admin Act)
- substantiation notices – Division 6 of Part 9A of the Agvet Code (and Division 5 of Part 7AB of the Admin Act)
- enforceable directions – Division 7 of the Agvet Code
- formal warnings – Division 8 of the Agvet Code (and Division 6 of Part 7AB of the Admin Act).

Presumption of innocence

Article 14(2) of the ICCPR provides that everyone charged with a criminal offence shall have the right to be presumed innocent until proved guilty according to law. Generally, consistency with the presumption of innocence requires the prosecution to prove each element of a criminal offence beyond reasonable doubt.

Offence provisions which require the defendant to carry an evidential or legal burden of proof with regard to the existence of particular facts will engage the presumption of innocence because a defendant's failure to discharge the burden of proof may permit their conviction despite reasonable doubt as to their guilt.

Reverse burden offences will not necessarily be inconsistent with the presumption of innocence provided that they are within reasonable limits taking into account the importance of the legitimate objective and maintain the defendant's right to a defence. Relevant factors to consider when determining if a reverse burden provision is justified include whether:

- the penalties are at the lower end of the scale
- the offences arise in a regulatory context where participants may be expected to know their duties and obligations
- the burden relates to facts which are readily provable by the defendant as matters within their own knowledge or to which they have ready access.

While provisions which impose only an evidential burden are more likely to be considered compatible with the presumption of innocence, they still require justification, particularly where the burden relates to an essential element of the offence.

A number of current offences in agvet chemical legislation place an evidential or legal burden on a defendant in certain circumstances. The new civil penalty provisions within the Bill place the same evidential or legal burden on a defendant in the same circumstances as the existing offences. The protections in article 14(2) of the ICCPR are applicable in criminal proceedings.

With two exceptions, the amendments in the Bill ensure minimal changes to existing offences so as not to disturb the existing provisions dealing with the evidential burden and legal burden. The exceptions are new section 45C of the Agvet Code (Schedule 3 of the Bill) and to a lesser degree new section 47E (Schedule 2 of the Bill).

Section 47E mirrors old section 54. New section 47E contains the same defence as in old section 54 with the same evidential burden for the defence. The old (pre-amendment) sections 45A and 55 have been amalgamated into new sections 45A, 45B and 45C. Just as is provided for in existing sections 45A and 55, new section 45C provides for a strict liability offence for possessing, having custody of or other dealing with a suspended active constituent or chemical product in contravention of the instructions in the notices provided to persons or notices which have been published. The amount of the penalty units (300) is for the same amount as the current sections 45A and 55. The defences in the old subsections 55(5) and (6) have been retained as subsections 45C(3) and (4). The defence and the reversal of the onus of proof in subsection 45C(4) mirrors the current defence and onus of proof in old subsection 55(6).

Subsection 45C(4) provides a defence to the defendant, who has not been given a notice, that he or she either did not know and could not reasonably have been expected to have known of the existence of the *Gazette* notice or that the possession etc was not in accordance with the instructions in the *Gazette* notice. This is an additional defence to the defence of honest and reasonable mistake of fact and, although the defendant bears the legal burden, is broader in scope. This is because it is not concerned with the requisite state of mistaken belief but is judged against the standard of what could be reasonably expected. The provision imposes the legal burden of proof on the defendant and this

must be discharged on the balance of probabilities that the person did not know and could not reasonably be expected to have known of the existence of the notice. The defence is that the defendant did not know *and* could not reasonably be expected to have known of the existence of the notice.

As an example, for a retailer that regularly sells chemical products, the prosecution could satisfy the court that even if the retailer did not know of the notice, the retailer's circumstances as a regular dealer was such that they *should* have known as they should have had steps in place to be aware of notices published under paragraph 45A(1)(b). The retailer might counter this by providing information that they did not know and could not reasonably be expected to have known of the existence of the notice. As these matters relate to what the defendant did not know and could not reasonably be expected to have known, it follows that this information would be peculiarly within the knowledge of the defendant. It would not be likely that this may be uncovered through the normal course of an investigation.

On this basis and recognising the defence and the reversal of the onus of proof in new subsection 45C(4) mirrors the defence and onus of proof in old subsection 55(6), new subsection 45C(4) is considered reasonable, necessary and proportionate and is consistent with the legitimate objective of protecting human health and the environment. Importantly, it also results in the least impact on all parties to which the current and amended offence provisions relate.

Privilege against self-incrimination

Article 14(3)(g) of the ICCPR protects the right to be free from self-incrimination by providing that a person may not be compelled to testify against him or herself or to confess guilt. The right to be free from self-incrimination may be subject to permissible limitations, provided that the limitations are for a legitimate objective, and are reasonable, necessary and proportionate to that objective. Generally, an abrogation of the right against self-incrimination is more likely to be considered permissible, where it is accompanied by both a use and derivative use immunity.

APVMA inspectors will have powers to seize evidential material, including documents and electronic equipment, as well as powers to photograph, take measurements or run tests. Depending on whether an inspector enters premises with consent or under warrant, an occupier may have to answer questions put to them by an inspector. Compulsory questioning engages the right against self-incrimination in article 14(3)(g) of ICCPR and the privilege against self-incrimination is available to a natural person where the inspector asks questions when they enter premises under a warrant or with consent.

Consistent with *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers* (published by the Attorney-General's Department) (the *Guide*), the Bill includes a new Division 2 in Part 9 that deals with notices requiring people to attend, give information and produce documents or things. This new division provides for the more efficient collation of information to provide a response that is complete and allows persons to consider their rights and obligations and seek appropriate legal advice before providing information, documents or answers to questions. The new division aligns with old section 144 but includes a new section 130C that abrogates the privilege against self-incrimination for the purposes of a notice under section 130. Section 130C requires persons to give information, produce a document or thing or answer a question in relation to a notice under section 130, even though this information, document or things might tend to incriminate the person or expose the person to a penalty. In other situations in the Agvet Code, the privilege against self-incrimination would continue to be available for natural persons.

The purpose of Division 2 of Part 9 is to ensure that the APVMA can monitor and enforce compliance with agvet chemical legislation, and has access to complete information that allows the APVMA to be fully informed in circumstances that require them to act in a timely, informed and

proportionate manner to protect public health and safety and the environment. The abrogation of the privilege against self-incrimination is necessary because based on past experience with existing provisions in the Agvet Code that require persons to provide information (for example, sections 160A and 161), the APVMA has had difficulty in obtaining the necessary information from persons because they are concerned that the information may incriminate them or expose them to a penalty, or because of a concern about 'brand damage' or a lack of awareness of relevant compliance requirements in the first place.

Division 2 of Part 9 addresses this by requiring information, documents or things to be provided through notices that allow persons to prepare the information in a specified time or be accompanied by a lawyer, and by providing a use and derivative use immunity for those persons that provide the information, documents or things. The abrogation of the privilege against self-incrimination and the safeguards are considered reasonable, necessary and proportionate and are consistent with the legitimate objective of ensuring the regulator has complete information to enable it to protect human health and the environment. This approach is also consistent with the existing section 34 of the Collection Act in relation to giving information or producing a document under that Act and with Commonwealth therapeutic goods legislation.

Fair hearing rights

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 Bill engages the right to a fair and public hearing through the creation of an infringement notice scheme. An infringement notice can be issued by an infringement officer for contraventions of a strict liability offence provision or a civil penalty provision that is enforceable under the Bill. The Bill ensures against arbitrariness or abuses of power through limitations as to who can issue an infringement notice. The Bill limits this exercise of power to an APVMA inspector, who are appointed by the APVMA and are members of the staff of the APVMA, persons engaged under the *Public Service Act 1999*, or other persons have appropriate qualifications.

The right of a person to a fair and public hearing by a competent, independent and impartial tribunal is preserved by the Bill as its 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 Bill outlines that this right must be stated in an infringement 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 Bill ensures that relevant courts have sufficient oversight to ensure against arbitrariness or abuses of power. Regulatory functions and powers in the issuing of infringement notices are limited to government officers and a person can elect to have the matter heard by a court.

The Bill amendments include measures which are intended to deter and punish those who do not comply with certain provisions, encouraging maximum compliance by affected parties. While the Bill amendments may limit human rights, those limitations are reasonable, necessary and proportionate in the context of protecting the community and the environment from inappropriate agricultural and veterinary chemical products. Consistent with other Commonwealth legislation, the limitations on human rights have appropriate safeguards to protect against arbitrary abuses of power.

Other provisions

The Bill also 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 Bill 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 appropriate safeguards in place and are appropriate in the context of protecting the community and the environment from inappropriate agricultural and veterinary chemical products.

AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT BILL 2012

NOTES ON ITEMS

Section 1: Short Title

Section 1 is a formal provision specifying the short title of the Act and that it may be cited as the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2012*.

Section 2: Commencement

Section 2 provides for the commencement of the Act.

Sections 1 to 4 will commence upon Royal Assent.

Schedules 1 to 6 commence on 1 July 2013.

Section 3: Schedule(s)

Section 3 provides that each Act specified in a Schedule to the Act is amended or repealed as set out in the applicable items of the Schedule concerned, and any other item in a Schedule to the Act has effect according to its terms.

Section 4: Review of operation of amendments

Section 4 requires the Minister to cause a review to be conducted of the operation of the amendments made by this Act and any other matter specified by the Minister. This section also specifies certain requirements for this review. These include requirements for an independent person to be involved in the conduct of the review and a requirement for public submissions to be sought. This section also requires a report of the review to be laid before each House of Parliament within 15 sitting days of all the provisions in this Act having been in place for five years.

SCHEDULE 1 – APPROVALS, REGISTRATIONS, PERMITS AND LICENCES

SUMMARY

Schedule 1 amends the Agvet Code. These amendments enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations (chemical reviews) and aid the APVMA to align its regulatory effort with chemical risk.

The amendments in Schedule 1 improve the transparency and predictability of decision-making under agricultural and veterinary chemical legislation. The APVMA will be required to implement the Agvet Code having regard to several important principles (section 1A), including that the first priority of the system for regulating agvet chemicals is the health and safety of human beings, animals and the environment and that regulatory effort and regulatory burden is to be balanced with chemical risk. Amendments provide for the APVMA to develop, publish and have regard to guidelines (the risk compendium) when exercising powers and performing functions under the Agvet Code (section 6A). The risk compendium would also assist applicants in ensuring that the information supplied with their application consistently meets the APVMA's requirements set out in a legislative instrument (sections 8A and 8B).

The APVMA is to determine the scale of an assessment appropriate to the application or reconsideration before it. The amendments in Schedule 1 allow flexibility for the APVMA to determine the matters it must have regard to, and those matters that the APVMA may have regard to, in making certain decisions. These apply when the APVMA is considering an application or reconsideration, or determining whether to cancel or suspend an approval or registration. The APVMA must consider safety matters in all cases and must consider other matters that are prescribed in regulations (new sections 5A to 5D).

The Schedule 1 amendments also improve the efficiency of the APVMA in assessing applications and reconsiderations by providing for total elapsed times for determining applications (section 165) and reconsiderations (section 165A). Additional efficiencies include requiring the APVMA to refuse applications where requested information is not provided to the APVMA within set timeframes (section 159). Further measures include 'shut the gate' provisions that require the APVMA to only consider certain information from the applicant (or on the applicant's behalf), specifically, information in the application that was made, information requested by the APVMA, or certain other information as required by the Agvet Code (section 8C).

Schedule 1 includes a number of amendments that simplify, reorganise and modernise the Agvet Code to reduce uncertainty and complexity in the legislation, and improve the operability and understanding of the legislation. Extensive technical revisions to the Agvet Code include amendments to provisions around applications, reconsiderations, suspensions, cancellations and notices. These amendments provide a streamlined and simplified way of achieving the existing objectives of the Agvet Code.

Detailed Explanation

Agricultural and Veterinary Chemicals Code Act 1994

Items 1 and 2 – new section 1A of the Agvet Code

These items insert a new heading and a section specifying further objects of the Agvet Code. The purpose of the new objects section is to explicitly state the purpose and framework for regulatory decision making for agvet chemicals. The new objects section reflects the current preamble of the

Code Act and will improve understanding about what the Agvet Code is seeking to achieve, particularly for industry and community stakeholders. The objects section will improve statutory application by the APVMA and assist in interpretation by the APVMA, decision review bodies and the courts.

Subsection 1A(1) reflects paragraph (c) of the preamble to the Code Act and recognises the importance of agvet chemicals to Australia and that the regulatory system for those chemicals expressed in the Agvet Code is to have certain characteristics

Paragraph 1A(2)(a) makes clear that the health and safety of human beings, animals and the environment is the first priority for the regulatory system for agvet chemicals. This paragraph reflects paragraph (b) of the preamble to the Code Act about the principle of ecologically sustainable development.

Paragraph 1A(2)(b) sets out that the Agvet Code is to be implemented through science-based risk analysis, including risk assessment and management, and that the APVMA continually update its practices to follow best practice. Risk analysis provides a scientific, structured, systematic and transparent method for making decisions. It allows the risks of agvet chemicals to be considered on the basis of relevant, reliable and sound scientific evidence within the overall context of human and animal health and safety and environmental protection. Risk assessment is primarily the scientific part of risk analysis. In risk assessment experimental and other available data are used to arrive at a conclusion about the potential risks associated with an agvet chemical. Risk management is the part of risk analysis that considers the options for managing the identified risks.

Paragraph 1A(2)(c) highlights the importance of maintaining a balance between APVMA regulatory effort, any regulatory burden imposed on the regulated community, and risk associated with chemical use. In implementing the Agvet Code the APVMA is not to impose regulatory burdens greater than is reasonably necessary to manage risks to the health and safety of human beings, animals and the environment.

Paragraph 1A(2)(d) emphasises a logical outcome of science-based risk analysis – that chemicals that pose unmanageable risks to humans, animals or the environment are not appropriate for Australia and so are not to be approved or registered. Paragraph 1A(2)(e) reflects the importance of community confidence in the APVMA's work regulating agvet chemicals and that community involvement is important to achieving that confidence. Paragraph 1A(2)(f) sets out some important characteristics for APVMA compliance and enforcement activities.

The objects in section 1A are relevant to all APVMA decisions under the Agvet Code. However, the extent to which they may be applied varies according to the nature of the particular decision. The inclusion of section 1A in the Agvet Code does not expand the subject matter, scope and purpose of the Code; it reflects that subject matter, scope and purpose. It therefore does not extend the regulatory burden but clarifies how the Agvet Code is to be implemented.

The different principles described in section 1A may be more or less relevant to different decisions. For example, the principle at paragraph 1A(2)(f) relating to securing compliance with the Code through effective and proportionate compliance and enforcement measures is not relevant to registration and approval decisions under the Code.

Overall, these objects are intended to further promote community confidence in the regulation of chemical products and their constituents and assist the APVMA in its work regulating agvet chemicals, particularly when that work involves the exercise of discretion on which the Agvet Code imposes no limits.

Items 3, 4 and 5 – subsection 3(1) of the Agvet Code

Item 3 repeals the definition of acknowledge as it is no longer used in the Agvet Code. Item 4 amends the definition of 'adequate' as a result of terminology changes made to consolidate the

safety, trade, efficacy and labelling criteria. Item 5 inserts a definition of application to clarify that it includes an application made under ‘this Code’. The term ‘this Code’ is already defined to include the Agvet Code and the Agvet Regulations (that is, the Agricultural and Veterinary Chemicals Code Regulations 1995). The definition therefore includes applications made under the Agvet Code and the Agvet Regulations.

Item 6 – subsection 3(1) of the Agvet Code

This item repeals the definition of ‘approved person’ as this term will be replaced by terms describing ‘holders’ (in the case of an approval or registration) and ‘nominated agents’.

Item 7 – subsection 3(1) of the Agvet Code

This item inserts a new definition of ‘determine’. This amendment is required to clarify that the APVMA decision on an application includes a decision to refuse an application, as well as a decision to approve, re-approve, register, re-register, vary or issue (for example, a permit or licence). In determining an application, the APVMA must assess it. The APVMA also determines an application if a re-registration or re-approval application is referred to reconsideration for section 29H and the APVMA cancels the approval or registration.

Item 8 – subsection 3(1) of the Agvet Code

This item inserts a definition of ‘electronic signature’ to facilitate more efficient electronic communication as provided for by section 156A of the Agvet Code. Section 156A specifies the requirements for the giving of information in electronic form.

Item 9 – subsection 3(1) of the Agvet Code

This item amends the definition of ‘established standard’ as a result of the reorganisation of the Agvet Code and that established standards are now developed in Division 6 of Part 1 of the Agvet Code (new sections 8T to 8V).

Item 10 – subsection 3(1) of the Agvet Code

Item 10 inserts a definition of ‘holder’ which, together with ‘nominated agent’, replaces the previous and confusing ‘approved person’/‘interested person’ model in the Agvet Code. Currently in the Agvet Code a person who holds a registration or approval is referred to as ‘an interested person’, while a person to whom a permit or licence is issued is already referred to as a ‘holder’.

Under the new model, the holder is the person (individual or body corporate) to which the APVMA issues the authority (approval or registration) and which the APVMA records (in the Record, Register or its files). The definition of ‘holder’ provides for the authority to transfer an approval or registration, and provides for circumstances where an individual holder dies or a body corporate holder is succeeded, as was previously the case for an ‘interested person’. For consistency throughout the Agvet Code and as was previously the case, the term ‘holder’ includes a person to whom the APVMA issues a permit or licence.

The consistent use of the term ‘holder’ throughout the Agvet Code and other amendments address some inconsistency in the Agvet Code about who makes an application, who must respond to an APVMA request or requirement and who must notify the APVMA of particular things. These amendments make clear who is responsible for an application (an applicant) and, once an application is determined, who is responsible for an approval or registration (the holder or nominated agent) or permit or licence (the holder).

Item 11 – subsection 3(1) of the Agvet Code

This item repeals the definition of instructions for use as the new definition of ‘use’ includes all dealings with an active constituent or chemical product.

Item 12 – subsection 3(1) of the Agvet Code

This item repeals the definition of interested person as this term has been replaced with ‘holder’.

Item 13 – subsection 3(1) of the Agvet Code

This item inserts a new definition of ‘limitation period’ which describes the periods for which the APVMA and consulted persons and bodies must not use certain information to consider another application (that is, the period that information is protected from use for another approval or registration).

Items 14, 15, 16 and 17 – subsection 3(1) of the Agvet Code

These items repeal the definition of ‘listable chemical product’ and replace it with the term ‘listed chemical product’ which will be used throughout the Agvet Code and regulations. The definition refers to the new section 8T which provides the authority for regulations to specify listed chemical products. These items also repeal the definitions of ‘listed registration’ and ‘Listing Schedule’.

These amendments simplify the provisions related to listed registration by ‘mainstreaming’ these registrations with registrations of chemical products and approvals of labels. The Agvet Code is substantially simplified by providing for eligible listed chemical products to be registered in the same way as other chemical products, while also providing for simplified requirements for registration of listed chemical products.

Item 18 – subsection 3(1) of the Agvet Code

This item inserts new definitions of ‘meets the application requirements’, ‘meets the efficacy criteria’, ‘meets the labelling criteria’, ‘meets the safety criteria’ and ‘meets the trade criteria’ by signposting where these criteria are specified in the Agvet Code. The definition of these terms allows them to be consistently throughout the Agvet Code and simplifies requirements for applications, reconsiderations and other matters that relate to these criteria.

Item 19 – subsection 3(1) of the Agvet Code

This item inserts a new definition of ‘nominated agent’ which will replace the term ‘approved person’ and together with ‘holder’ replaces the previous and confusing ‘approved person’/‘interested person’ model in the Agvet Code. The nominated agent is the person (individual or body corporate) which the APVMA records as the nominated agent for the holder of an approval or registration in the Record, Register or its files.

Items 20 and 21 – subsection 3(1) of the Agvet Code

These items update the definition of the Record of Approved Active Constituents for Chemical Products so that the term ‘Record’ is used consistently throughout the Agvet Code to refer to this record.

Items 22, 23 and 24 – subsection 3(1) of the Agvet Code

Items 22 and 23 update the definition of the Register of Agricultural and Veterinary Chemical Products so that the term ‘Register’ is used consistently throughout the Agvet Code to refer to this register. Item 24 repeals the definition of ‘registered listed chemical product’ as these products will be registered chemical products and a separate definition is no longer necessary.

Item 25 – subsection 3(1) of the Agvet Code

This item updates the definition of the ‘relevant APVMA file’ so that the term is used consistently throughout the Agvet Code to refer to this file.

Item 26 – subsection 3(1) of the Agvet Code

This item updates the definition of ‘relevant particulars’ as a result of amendments to sections 19, 20 and 21, and so that it includes variations to these particulars made under sections 26, 26C, 29, 29A, 29G, 34A or 34AF.

Item 27 – new sections 5A, 5B, 5C and 5D of the Agvet Code

This item inserts new provisions which specify how the safety criteria, efficacy criteria, trade criteria and labelling criteria are met for an active constituent and chemical product. The definitions for these criteria align with the safety matters, trade matters, efficacy matters and labelling matters in the Agvet Code. Specifying these criteria at the start of the Agvet Code provides for considerable simplification and consistency of application throughout the Agvet Code.

New section 5A specifies that the safety criteria apply for the use of the constituent or product in accordance with any instructions approved or proposed to be approved or contained in the established standard. The matters specified in the criteria are the same as were previously used for safety matters throughout the Agvet Code. That is, that the use of the constituent or product would not be an undue hazard to the safety of people, would not be likely to have an effect that is harmful to human beings, and would not be likely to have an unintended effect that is harmful to animals, plants, things or to the environment, as, for example, in previous subparagraphs 14(3)(e)(i), (ii) and (iii).

New section 5A also includes the matters that the APVMA must have regard to and may have regard to in determining whether the use of an active constituent or chemical product meets the safety criteria. These matters are consistent with the matters previously specified in the Agvet Code, for example, in previous subsections 14(4) and (5).

New paragraphs 5A(2)(a) and 5A(3)(a) specify those matters that the APVMA must have regard to and include those matters that relate to the safety of the active constituent and chemical product. These matters include the toxicity of the constituent or product, the formulation and manufacture method, and the extent of any impurities. The matters also include any conditions to which an approval or registration is or would be subject, as well as any relevant particulars for the constituent or product. Regulations may also include additional matters.

New paragraph 5A(3)(b) specifies the matters where the APVMA can use its discretion to determine whether it needs to have regard to these matters for a chemical product. These are matters which may not always be relevant for a particular chemical product use (for example, non-food uses) and include the acceptable daily intake of the active constituent, the dietary exposure and amount of residues, as well as the stability of the product. By providing the APVMA with this discretion, the APVMA is better able to match its regulatory effort with risk.

New section 5B specifies how the use of a chemical product meets the efficacy criteria. As with the safety criteria, the efficacy criteria applies for the use of the chemical product in accordance with any approved or proposed to be approved instructions or the established standard. New section 5B includes the matters that the APVMA must have regard to in determining whether the use of chemical product meets the efficacy criteria. The matters specified in the efficacy criteria are the same as were previously specified for efficacy (for example, previous subsection 14(6)) and include the results of any trials or experiments carried out to determine the efficacy of the product. The matters also include any conditions to which a registration is or would be subject, as well as any relevant particulars for the product. Section 5B also clarifies that the criteria determined by the APVMA about being satisfied a product is effective is a legislative instrument. New section 163A (see Schedule 6) provides that the legislative instrument setting out efficacy criteria is not disallowable.

New section 5C specifies how the use of a chemical product meets the trade criteria. As with the safety criteria and the efficacy criteria, the trade criteria apply for the use of the chemical product in

accordance with any approved or proposed to be approved instructions or the established standard. New section 5C includes the matters that the APVMA must have regard to determining whether the use of chemical product meets the trade criteria. To meet the trade criteria the use of the chemical product would not unduly prejudice trade or commerce between Australia and places outside of Australia. The matters also include any conditions to which a registration is or would be subject, as well as any relevant particulars for the product.

Subsections 5B(3) and 5C(3) provide for regulations to specify the extent to which the APVMA must consider certain matters for the efficacy criteria or the trade criteria. That is, when the APVMA must consider efficacy and trade in determining whether the use of a chemical product meets the efficacy criteria or meets the trade criteria. Where no matters are prescribed, the APVMA may consider whether the use of a chemical product meets the efficacy criteria or meets the trade criteria where it thinks relevant. By providing the APVMA with this discretion, constrained within appropriate limits by the regulations, the APVMA is better able to match its regulatory effort with risk.

It is intended that trade will be a relevant consideration for assessment of a chemical product if there is a reasonable expectation that the crop or animal on which the product is used will be exported, or if the crop will be fed to animals that will be exported. For example, the APVMA would not need to consider prejudice to international trade when considering registrations for companion animal products. However, if a chemical product would be used on export exposed animals or plants, the APVMA would be required to consider this matter.

It is intended that the APVMA should not consider the efficacy of a chemical product unless there is a need to ensure that the product is effective to protect public health and safety or protect animal or plant health. For example, the APVMA would consider efficacy a relevant consideration when the relevant chemical product is represented as a control for microorganisms (bacteria, fungi or viruses) of public health significance, or if the product is intended as a remedy for an illness or disease of a plant or animal that is of national significance, or if the chemical is used on a major food crop or animal. Efficacy would be a relevant consideration for assessments of chemical products that are antibiotics used on food-producing animals or where the product contains a constituent for which resistance must be managed. These examples represent situations where consumer or environment exposure should or can be minimised, while maximising community benefits of chemical use

New section 5D specifies the labelling criteria that the APVMA is to consider in determining if the label for containers for a chemical product contains adequate instructions. The matters specified in the criteria are the same as were previously used for determining adequate instructions for labels, for example, previous paragraph 14(3)(g). The matters include how the product will be used, withholding periods, the disposal of product and product containers, as well as the safe handling of the product and first aid in the event of an accident. New subsection 5D(2) ensures that the APVMA must have regard to any conditions to which an approval for a label for containers for a chemical product would be subject, as well as any relevant particulars and instructions on the relevant APVMA file for the label. This ensures that the APVMA consideration of the label is based on any conditions or recorded details that are or would be applied.

Item 28 – new sections 6A, 6B, 6C and 6D of the Agvet Code

These items insert new provisions to clarify certain matters about the functions and powers of the APVMA.

New section 6A deals with guidelines and provides that while the APVMA may make guidelines for performing any of its functions and powers, it must make certain guidelines. These guidelines are for the principles and processes for the efficient and effective regulation of agvet chemicals, as well as guidelines relating to approvals, registrations, permits and licences that it issues. Subsection 6A(6) has been included to indicate that these guidelines are not legislative instruments and that an exemption from the LI Act is not being sought. The guidelines will contain rules of general

application that apply in relation to decisions by the APVMA. Subsection 6A(2) states that the APVMA must ‘have regard to’ the guidelines, meaning the AVPMA is not strictly compelled to follow the guidelines, and on that basis, the guidelines are not legislative in character. This allows for appropriate flexibility for the APMVA in circumstances where the guidelines have not considered a specific circumstance or particular matter.

New section 6A improves predictability for applicants and holders by requiring the APVMA to publish guidelines on its website. This ensures that information is available to assist applicants and holders in their interaction with the APVMA in the regulation of agvet chemicals.

New section 6B has been included to clarify that the APVMA is not empowered to vary conditions or particulars that it has not imposed. For example, the Agvet Code provides for conditions to be prescribed in regulations (section 23). It is not appropriate that the APVMA consider an application to amend these prescribed conditions. Where a condition prescribed in regulations is no longer appropriate then it is more appropriate that the regulations be reviewed.

New section 6C clarifies that the APVMA can use any information it obtains for exercising any of its powers and functions. New section 6C is consistent with the previous section 58 of the Agvet Code (Part 3). By locating this provision in Part 1 of the Agvet Code, it clarifies that the measure applies for the exercise of all functions and powers by the APVMA, and that the measure is not limited to Part 3 of the Agvet Code. Subsection 6C(2) explains that the allowed use of information is, however, constrained by other provisions of the Code that relate to the use of information (for example, section 8C, Division 4A of Part 2 and Part 3).

New section 6D clarifies that the validity of anything done by the APVMA is not affected if it does not comply with a time limit in the Agvet Code. A number of provisions require the APVMA to undertake certain actions in specified timeframes. New section 6D ensures that these actions remain valid even if the APVMA is unable to comply with a specified time limit. This provision is necessary as it would be unacceptable for APVMA actions to protect public health and safety to be invalid for non-compliance with a time limit.

Item 29 – new Divisions 2, 3, 4, 5 and 6 – new sections 8A to 8V of the Agvet Code

This item inserts new provisions that consolidate general application (sections 8A to 8D) and notice requirements (sections 8E to 8K) into a single division of the Agvet Code. Item 29 includes a new division to deal with holders of approval and registration and their nominated agents (sections 8L to 8R). The item inserts a new section 8S to generally provide for procedural fairness in relation to certain decisions that the APVMA proposes to make. This item also inserts new provisions about established standards for listed chemical products (sections 8T to 8V).

General provisions about applications

New section 8A specifies the requirements that applications must meet. These requirements align with previous application requirements and include the provision for regulations to include additional matters for applications about active constituents, chemical products or labels for containers for a chemical product. Applications must be lodged with the APVMA and must be in an approved form, contain specified information (new section 8B) and be accompanied by any prescribed fee. These are matters that are common to all applications made under the Agvet Code or the Agvet Regulations.

New section 8B provides for the APVMA to make a legislative instrument that will specify the requirements for information to be in an application or to accompany an application. However, new subsection 8B(2) limits the information specified in this legislative instrument only to information necessary for the APVMA to determine the application. New section 163A (see Schedule 6) provides that the legislative instrument specifying application requirements is not disallowable.

Paragraph 8B(2)(b) also specifies that for applications for re-approval or re-registration, the information contained in or to accompany an application must be information that the applicant

could be reasonably expected to have or have access to. It will not be necessary to provide information with an application for re-approval or re-registration (see Schedule 2) to fill any information gaps that may exist in the APVMA's file for the constituent or product because the information requirements when the constituent or product was approved or registered were less than would be the case for a new approval or registration.

Section 8B enhances transparency and predictability for applicants by ensuring that application requirements are publicly available and that the information requirements are limited to information that is necessary and reasonable for the applicant to provide for their particular application.

New section 8C specifies the information the APVMA must consider in determining an application (other than an application for a manufacturing licence). The provisions specify that only certain information from the applicant (or provided on the applicant's behalf) is to be taken into account by the APVMA. This is information provided in the application at the time that the application is lodged, information required of the applicant by the APVMA during assessment of the application and information required to be provided by section 160A. The purpose of this provision is to prevent applicants from ongoing voluntary submission of information to the APVMA about their application, delaying the assessment and preventing the APVMA from efficiently dealing with applications. Applicants are to provide complete applications to the APVMA in the first instance.

New section 8C does not prevent the APVMA from considering matters that it considers relevant in determining an application and it does not limit the APVMA in determining the application with information from sources other than the applicant (or on the applicants behalf), for example, by using information from national regulatory authorities of foreign countries (section 160) or with information in submissions made for sections 12 or 13 or sourced from agencies consulted for section 8 of the Admin Act.

New section 8D provides for an applicant to withdraw an application at any time before it is determined by the APVMA. This section aligns with a number of previous provisions that provided for the voluntary withdrawal of an application by an applicant. This provision ensures that applicants have the option to withdraw an application if circumstances change or, if they wish, to vary their application by withdrawing it and resubmitting the amended application..

General provisions about notices

New section 8E requires the APVMA to notify Food Standards Australia New Zealand (FSANZ) when it receives an application for the registration of a chemical product, which, if used, would be likely to result in chemical residues occurring in food at a level not already permitted under the Maximum Residue Limit Standard (MRL Standard). As provided by the previous section 13A, the new section 8E requires APVMA notification to FSANZ if an application or reconsideration would require the MRL Standard to be amended to allow the sale of foods lawfully treated with chemical products.

New section 8F specifies the requirements for notices to holders of approval or registration. It aligns with the previous section 24 and requires the APVMA to advise the holder, within 14 days, of particular matters that are relevant to an approval or registration after determining an application or varying relevant particulars or conditions other than on application). These matters include a statement about the approval or registration, the relevant particulars and conditions of approval or registration and the date the approval or registration ends. Additional matters for these notices may be prescribed in regulations.

New section 8G replaces the previous section 25 of the Agvet Code and specifies the requirements for notices to applicants where an application has been refused. New section 8G requires the APVMA to provide a notice to the applicant within 14 days stating that the application has been refused and setting out the reasons for this refusal and any amounts that are repayable. The reasons for the refusal would include the defects that the APVMA has identified to assist applicants in

improving future applications. In addition and where relevant the notice would include information about the opportunities for the applicant to have the decision internally reviewed by the APVMA (under section 166) or reviewed by the Administrative Appeals Tribunal (under section 167).

New sections 8H and 8J deal with published notices of approvals and registrations. Section 8H deals with approvals and registrations and new section 8J deals with variations to existing approvals and registrations. These published notices inform the public of approvals and registrations that the APVMA has issued.

New sections 8H and 8J require notices to be published in the *Gazette* and any other manner that the APVMA thinks appropriate (for example, its website). Certain information must be included in these notices including the date of approval or registration and a statement about the conditions of approval or registration that directly regulate the use of the active constituent or chemical product.

The regulations may include additional requirements for notices and these may include summaries of advice that the APVMA has relied on in determining an application (specified in the previous section 34G of the Agvet Code). The regulations may prescribe different requirements for the notices published in the *Gazette* and notices published in any other manner. This is because it is more convenient for stakeholders and more cost effective for the APVMA if larger amounts of information, such as advice summaries, are provided on the APVMA website rather than in the *Gazette*.

New section 8K has been included to clarify that the APVMA is not to disclose confidential commercial information in notices.

Holders and nominated agents

New sections 8L to 8R in Division 4 of Part 1 deal with holders of approval and registration, and nominated agents for the approval or registration. These provisions replace and substantially simplify provisions for ‘interested persons’ and ‘approved persons’. These amendments address some inconsistency in the Agvet Code about who makes an application, who must respond to an APVMA request or requirement and who must notify the APVMA of particular things. The provisions clarify who is responsible for an application and, once an application is determined, who is responsible for an approval, registration, permit or licence. The provisions also provide for nominated agents for an approval or registration, as is the case now, while ensuring that approvals or registrations with holders overseas have a nominated agent in Australia that has the same obligations and rights as the holder.

The concept of the nominated agent will replace the previous concept of an ‘approved person’. Nominated agents have the same rights and obligations, and are treated the same way, as a holder. They may do anything that a holder may do under the Agvet Code, and the APVMA may do anything they may do in relation to the nominated agent as they may do in relation to the holder (section 8R). Holders must also apply to have or to change a nominated agent.

A person (individual or body corporate) who makes an application for an approval, registration, permit or licence is now referred to consistently as the applicant. Applicants may either be an existing or prospective holder of the approval, registration, permit or licence irrespective of whether or not the person is in Australia. Applicants may also be an authorised agent of a person (for example, a registration consultant that may be, but doesn’t have to be, an existing or proposed nominated agent).

Where an application is determined positively, the person to whom the approval, registration, permit or licence is issued will be referred to as the holder of the approval, registration, permit or licence. Currently in the Agvet Code a person who holds a registration or approval is referred to as ‘an interested person’, while a person to whom a permit or licence is issued is already referred to as a ‘holder’.

A holder of an approval or registration may appoint a person to be the nominated agent for the approval or registration. Holders who do not reside in Australia or which carry on business in Australia will be required to appoint an Australian ‘nominated agent’. New section 8L provides for holders to be able to apply to have a different person become the holder of their approval or registration (that is, ‘transfer’ the approval or registration). The application must include the consent of the new holder and any nominated agent for the approval or registration if the new holder is not a resident of, and does not carry on business in, Australia.

New section 8M provides for holders to apply to the APVMA for a nominated agent for the approval or registration. New section 8P provides for holders to change the nominated agent. This allows multiple nominated agents for holders with multiple approvals or registrations, as for approved persons currently. The nominated agent for the holder must be recorded by the APVMA in the Record, Register and its files. The nominated agent must be a resident of or carry on business in Australia. This requirement is implemented through a condition of approval or registration (new subsection 8M(4)).

New section 8N provides that there must be a nominated agent for an approval or registration where the holder is not a resident of or doesn’t carry on business in Australia. This ensures that there is a person in Australia with the same liabilities as the holder for the active constituent or chemical products. This is particularly important for matters relating to notices and records, where the APVMA may be unable to deliver notices to or obtain records from an overseas holder.

New section 8Q provides for a nominated agent to withdraw from being the nominated agent for an approval or registration. However, this is contingent on the nominated agent having notified the holder of the withdrawal. This ensures that the holder is aware of the nominated agent’s withdrawal. The APVMA must update the Record, Register and its relevant files where a nominated agent withdraws.

New section 8R specifies the role of a nominated agent. The operation of new section 8R is to place the nominated agent in the position of the holder of approval and registration with the same authority and liability. Its purpose is to provide the nominated agent with the ability to do the same things as a holder of approval or registration and that the nominated agent is also liable in the same way as the holder of approval or registration. Some liabilities associated with this role are set out in section 152.

New section 8R provides that only a nominated agent for an approval or registration has the same liabilities imposed under the Agvet Code as the holder of the approval or registration. This combined with the other provisions about holders and nominated agents ensures that there is transparency and clear responsibilities for holders and nominated agents.

New section 8R does not affect the current use of authorised agents by holders. These authorised agents may act for current or prospective holders in the context of applications and may be an applicant for a holder. Authorised agents would not be subject to new section 8R unless they become a nominated agent or a holder of approval or registration. Authorised agents (if acting as an applicant) have some other responsibilities in the context of the application that is made (for example, in relation to not providing false or misleading information).

Notice of certain proposed decisions

New section 8S is a new provision in the Agvet Code to provide for procedural fairness for certain decisions that the APVMA is proposing to make. New section 8S confines the types of decisions to which the ‘notice of draft decision’ step will apply. These are proposed decisions to refuse an application, or approvals, registrations or variations other than as set out in an application for approval, registration or variation.

If section 8S applies, the APVMA is to provide its reasons for the proposed decision, any other information that the APVMA based its proposed decision on (for example, information which the applicant did not provide) and invite comment from the applicant. Subsection 8S(3) provides that the

APVMA is not required to consider anything in a submission that is not related to information the APVMA already has. This subsection prevents applicants from providing further information for assessment, subverting the intent of section 8C.

Section 8S is provided to assist applicants by providing an opportunity to comment on proposed decisions and for this reason the time taken to respond to a notice issued under new section 8S is not part of the timeframe for the application. In addition, section 8S only applies once as it is not the intention that section 8S require the APVMA to endlessly negotiate with the applicant or holder about the matter under consideration. Section 8S does not apply to decisions on the preliminary assessment of applications.

Listed chemical products and established standards

A system of developing established standards for listed chemical products allows for a substantially simplified path to registration of low regulatory concern chemical products. A chemical product that is a listed chemical product and that complies with the relevant established standard may be registered without the APVMA being satisfied about the safety, trade, efficacy or labelling criteria as satisfaction against those criteria is pre-assessed in developing the established standard. Listed chemical products that comply with the relevant established standard are excluded from the re-registration scheme in Division 3A of Part 2 (see Schedule 2).

New sections 8T, 8U and 8V align with the previous sections 56C, 56D and 56E but simplify the arrangements for listing and developing established standards for listed chemical products. These new sections reduce the bureaucracy associated with listed chemical products while maintaining suitable transparency and oversight about the listing and the development of relevant established standards.

New section 8T provides for regulations to include a schedule specifying chemical products that are listed chemical products. The new section 8T aligns with the previous section 56C but simplifies the arrangements for specifying chemical products. New section 8T requires a number of steps be followed before regulations are made to allow stakeholder involvement in development of standards for listed chemical products. These steps include publication of the intention to make regulations specifying the chemical products concerned, publication of a draft standard that the APVMA proposes to apply to these products and seeking submissions on the proposed regulations. Submissions need to be based on the matters relating to the safety criteria, efficacy criteria and trade criteria. The APVMA must then consider submissions before making a recommendation to the Minister about whether regulations should be made for the proposed listed chemical products.

New section 8U aligns with previous section 56D but provides for the APVMA to approve an established standard for listed chemical products and removes the need for the Minister to approve any established standard. The APVMA can already develop standards for chemical products and their constituents. There is no reason why the development of established standards for listed chemical products should be more onerous. All established standards are subject to disallowance and therefore remain subject to Parliamentary oversight.

New section 8U specifies the matters that must be contained in an established standard and the matters that may be contained in an established standard. An established standard must require that products be labelled in a particular manner or kept in containers that comply with requirements. The established standard may apply for chemical products or a class of chemical products. The established standard may reference other standards; including standards published by Standards Australia, and may specify procedures for manufacture and the composition or form of the constituents of the products.

New section 8V aligns with previous section 56E and requires the APVMA to be satisfied that use of a product in accordance with the established standard would meet the safety criteria, trade criteria,

efficacy criteria and labelling criteria. This is necessary because the established standard will form the basis for simplified consideration of registration of listed chemical products.

Item 30 – new section 9 of the Agvet Code

This item replaces the previous section 9 and includes a new explanation of Part 2 of the Agvet Code. The explanation has been replaced to reflect changes to Part 2.

Items 31 and 32 – new sections 9A to 14A of the Agvet Code

This item inserts new sections that deal with applications for approval of active constituents, registration of chemical products and approval of labels for containers for chemical products.

New section 9A inserts an explanation for Division 2 which deals with approving and registering active constituents, chemical products and labels for containers for chemical products.

New section 10 aligns with the previous section 10 by providing for persons to apply to the APVMA for approval of active constituents, registration of chemical products and approval of labels for containers for chemical products. An application must meet the application requirements (section 8A) and must include proposed instructions for the use of the active constituent or chemical product.

Preliminary assessment

New section 11 requires the APVMA to complete a preliminary assessment of an application within one month of being lodged and advise the applicant within 14 days of the decision being made as to whether the application has passed preliminary assessment or whether it has refused the application. The APVMA is not to refuse the application only if it has not finished its preliminary assessment in the one month timeframe. In conducting a preliminary assessment the APVMA only needs to determine if the application appears to meet the application requirements. The preliminary assessment is not a technical assessment where the APVMA must be satisfied that the application meets the application requirements as this is dealt with in new section 14. The purpose of the preliminary assessment is to provide for an administrative check of the application. The APVMA must refuse applications that appear inferior or deficient at preliminary assessment so that it only needs to assess applications that are of the required standard.

The APVMA must publish a summary of the application (paragraph 11(2)(b)) if an application passes preliminary assessment. Where an application passes preliminary assessment the application may be altered by the APVMA with the written consent of the applicant (subsection 11(4)). The purpose of this provision is to allow the APVMA to alter an application when appropriate, rather than refuse it and have to consider a new application. The APVMA is to use the flexibility afforded by this provision where it is efficient to do so. The APVMA cannot be compelled into amending an application.

Notices about new active constituents

Section 12 aligns with the previous section 12 of the Agvet Code and requires the APVMA to publish a notice and seek submissions about an application for an active constituent that has not previously been contained in a chemical product registered in Australia (that is, new active constituents). The purpose of this section is to require the APVMA to take into account the views of the public in determining an application for a 'new' active constituent. The notice must be published in the *Gazette* and set out specified information, including a summary of the APVMA's assessment of whether the constituent meets the safety criteria and an invitation to make a submission based on grounds that relate to the safety criteria.

Section 13 aligns with the previous section 13 of the Agvet Code and requires the APVMA to publish a notice and seek submissions about an application for registration of a chemical product containing an active constituent that has not previously been contained in a chemical product

registered in Australia (that is, a chemical product containing a new active constituent). As with section 12, the purpose of this section is to require the APVMA to take into account the views of the public in determining an application for chemical products containing ‘new’ active constituents. The notice must be published in the *Gazette* and set out specified information, including a summary of the APVMA’s assessment of whether the product meets the safety criteria, trade criteria and the efficacy criteria, along with an invitation to make a submission based on grounds that relate to the safety criteria, trade criteria or efficacy criteria.

Approvals and registrations

Section 14 requires the APVMA to approve an active constituent, register a chemical product and approve a label for containers of a chemical product if it is satisfied that the application meets the application requirements in section 8A, and the constituent, product or label meets the criteria specified in subsection 14(1). If the APVMA is not satisfied then it must refuse the application (subsection 14(2)).

Paragraphs 14(1)(c) and (d) provide for a simplified alternative approach for listed chemical products and their labels in that the APVMA need only be satisfied that these products and labels comply with the relevant established standard for these products. (The established standard for listed chemical products includes requirements to ensure the safety criteria, trade criteria, efficacy criteria and labelling criteria are met, see section 8V.)

Section 14A aligns with the previous section 14A of the Agvet Code and allows the APVMA to approve an active constituent irrespective of whether an application has been made for this approval or not. However, this measure only applies where the APVMA is satisfied that the constituent would meet the safety criteria.

Items 33 to 39 – section 14B of the Agvet Code

Section 14B gives effect to the terms of Article 17.10:1(e) of the Australia-United States Free Trade Agreement by providing that the APVMA is not to use certain information for a period of 10 years. This information is the information that has been given to it in connection with an application for registration of certain new agricultural chemical products, when that information has been disclosed by a government entity or an entity acting on behalf of a government and that information was not previously publicly available. The APVMA is not to use this information to approve another product that is the same or similar without the authorising party’s consent or if it would be commercially unfair.

Item 33 inserts a new heading for the section that better reflects the content of the section.

Item 34 removes the specific reference to ‘agricultural’ and this has the effect of extending the scope of section 14B so that it now applies for both agricultural chemical products and veterinary chemical products. This removes an inconsistency in approach and provides incentives for new veterinary chemical products with improved data protection for these products. It also aligns with the new limitation periods for applications in new section 34M (Schedule 4).

Item 35 amends section 14B to reflect the use of the new ‘safety criteria’ terminology. Item 36 amends paragraph 14B(1)(e) to refer to the applicant as the expression interested person is no longer used. Items 37, 38 and 39 amend subsections 14B(2) and (3) to clarify that these subsections apply in determining whether to register the second product rather than grant an application.

Items 40 and 41 – section 15 of the Agvet Code

These items amend section 15 which restricts the APVMA in issuing approvals and registrations. Item 40 amends the heading and section 15 to clarify that these subsections apply in determining whether to register a chemical product rather than grant an application.

The APVMA must not register a chemical product unless it has also approved the label for the containers for the chemical product and the active constituent for the chemical product. However, the APVMA may exempt certain active constituents from this provision. The APVMA must not approve a label for containers for a chemical product unless it has also registered the chemical product. This is consistent with the close linkage between the approval of a label and registration of a chemical product.

Item 42 – section 16 of the Agvet Code

This item removes unnecessary text from this section. The term ‘active constituent’ is sufficient to describe an ‘active constituent for a proposed or existing chemical product’ in this situation.

Item 43 – new sections 19 to 26 of the Agvet Code

This item replaces the previous sections 19 to 26 of the Agvet Code as part of the consolidation and clarification of current requirements.

How approvals or registrations take place

New section 19 specifies how and when approval of an active constituent takes place. It aligns with the previous section 19 but clarifies that approval takes place when the specified details in subsection 19(1) are recorded by the APVMA in the Record of Approved Active Constituents for Chemical Products. Section 19 also requires the APVMA to record when an approval ends, which must be the last day of a calendar month at least 7 years but not more than 15 years after the approval takes place. Regulations are to include a method for working out the date when an approval ends within this 7 to 15 year range. However, the APVMA may approve an active constituent with an end date of less than seven years where this is necessary to align with another approval of the active constituent. This allows the APVMA to align approvals for the same active constituent so they can be efficiently dealt with (in re-approval (Division 3A, see Schedule 2)) at the same time. In addition, the 7 to 15 year range does not apply if the approval is subject to the condition that it remains in force only for a stated period of less than 1 year.

New section 20 specifies how and when registration of a chemical product takes place. It aligns with the previous section 20 but clarifies that registration takes place when the specified details in subsection 20(1) are entered by the APVMA in the Register of Agricultural and Veterinary Chemical Products. Section 20 requires the APVMA to record when a registration ends as registrations are subject to renewal (Division 6), which is intended to be annual. Section 20 also requires the APVMA to record the date after which a registration cannot be renewed, the last renewal date and therefore when a re-registration application under Division 3A is required, unless the product is a listed chemical product that complies with the relevant established standard (see Division 6 of Part 1). This last renewal date must be the last day of a calendar month at least 7 years but not more than 15 years after the registration takes place. Regulations are to include a method for working out the date after which a registration cannot be renewed in the 7 to 15 year range. However, the APVMA may register a chemical product with a last renewal date of less than seven years where this is necessary to align with another registration of a chemical product that contains one or more of the same active constituents. This allows the APVMA to align registrations for chemical products containing the same active constituent so they can be efficiently dealt with in re-registration at the same time.

New section 21 specifies how and when an approval of labels for containers for chemical products takes place. It aligns with the previous section 21 but clarifies that the approval takes place when the APVMA determines the prescribed particulars that are appropriate for the label, gives a distinguishing number to the label and records the specified details in paragraph 21(c) in the relevant APVMA file.

New section 22 specifies that the date of approval or registration is the date on which the APVMA enters the relevant particulars of the approval or registration on the relevant Record, Register or

APVMA file. If any of the particulars or conditions of approval or registration are varied then the date of approval or registration is the date on which the variations are entered in the relevant record, register or APVMA file. The purpose of this provision is to ensure that the date of any approval or registration or any varied approval or registration is clear.

Conditions for approvals or registrations

New section 23 aligns with the previous section 23A by providing for two types of conditions of approval or registration: mandatory statutory conditions that apply in all cases of a particular kind; and the case-by-case conditions of approval or registration that the APVMA thinks appropriate. New paragraph 23(1)(a) provides for conditions to be applied to approvals or registrations in regulations. These conditions may apply irrespective of when the constituent or product was approved or registered. New paragraph 23(1)(b) also provides for the APVMA to impose conditions at the time of approval or registration.

While the previous section 23 authorised the APVMA to apply conditions, this was only able to be done at the time of approval or registration. As new information becomes available, it may be necessary to vary existing conditions or impose new conditions to ensure the continuing safety of active constituents or chemical products. Amending conditions after approval or registration currently requires the APVMA to undertake an unnecessarily onerous reconsideration (chemical review) of the active constituent or chemical product. The new section 23 addresses this by allowing for conditions to be imposed after approval or registration with these conditions to be prescribed in regulations. The prescription of these conditions in regulations would be subject to the usual mechanisms for developing subordinate legislation, including regulatory impact analysis and consultation.

Incorrect particulars or conditions

New section 26 provides for the APVMA to vary prescribed particulars or conditions where entries made in the Record, Register or relevant APVMA file are incorrect. However, where the APVMA is satisfied that entries are materially incorrect because of inaccurate recording the APVMA may amend these entries, irrespective of the particular or condition. These provisions ensure that the APVMA can maintain accurate records of approvals and registrations without unnecessary bureaucratic process.

New section 26 also requires a holder of an approval or registration to advise the APVMA within 28 days if the holder has reasonable cause to believe that the Record, Register or relevant APVMA file is materially incorrect in relation to a particular or condition. As provided for in the previous section 26, there is an offence for not complying with this requirement. The offence in both the previous and new section 26 is a strict liability offence. The penalty in the previous section 26 has been reduced from 60 penalty units to 30 penalty units as this is more consistent with the *Guide*. The new section 26 provides that the offence is also a civil penalty provision.

Item 44 – new sections 26A to 29B of the Agvet Code

This item replaces the previous Divisions 2A and 3 of the Agvet Code with simplified application requirements for variations of relevant particulars and conditions of approval or registration.

Varying prescribed relevant particulars

As provided for by the previous Division 2A of Part 2 of the Agvet Code, the new Division 2A of Part 2 provides for applications for variations to relevant particulars of low regulatory concern for existing approvals or registrations through a simplified application process rather than a variation made through the APVMA's technical assessment process under Division 3.

New section 26A is an explanation of Division 2A of Part 2 of the Agvet Code.

New section 26B aligns with the previous section 26A and specifies that the section applies when a holder of approval or registration wishes to make minor, low regulatory concern variations to a relevant particular of an approval or registration. The relevant particular must be of a kind listed in a legislative instrument made by the APVMA for the purposes of this section. A legislative instrument made by the APVMA is the most appropriate mechanism to identify permissible low regulatory concern variations as such an instrument can be varied at short notice and APVMA has the technical expertise to know what variations are appropriate. The legislative instrument is disallowable.

As with other applications, the application must meet the application requirements, however, recognising the simple, low regulatory concern variations made under this division a preliminary assessment step is not considered necessary. The APVMA may alter the application with the consent of the applicant where it is efficient to do so.

New section 26C requires the APVMA to vary the relevant particular if it is satisfied that the application meets the application requirements in section 8A, and the constituent, product and label meets the criteria specified in subsection 26C(1). This provides for a safeguard that even if variation of the particular is within the legislative instrument, a full application and assessment would still be required if the APVMA does not consider the variation meets the conditions in subsection 26C(1). If the APVMA is not satisfied then it must refuse the application (subsection 26C(2)).

Paragraphs 26C(1)(c) and (d) provide for a simplified alternative approach for listed chemical products and their labels in that the APVMA need only be satisfied that these products and labels comply with the relevant established standard for these products. (The established standard for listed chemical products includes requirements to ensure the safety criteria, trade criteria, efficacy criteria and labelling criteria are met, see section 8V.)

New section 26D specifies that the variation takes place when the APVMA records the variations in the Record, Register or the relevant APVMA file, along with the date the variation takes place. If the variation of relevant particulars of the registration of a listed chemical product would mean the product or any approved label for the product no longer complies with the relevant established standard, then the APVMA must enter a date after which the registration of the product can't be renewed (see section 20). Similarly, the APVMA must remove any date after which the registration of the listed chemical product can't be renewed (see section 20) from the Register, if the variation of relevant particulars of the registration of the product would mean the product and all approved labels for the product comply with the relevant established standard. The purpose of this provision is to ensure that listed chemical products that comply with the established standard do not have a last renewal date in the Register and are therefore exempt from the re-registration scheme.

Varying relevant particulars and conditions

As provided for by the previous Division 3 of Part 2 of the Agvet Code, the new Division 3 of Part 2 provides for the variation of relevant particulars or conditions of existing approvals or registrations. New section 26E is an explanation of Division 3 of Part 2 of the Agvet Code.

New subsection 27(1) aligns with the previous section 27 and provides for holders of approval or registration to apply to vary the particulars or conditions of an active constituent approval, chemical product registration or label approval. New subsection 27(2) also provides for other persons to apply to vary the particulars or conditions of a registration or label approval but only with the consent of the holder of approval or registration. For example, permit holders may apply to have permitted uses included on-label (for example, minor uses), with the consent of the holder of the registration.

New section 27 also specifies that an application must meet the application requirements and new subsection 27(4) aligns with the previous subsection 28(1A) and provides for a fee to be reduced by the fee provided for a previous application under Division 2A that was unsuccessful.

New section 28 requires the APVMA to complete a preliminary assessment of an application within one month of being lodged and advise the applicant within 14 days of the decision being made as to

whether the application has passed preliminary assessment or whether it has refused the application. The APVMA is not to refuse the application only if it has not finished its preliminary assessment in the one month timeframe. In conducting a preliminary assessment the APVMA only needs to determine if the application appears to meet the application requirements. The preliminary assessment is not a technical assessment where the APVMA must be satisfied that the application meets the application requirements as this is dealt with in new section 29. The purpose of the preliminary assessment is to provide for an administrative check of the application. The APVMA must refuse applications that appear inferior or deficient at preliminary assessment so that it only needs to assess applications that are of the required standard.

Where an application passes preliminary assessment then the APVMA must publish a summary of the application if the variation relates to the use of a chemical product. Where an application passes preliminary assessment the application may be altered by the APVMA with the written consent of the applicant and where relevant the holder. The purpose of this provision is to allow the APVMA to alter an application when appropriate, rather than refuse it and have to consider a new application. The APVMA is to use the flexibility afforded by this provision where it is efficient to do so. The APVMA cannot be compelled to amend an application.

New section 29 requires the APVMA to vary the relevant particular if it is satisfied that the application meets the application requirements in section 8A, and the constituent, product and label meets the criteria specified in subsection 29(1). If the APVMA is not satisfied then it must refuse the application (subsection 29(2)).

Paragraphs 29(1)(c) and (d) provide for a simplified alternative approach for listed chemical products and their labels in that the APVMA need only be satisfied that these products and labels comply with the relevant established standard for these products. (The established standard for listed chemical products includes requirements to ensure the safety criteria, trade criteria, efficacy criteria and labelling criteria are met, see section 8V.)

New section 29A authorises the APVMA to vary relevant particulars or conditions on its own initiative but only if the holder of approval or registration consents. No fee is payable if the APVMA varies relevant particulars or conditions on its own initiative. The APVMA cannot be compelled to vary relevant particulars or conditions on its own initiative. The purpose of new section 29A is to allow the APVMA some flexibility in varying relevant particulars or conditions and it is intended that it would only exercise this authority where it is efficient to do so.

New section 29B specifies that the variation of relevant particulars or conditions takes place when the APVMA records these variations in the Record, Register or the relevant APVMA file, along with the date the variation takes place. If the variation of relevant particulars or conditions of the registration of a listed chemical product would mean the product or any approved label for the product no longer complies with the relevant established standard, the APVMA must enter a date after which the registration of the product can't be renewed (see section 20). Similarly, the APVMA must remove any date after which the registration of the listed chemical product can't be renewed (see section 20) from the Register, if the variation of relevant particulars or conditions of the registration of the product would mean the product and all approved labels for the product comply with the relevant established standard. The purpose of this provision is to ensure that listed chemical products that comply with the established standard do not have a last renewal date in the Register and are therefore exempt from the re-registration scheme.

Item 45 – new Division 4 of the Agvet Code heading

This item replaces the heading of Division 4 of the Agvet Code with a heading that better reflects the purpose of the division specifically that Division 4 is about reconsidering approvals and registrations. The reconsideration of an approval or registration has been commonly known as a 'chemical review' of the approval or registration.

Item 46 – new section 29L of the Agvet Code

This item inserts new section 29L which is an explanation of Division 4 of Part 2 of the Agvet Code.

Items 47, 48 and 49 – subsection 30(1) of the Agvet Code

Items 48 and 49 amend subsection 30(1) to clarify that the APVMA can at any time publish a notice in the *Gazette* or any other manner inviting persons to propose active constituents, chemical products or labels that it might reconsider. The new subsection also addresses an anomaly by authorising the APVMA to invite persons to propose labels that it might reconsider, in addition to the current authority that only specifies active constituents and chemical products as subject matter for reconsiderations. Item 47 replaces the heading of section 30 with a heading that better reflects its amended content.

Item 50 – section 31 of the Agvet Code

This item amends section 31 by providing that the APVMA must prepare a work plan for a reconsideration before commencing the reconsideration. The regulations would include details that need to be included in work plans. It is intended that work plans canvass the consultation opportunities, timeframes and other important matters about the reconsideration and how the reconsideration is to be conducted. The regulations would also provide for how work plans are to be maintained. It is intended that work plans would be updated annually. The purpose of this amendment is to provide transparency and predictability about reconsiderations. A work plan is not a legislative instrument and paragraph 31(3)(b) has been included to make this clear. A work plan is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Paragraph 31(3)(b) has been included to indicate that an exemption from the LI Act is not sought or required.

Items 51, 52, 53 and 54 – section 32 of the Agvet Code

These items amend section 32 which deals with notices of reconsiderations. Item 51 amends the heading and item 52 inserts new subsections that require the APVMA to provide a notice to a holder about a reconsideration, providing the work plan for the reconsideration and inviting and requiring certain information from the holder about the reconsideration. New subsections 32(2) and (2A) also allow the APVMA to inform any other person about a proposed reconsideration and requires the APVMA to invite submissions from other persons and provide a work plan to the person if the APVMA informs them of a proposed reconsideration. These provisions align with old subsections 32(1), (2) and (3).

New subsection 32(2B) makes it clear that the APVMA is not limited to the initial scope of a reconsideration or prevented from refining the scope of a reconsideration to more specific matters when it identifies the matter or matters to be dealt with in the reconsideration.

The holder must comply with a notice to provide required information under paragraph 32(1)(b) (new subsection 32(3)) and this aligns with old subsection 32(3). Item 54 reinserts the previous strict liability offence for not complying with this requirement and provides that this is also a civil penalty provision (new subsections 32(5) and (6)). The amount of the penalty (120 penalty units) is unchanged. The offence and civil penalty provision do not apply if the holder requests cancellation of the approval or registration and the APVMA complies with this request (current subsection 32(7)).

Item 53 is a consequential amendment to reflect the new terminology of 'holder'.

Items 55, 56, 57 and 58 – section 33 of the Agvet Code

These items amend section 33 which provides that the APVMA may require information, reports, results or samples for the purposes of reconsiderations. The amendments incorporate the requirements from previous section 159 of the Agvet Code so that matters relating to information for reconsiderations are co-located in Division 4.

Item 56 amends section 33 to move the provision allowing the APVMA to require information, reports and samples from the previous section 159 of the Agvet Code. This corrects an anomaly in the previous Agvet Code where the APVMA could compel a holder to conduct and provide results of trials and experiments but could not do this for other information, samples and reports which may be as important to a reconsideration as trial and experiment data.

The amendments require that the holder must provide the information, reports, samples and trials and experiments data in a specified form and even if the holder has provided this material to the APVMA previously (subsection 33(1C)). This amendment means that the APVMA can compel holders to provide this material provided that it is relevant to the reconsideration. The purpose of these new provisions is to require a full engagement of holders of approval or registration in a reconsideration. Holders would have the option of either providing the requested material or seeking to have their approval or registration cancelled (current subsection 33(3)).

Subsections 33(1A) and (1B) provide for time limits to apply to requests for information, reports, samples and trials and experiments data with these to be prescribed in regulations. The purpose of this is to provide predictability about the timeframes for reconsiderations by placing limits on when reconsideration material should be provided and improve the timeliness of reconsiderations.

Item 57 is a consequential amendment to reflect the new terminology of 'holder'.

The holder must comply with a requirement under subsection 33(1) (new subsection 33(2)) to give specified information to the APVMA. This aligns with old subsection 33(2) but as a result of the amendments to section 33 the offence now also applies for not complying with an APVMA notice to provide information, reports and samples. Item 58 reinserts the previous strict liability offence for not complying with this requirement and provides that this is also a civil penalty provision (new subsections 33(4) and (5)). The amount of the penalty (120 penalty units) is unchanged. The offence and civil penalty provision do not apply if the holder requests cancellation of the approval or registration and the APVMA complies with this request (current subsection 33(3)).

Item 59 – new sections 34 to 34AF of the Agvet Code

This item inserts new provisions for the reconsideration of approvals and registrations.

Reconsideration

New section 34 requires the APVMA to affirm the existing approval or registration if it is satisfied that the constituent, product and label meet the criteria specified in subsection 34(1).

Subsection 34(2) provides that the APVMA must only consider its satisfaction about the criteria as mentioned in subsection 34(1) to the extent that the APVMA considers matters about the approval or registration in the reconsideration. The purpose of this provision is to allow the APVMA to choose the matters to be dealt with in a reconsideration. It is the intention that reconsiderations be focussed on specific matters to do with an approval or registration and conclude when those matters have been addressed, with any additional concerns identified in the course of the reconsideration dealt with as the subject of a new reconsideration with a different work plan. New subsection 32(2B) makes clear the APVMA has this improved flexibility to manage and progress a reconsideration.

In determining its satisfaction as mentioned in subsection 34(1) the APVMA must only consider the information specified in subsection 34(3). The provisions specify that only certain information is to be taken into account by the APVMA. This is information provided in submissions, in response to notices and information provided as required by section 161. The purpose of this provision is to address an incentive for stakeholders in a reconsideration to frustrate the process by continually providing information to the APVMA about the reconsideration, delaying final action about the reconsideration. This provision prevents delays in assessments and allows the APVMA to efficiently deal with reconsiderations. However, the provision does not prevent the APVMA from considering matters that it considers relevant in concluding a reconsideration and new section 34 does not limit

the ability of the APVMA in satisfying itself about the reconsideration with information from other sources, for example, submissions from particular stakeholders because of their particular expertise with the use of the constituent or product or national regulatory authorities of foreign countries.

If the APVMA is not satisfied for subsection 34(1), section 34A requires the APVMA to vary relevant particulars or conditions of an approval or registration if it could be satisfied about the criteria in 34(1) if these particulars and conditions were varied. Before doing so, the APVMA must seek the views of the holder of approval or registration and any other persons that it sought submissions from under paragraph 34AB(2)(f). In subsequently varying any particulars or conditions, the APVMA must only consider the information it previously considered and any submissions from the holder or other persons (subsection 34A(2)). For new subsection 34A(3) the APVMA must consult each coordinator designated for a jurisdiction and take any recommendations into account before varying any particulars or conditions that would affect any instructions for use. New section 34A(4) requires the APVMA to record the variation of relevant particulars or conditions in the Record, Register or the relevant APVMA file, along with the date the variation takes place. If the variation of relevant particulars or conditions of the registration of a listed chemical product would mean the product or any approved label for the product no longer complies with the relevant established standard, the APVMA must enter a date after which the registration of the product can't be renewed (see section 20). Similarly, the APVMA must remove any date after which the registration of the listed chemical product can't be renewed (see section 20) from the Register, if the variation of relevant particulars or conditions of the registration of the product would mean the product and all approved labels for the product comply with the relevant established standard. The purpose of this provision is to ensure that listed chemical products that comply with the established standard do not have a last renewal date in the Register and are therefore exempt from the re-registration scheme.

New subsection 34AA(1) requires the APVMA to suspend or cancel an approval or registration if it does not affirm the approval or registration or does not affirm the approval or registration with varied relevant particulars or conditions. In addition, the APVMA may suspend or cancel an approval of a label for containers for a chemical product if the holder does not satisfy the APVMA that a label with the varied particulars will be attached to the containers (subsection 34AA(2)). This provision is consistent with old section 40 and its co-location in the reconsideration provisions improves the operability and understanding of the reconsideration arrangements. As provided for previously and despite new section 34AA, the APVMA may suspend or cancel an approval or registration during a reconsideration as provided for in Division 5 of Part 2 of the Agvet Code which deals generally with suspensions and cancellations.

New section 34AB applies where the APVMA proposes to either vary relevant particulars or conditions under section 34A or proposes to suspend or cancel an approval or registration under section 34AA. Before taking these actions, the APVMA must inform the holder and other persons it has informed of the reconsideration of what it proposes to do and provide its reasons and seek the views of the holder and other persons. A period of three months is provided for submissions and this allows a holder and other persons an opportunity to respond to the APVMA. The APVMA must consider these responses.

New section 34AC specifies that notices must be provided to the holder of an approval or registration if the APVMA affirms or does not affirm the approval or registration, and specifies the content of these notices, including that regulations may prescribe additional notice matters.

New section 34AD requires the APVMA to, respectively, re-approve or re-register an active constituent or chemical product if the APVMA affirms the approval or registration following a reconsideration that resulted because the APVMA did not re-approve or re-register under section 29H (see Schedule 2). This provision deals with those re-approval and re-registration applications which remain undetermined because the approval or registration was subjected to a reconsideration by section 29H.

New section 34AE specifies that the APVMA may vary the date that an approval or registration ends if it affirms the same after a reconsideration, although the APVMA cannot be compelled to do so. The date an approval ends and the date after which a registration cannot be renewed (last renewal date) must be the last day of a calendar month at least 7 years but not more than 15 years after the approval or registration takes place. Regulations are to include a method for working out the approval end date or last renewal date and the APVMA may approve an active constituent or register a chemical product with an end date of less than seven years where this is necessary to align with another approval of the active constituent or registration of a chemical product containing the active constituent. This allows the APVMA to align approvals and registrations so they can be efficiently dealt with at the same time. New section 34AE does not apply where a reconsideration has occurred because the APVMA has not re-approved an active constituent or re-registered a chemical product (see Schedule 2). This is because this variation would occur as part of determining the re-approval or re-registration application.

New section 34AF aligns with previous section 34A but extends the prescribed situations in which the APVMA may, without notice, reconsider the approval of a label for containers of a chemical product. Section 34AF only applies where the reconsideration is about the matters prescribed in regulations, and further limited to the labelling criteria matters in new section 5D. In these circumstances the APVMA may vary the label particulars without notice to ensure that they contain adequate instructions. The APVMA must record the varied particulars and notify the holder of these varied particulars. In these circumstances, sections 30 to 34AE do not apply. It is not intended that section 34AF require the APVMA to undertake a series of label reconsiderations as a substitute for a full reconsideration of the product registration. The provision is intended to enable the APVMA to amend label particulars as a consequence of another change that affects a label approval, for example, a change to the poisons scheduling of a product or to update first aid directions.

Item 60 – section 40 of the Agvet Code

This item omits section 40 as the amendments to section 41 and new section 34AA mean it is no longer required.

Item 61 – subsection 43(2) of the Agvet Code

This item inserts a reference to section 29D into section 43 to provide that an approval or registration remains in force for section 29D even though the approval or registration is suspended. It has the effect of requiring a re-approval or re-registration application even though an approval or registration may be suspended.

Item 62 – repeal Division 7 of Part 2 of the Agvet Code

This item repeals Division 7 because notices are now dealt with in sections 8E to 8K.

Item 63 – repeal Part 2A of the Agvet Code

This item repeals Part 2A because the process for what was called listed registration is now included in provisions dealing with registration of a chemical product and because the process for specifying listed chemical products and establishing standards for listed chemical products are now dealt with in sections 8T to 8V.

Items 64 and 65 – subsections 56ZU(3) and (4) of the Agvet Code

Item 64 omits reference to other dealing with a chemical product because ‘other dealing’ is already included as part of the amendments to the definition of ‘use’ of a chemical product. Item 65 simplifies subsection 56ZU(4) by referring to the safety criteria, trade criteria and efficacy criteria that are defined in new sections 5A to 5C.

Items 66 and 67 – section 72 of the Agvet Code

These items amend the explanation in section 72 to remove reference to ‘listed registration’ and to improve the readability of the section.

Item 68 – subsection 74(5) of the Agvet Code

This item removes an unnecessary cross-reference to section 168 of the Agvet Code.

Items 69, 70 and 71 – section 75 of the Agvet Code

These items remove unnecessary references to ‘listed registration’ in section 75 of the Agvet Code which deals with possession or custody of certain chemical products.

Items 72 and 73 – subsections 75(5) and 76(5) of the Agvet Code

These items remove an unnecessary cross-reference to section 168 of the Agvet Code.

Items 74 to 79 – section 78 of the Agvet Code

These items remove unnecessary references to ‘listed registration’ in section 78 of the Agvet Code which deals with supply of certain chemical products.

Item 80 – subsection 78(5) of the Agvet Code

This item removes an unnecessary cross-reference to section 168 of the Agvet Code.

Item 81 – subsection 83(1) of the Agvet Code

This item removes unnecessary words from section 83 given the definition of ‘Register’ in section 3 of the Agvet Code.

Item 82 – section 83A of the Agvet Code

This item removes section 83A which dealt with substances in registered listed chemical products as these issues are now addressed by the more general requirements for registered chemical products.

Items 83, 84 and 85 – section 84 of the Agvet Code

These items remove unnecessary references to ‘listed registration’ in section 84 of the Agvet Code which deals with claims inconsistent with labels.

Item 86 – subsection 87(1) of the Agvet Code

This item includes listed chemical products in the current section 87 which provides for products to comply with any standards including any established standards that are prescribed for prescribed products. It allows the previous section 87A to be repealed (Schedule 3) and simplifies the Agvet Code without any impact on the application of standards.

Items 87 to 92 – sections 88, 89A and 97 of the Agvet Code

These items remove unnecessary references to ‘listed registration’ in sections 88 and 97 of the Agvet Code, and replace ‘listable’ with ‘listed’ in section 89A to reflect the new terminology of ‘listed chemical product’.

Items 93 to 100 – section 99 of the Agvet Code

These items amend section 99 (which deals with the analysis of chemical products) so that the heading more properly reflects the content of the section (item 93), improve the readability of the section (items 94, 95 and 98), remove reference to ‘listed registration’ (item 96), remove unnecessary words (item 97), replace ‘interested person’ with the new concept of ‘holder’ (item 99) and remove an unnecessary cross-reference to section 168 of the Agvet Code (item 100).

Items 101 to 105 – section 101 of the Agvet Code

These items amend section 101 of the Agvet Code (which deals with product recalls) to amend the heading to more properly reflect the content of the section (item 101), remove reference to ‘listed registration’ (items 102, 103 and 104) and remove an unnecessary cross-reference to section 168 of the Agvet Code (item 105).

Items 106 to 113 – section 102 of the Agvet Code

These items amend section 102 (which deals with product recalls in certain circumstances) to align with the new definitions of safety criteria, trade criteria and efficacy criteria in sections 5A to 5C (item 106), remove unnecessary words (items 107, 109 and 111), remove reference to ‘listed registered chemical product’ (items 108, 110 and 112) and remove an unnecessary cross-reference to section 168 of the Agvet Code (item 113).

Items 114 and 115 – section 103 of the Agvet Code

These items amend section 103 to improve the readability of the section and remove reference to ‘listed registered chemical product’ (item 114) and remove an unnecessary cross-reference to section 168 of the Agvet Code (item 115).

Item 116 – section 104 of the Agvet Code

This item amends section 104 which deals with recall notices to require the APVMA to publish recall notices in 14 days instead of as soon as practicable.

Items 117 to 120 – section 108 of the Agvet Code

These items amend the explanation of Part 7 (which deals with permits) in section 108 to remove reference to ‘listed registered chemical product’.

Items 121 to 127 – Part 7 of the Agvet Code

Permits

These items amend sections 110, 111, 112 and insert new sections 110A (preliminary assessment) and 112A (APVMA may issue a permit on its own initiative) in Part 7 of the Agvet Code. Part 7 of the Agvet Code deals with permits issued to persons who want to do something or omit to do something in respect of an active constituent or chemical product that would otherwise be prohibited.

Item 121 amends the heading of section 110 to better reflect the content of the section. Item 122 replaces the previous application requirements with a provision that refers to the general application requirements in new section 8A. This ensures consistency of application requirements across the Agvet Code. Item 124 amends section 111 to specify that the advice of a jurisdiction coordinator should relate to whether a permit should be issued rather than an application granted.

Preliminary assessment

Item 123 inserts a new section 110A that deals with the preliminary assessment of permit applications. This new section requires the APVMA to complete a preliminary assessment of an application within a month of being lodged and advise the applicant within 14 days as to whether the application has passed preliminary assessment. If it appears to the APVMA that there are defects in the application that can reasonably be rectified then within 14 days the APVMA must advise the applicant that the application has defects, provide particulars of those defects and allow the applicant to rectify the defects within one month. The APVMA must refuse an application if the defects cannot reasonably be rectified within one month or if the defects are not rectified satisfactorily in the required time.

In conducting a preliminary assessment the APVMA only needs to determine if the application appears to meet the application requirements. The preliminary assessment is not a technical assessment where the APVMA must be satisfied that the application meets the application requirements as this is dealt with in amended section 112. The purpose of the preliminary assessment is to provide for an administrative check of the application. The APVMA must refuse applications that appear unreasonably inferior or deficient at preliminary assessment so that it only needs to assess applications that are of the required standard. However, the preliminary assessment for permit applications is different from that for other applications to reflect the need for more flexibility for prospective permit applicants. The preliminary assessment for permit applications allows for a single opportunity to correct defects identified during preliminary assessment if defects can be reasonably rectified. If the response provided does not satisfy the APVMA then the APVMA must refuse the application.

Where an application passes preliminary assessment the application may be altered by the APVMA with the written consent of the applicant (subsection 110A(5)). The purpose of this provision is to allow the APVMA to alter an application when appropriate, rather than refuse it and have to consider a new application. The APVMA is to use the flexibility afforded by this provision where it is efficient to do so. The APVMA cannot be compelled to amend an application.

Issuing permits

Item 125 amends the heading of section 112 to better reflect that the content of the section deals with the issuing of permits. Item 126 amends section 112 to require the APVMA to issue a permit if it is satisfied that the application meets the application requirements in section 8A, and the constituent, product and label meet the safety criteria, trade criteria and the efficacy criteria as specified in paragraphs 112(2)(c) and (d), as well as any matters prescribed in regulations. For permits, the APVMA must also be satisfied that there are reasonable grounds for an application for approval or registration not having been made or for issuing the permit pending determination of an application for approval or registration. These measures align with the previous measures and are intended to ensure that permits are not used as a means of allowing users to circumvent seeking active constituent approvals or chemical product registrations.

New paragraph 112(2)(f) provides for the APVMA to issue a permit in relation to the manufacture of chemical products. This extends the situations where the APVMA may issue a permit to include the manufacture of chemical products in contravention of subsections 121(4A) or (5A) (which deal with carrying out a step in the manufacture of chemical products and compliance with licence conditions for manufacturing chemical products). However, the APVMA must only grant an application for a permit to manufacture in contravention of these sections where there are exceptional circumstances. This is because it is not intended that these permits are used to circumvent good manufacturing practice requirements for the manufacture of chemical products.

If the APVMA is not satisfied about an application then it must refuse the application (subsection 112(3)). The APVMA must also refuse an application for a permit where the applicant will be unable to comply with the conditions of the permit (subsection 112(4)(a)).

New paragraph 112(4)(b) replaces the previous 'suitable person' test (previous paragraph 112(2)(a)) as it is unduly broad and thus ineffective. New paragraph 112(4)(b) narrows and clarifies the scope of the test, in line with similar practical tests applied under other relevant legislation (for example, therapeutic goods legislation). New paragraph 112(4)(b) specifies that the APVMA must refuse an application where it is satisfied that the applicant or persons with a specified relationship with the applicant has within the previous 10 years been convicted of certain offences, ordered to pay a pecuniary penalty for contraventions of certain penalty provisions or has had a permit cancelled in certain situations (subparagraph 112(4)(b)(x)). A reference to a person convicted of an offence in new paragraph 112(4)(b) includes a reference to a person who has been discharged without a

conviction after an offence has been proved under section 19B of the *Crimes Act 1914*, or equivalent state or territory legislation (subsection 112(5)).

If the APVMA proposes to refuse an application then new section 8S applies in this situation and so the APVMA will need to provide an applicant with a notice detailing its reasons for the proposed refusal. The APVMA must also invite submissions from the applicant on the proposed refusal but in considering the response the APVMA is not required to take into account information that was not set out in the notice or in the application. It is not the intention that this draft decision mechanism be used to present new or different information that should have been provided in the initial permit application.

In special circumstances, the APVMA may still issue a permit to a person that the criteria in paragraph 112(4) apply to (subsection 112(6)).

Permits issued on the APVMA's initiative

Item 127 inserts a new section 112A which deals with permits that the APVMA may issue on its own initiative. New section 112A mirrors amended section 112 in that the APVMA must be satisfied about the safety criteria, trade criteria and efficacy criteria for the active constituent or chemical product, as well as the criteria for the proposed permit holder. New section 112A also provides for regulations to include additional requirements for the permits that the APVMA issues on its own initiative. Before the APVMA issues a permit on its own initiative it must notify the holders of approval or registration for the relevant constituent or product about what it intends to do (subsection 112A(6)). The notice is to include any information prescribed by the regulations. The APVMA must not issue the permit before 28 days after the day the notice was given. These new provisions do not apply if, in the opinion of the APVMA, special circumstances apply, for example, where the permit is required in a very short timeframe to address an emergency, or if the permit sought was for research purposes and information about making the application would be commercially sensitive.

Items 128 to 130 – section 114 of the Agvet Code

These items amend section 114 to amend the heading to more properly reflect the content of the section (item 128), repeal unnecessary subsections 114(1) and (1A) as these matters are dealt with in sections 112 and 112A, and to require the APVMA to inform a jurisdiction co-ordinator and prescribed authority of the permit and update the Record of Permits within 14 days (instead of 'as soon as practicable').

Items 131 to 134 – section 115 of the Agvet Code

These items amend section 115 which deals with applications for extensions for permits. Items 131 and 132 insert a new subsection that specifies the matters that the APVMA must consider in determining an application for a permit extension including any application requirements in section 8A and any requirements prescribed in regulations. It is intended that the APVMA satisfy itself about some matters before granting an extension. For example, the APVMA may have to consider whether the product would continue to meet the safety criteria or consider whether there are reasonable grounds for not making an application for variation of a registration or label approval in relation to the product.

Item 133 adds a note so readers are aware that requirements for refusal notices are in section 8G and item 134 removes an unnecessary cross-reference to section 168 of the Agvet Code.

Items 135 and 136 – section 117 of the Agvet Code

These items amend section 117 (which deals with permit surrenders) to replace 'approved person' with the new concept of 'holder' (item 135) and to require the APVMA to inform a jurisdiction co-ordinator of the surrender of a permit within 14 days (instead of 'as soon as practicable').

Items 137 and 138 – section 118 of the Agvet Code

These items amend section 118 (which deals with permits suspensions) to remove an unnecessary cross-reference to section 168 of the Agvet Code (item 137) and to require the APVMA to inform a jurisdiction co-ordinator of the suspension or revocation of a suspension of a permit within 14 days (instead of ‘as soon as practicable’).

Items 139 and 140 – section 119 of the Agvet Code

These items amend section 119 (which deals with permit cancellations) to remove an unnecessary cross-reference to section 168 of the Agvet Code (item 139) and to require the APVMA to inform a jurisdiction co-ordinator of the cancellation or revocation of a cancellation of a permit within 14 days (instead of ‘as soon as practicable’)(item 140).

Item 141 – section 120A of the Agvet Code

This item amends section 120A (which deals with exclusions from Part 8 which in turn deals with the manufacture of chemical products) to amend ‘listable’ to ‘listed’ to reflect that the relevant products are now to be known as ‘listed chemical products’.

Items 142 to 147 – sections 122 and 123 of Part 8 of the Agvet Code

Item 142 modifies the application requirements for applications for manufacturing licences in section 122. These requirements align with those in new section 8A and require the application to be in writing in the approved form, signed by the applicant, lodged with the APVMA, accompanied by the prescribed fee and include information specified for a manufacturing licence application. Item 143 deletes unnecessary words from subsection 122(2).

Item 144 amends section 123 to require the APVMA to issue a licence to carry out steps in the manufacture of chemical products unless it is satisfied that the applicant or the application does not comply with the application requirements in section 122 or any requirements prescribed in the regulations. In addition the APVMA must issue a licence unless the applicant will be unable to comply with either the conditions of the licence or the manufacturing principles.

New paragraph 123(1)(e) clarifies the scope of the test for licence holders, in line with similar tests applied under other legislation (for example, therapeutic goods legislation). New paragraphs 123(1)(e) and (f) specify that the APVMA must issue a licence to a person unless it is satisfied that the applicant or persons with a specified relationship with the applicant has within the previous 10 years been convicted of certain offences, ordered to pay a pecuniary penalty for contraventions of certain penalty provisions, contravened a condition of a licence, had a licence cancelled in certain situations or failed to comply with a manufacturing principle in the 5 years immediately before the application was made. Recognising that some manufacturing principles are more relevant than others to decisions to issue a licence, new subsection 112(1C) allows the APVMA to issue a licence where it thinks that failure to comply with a particular manufacturing principle is not relevant. The APVMA is therefore able to decide if the manufacturing principle that has not been complied with should disqualify a licence applicant from being issued with the licence. A reference to a person convicted of an offence in new paragraph 123(1)(e) includes a reference to a person who has been discharged without a conviction after an offence has been proved under section 19B of the *Crimes Act 1914*, or equivalent state or territory legislation.

If the APVMA does not issue the licence then it must refuse the application (subsection 123(1A)). If the APVMA proposes to refuse an application then new section 8S applies in this situation and so the APVMA will need to provide an applicant with a notice detailing its reasons for the proposed refusal. The APVMA must also invite submissions from the applicant on the proposed refusal but in considering the response the APVMA is not required to take into account information that was not set out in the notice or in the application. It is not the intention that this draft decision mechanism be used to present new or different information that should have been provided in the initial application.

In special circumstances, the APVMA may still issue a licence to a person that the criteria in paragraphs 123(1)(e) and (f) apply to (item 145) (subsection 123(2) as amended).

Items 146 and 147 amend subsection 123(5) which deals with publication of licence particulars to improve its readability without changing the purpose of the subsection.

Item 148 – section 124 of the Agvet Code

This item repeals section 124 as requirements for refusal notices for manufacturing licence applications are now provided for in new section 8G.

Items 149 and 150 – section 126 of the Agvet Code

Item 149 amends section 126 (which deals with manufacturing licence conditions) to provide for a new or varied condition to take effect on the day the notice is given if the condition is necessary to prevent the risks specified in paragraph 126(3)(a). In other circumstances, the new or varied conditions take effect 28 days after the notice is given to the holder, unless the APVMA and the holder agree that the new or varied conditions can take effect earlier. This allows the APVMA and the holder to mutually agree on new or varied conditions commencing earlier than 28 days. Item 150 removes an unnecessary cross-reference to section 168 of the Agvet Code.

Items 151 to 153 – section 127 of the Agvet Code

These items amend section 127 (which deals with licence suspensions and cancellations) to replace ‘approved person’ with the new concept of ‘holder’ (items 151 and 152) and to remove an unnecessary cross-reference to section 168 of the Agvet Code (item 153).

Item 154 – section 149 of the Agvet Code

This item removes an unnecessary reference to ‘listed’ products in section 149 of the Agvet Code.

Items 155 to 160 – section 152 of the Agvet Code

These items amend section 152 which deals with the liability of persons acting on behalf of non-residents (nominated agents). The items replace terms in section 152 so that the terms ‘holder’ and ‘nominated agent’ are used to reflect this new model in the Agvet Code. Item 156 amends section 152 to improve its readability.

Item 161 – new section 156A of the Agvet Code

This item inserts a new provision (section 156A) that deals with the provision of information to and from the APVMA in electronic form. Electronic provision of information reduces the likelihood of administrative errors in applications and reduces administrative costs.

The provision specifies the information that can be provided electronically. Where the APVMA and the person consent, the information that can be provided electronically includes making applications to the APVMA, the issuing of notices by the APVMA and the APVMA providing a statement of reasons.

The new section also provides that regulations may require information to be given to the APVMA only in electronic form. In the situations prescribed in the regulations, the providers of information would have to provide the information in electronic form. In practice and to ensure accessibility, the regulations would provide for information to be provided in non-electronic form and converted to electronic form for a specified fee.

Item 162 - section 157 of the Agvet Code

This item amends section 157 which deals with providing samples for analysis to the APVMA. The amendment clarifies that the section only applies for the purposes of determining an application and that it has no application after an application has been determined.

Items 163 to 174 - section 159 of the Agvet Code

These items amend section 159 which deals with the APVMA requiring additional information, reports or samples.

Item 164 removes reconsideration matters from section 159 as additional information, reports or samples will now be dealt with in section 33 of the Agvet Code. Item 165 removes an unnecessary reference to listed registration as this is now included in 'registration'. Items 166, 169 and 170 replace the terms 'person', 'interested person' and 'approved person' with the new model of 'holder' or 'applicant'. Item 171 inserts a note referring to new section 156AA and the giving of information electronically.

Items 163 and 167 move the previous requirements for information and analysis to be relevant to the application to the start of paragraphs 159(1)(a) and (b). This improves the readability of the section.

Item 168 provides for regulations to prescribe the time in which information, reports or samples must be provided. The APVMA may only allow a further period in the circumstances provided by the regulations.

Items 172 and 174 amend subsection 159(3) and delete subsections 159(4) and 159(5) in relation to information, reports or a sample requested by the APVMA or another prescribed authority for the purposes of an application. The purpose of these amendments is to require the APVMA to refuse an application where the APVMA or another prescribed authority has required a person to provide information, a report or a sample and that person fails, without reasonable excuse, to provide that information, report or sample.

As the regulations are to include the timeframes for providing the information, samples or reports, including where the APVMA may allow a further period, the amendments mean that the APVMA would no longer have the option to treat an application as withdrawn or suspend further consideration of an application until the applicant complies with the requirement. The purpose of these amendments is to reduce the administrative burden on the APVMA and agencies it consults, and improve the timeliness of assessments. Item 173 inserts a note referring to refusal notices.

Items 175 to 182 – section 160 of the Agvet Code

Item 175 amends the heading of section 160 to better reflect the content of the section. Section 160 deals with the use of overseas trials and experiments, information, assessments and decisions by the APVMA (and its partner agencies) in assessing applications, reconsidering approvals and registrations and deciding whether to suspend or cancel permits. Items 176 and 180 amend section 160 to improve its readability. Item 179 removes an unnecessary reference to listed registration as this is now included in 'registration'.

Items 177 and 178 amend section 160 to clarify that the provisions apply for determining an application. The circumstances where the section applies and where overseas data may be used are unaffected. For example, the section would continue to apply for applications for a proposed chemical product or reconsideration of the approval of an active constituent. In addition, the section would apply for re-approval and re-registration applications.

Items 181 and 182 amends section 160 to specifically provide that the APVMA may take account of evaluations and decisions undertaken by regulators of agricultural and veterinary chemicals in a foreign country and the information on which those evaluations or decisions were made. The purpose

is to encourage the APVMA and its regulatory partners to make more effective use of work conducted by comparable overseas agencies.

While the APVMA may take these matters into account when performing its functions and exercising its powers, the amendments insert a new subsection 160(3) that requires the APVMA to take into account ‘any significant differences in the way decisions or evaluations are made in Australia and by the national regulatory authority in that foreign country’. This amendment means that the APVMA may take into account that different countries may use different approaches in assessing and making decisions in relation to agvet chemicals. The amendment therefore retains the APVMA discretion in how this information may be used, taking into account the use of the chemical product, environmental factors and any other significant contemporary information available to it or its partner agencies.

Overall, these amendments ensure there is no impediment to the appropriate use of overseas data, assessments and decisions, including, where appropriate, specific reliance on decisions made by specified overseas regulators.

Items 183 to 191 – section 160A of the Agvet Code

These items amend section 160A which deals with information that must be notified to the APVMA for a pending application.

Item 183 removes an unnecessary reference to listed registration as this is now included in ‘registration’. Items 184, 185, 186, 187, 189 and 190 replace ‘the appropriate person’ throughout section 160A with the term ‘applicant’ as it is the applicant to which the obligations in section 160A apply.

Item 188 amends section 160A to clarify the relevant information that must be notified to the APVMA by the applicant after an application is lodged. The relevant information is any information that shows the active constituent or chemical product may not meet the safety criteria, trade criteria or efficacy criteria. The relevant information also includes any information that contradicts any information given to the APVMA by the applicant that relates to the relevant particulars prescribed for an approval of an active constituent (new paragraph 19(1)(c)) and the registration of a chemical product (new paragraph 20(1)(c)).

Item 191 inserts a note referring to new section 156AA and the giving of information electronically.

Items 192 to 197 – section 161 of the Agvet Code

These items amend section 161 which deals with information that must be notified to the APVMA.

Item 192 replaces the previous paragraph 161(1)(a) with a new paragraph that no longer refers to listed registered chemical product (as this is now included in ‘registered chemical product’) and replaces ‘interested person’ with the new term ‘holder’.

Items 193, 195 and 196 amend subsections 161(1) and (3) respectively to use the new terminology of ‘holder’ and to also require the holder to notify the APVMA of relevant information as soon as they become aware of the relevant information (rather than as soon as practicable).

Item 194 amends section 161 to clarify the relevant information that must be notified to the APVMA by the holder. The relevant information is any information that shows the active constituent or chemical product may not meet the safety criteria, trade criteria or efficacy criteria. The relevant information also includes any information that contradicts any information entered in the Record, Register or Record of Permits for the active constituent or chemical product.

Item 197 inserts a note referring to new section 156AA and the giving of information electronically.

Items 198 to 206 – section 162 of the Agvet Code

These items amend section 162 that deals with disclosure of confidential commercial information.

Items 198 and 200 replace the term ‘assessment’ with the more appropriate term of ‘evaluation’.

Items 199 and 201 remove reference to listed registration as this is now included in ‘registration’.

Items 202, 203, 204 and 205 replace the reference to ‘interested person’ with the new term ‘holder’ or where appropriate ‘applicant’. Item 206 removes the unnecessary reference to another section of the Agvet Code.

Items 207 to 211 – section 163 of the Agvet Code

These items amend section 163 which deals with notices to holders of the proposed disclosure of confidential commercial information. Item 207 replaces the heading with a heading that better reflects the content of the section. Items 209 and 210 replace the reference to ‘interested person’ with the new terms holder or applicant.

Item 211 removes the unnecessary reference to another section of the Agvet Code and item 208 is a consequential amendment to remove the unnecessary ‘(1)’ in the section.

Item 212 – section 164 of the Agvet Code

Item 212 removes the unnecessary reference to another section of the Agvet Code.

Items 213 to 217 – section 165 of the Agvet Code

Item 213 replaces paragraph 165(2)(a) to exclude time periods from the application assessment periods in which the APVMA must determine an application. The purpose of the item is to allow the regulations to specify timeframes that take account of the total elapsed time for determining all components of the application, except for applications for re-approval or re-registration. Timeframes for re-approval or re-registration applications are to exclude the time for an applicant to respond to an APVMA requirement and the time taken to complete a reconsideration, if relevant.

The timeframes for determining the application would be prescribed in the regulations (as previously provided for). It is intended the regulations would specify a maximum assessment period (where the APVMA does not make a requirement of an applicant) and an extended maximum assessment period (where the APVMA makes any requirement of an applicant). Section 159, as amended, provides that should the APVMA make a requirement of the applicant, the applicant must address the requirement within the period specified in the regulations or the APVMA must refuse the application. The prescribed timeframes would also make allowance for the time required for any public consultation.

Items 214 and 215 are editorial amendments to improve the readability of the section. Item 216 inserts a new paragraph to exclude the time for an applicant to respond to a draft decision notice from the statutory timeframe for an application.

Item 217 inserts new subsection 165(3), (4) and (5) to clarify the opportunities for applicants to have their application treated as refused where an application has not been determined within a statutory timeframe and where the applicant has given written notice of this to the APVMA. The purpose of the provision is to allow an applicant to seek to have their application refused and then dealt with by the Administrative Appeals Tribunal if the application is not determined within the statutory timeframe. The provisions produce the same outcome as those in previous subsection 167(2) but are more consistent in structure to those in other Commonwealth legislation (for example, therapeutic goods legislation).

Item 218 – new section 165A of the Agvet Code

This item inserts a new section 165A to provide for timeframes for reconsideration of approvals and registrations. At present, there is no requirement for the APVMA to determine a reconsideration of approval or registration within a particular period. The purpose of the amendment is to improve the

predictability of outcomes for reconsiderations and assist in reducing the backlog of chemical reviews.

As currently applies for application timeframes, new section 165A provides for the regulations to specify timeframes or a means of determining these timeframes for concluding a reconsideration. Timeframes exclude the public consultation notice periods (paragraph 32(1)) and the notice period for a notice for section 33.

Items 219 to 223 – section 166 of the Agvet Code

These items amend the provisions relating to the internal review of decisions (section 166) to reflect the changes made to the consideration of applications by the APVMA. The purpose of these items is to specify those decisions which the APVMA may internally review and to limit the APVMA review to the specific information used to make the original decision. While the APVMA is limited in reviewing these decisions, this does not prevent an applicant from making a new application where new information becomes available after the original decision maker made a decision.

Item 219 amends the heading of section 166 to better reflect the content of the section and to avoid confusion with ‘reconsideration’ used elsewhere in the Agvet Code. Item 220 amends section 166 to clarify that section 166 does not apply to a decision under section 166 as it is not intended that the APVMA conduct internal reviews of internal reviews.

Item 221 amends section 166 to provide that an internal review is available for any decision that is reviewable by the Administrative Appeals Tribunal, other than decisions under subsections 29G(1) or 34A(1) to vary relevant particulars or conditions and decisions under subsections 34AA(1) or (2) to suspend or cancel an approval or registration in Division 4 of Part 2. The amendments also specify that an internal review of decisions made under subsections 14(2), 26C(2), 29(2) and 29E(3) is available where that decision was based only on the application requirements in paragraphs 8A(a) or (b). Furthermore, the amendments specify that an internal review of decision made under subsection 112(3) is available where that decision was based only on the application requirements in paragraphs 8A(a) or (b), or the APVMA requirements in subparagraph 111(1)(b)(iii). These decisions are based solely on whether application requirements were complied with and are not subject to the Administrative Appeal Tribunal review. It is therefore appropriate that they be subject to internal review.

Item 222 amends section 166 to specify that the internal review by the APVMA of the original decision must be based on the information used to make the original decision. This limits the APVMA internal review to the specific information used to make the original decision and prevents further information from being considered if it is provided after the original decision is made.

Item 223 removes the unnecessary reference to another section of the Agvet Code.

Items 224 to 238 – section 167 of the Agvet Code

Item 224 amends the heading of section 167 so that it more properly reflects the content of the section. Items 225, 228 and 232 amend section 167 to specify those decisions that are subject to review by the Administrative Review Tribunal (AAT).

The purpose of these items is to specify that AAT review is available for most decisions including for applications; reconsiderations; permits; licences; conditions that may apply to approvals, registrations, permits and licences; refusing to accept a late renewal application; the use of information in the public interest; extensions of approval or registration periods in relation to certain offences; suspensions; cancellations; issuing recall notices; requiring analysis of a substance or substance mixture; disclosure of information; and refusing to waive or remit fees. However, AAT review is not available for certain APVMA decisions. These decisions are those which relate to refusing an application solely on the administrative application requirements. In these circumstances, a person may only seek to have the APVMA internally review its original decision for these

applications (under section 166) and AAT review is not available. No change is proposed to judicial review arrangements. This change will allow the APVMA to focus its resources on applications that are administratively complete and place a greater onus on applicants to submit applications of sufficient quality.

Items 226, 227, 229, 230, 231, 233 and 234 are consequential amendments to reflect changes in section numbering and the removal of specific provisions relating to listed registration. Item 235 replaces the reference to 'interested person' with the new terms 'holder' or 'applicant'. Item 236 repeals subsection 167(2) as these matters are now part of section 165. Items 237 and 238 are consequential amendments as the matters previously dealt with by section 34E are now in section 34K and the expression 'death, serious injury or serious illness' is now used throughout the Agvet Code (consistent with other Commonwealth legislation).

Items 239 to 243 – sections 178, 180 and 184 of the Agvet Code

Item 239 removes unnecessary words from section 178. Item 240 is a consequential amendment to section 180 to reflect that the requirements in the previous subsection 32(2) are now contained in subsection 32(1). Item 241 removes a redundant paragraph related to the commencement of the Code Act. Items 242 and 243 are editorial amendments to improve the readability of section 184.

SCHEDULE 2 – RE-APPROVALS AND RE-REGISTRATIONS

Summary

Schedule 2 amends the Agvet Code to ensure the ongoing safety of agvet chemicals and improve the effectiveness and efficiency of agvet chemical reconsideration arrangements. This is achieved by implementing a mandatory scheme for the re-approval of active constituents and re-registration of chemical products to periodically review (every 7-15 years) active constituents and products to ensure that they do not pose unacceptable risks to human or environmental health and safety. The scheme is designed to minimise impacts on affected businesses.

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. Reflecting their low regulatory concern, the re-registration scheme does not apply to listed chemical products where the product and all approved labels for the product comply with the established standard.

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 fifteen years. If the APVMA does identify relevant concerns, the active constituent approval or chemical product registration would be referred for reconsideration under Division 4 of Part 2 before a final decision on the re-approval or re-registration application. The APVMA may amend the relevant particulars and conditions of an approval or registration to allow the re-approval or re-registration and avoid the need for a reconsideration if doing so could address the concerns the APVMA has identified about the active constituent or chemical product.

The scheme complements the existing chemical reconsideration arrangements and brings Australia into line with other countries which have similar schemes to ensure the protection of human, animal and environmental health and provide community confidence in the regulation of agvet chemicals.

Detailed Explanation

Agricultural and Veterinary Chemicals Code Act 1994

Items 1, 2, 3 and 4 – subsection 3(1) of the Agvet Code

These items insert new definitions of ‘approval’, ‘re-approval’, ‘registration’ and ‘re-registration’ that apply throughout the Agvet Code. The definitions of ‘approval’ and ‘registration’ include ‘re-approval’ and ‘re-registration’ respectively except in Division 2 of Part 2 and Part 3. Division 2 of Part 2 deals with approvals of active constituents and registrations of chemical products and the exclusion of this Division in the definitions ensures that there is no conflict between the requirements in Division 2 and Division 3A of Part 2. Part 3 deals with compensation for providers of certain information and the words ‘approve’ and ‘register’ in that Part don’t include re-approve or re-register.

Item 5 – new Division 3A of the Agvet Code

This item inserts new Division 3A that deals with the re-approval of active constituents and the re-registration of chemical products. New section 29C is an explanation of the new division.

New section 29D provides for the holder of an approval or registration to apply to the APVMA for re-approval of an active constituent or re-registration of a chemical product. The application must

meet the applications requirements in section 8A. An application must be made in the period between three and six months before the approval ends or the day after which the registration cannot be renewed. Provision has been made for the APVMA to allow a late application to be made up until the day the approval ends or the day after which the registration cannot be renewed (subsection 29D(3)). As registrations are subject to annual renewal, the requirements for re-registration are based on the date after which a registration cannot be renewed.

New section 47B (see below) provides that the APVMA must give holders of approval and registration 12 months notice of the end of an approval or registration and so holders will be given advance notice and can prepare for applications that will need to be made.

Preliminary Assessment

New section 29E requires the APVMA to complete a preliminary assessment of an application within a two months of being lodged and advise the applicant within 14 days of the decision being made as to whether the application has passed preliminary assessment or whether it has refused the application. In conducting a preliminary assessment the APVMA only needs to determine if the application appears to meet the application requirements. The purpose of the preliminary assessment is to provide for an administrative check of the application. For subsection 29E(3), the APVMA must refuse applications that appear inferior or deficient at preliminary assessment so that it only needs to assess applications that are of the required standard.

After an application passes preliminary assessment the application may be altered by the APVMA with the written consent of the applicant (subsection 29E(4)). The purpose of this provision is to allow the APVMA to alter an application when appropriate, rather than refuse it and have to consider a new application. The APVMA is to use the flexibility afforded by this provision where it is efficient to do so. The APVMA cannot be compelled to amend an application.

Re-approval and re-registration

New section 29F deals with re-approval and re-registration. The APVMA must re-approve an active constituent unless it appears to the APVMA that there are reasonable grounds to believe that the constituent does not meet the safety criteria. Similarly, the APVMA must re-register a chemical product unless it appears to the APVMA that there are reasonable grounds to believe that the product does not meet the safety criteria, trade criteria or efficacy criteria. The use of the expression 'it appears' in this assessment imposes a lighter test than required for approval or registration. It is intended that the APVMA apply this lighter test for the purposes of re-approval or re-registration as it is not intended that a complete reconsideration of an approval or registration be undertaken.

It is also intended that the information to be provided about the existing approval or registration would be information about the constituent or product that the holder has, or could be reasonably expected to have or have access to (see new paragraph 8B(2)(b)). It is intended that holders not generate new information for a re-approval or re-registration application, although this may be required in any subsequent reconsideration. Overall, the purpose is to identify approvals or registrations for which it appears there are reasonable grounds to believe that the active constituent or product might not meet the safety criteria, trade criteria or efficacy criteria, as relevant to the constituent or product.

To facilitate re-approval and re-registration, new subsection 29G(1) authorises the APVMA to vary relevant particulars or conditions of approvals or registrations. New subsection 29G(2) requires the APVMA to consult a jurisdiction co-ordinator and take into account recommendations about the variation if it would affect the instructions for use for an active constituent or chemical product.

If the APVMA decides to vary relevant particulars or conditions of approvals or registrations it must record these variations in the Record, Register or relevant APVMA file along with the date the variations are made. The APVMA must remove any date after which the registration of the listed

chemical product can't be renewed (see section 20) from the Register, if the variation of relevant particulars or conditions of the registration of the product would mean the product and all approved labels for the product comply with the relevant established standard. The purpose of this provision is to ensure that listed chemical products that comply with the established standard do not have a last renewal date in the Register and are therefore exempt from the re-registration scheme.

Reconsideration

New section 29H address the situation where the APVMA does not re-approve an active constituent or re-register a chemical product and instead reconsiders the approval or registration under Division 4. In this situation, the APVMA must notify the applicant of this and advise the applicant of the reasons for the reconsideration and that the approval or registration will not end until the reconsideration is completed.

New section 29H also specifies that the notice for section 29H may include the notice provided for subsection 32(1) (reconsiderations). This allows the APVMA to issue a single notice to deal with re-approval and re-registration and reconsideration matters.

How re-approval or re-registration take place

Section 29J and 29K specify how re-approval and re-registration take place.

Section 29J specifies that re-approval of an active constituent takes place when the APVMA records in the Record that the constituent has been approved, the date of approval and the date the approval ends. Except as provided for by subsection 29J(3) and unless the approval is only in effect for a period of less than a year, the date the approval ends must be the last day of a calendar month and must not be less than 7 years and not more than 15 years after the re-approval takes place. The date the approval ends in this 7 to 15 year range must be worked out in accordance with a method prescribed in the regulations.

Subsection 29J(3) allows the APVMA to re-approve an active constituent for a period less than 7 years to allow the approval to end at the same time as another approval for the active constituent. Allowing the APVMA to set an approval end date of less than seven years if it is convenient to do so improves efficiency by aligning future applications for re-approval for a particular chemical.

Section 29K specifies that re-registration of a chemical product takes place when the APVMA records in the Register that the chemical product has been registered, the date of re-registration and the date the registration ends. Unless the registration is for a listed chemical product that complies with the established standard, the APVMA must also record the date after which the registration cannot be renewed, the last renewal date. Except as provided for by subsection 29K(3) and unless the registration is only in effect for a period of less than a year, the date after which the registration cannot be renewed must be the last day of a calendar month and must not be less than 7 years and not more than 15 years after the re-registration takes place. The purpose of excluding listed chemical products that comply with the established standard is so that these products are exempt from the re-registration scheme.

The date after which the registration cannot be renewed in this 7 to 15 year range must be worked out in accordance with a method prescribed in the regulations. Subsection 29K(3) allows the APVMA to re-register a chemical product for a period less than 7 years to allow the registration to end at the same time as another registration of a chemical product that contains one or more of the same active constituents. This improves efficiency by aligning future applications for re-registration of chemical products containing the same active constituent.

Items 6 and 7 – new Division 6 of the Agvet Code

These items replace the old Division 6 with a new division that deals with the duration of approvals and registrations, as well as the annual renewal of registrations of chemical products. New section 46A is an explanation of the division.

New section 47 specifies when approvals and registrations end which, unless cancelled earlier, is the day entered in the Record or Register. However, subsections 47(1) and (2) provide that approvals or registrations remain in force while an application for re-approval or re-registration is under consideration by the APVMA.

Subsection 47(3) specifies that the registration of a chemical product ends if the approval of the active constituent for the product ends. Subsection 47(4) specifies that the approval of a label for containers for a chemical product ends when the registration of a chemical product ends. However, subsection 47(5) specifies that the approval of a label for containers for a chemical product remains in force while a permit has been taken to have been issued, even though the registration of a chemical product ends. These requirements are consistent with the old section 47 and ensure that approvals or registrations end when other corresponding approvals and registrations also end.

Decisions of foreign regulators

New section 47A details when the APVMA must vary the day an approval or registration ends 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).

New section 47A applies if the regulators have decided to prohibit all the uses of an active constituent or chemical products containing the same active constituent approved or registered under the Agvet Code during a seven year period since the approval or registration or since the last re-approval or re-registration. As the APVMA has determined its satisfaction about the chemical at each registration or re-registration (at that time considering the relevance of overseas decisions), only decisions made by foreign regulators since the last registration or re-registration are to be relevant to section 47A. New section 47A does not apply where an approval or registration is already being reconsidered by the APVMA (paragraph 47A(1)(d)) or where an approval or registration ends before the varied dates that the approval or registration ends (subsection 47A(5)).

Where new section 47A applies the APVMA must vary the day the approval ends or the registration cannot be renewed so that it ends on the last day of a calendar month between six and 18 months after the second decision was made. This variation can only occur once and the holder of approval or registration must be given at least six months notice of the varied date that an approval or registration ends (subsection 47A(5)).

The APVMA is not prevented from commencing a reconsideration by section 47A and may commence a reconsideration irrespective of actions taken under section 47A.

Notices of approval or registration

New subdivision C and new sections 47B, 47C, 47D and 47E specify the requirements for notices and phase out of existing stocks when approvals and registrations end.

New section 47B specifies the advance notices that the APVMA must provide or publish about the end of approvals or registrations. The APVMA must publish in the *Gazette* a notice of the impending end of the approval of an active constituent and the date after which a registration cannot be renewed. This notice must invite submissions from the community about whether an active constituent should be re-approved and a chemical product re-registered. This provides an opportunity

for the community to provide submissions about continued use of active constituents and chemical products, and allows the APVMA to consider these submissions in assessing applications for re-approval or re-registration.

New section 47B also requires the APVMA to notify holders 12 months in advance of an approval ending or when a chemical product cannot be renewed. This notification must include the relevant particulars and conditions of approval or registration along with the date the approval ends and the date after which the registration 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. The purpose of these requirements is to ensure that holders are aware of the current relevant particulars and conditions for their approval or registration. This allows holders to either ensure active constituents or chemical products comply with these relevant particulars or conditions, or alternatively, allows holders to apply to the APVMA to vary the relevant particulars or conditions in the time before an application for re-approval or re-registration is required.

New section 47C specifies notice requirements when an approval or registration ends and aligns with the previous section 54 requirements. Unless the APVMA thinks it is unnecessary, these notices must be published in the *Gazette* and in any other manner the APVMA thinks appropriate (for example, APVMA website). The notices must include certain information, including the date that approval or registration ended, instructions for possessing, having custody of or using the active constituent or chemical product and warnings about the consequences of failing to comply with these instructions. The notices must also include a statement of the period after which it would be an offence to supply, possess or have custody of the active constituent or chemical product, as well as any other information, explanations or warnings that the APVMA thinks appropriate or desirable. If the APVMA publishes this notice then it must also give a copy of the notice to the holder and any other person it thinks should be given the notice. These measures ensure that the requirements and consequences for supply, possession and custody are clear.

Permit taken to have been issued

New sections 47D and 47E provide for permits for an orderly sell-out period for stock-in-trade active constituents or chemical products for which approval or registration has ended. They are consistent with new sections 45A, 45B and 45C which also deal with orderly sell-out periods. With some differences, these new sections are consistent with the old section 54 but the new sections also deal with when an approval ends.

New section 47D provides for a person to possess, have custody of or use an active constituent or chemical product even though its approval or registration has ended. This applies for a period of one year, unless the APVMA declares that this does not apply and publishes a notice to this effect. For example, the APVMA can determine that a shorter sell-out period or no sell-out period at all is to apply (where allowing continued possession may not be safer than recall and disposal.)

Unlike old section 54, new section 47D only provides for a one year sell-out period and does not authorise ongoing importation or manufacture (the sell-out period is only available to existing stocks). The purpose of the sell-out period is to exhaust existing stocks where it is safer and more practical to allow continued possession and use rather than recall and subsequent disposal of these products. New section 47D is not intended to provide for an extension of the approval or registration.

As provided in old section 54, new section 47E provides for a strict liability offence for possessing, having custody of or other dealing with an active constituent or chemical product in contravention of the instructions in the notices provided to persons or the notices which have been published. The amount of the penalty units (300) is for the same amount as the previous section 54 and the defence in the previous subsection 54(5) has been retained in subsection 47E(3). However, the new section

47E provides that the offence is also a civil penalty provision and therefore provides for civil penalty orders and pecuniary penalties for contravening new section 47E.

Items 8, 9, 10 and 11 – section 48 of the Agvet Code

These items amend section 48 which provides for applications for the renewal of registrations of chemical products. Item 8 amends the heading to better reflect the subject matter of the section.

Item 9 also updates the section to refer to the new terminology of ‘holder’ rather than ‘interested person’.

Item 10 replaces the existing subsection (2) and specifies an application for renewal of registration must be made one month before the registration ends and before date entered in the Register as the date after which the date cannot be renewed. The amended subsection 48(2) provides that in the year after which a registration cannot be renewed, the holder of registration would need to both renew their registration for another year and apply to re-register their chemical product.

Item 11 provides for the day entered in the Register as the day after which a registration cannot be renewed to be the day a re-registration application is determined, if the application is not determined by the day a renewal application is required. This amendment allows the day entered in the register to move forward and to provide for an annual application for renewal in any subsequent years after a re-registration application has been made but before it has been determined. This allows for annual renewal of registration, as occurs now, for all the time a re-registration application has not been determined as a result of the registration being reconsidered under section 29H.

Item 11 also inserts new subsection (5) specifies that the APVMA may alter an application with the written consent of an applicant. This new measure is to allow the APVMA and the applicant to flexibly and efficiently deal with an application for renewal of registration.

Item 12 – sections 49 and 50 of the Agvet Code

This item replaces the old sections 49 and 50 with new sections that deal with applications for renewal.

Similar to old section 49, new section 49 requires the APVMA to renew the registration of a chemical product if the application under section 48 meets the application requirements in section 8A and the application is made before the registration ends.

Similar to the old section 50, new section 50 specifies that renewal takes place when the APVMA enters that the registration has been renewed in the Register. New section 50 also specifies that the date of registration must be the last day of a calendar month and not more than 12 months after the renewal takes place. New section 50 provides for annual renewal of the registration of a chemical product.

SCHEDULE 3 – ENFORCEMENT

Summary

The APVMA lacks a modern graduated compliance regime. The current legislation provides no intermediate measures between the extremes of warning letters and criminal prosecution. In addition, some provisions prevent the APVMA from responding as effectively as possible when new information becomes available.

Schedule 3 amendments improve the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance and enforcement powers and introducing a power to apply statutory conditions to registrations and approvals. The amendments in Schedule 3 improve the ability of the APVMA to efficiently administer its regulatory decisions by tailoring regulatory sanctions to the seriousness of the non-compliance, to enhance protection of public health and safety and the environment. The measures are similar to those available to other regulators under Commonwealth laws and modernise current investigation and enforcement provisions, consistent with contemporary standards.

Detailed Explanation

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

Items 1 and 2 – subsection 3(1) of the Collection Act

Item 1 inserts a definition of ‘civil penalty order’ by signposting to the definition in the Admin Act which includes the enforcement provisions for both the Collection Act and the Admin Act. Item 2 inserts a definition of ‘civil penalty provision’ that specifies that a civil penalty provision is any provision that declares a provision to be a civil penalty provision. These amendments are necessary to provide for civil penalty orders for contraventions of provisions in the Collection Act.

Items 3 and 4 – subsection 3(1) of the Collection Act

These items remove the definitions of ‘occupier’ and ‘premises’ from the Collection Act as these are no longer required. These definitions are only relevant for monitoring and investigation powers. Other items in this Schedule update the monitoring and investigation provisions in the Admin Act and apply these provisions for the purposes of the Collection Act. There is therefore no need to duplicate these definition provisions in the Collection Act.

Items 5, 6, 7 and 8 - section 15 of the Collection Act

These items update the previous offence provision in section 15 of the Collection Act. The provision relates to a person refusing or failing to comply with a request to provide information about the amount of levies that are payable under the Collection Act (section 15). The update to the offence provision maintains the previous strict liability of the offence but increases the penalty from 30 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation and is consistent with the *Guide* (for example, failure to lodge a report).

The amendments also provide that the offence is a civil penalty provision and therefore provides for pecuniary penalties for contraventions of the provision. This is provided for in section 69EJ of the Admin Act. A civil penalty provision provides the APVMA with more flexibility in requiring information about the leviable value of chemical products, and subsequently the levies that are payable. The APVMA may apply to the court for a civil penalty order against a person who has contravened a civil penalty provision. The APVMA must seek the order no later than six years after

the contravention. The court may order a civil penalty if it is satisfied a person has contravened a civil penalty provision.

The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 15 in the Collection Act, including monitoring and investigation powers, warnings and enforceable undertakings.

Items 9, 10, 11 and 12 – section 20 of the Collection Act

These items update the previous offence provision in section 20 of the Collection Act. The offence provision relates to failing or refusing to comply with a requirement to provide information to the APVMA about disposals of chemical products. The update maintains the previous strict liability of the offence and increases the penalty from 30 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation and is consistent with the *Guide* (for example, failure to lodge a report).

The amendments also provide that subsection 20(1) is a civil penalty provision and that civil penalties may therefore be imposed against a person who contravenes the subsection. The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 20 in the Collection Act, including monitoring and investigation powers, warnings and enforceable undertakings.

Items 13, 14 and 15 – sections 21 to 32 and sections 34 and 35 of the Collection Act

Items 13 and 15 repeal the monitoring and investigation powers in the Collection Act as these are no longer required in the Collection Act (sections 21 to 32 and section 35). Other items in this Schedule update the monitoring and investigation provisions in the Admin Act and apply these provisions for the purposes of the Collection Act. There is therefore no need to duplicate these provisions in the Collection Act. The co-location of these provisions makes it easier to maintain them in a consistent and contemporary form, including making them easier to amend as required.

Item 14 updates section 34 of the Collection Act that deals with the abrogation of the privilege against self-incrimination. The purpose of the update is to align with the new provision in the Agvet Code that deals with the abrogation of this privilege for notices to produce or attend (new section 130C). This ensures that the abrogation of this privilege is consistent for regulated entities across agvet chemical legislation. The update also provides that the use and derivative use immunity does not extend to the obstruction of Commonwealth officials (section 149.1 of the *Criminal Code*). This approach is consistent with the *Tertiary Education Quality and Standards Agency Act 2011*.

Items 16 and 17 – section 36 of the Collection Act

These items update a previous offence provision in the Collection Act. The provision relates to a person retaining records about the manufacture, importation and disposal of chemical products. The update to the offence provision maintains the previous strict liability of the offence but increases the penalty from 30 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation. This penalty is more than is specified in the *Guide* (for example, failure to keep records). However, this is considered justified given the importance of record keeping for managing the potential public health implications associated with agvet chemicals.

The amendments also provide that subsection 36(1) is a civil penalty provision and that civil penalties may therefore be imposed against a person who contravenes the subsection. The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 36 in the Collection Act, including monitoring and investigation powers, warnings and enforceable undertakings.

Agricultural and Veterinary Chemicals (Administration) Act 1992

Items 18 to 37– section 4 of the Admin Act

These items introduce new definitions into the Admin Act including for ‘civil penalty order’, ‘civil penalty provision’, ‘Collection Act’ and ‘evidential burden’. These definitions are needed to introduce civil penalty provisions and amend monitoring and investigation powers in the Admin Act. These definitions refer to specific provisions in the Admin Act and refer to definitions in the Agvet Code for ‘premises’ and ‘occupier’ and ‘confidential commercial information’ to ensure consistency. The definitions of ‘evidential material’ and ‘relevant data’ include reference to both the ‘Collection Act’ and the ‘Admin Act’ as the provisions relating to evidential material and relevant data apply for the purposes of both the Admin Act and the Collection Act.

Item 38 – new subsection 11(1A) of the Admin Act

This item stipulates that the authority to issue notices to attend, give information or produce documents under the Agvet Code (see new section 130) may be delegated by the CEO of the APVMA but only to a Senior Executive Service officer or an officer acting in that capacity. This ensures that the issue of notices is considered by senior members of agencies and is consistent with requirements in the *Guide* that this authority should generally not be delegated lower than members of the Senior Executive Service.

Item 39 – new paragraph 59(ca) of the Admin Act

This item amends provisions in the Admin Act to introduce a new amount that may be credited to the APVMA Special Account (provided for in Division 1 of Part 7 of the Admin Act). The purpose of this amendment is to allow the APVMA to credit certain costs and expenses to the APVMA Special Account. These are the costs that a court may order be paid to the APVMA for costs incurred in taking samples, inspections or analysis during investigations (as provided for new section 149A of the Agvet Code).

Item 40 – new paragraph 61(2)(ca) of the Admin Act

This item amends provisions in the Admin Act to introduce a new reporting requirement in the APVMA Annual Report. The purpose of the amendment is to require the APVMA to report whenever it uses the new authority provided for in section 131AA. New section 131AA provides for the APVMA to exercise monitoring powers without consent or a warrant where it is necessary to prevent imminent risk to persons of death, serious injury or serious illness. This reporting approach is consistent with the *Guide* in that rigorous reporting requirements should be imposed to ensure a sufficient level of accountability.

Items 41 and 42 – section 69A of the Admin Act

These items remove the definition of ‘inspector’ from section 69A as it is unnecessary given the new definition in section 4.

Items 43 to 50 – section 69B and Subdivision A heading in Division 2 of the Admin Act

These items insert a new heading in Division 2 for importation matters and update the format of the previous offence provision that deals with importing an unapproved active constituent or unregistered chemical product. The amendments also provide that the offence provision is also a civil penalty provision and that civil penalties may therefore be imposed against a person who contravenes the section. The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 69B of the Admin Act, including pecuniary orders for contravening civil penalty provisions.

Item 50 introduces new provisions that allow the APVMA to apply conditions to any consent relating to the importation of an active constituent or chemical product. This extends to any existing consent. Provisions allowing for conditions to be applied to the consent for import of unregistered or unapproved chemicals via the existing import permit system facilitates a more efficient and effective control of otherwise prohibited material (for example, in emergencies).

Item 51 - new Subdivision B heading in Division 2 of the Admin Act

This item inserts a new heading in the Admin Act to improve the readability of the Admin Act.

Items 52 and 53 – section 69CD of the Admin Act

These items amend the heading of section 69CD to better reflect the amended section. The amendments also provide that the current offence provision is also a civil penalty provision and that civil penalties may therefore be imposed against a person who contravenes the section. The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 69CD of the Admin Act, including pecuniary penalties for contravening civil penalty provisions.

Item 54 – new subdivision C in Division 2 of the Admin Act

This item introduces a new heading to improve the readability of the Admin Act.

Items 55 and 56 – section 69D of the Admin Act

These items introduce a new heading in the Admin Act to improve the readability of the Admin Act and remove the unnecessary words 'brief particulars of' from section 69D.

Items 57, 58 and 59 – section 69E of the Admin Act

These items introduce a new subdivision heading in the Admin Act to improve the readability of the Admin Act. These items also update the previous offence provision in section 69E of the Admin Act. The offence provision relates to not complying with a requirement to provide a return setting out quantities of active constituents and chemical products that were imported, exported or manufactured in Australia. The update maintains the previous strict liability of the offence and increases the penalty from 30 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation and is consistent with the *Guide* (for example, failure to lodge a report).

The amendments also provide that subsection 69E(1) is a civil penalty provision and that civil penalties may therefore be imposed against a person who contravenes the subsection. The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 69E of the Admin Act, including pecuniary penalties for contravening civil penalty provisions.

Items 60 to 63 – section 69EA of the Admin Act

These items update the previous offence provisions in section 69EA of the Admin Act. The offence provisions relate to not complying with record keeping requirements for quantities of active constituents and chemical products that were imported, exported or manufactured in Australia. The update maintains the previous strict liability of the offence and increases the penalty from 30 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation. This penalty is more than is specified in the *Guide* (for example, failure to keep records). However, this is considered justified given the importance of record keeping for managing the potential public health implications associated with agvet chemicals.

The amendments also provide that subsections 69EA(1) and (1A) are civil penalty provisions and that civil penalties may therefore be imposed against a person who contravenes these subsections.

The amendments also direct the reader to relevant provisions in the Admin Act that can be used to enforce compliance with section 69EA of the Admin Act, including pecuniary penalties for contravening civil penalty provisions.

Item 64 – new Part 7AA of the Admin Act

This item inserts modernised investigative powers of entry, search and seizure in the Admin Act with a new Part 7AA and repeals the old provisions that dealt with investigative powers. The amendments relate to monitoring and investigation powers, and include updates to entry, search and seizure provisions to bring them into line with contemporary standards.

Monitoring and investigation powers

Part 7AA provides the APVMA with powers to seek and obtain information to ensure compliance with the Admin Act and the Collection Act. The powers have been included in both the Admin Act and the Agvet Code, and the powers in the Admin Act can be exercised for the purposes of the Collection Act. In some cases, the exercise of these powers is subject to court supervision.

The powers, as amended, are similar to those available to other Commonwealth regulatory agencies (for example, Therapeutic Goods Administration) and the provisions mirror those in other contemporary Commonwealth legislation. Except where indicated, the provisions are also consistent with the *Guide*.

The APVMA currently appoints inspectors under the Admin Act (section 69F) and must issue them with an identity card that includes a photograph. An inspector must comply with any direction given by the APVMA. Inspectors have powers to enter premises to monitor activities, and to investigate potential contraventions. However, these activities are subject to specific rules about how these inspectors enter premises and how they conduct themselves. The occupier of the premises also has specific rights and responsibilities in relation to how the monitoring and investigation powers are exercised.

The amended provisions allow an inspector to enter any premises (including private residential premises) with consent or, if there is not consent, with a warrant to determine whether the Admin Act is being complied with (sections 69EAB and 69EB). Having entered the premises, an inspector may exercise a range of monitoring (section 69EAC) and investigation (section 69EBA) powers including to examine or test anything, photograph or record anything and copy documents for relevant information. As with other chemical product regulators, APVMA inspectors may take samples of these products when exercising monitoring and investigation powers. In order to ensure appropriate disposal of sampled containers, the monitoring and investigation powers have been extended to authorise an inspector to give directions about sampled containers, and to require a person to comply with these directions. As provided for in the previous section 131 of the Agvet Code, a strict liability offence of 30 penalty units has been included for not complying with a direction. This authority is to be used to ensure that directions to make chemical products harmless are complied with. These powers also provide for sampled containers to be supplied to the market (with appropriate labelling) and not have to be disposed of through less practical or more costly mechanisms such as recalls or landfill disposal.

The monitoring and investigation powers include the authority to operate electronic equipment (sections 69EAD and 69EBB) and to secure evidence (section 69EAE) or seize things (section 69EBC). Evidence may be secured for up to seven days and electronic equipment (that is not evidence) may be secured for up to 72 hours. These represent longer periods than are usually provided to other regulators and are necessary to allow the APVMA to practically exercise its investigative powers in remote, rural and regional areas of Australia where chemical products are used (s 69EAE, 69EDD). Undertaking these activities in remote areas requires APVMA inspectors (and electronic equipment experts) to travel long distances to and from implicated premises and securing authorities need to provide for these operational requirements.

An inspector may be assisted by other persons for example, an interpreter or information technology specialist (sections 69EAF and 69EBD). Assistants may do anything the relevant inspector reasonably requires them to do to assist in the exercise of his or her compliance powers and must not do anything that the inspector does not have power to do. This section ensures that assistants are always subject to directions from inspectors and the same restrictions that apply to inspectors. The inspector is accountable for the actions of the assistant and persons assisting an inspector must act in accordance with any direction given by the inspector. A written direction is not a legislative instrument, as it is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Provisions stating this have been included in the relevant sections to indicate that an exemption from the LI Act is not sought or required.

The monitoring and investigation powers authorise the use of reasonable force against things when executing a warrant (sections 69EAG and 69EBE). This authority for use of force is considered necessary as agricultural and veterinary chemical products may be secured in storage cabinets or transported in wooden crates that require physical actions to identify and take custody of these products. In executing a warrant, APVMA inspectors and persons assisting them have the authority to use force against things but not against persons.

The monitoring and investigation powers also include the authority to require people to provide information or produce documents (sections 69EAH and 69EC). These powers are consistent with those in the Agvet Code.

If an inspector enters premises with the occupier's permission, the inspector is permitted to ask the occupier to answer questions and produce documents that relate to the inspector's reasons for entering the premises. However, as the inspector's right to be present on the premises is based on the consent of the occupier, it is not an offence to refuse to comply with an inspector's request.

If the inspector enters premises under a warrant, he or she may require any person on the premises to answer any questions or produce any documents that relate to the inspector's reasons for entering the premises. A person who fails to comply with any such request will have committed an offence. A penalty of 50 penalty units (not strict liability) is included for not complying with this requirement. This penalty amount is consistent with other offence provisions in the Admin Act and the Agvet Code and is considered necessary to ensure that when executing a warrant, the inspector is provided with information necessary to determine if legislation is being complied with and to protect public health and the environment.

In the exercise of their functions, inspectors are subject to a range of obligations aimed at protecting the rights and interests of the occupiers of premises, including:

- the inspector must inform the occupier of premises that consent for access is voluntary, may be refused, subject to time limitations or withdrawn. If consent is withdrawn, the inspector and any person assisting him or her must leave the premises (section 69ED)
- where a warrant has been obtained, the inspector must, before entering the premises, announce that he or she is authorised to enter the premises, show his or her identity card and give the occupier of the premises the opportunity to permit entry into the premises (section 69EDA)
- when executing a warrant, the inspector must be in possession of the warrant (section 69EDB), although persons assisting the inspector may remain on the premises while the warrant is in force, even if the APVMA inspector has left the premises. For example, a guard may be placed while an inspector returns to the office to obtain personal protective equipment to further a search on premises
- the inspector must provide a copy of the warrant to the occupier who is present and inform him or her of the rights and responsibilities of the occupier (section 69EDC)
- as above, specific requirements apply for securing electronic equipment (for example, computers containing relevant data) until an expert assistant is able to attend and operate the equipment (section 69EDD)

- the Commonwealth must provide compensation for damage to electronic equipment due to a failure to exercise sufficient care (section 69EDE).

Rights and responsibilities of occupiers

The occupiers of premises have rights and responsibilities in Part 7AA of the Admin Act. These include providing reasonable facilities and assistance to an inspector to execute a warrant (section 69EFA), for example, to enable access to business records held off-site on remote servers and password protected devices. Consistent with other Commonwealth legislation a penalty of 30 penalty units is included for not complying with this requirement. This is considered necessary to ensure that the occupier of the premises assists the inspector with equipment or access that enables the warrant to be effectively and efficiently executed.

Seizure

Specific provisions relating to seizure have been included in the Admin Act to update old provisions and align with other similar Commonwealth legislation. New section 69EBC provides for seizure of evidential material or things that an inspector believes on reasonable grounds to be evidence of an offence or contravention. This new section also provides for inspectors to give directions in relation to seized things. As provided for in the previous section 131 of the Agvet Code, a strict liability offence of 30 penalty units has been included for not complying with a direction. This offence is also a civil penalty provision and is to be used to ensure that directions are complied with in order to cause the least danger to the health of the public or any person.

Additional provisions require the return of seized things, where this is appropriate (section 69EGB) and provide for consideration by a magistrate if an inspector requires a seized thing for longer than 60 days (section 69EGC). The provisions also retain requirements in the old provisions for inspectors to provide a receipt for seized things (section 69EGA). New requirements for the disposal of seized things (section 69EGD) have been included and require the APVMA inspector to take reasonable steps to return a seized thing to a person.

Warrants

Warrants are essential tools for furthering investigations as they authorise the regulator to enter premises to gather evidence. Monitoring powers and investigation powers may be exercised with consent or with a warrant issued by a magistrate.

Warrants were previously referred to as ‘offence related warrants’ in the Admin Act. However, as civil penalty provisions are being included in the Act, it is no longer appropriate to refer to the warrants as ‘offence-related warrants’. For this reason and consistent with other Commonwealth legislation, ‘monitoring warrants’ and ‘investigation warrants’ have been included.

An inspector may apply to a magistrate for a monitoring warrant (section 69EH) or an investigation warrant (section 69EHA), which must contain specified information. The magistrate may issue a warrant if he or she is satisfied, based on information given under oath or affirmation (including further information sought by the magistrate), that access to the premises is necessary.

Reflecting the modernised provisions, further provisions specify that warrants may also be issued by electronic means (for example, telephone) (section 69EHB) and the restrictions that apply to these warrants (sections 69EHC and 69EHD). Consistent with other Commonwealth legislation, these requirements include an offence that would apply to an APVMA inspector in relation to the form of a warrant and its presentation to a magistrate or other persons (section 69EHD). Specific provisions have been included to deal with when the execution of an investigation warrant has been interrupted (sections 69EE and 69EEA). Consistent with other Commonwealth legislation, further provisions have been incorporated to reflect the powers of magistrates in issuing warrants (section 69EI).

Items 65 and 66 – new Part 7AB of the Admin Act

These items insert a new Part 7AB that deals with enforcement. The provisions relate to:

- civil penalty orders and the enforcement of civil penalty provisions (sections 69EJ to 69EJS)
- infringement notices (sections 69EK to 69EKE)
- the acceptance and enforcement of undertakings to comply with provisions (sections 69EL and 69ELA)
- injunctions (sections 69EM to 69EMC)
- the issue and compliance with substantiation notices in relation to certain claims and representations (sections 69EN to 69 ENB)
- the issue of formal warnings in relation to suspected contraventions (section 69EO).

Civil penalty orders

The provisions in Division 1 of Part 7AB for civil penalty orders are consistent with those available to other Commonwealth regulators. In accordance with Division 1 of Part 7AB of the Admin Act the APVMA may apply to the court for a civil penalty order against a person who has contravened a civil penalty provision in the Admin Act or the Collection Act (section 69EJ). The APVMA must seek the order no later than six years after the contravention.

Courts with sufficient jurisdiction may make civil penalty orders. The court may order a civil penalty if it is satisfied a person has contravened a civil penalty provision. The provisions relating to civil penalty orders in the Admin Act also apply for the purposes of the Collection Act. By referencing the requirements, consistent provisions for civil penalty orders can be applied. The civil penalty order provisions in the Admin Act include provisions relating to ancillary contraventions, such as aiding a contravention, multiple contraventions and limits for pecuniary penalties.

The use of civil penalty orders for the Admin Act and the Collection Act represent important sanctions and disincentives for non-compliance. The integrity of the regulatory system for agvet chemicals could be compromised by persons failing to comply with the Admin Act, and to a lesser degree the Collection Act, and there may be significant impacts on public health or the environment arising from this non-compliance. Furthermore, a person who does not comply could obtain substantial financial gains.

A State and Territory court is a court with jurisdiction to decide matters covered by the provisions relating to civil penalty orders. This is generally determined by any limits on the amount of pecuniary orders that may be made by a court. If a court is satisfied that a person has contravened a civil penalty provision, then it may order the person to pay a civil penalty. Section 69EJB provides that a pecuniary penalty is a debt payable to the Commonwealth. However, section 69EJC provides a double jeopardy provision which states that a person cannot be liable for two or more pecuniary penalties for the same conduct.

The court may have regard to all relevant matters in determining the amount of the penalty. To assist the court, provisions in the Admin Act identify specific matters to which it may have regard. These include the nature and extent of the contravention and the loss or damage it resulted in, the circumstances in which the contravention took place, whether the person has engaged in similar conduct and whether they have cooperated with the authorities, and, if the person is a body corporate, the seniority of the involved officers and employees, whether any due diligence was undertaken and whether the corporation has a corporate culture conducive to compliance (section 69EJ).

Consistent with other Commonwealth legislation, new provisions in the Admin Act deal with specific aspects of civil penalty orders, including maximum penalties (sections 69EJA to 69EJD) as well as continuing (section 69EJL) and ancillary contraventions (section 69EJM).

Except for multiple contraventions of civil penalty provisions, section 69EJA limits the pecuniary penalty for contravening a civil penalty provision. For a body corporate this is limited to five times the amount that would apply if the body corporate were convicted of an offence for the same contravening conduct. For an individual, the maximum penalty is three times the amount that would apply if the person were convicted of an offence for the same contravening conduct. For example, if a body corporate contravenes the civil penalty provision in section 69B (importation offence), the maximum penalty that a court could impose would be 7500 penalty units (that is, 5 times 1500 penalty units) as 1500 penalty units is the maximum penalty (that is, 5 times 300 penalty units) that could be imposed for committing an offence against that provision. For an individual the maximum penalty would be 900 penalty units (that is, 3 times 300 penalty units).

Section 69EJD deals with multiple contraventions of civil penalty provisions. A court may make a single civil penalty order for multiple contraventions of a civil penalty provision on the proviso that the contraventions are founded on similar facts, or are part of a series of contraventions of the same or similar character. Provisions in section 69EJD clarify that the penalty imposed for multiple contraventions must not exceed the maximum sum for separate penalties that could be ordered for each contravention. This is consistent with other Commonwealth legislation.

Section 69EJE provides that a court may direct that two or more proceedings for a civil penalty may be heard together. For example, the court may do this for proceedings concerning multiple contraventions by a single entity or members of a corporate group. This will streamline the process for civil proceedings, remove the need for a person to be subject to multiple proceedings, and thereby reduce legal costs for the person and the Commonwealth. Civil penalties are imposed by the courts according to civil standard of proof (section 69EJF).

Further provisions deal with civil proceedings and criminal proceedings relating to contraventions of civil penalty provisions and offences (sections 69EJG to 69EJJ). Section 69EJH provides that if a person has been convicted of a criminal offence concerning conduct which is substantially the same as that to which the alleged contravention relates, then the court must not make a civil pecuniary penalty order against the person. However, section 69EJJ provides that criminal proceedings may be commenced even if a civil penalty has been imposed for substantially similar conduct.

Section 69EJI provides that civil proceedings for a contravention of the Act must be stayed if criminal proceedings are commenced concerning conduct which is substantially the same as that to which the alleged contravention relates. If the criminal proceedings result in a conviction, this section will ensure that civil proceedings related to the same conduct are dismissed and costs for the civil proceedings are not awarded. Section 69EJK provides that evidence given in civil proceedings is not admissible in subsequent criminal proceedings, unless that evidence concerns the question of whether the evidence given in the civil proceedings was false.

Civil penalty provisions - evidential burden

Civil penalties are imposed by the courts according to civil standard of proof. A matter brought to the court seeking a civil pecuniary penalty is subject to the 'on the balance of probabilities' standard of proof. Section 69EJN provides that a person is not liable to have a civil penalty order made against them if the person considered whether or not facts existed and was under a mistaken but reasonable belief about those facts and had those facts existed, the conduct would not have constituted a contravention of the civil penalty provision.

The evidential or legal burden for offences has not changed but some provisions have been co-located for clarity. Where the defendant currently bears an evidential or legal burden in these offence provisions, the same evidential or legal burden applies in proceedings for civil penalty orders where these offence provisions are also civil penalty provisions. Section 69EJP has only been included to deal with evidential burden for civil penalty provisions throughout the Admin Act and to reduce duplication. It does not change the evidential burden for any civil penalty provision.

In seeking a civil penalty order, section 69EJO provides that the APVMA does not need to prove the person's intention, knowledge, recklessness, negligence or any other state of mind with regard to civil penalty provisions. This provision makes it clear that it is not necessary to prove a matter concerning a person's state of mind at the time the conduct occurred. It is only necessary to prove whether the relevant provision has been contravened. Where a person's state of mind is relevant to the issue, then this is specifically dealt with in the relevant provision.

Civil penalty provisions - liability for executive officers of body corporate

Section 69EJR provides that executive officers of bodies corporate are liable for a contravention of a civil penalty provision by that body corporate in certain circumstances. An 'executive officer' of a body corporate is a person, by whatever name called and whether or not a director of the body, who is concerned in, or takes part in, the management of the body (for example, a director or chief executive officer).

It is appropriate that extended accessorial liability applies to such officers, given the importance of ensuring compliance with the Admin Act and the Collection Act. Liability is not being imposed simply because the person is an office holder at the relevant time, but requires a degree of responsibility on the part of the officer concerned before a civil penalty may be imposed.

Where a body corporate contravenes a civil penalty provision, and one of its executive officers knew that the contravention would occur, then the officer is subject to a civil penalty if he or she was in a position to influence the conduct of the body corporate concerning the contravention, but failed to take all reasonable steps to prevent it

Section 69EJS provides that executive officers have a defence that they took reasonable steps to prevent the contravention. In considering whether an officer failed to take reasonable steps, the court may have regard to all relevant matters. These matters may include what action (if any) the officer took towards ensuring (to the extent that the action is relevant to the contravention) that the body corporate's agents, employees and contractors had a reasonable understanding of the requirements in the Admin Act and the Collection Act. This takes into account that the actions of an employee are attributable to the body corporate (section 69EJQ).

These provisions take the same approach as the liability imposed on executive officers in other Commonwealth laws, including section 494 of the *Environmental Protection and Biodiversity Conservation Act 1999*. It ensures compliance with obligations under the mechanism is taken seriously at a high level within liable entities. However, it includes measures that allow executive officers to demonstrate that they took reasonable steps to ensure compliance and prevent contraventions. This approach ensures fairness and offers some protection to the individuals involved.

Infringement notices

The APVMA may issue penalty infringement notices (PINs) for the alleged contravention of civil penalty provisions that are prescribed in the regulations (section 69EK). These infringement notices may only be issued to persons who are covered by the Admin Act or the Collection Act and they cannot be issued to members of the public more generally. The ability to issue infringement notices represents a means for rapid conclusion to instances of non-compliance without the expense associated with civil proceedings. The ability to issue PINs would align the APVMA's regulatory control options with those of other comparable regulators.

PINs must be issued within 12 months of the alleged contravention (section 69EK) and must include specified information (section 69EKA). The infringement notice penalty must be less than one-fifth of the maximum that a court could impose (subsection 69EKA(2)) and provision is also made for a scale of amounts that may apply for alleged contraventions to be detailed in regulation (section 69EKA(3)). Providing for a scale is intended to provide for a proportionate response to

contraventions based, for example, on the amount of substance concerned or the number of containers implicated in an alleged contravention.

The APVMA may extend the time to pay an infringement notice penalty (section 69EKB) and a PIN may be withdrawn by the APVMA (section 69EKC). The payment of the PIN discharges liability (section 69EKD). Non-payment would lead to exposure to further proceedings. Section 69EKE includes specific provisions that state the effect of the infringement notice provisions, including specifying that two or more PINs may be issued and that the issuing of an infringement notice is discretionary.

Enforceable undertakings

The APVMA may accept undertakings from a person about their compliance with the Admin Act or the Collection Act (section 69EL). This provides the APVMA with an avenue to formalise agreed remedial actions between the APVMA and parties seeking to actively address instances of non-compliance. This would allow for ongoing compliance where the APVMA agrees that an individual or a company in breach is genuinely committed to correcting their behaviour. A person may, for example, undertake to take specific action to comply with their obligations under the legislation, or stop doing something which is not in compliance with the Admin Act or the Collection Act.

These undertakings may be accepted from persons who are covered by the Admin Act or the Collection Act. They cannot be imposed on persons that are not regulated by the Admin Act and the Collection Act, for example, members of the public or persons who do not have compliance obligations under the legislation. The APVMA would publish these undertakings to encourage compliance through increased transparency. However, this must not include confidential commercial information, personal information (within the meaning of the *Privacy Act 1988*) or information for which disclosure would not be in the public interest.

A person may withdraw or vary the accepted undertakings at any time, but only with the written consent of the CEO ((subsection 69EL(3)). In addition, the CEO can cancel the undertaking. The written consent of the APVMA CEO to withdraw or vary an undertaking is not a legislative instrument, as it is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Provisions stating this have been included to indicate that an exemption from the LI Act is not sought or required.

Enforceable undertakings are a useful tool to promote compliance, without the need to take court action. They are used extensively by other Commonwealth regulators. However, where the APVMA considers that a person has breached any of the terms of the undertaking; it may apply to the court (section 69ELA) for an order that includes any or all of the following:

- directing the person to comply with the undertaking
- directing the person to pay the Commonwealth an amount up to the amount of any financial benefit reasonably attributable to the breach of the undertaking
- directing the person to compensate any other person who has suffered loss or damage as a result of the breach
- any other order the court considers appropriate.

Injunctions

Section 69EM authorises any person (including the APVMA) to apply to the court for an injunction in circumstances where a person has engaged or is proposing to engage in conduct that either constitutes or would constitute a contravention of the Admin Act or the Collection Act. Section 69EMB provides for restraining or performance injunctions. The terms of the injunction would be determined by the court but may include an order to undertake particular actions.

Substantiation notices

The APVMA may seek evidence with substantiation notices to support representations made about the import or export of a product (section 69EN). The use of these notices is limited to providing information or producing documents and do not apply to a person who publishes claims made by another person and where there is no commercial relationship between these persons (other than the role of publishing the claims) (for example, advertising agencies that merely publish claims on behalf of others).

The authority to issue substantiation notices is intended as a preliminary investigative tool where the APVMA suspects a representation may not be able to be substantiated and subsequently in breach of the Admin Act or the Collection Act. Their use would mean that the APVMA would not have to attempt to establish the veracity of the claims itself but would be able to seek information and documents from relevant persons about such claims. It therefore promotes a more efficient resolution of instances of alleged non-compliance (for example, claims about products).

The substantiation notice would require the person to provide information, including documents within 21 days of the notice being issued. With the agreement of the APVMA the notice period may be extended (section 69ENA). An offence and civil penalty provision for non-compliance with a substantiation notice of 50 penalty units has been included (section 69ENB). This penalty is more than is specified in the *Guide* (for example, failure to keep records). This is considered justified given the importance of protecting public health and the environment and the need for the APVMA to be fully informed of the potential implications of agvet chemical supply.

Given the timeframe for response, the provisions are framed in such a way that a genuine attempt to provide information which may support a claim would be sufficient; recognising that more time may be required for the material that would be capable of fully substantiating the claim or representation. An individual is also able to refuse to provide particular documents or information on the grounds they might incriminate the person (subsection 69ENA(4)).

Warnings

The APVMA may issue formal warnings to a person (section 69EO) which states the APVMA's belief that the person's specific actions may constitute non-compliance with the Admin Act or the Collection Act. The APVMA would use these notices in instances where it believed the non-compliant behaviour was inadvertent.

The APVMA may use this option at its discretion. Warnings would be considered in the context of any future compliance and enforcement and penalty considerations. Non-compliance may result in a matter being escalated to investigation and used to support an increased penalty for the same offence or contravention at a later stage. Warnings may be issued generally or to address possible breaches or contraventions against specific provisions in the Admin Act and the Collection Act, including the regulations.

Item 67 – subsections 69EP(6) and (7) of the Admin Act

This item updates previous offence provisions in the Admin Act. The provisions relate to directions that the APVMA issues in relation to hearings it may hold. The update to the offence provisions increases the penalty from 20 penalty units to 50 penalty units. This brings the penalty in line with other penalties in agvet chemical legislation but is more than is specified in the *Guide* (for example, giving information). This higher penalty is justified given the importance of protecting confidential commercial information which may be provided at hearings and about which the APVMA may give directions restricting or prohibiting publication (and for which unauthorised disclosure carries a penalty of up to two years imprisonment).

Item 68 – section 69EQ of the Admin Act

This item is a consequential update to reflect the creation of new Parts 7AA (Investigative Powers) and 7AB (Enforcement), while retaining reference to the existing Part 7A.

Item 69 – section 69ER of the Admin Act

This item is a consequential update to reflect the creation of new Parts 7AA (Investigative Powers) and 7AB (Enforcement), while retaining reference to the existing Part 7A. It provides for two previous offences in relation to false and misleading information to be retained in the Admin Act. It further provides for the previous offence to be retained in relation to providing false or misleading information or document to an inspector and to apply for the purposes of Parts 7A, 7AA and 7AB. The offences are not strict liability offences and the amount of the penalties has not changed.

The first offence relates to providing false or misleading information in relation to seeking the APVMA's consent to import an active constituent that is not approved or a chemical product that is not registered, reserved or exempt (section 69B of the Admin Act). Recognising the potential public health consequences associated with unapproved or unregistered chemical products, this is considered a serious offence and the level of the penalty (300 penalty units) is the same as for the offence in the previous section.

The second offence relates to providing false or misleading information to an inspector for matters not related to section 69B of the Admin Act and mirrors the previous offence in the Admin Act but applies for the purposes of the new Parts 7AA and 7AB, in addition to the existing part 7A. The level of penalty (60 penalty units) is the same as for the offence in the previous section.

Items 70 and 71 – subsections 69ET(1), 69EU(1) and 69EU(3) and paragraph 69EU(5)(a) of the Admin Act

These items are consequential updates to reflect the creation of new Parts 7AA and 7AB, while retaining reference to the existing Part 7A.

Items 72 and 73 – section 69F of the Admin Act

Item 72 deletes the word 'particular' and allows the APVMA CEO to authorise inspectors for any relevant agricultural and veterinary chemical law that the APVMA administers. This amendment removes any doubt that the APVMA CEO could authorise inspectors to exercise functions under the Admin Act, the Collection Act and the Code Act (including the Agvet Code). Item 73 requires a person who ceases to be an APVMA inspector to return their identity card in 14 days instead of the previous 'as soon as practicable'.

Item 74 – new section 69HA of the Admin Act

This item introduces a general immunity from civil actions for APVMA officers and persons assisting them to align with provisions in other more contemporary legislation, for example, therapeutic goods legislation.

Agricultural and Veterinary Chemicals Code Act 1994

Item 75 – section 6 of the Code Act

This item updates the maximum amount of penalty units that can be prescribed in regulations to increase it from 10 to 50 penalty units. This brings the maximum penalty amount in line with the maximum specified in the *Guide* (penalties in regulations). This item also allows for the regulations to declare certain provisions to be civil penalty provisions, relying on the new definition of 'civil penalty provision' in section 3.

Items 76 to 98 – subsection 3(1) of the Agvet Code

These items introduce new definitions into the Agvet Code including for ‘civil penalty order’, ‘civil penalty provision’, ‘evidential burden’ and ‘relevant data’. These definitions are needed to introduce civil penalty provisions and amend monitoring and investigation powers in the Agvet Code. The definitions include ‘agvet law’ and ‘agvet penalty provision’ which are terms used throughout the Agvet Code to generally refer to provisions in the Admin Act, the Agvet Code and the Collection Act. A new definition of ‘use’ has been included to include existing use and therefore allows the previous definition of ‘continued use’ to be repealed. A definition of ‘manufacture’ has been included to provide clarity about the term manufacture as it is used in the Agvet Code. A definition of ‘copy’ has also been included to clarify a copy of a warrant includes a copy sent by electronic means.

New definitions of ‘approved active constituent’ and ‘registered chemical product’ have been introduced. These new definitions directly link to the particulars in the Record for the approved active constituent and the particulars in the Register for the registered chemical product. This clarifies that an approved active constituent is an active constituent that complies with all the relevant particulars for the active constituent in the Record of Approved Active Constituents for Chemical Products (Record) and a registered chemical product is a chemical product that complies with all the relevant particulars for the chemical product in the Register of Agricultural and Veterinary Chemical Products (Register). These definitions mean that there is no need for specific provisions to deal with counterfeit products because counterfeit products would not comply with all the relevant particulars in the Record or Register. Counterfeit products would not therefore be approved active constituents or registered chemical products and the relevant offences for possession, custody or supply would apply.

Item 99 – section 8A of the Agvet Code

This item renumbers section 8A which deals with the application of the Criminal Code.

Items 100 and 101 – new sections 34N and 34P of the Agvet Code

These items insert a new division heading that better reflects the division and inserts new sections 34N and 34P. New section 34N is an explanation of the division for suspending and cancelling approval and registrations. New section 34P provides for a procedural fairness mechanism where the APVMA is proposing to suspend or cancel an approval or registration. New section 34P requires the APVMA to inform the holder that it proposes to suspend or cancel an approval or registration, and to provide its reasons to the holder and seek the views of the holder. This allows a holder an opportunity to respond to the APVMA and the APVMA must consider this response.

New section 34P does not apply where a suspension or cancellation arises from reconsideration (34AA), is to prevent imminent risk to persons of death, serious illness or serious injury (section 35A), where the holder requests cancellation (section 42) or where use of protected information cannot be arbitrated (section 39).

Items 102 to 105 – new section 35A

These items insert a new section 35A and consequentially amends the current section 35.

Item 105 inserts new section 35A that allows the APVMA to suspend or cancel a registration without prior notice, where it considers this is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA may exercise this authority whether or not the product is being used in accordance with its instructions for use. This measure provides for the APVMA to only take action in those situations where action is strictly necessary to protect people.

There must be an imminent risk of death or serious illness or serious injury to a human that relates to use of a registered chemical product. The imminent risk must be able to be addressed (even in part)

by cancelling or suspending the registration. Suspension or cancellation of the registration must be necessary (and thus proportionate to the risk and the most appropriate course of action to take) to address the imminent risk.

While the APVMA need not consult a co-ordinator in a jurisdiction before exercising the authority under section 35A (items 103 and 104), the APVMA is not prevented from obtaining advice or consulting other agencies. For example, the authority in section 35A may be exercised by the APVMA as part of a whole of government response to an emergency or major public health incident, where other agencies are taking commensurate and parallel action.

Item 106 – repeal section 37 of the Agvet Code

This item repeals section 37 as the matters in this previous section are now included in section 38.

Items 107 to 109 – section 38 of the Agvet Code

These items amend section 38 which provides for the APVMA to suspend or cancel an approval or registration for failing to provide information, results, reports or samples to the APVMA as part of a reconsideration. The amendments include information and results that the APVMA currently requests as part of notices under sections 32 and 33, and combines these with the existing information requirements in section 38. This means that all the information, results, reports and samples for reconsiderations are now co-located in the same section (that is, section 38).

Item 110 – new section 38A of the Agvet Code

This item introduces a new provision into the Agvet Code (section 38A) that allows the APVMA to suspend or cancel an approval or registration, where false or misleading information was provided as part of the application or subsequently in response to a request by the APVMA. The amendment provides an incentive for the submission of *bone fide* information to the APVMA and limits any commercial benefit obtained through fraud.

New section 34P applies for this section and the APVMA must give notice of its intention to suspend or cancel approval or registration, and provide reasons for its intended action. This provides an opportunity for a holder of approval or registration to provide submissions on the proposed suspension or cancellation. Any APVMA decision to suspend or cancel approval or registration would also be subject to internal review of the decision and Administrative Appeals Tribunal review.

Items 111 to 119 – sections 39, 41, 42, 44 and 45 of the Agvet Code

Items 111, 112, 114, 115 and 116 amend sections 39, 41 and 42 to replace ‘interested person’ with the new concept of ‘holder’ and insert a note in sections 39 and 42 to indicate that the procedural fairness provisions for suspensions and cancellations in section 34P do not apply for these sections. Item 113 replaces section 41 which deals with suspensions and cancellations for not complying with criteria for approval, registration or prescribed requirements. The new section 41 refers to the safety criteria, trade criteria, efficacy and labelling criteria as now defined in sections 5A, 5B, 5C and 5D, and also provides for regulations to include prescribed matters for constituents or products (as applies for applications). Other items align expressions with the definitions in section 3 of the Agvet Code (items 117 and 119). Item 118 removes an unnecessary editorial reference.

Item 120 – new sections 45A, 45B and 45C of the Agvet Code

This item inserts new sections to reduce the minimum sell-out period for stock-in-trade chemicals when the approval or registration ends and to improve the format of the unnecessarily long previous section. Old sections 45A and 55 have been amalgamated into new sections 45A, 45B and 45C.

As provided in old sections 45A and 55, when approvals or registrations are suspended or cancelled, new section 45A requires the APVMA to provide notice to a holder and other persons that the

APVMA thinks appropriate, and to publish notices in the *Gazette*. The notices to the holder or other persons must include instructions for any possession, custody or use of the active constituent or chemical product, and any warnings. The notices published in the *Gazette* must identify if the suspension or cancellation was because the active constituent or chemical product did not meet the safety criteria, trade criteria, efficacy criteria or labelling criteria. In these circumstances the notices in the *Gazette* must also include instructions for any possession, custody or use of the active constituent or chemical product, and any warnings. These measures ensure that the requirements and consequences for possession, custody and use of suspended or cancelled active constituents and chemical products are clear.

As provided in old sections 45A and 55, new section 45B provides for a permit to have been issued to possess have custody or use an active constituent or chemical product, unless the APVMA considers that this should not apply in the particular circumstance. The purpose of the new section 45B is to limit the sell out period to one year and to existing stocks of chemical products or active constituents. The purpose of a one year sell-out period is to allow for a mechanism that exhausts existing stocks where it is safer and more practical to allow continued use rather than recall and subsequent disposal of these products. This sell-out period may not apply if the APVMA declares that it does not apply and publishes a notice to this effect in the *Gazette*, for example, where allowing continued use may not be safer than recall and disposal.

As provided in old sections 45A and 55, new section 45C provides for a strict liability offence for possessing, having custody of or other dealing with a suspended active constituent or chemical product in contravention of the instructions in the notices provided to persons or notices which have been published. The amount of the penalty units (300) is for the same amount as the previous sections 45A and 55. The defences in the previous subsections 55(5) and (6) have been retained as subsections 45C(3) and (4). The defence and the reversal of the onus of proof in subsection 45C(4) mirrors the current defence and onus of proof in old subsection 55(6).

Subsection 45C(4) provides a defence to the defendant, who has not been given a notice, that he or she either did not know and could not reasonably have been expected to have known of the existence of the *Gazette* notice or that the possession etc was not in accordance with the instructions in the *Gazette* notice. This is an additional defence to the defence of honest and reasonable mistake of fact and, although the defendant bears the legal burden, is broader in scope. This is because it is not concerned with the requisite state of mistaken belief but is judged against the standard of what could be reasonably expected. The provision imposes the legal burden of proof on the defendant and this must be discharged on the balance of probabilities that the person did not know and could not reasonably be expected to have known of the existence of the notice. The defence is that the defendant did not know *and* could not reasonably be expected to have known of the existence of the notice.

As an example, for a retailer that regularly sells chemical products, the prosecution could satisfy the court that even if the retailer did not know of the notice, the retailer's circumstances as a regular dealer was such that they *should* have known as they should have had steps in place to be aware of notices published under paragraph 45A(1)(b). The retailer might counter this by providing information that they did not know and could not reasonably be expected to have known of the existence of the notice. As these matters relate to what the defendant did not know and could not reasonably be expected to have known, it follows that this information would be peculiarly within the knowledge of the defendant. In addition, it would not be likely that this may be uncovered through the normal course of an investigation.

Items 121 and 122 – section 46 of the Agvet Code

These items amend section 46 which deals with the revocation of suspensions and cancellations. These items amend the references to Record and Register to align with the new definitions in section 3 of the Agvet Code, replace 'approved person' with the new concept of 'holder' and require the

APVMA to provide written notice of a revocation in 14 days instead of the previous ‘as soon as practicable’.

Items 123 to 165 – sections 74 to 81 of the Agvet Code

These items amend the sections in the Agvet Code that deal with the control of active constituents and chemical products, including possession, custody and supply of unapproved active constituents or unregistered chemical products or supply contrary to conditions of approval or registration.

The purpose of the amendments is to provide that the offence provisions in sections 74, 75, 76, 77, 78, 79, 80 and 81 are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of these provisions (items 127, 132, 137, 142, 147, 152, 156, 161 and 165). The amendments also recast a number of the provisions to improve their format and readability without changing the defences or the amount of the penalty (items 123 to 126, 128 to 131, 133 to 136, 138 to 141, 143 to 146, 148 to 151, 154 to 155, 157 to 160 and 162 to 164). Item 153 also repeals section 79A as section 79 now deals with the supply of registered listed chemical products.

Item 166 – section 82 of the Agvet Code

This item repeals section 82. It is no longer necessary given that APVMA inspectors can provide directions for dealing with sampled or opened containers.

Items 167 to 180 – sections 83, 84 and 85 of the Agvet Code

These items provide that the offence provisions in sections 83, 84 and 85 are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of these provisions (items 170, 175 and 180). The amendments also recast a number of the provisions to improve their format and readability without changing the defences or the amount of the penalty (items 167 to 169, 171, 173 to 174, 176, 178 to 179). Items 172 and 177 are consequential amendments to section 84 and 85 to reflect the repeal of section 55.

Items 181 to 190 – section 86 of the Agvet Code

These items amend section 86 which deals with labels for containers of chemical products, including alteration and defacement. Amendments to section 86 provide that the offence provision is also a civil penalty provision (items 181, 184 and 190) and that therefore pecuniary penalties may apply for contraventions of this provision. Section 86 has also been recast to improve its format and readability without changing the amount of the penalty (items 182, 183, 185, 186, 188, 189). Item 187 provides for a new defence in relation to labels that have been amended as authorised by a permit or in accordance with a direction from an APVMA inspector (exercised under the authority provided for in new sections 69EAC and 69EBA of the Admin Act or 131A and 132A of the Agvet Code). The purpose of this amendment is to provide for a practical means of enabling sampled containers to be supplied (rather than disposed of) with amended label information about the contents.

Items 191 to 221 – sections 87, 87A, 88, 89, 90, 91, 91A and 92 of the Agvet Code

These items provide that offence provisions in sections 87, 88, 89, 90, 91, 91A and 92 are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of these provisions (items 194, 200, 204, 209, 213, 217 and 221). The amendments also recast a number of the provisions to improve their format and readability without changing the defences (items 191 to 193, 196 to 197, 199, 201, 203, 206 to 208, 210 to 212, 214 to 216 and 218 to 220). Other than for sections 88 and 89 the amount of the penalties are unchanged.

Items 198 and 202 increase the penalties for the offences in sections 88 and 89 from 30 penalty units to 50 penalty units. These offences deal with making statements and publishing notices about unapproved products and inappropriate statements about chemical products and their use. The increases bring the penalties in line with other penalties in agvet chemical legislation, even though

the amount is below the maximum penalty amount of 60 penalty units provided in the *Guide* (false statements).

Item 195 also repeals section 87A as section 87 now deals with the supply of registered listed chemical products in conformance with an established standard.

Item 205 amends section 90 to require a person who manufactures or imports a date-controlled chemical to make records of these imports or manufacture with 28 days instead of the previous 'as soon as practicable'. This amendment provides certainty around when record of imports and manufacture should be made.

Items 222 to 229 – sections 94 and 95 of the Agvet Code

These items provide that offence provisions in sections 94 and 95 are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of these provisions (items 225 and 229). Sections 94 and 95 deal with restricted chemical products. The amendments also recast a number of the provisions to improve their format and readability without changing the defences or the amount of the penalties (items 222 to 224 and 226 to 228).

Items 230 to 236 – sections 97 and 98 of the Agvet Code

These items update sections 97 and 98 which deal with analysis and the results of analysis. The items replace the old references to monitoring powers with the section numbers of the new monitoring and investigation powers in Part 9 of the Agvet Code.

Items 237 to 243 – section 99 of the Agvet Code

These items update section 99 which deals with the analysis of chemical products. Item 237 inserts two new subsections 99(3A) and (3B) to provide for the analysis of active constituents in the same way as for chemical products. Currently the APVMA can require a person to have a substance analysed where the APVMA reasonable suspects that the product or constituents of the product may differ from that recorded in the Register of Chemical Products. The amendment therefore corrects an anomaly by providing for the APVMA to require a person to have a substance analysed where the APVMA reasonable suspects that the active constituent may differ from that recorded in the Record of Approved Active Constituents for Chemical Products. The amendment also means that subsection 99(3) applies to an active constituent in that the APVMA may require a person to have an active constituent analysed if the APVMA reasonable suspects that this constituent does not comply with a prescribed or established standard. Items 238 and 239 are consequential amendments to provide for the new subsection 99(3B) and items 240 to 242 improve the format and readability of the section without changing the defences or the amount of the penalty. Item 243 retains the strict liability offence in old section 99 and also provides that it is a civil penalty provision and that therefore pecuniary penalties may apply for contraventions of this provision.

Items 244 to 247 – section 105 of the Agvet Code

These items update section 105 which deals with non-compliance with recall notices. Item 247 provides that the strict liability offence provision in section 105 is also a civil penalty provision and that therefore pecuniary penalties may apply for contraventions of this provision. Items 244 to 246 recast the provision to improve its format and readability without changing the defences or the amount of the penalty.

Items 248 and 249 – section 109 of the Agvet Code

These items amend the definition of 'permit' so that it reflects the new civil penalty provisions in the Agvet Code and other amendments to the Agvet Code that extend the situations where the APVMA may issue a permit to alter a label or manufacture chemical products in contravention of sections 86 and 121 respectively.

Item 250 – section 115 of the Agvet Code

This item is a consequential amendment to update the old provision about the duration of permits to include reference to the new sections relating to suspension and cancellation of permits.

Items 251 and 252 – section 116 of the Agvet Code

These items insert a new offence into the Agvet Code for contravening the conditions of a permit and update the heading of the section. The APVMA may issue permits that allow the legal use and manufacture of active constituents and chemical products in ways that are different to that evaluated and approved. This may also include the limited use of an unregistered chemical. Part 7 of Agvet Code describes the circumstances under which permits are issued, how applications for these permits are made and the criteria that APVMA considers in determining these applications.

Currently, non-compliance with permit conditions may lead to suspension or cancellation of the permit. No specific penalty provisions for the behaviour are currently included within the Agvet Code. This is inconsistent with the other provisions in the Agvet Code which include offences for contravening conditions of approval or registration for active constituents or chemical products. Also, there are no penalty provisions for users that are non-permit holders and cancelling a permit would unnecessarily impact on other compliant permit holders. The amendments address these anomalies and include a penalty for the offence of not complying with permit conditions. The penalty is 300 penalty units, is not a strict liability offence and is consistent with the penalty for contravening the conditions for registration of a chemical product (for example, section 79A). Consistent with other provisions in the Agvet Code, this item also provides that the new provision is a civil penalty provision. This provision is limited to the person to whom the permit applies and this recognises that the use of the chemical product contrary to the permit would be a matter for State or Territory authorities.

Item 253 – new section 117A of the Agvet Code

This item inserts a new section to provide for a procedural fairness mechanism where the APVMA is proposing to suspend or cancel a permit. New section 117A requires the APVMA to inform the holder that it proposes to suspend or cancel a permit, and to provide its reasons to the holder and seek the views of the holder. This allows a holder an opportunity to respond to the APVMA and the APVMA must consider this response. New section 117A does not apply where a suspension or cancellation is to prevent imminent risk to persons of death, serious illness or serious injury (section 119A).

Items 254 to 261 – sections 118, 119, 119A and 119B of the Agvet Code

These items amend sections 118 and 119 and insert new sections 119A and 119B to improve the provisions that deal with suspensions and cancellation of permits.

Item 259 replaces subsection 119(4) which deals with cancellation of a permit if the holder has been convicted of certain offences or contravened the permit conditions. The new subsection provides for cancellation if a person is not suitable because of a range of matters consistent with the approach taken for other Commonwealth regulators like for therapeutic goods. The matters retain where the person contravenes a condition of a permit and lists convictions or pecuniary penalty orders that may form the basis for the cancellation of a permit. New subsection 119(4) specifies that the APVMA may cancel a permit where it is satisfied that the holder or persons with a specified relationship with the holder has within the previous 10 years been convicted of certain offences, ordered to pay a pecuniary penalty for contraventions of certain penalty provisions or has had a permit cancelled in certain situations (subparagraph 119(4)(b)(x)). A reference to a person convicted of an offence in new paragraph 119(4)(b) includes a reference to a person who has been discharged without a conviction after an offence has been proved under section 19B of the *Crimes Act 1914*, or equivalent state or territory legislation (subsection 119(4A)). Notwithstanding this measure, the APVMA still

retains discretion in determining whether the permit should be cancelled and the procedural fairness mechanism in new section 117A applies in this situation.

Item 261 inserts new sections 119A and 119B which provide the APVMA with new authorities to suspend or cancel permits. The amendments introduce new section 119A which allows the APVMA to suspend or cancel a permit where the APVMA considers it is necessary to prevent imminent risk to persons of death, serious injury or serious illness. This measure provides an essential means to take action in those situations where action is necessary to protect people. The APVMA may exercise this authority, whether or not the product is being used in accordance with its conditions. This measure provides for the APVMA to take action in those situations where action is strictly necessary to protect people. There must be an imminent risk of death or serious illness or serious injury to a human that relates to a permit. The imminent risk must be able to be addressed (even in part) by cancelling or suspending the permit. Suspension or cancellation of the permit must be necessary (and thus proportionate to the risk and the most appropriate course of action to take) to address the imminent risk. For example, the authority in section 119A may be exercised by the APVMA as part of a whole of government response to an emergency or major public health incident, where other agencies are taking commensurate and parallel action. The procedural fairness mechanism in new section 117A does not apply in this situation.

The amendments also introduce new section 119B into the Agvet Code that allows the APVMA to suspend or cancel a permit where false or misleading information was provided as part of the application or was subsequently provided at the request of the APVMA. The amendments provide an incentive for the submission of *bone fide* information to the APVMA and such a provision would also better protect the community and the environment and limit any commercial benefit obtained through fraud. The procedural fairness mechanism in new section 117A applies in this situation.

Items 254 and 257 insert new headings and items 256 and 260 remove unnecessary words or expressions. Items 255 and 258 are consequential amendments to sections 118 and 119 to align with the new provisions for meeting the safety criteria, trade criteria or efficacy criteria in new sections 5A, 5B and 5C of the Agvet Code.

Items 262 to 274 - sections 120, 121 and 126 of the Agvet Code

Item 262 amends the explanation in section 120 of Part 8 of the Agvet Code by removing a redundant provision about commencement of Part 8 and including a new explanation subsection describing that licence conditions must be complied with.

Items 263 to 265 and 267, 268, 270 to 272 are editorial changes to section 121 to improve the readability of the section and remove a redundant commencement provision (subsection 121(2)). Section 121 deals with the manufacture of prohibited chemical products and licensing for manufacture of certain chemical products. Items 266 and 269 amend section 121 to recognise that the APVMA may issue a permit in relation to the manufacture of chemical products. The level of the penalty and the defences are unchanged. Item 273 provides that the current offences in section 121 are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of these provisions.

Item 274 inserts a new paragraph in section 126 (which deals with conditions of manufacturing licences) to provide that the conditions of a licence include allowing an inspector to enter premises at which the chemical products are manufactured, and to exercise the monitoring powers under section 131A. This approach is consistent with the approach described in the *Guide* (licensed premises).

Items 275 to 280 - section 127 of the Agvet Code

These items amend section 127 which deals with suspension and cancellation of licences to manufacture chemical products.

Item 275 replaces paragraphs 127(1)(a), (b) and (c) which deal with suspension or cancellation of a licence if the holder has been convicted of certain offences, contravened civil penalty provisions or contravened licence conditions. The new paragraphs provide for suspension or cancellation if a person is not suitable because of a range of matters consistent with the approach taken for other Commonwealth regulators (for example, the manufacture of therapeutic goods). The matters retain the contravention of a condition of a licence and lists convictions or pecuniary penalty orders that may form the basis for the suspension or cancellation of a licence, where these have occurred in the previous ten years. The matters also include where the person has failed to comply with manufacturing principles in connection with the manufacture of chemical products in the last five years. Further circumstances for suspension or cancellation may be included in regulations. Notwithstanding these measures, the APVMA still retains discretion in determining whether the licence should be suspended or cancelled in the circumstances described.

Items 276 and 277 provide for the APVMA to suspend or cancel a licence where failure to do so immediately would result in an imminent risk of certain situations. These include death, serious injury or serious illness to persons; unintended harm to animals, plants or things, or to the environment; or impact on trade or commerce between Australia and places outside Australia.

Items 278, 279 and 280 are editorial amendments to improve the wording of section 127.

Items 281 and 282 – Part 9 and section 129 of the Agvet Code

These items introduce a new Part into the Agvet Code that deals with investigative powers and replaces section 129 with a new section 129 that explains the content of Part 9 and that this includes monitoring and investigation powers.

Item 283 – New Division 2 of Part 9 of the Agvet Code

Notices to produce or attend

Consistent with the *Guide*, this item introduces a new division into Part 9 of the Agvet Code that provides the APVMA with the authority to require people to provide information or produce documents or things, or appear before an inspector to answer questions (section 130). This is a common enforcement mechanism used to assist in the administration of Commonwealth legislation.

This division ensures that the APVMA can monitor and enforce compliance with agvet chemical legislation, and has access to complete information that allows the APVMA to be fully informed in circumstances that require them to act in a timely, informed and proportionate manner to protect public health and safety and the environment.

The introduction of notices to produce or attend to answer specific questions allows the APVMA to address lesser scale instances of non-compliance without physical attendance at the place of business. These notices also allow the APVMA to access appropriate individuals (for example, operations manager) at a fixed place and time, while allowing these individuals time to arrange representation (for example, legal representation), as required. These notices increase the efficiency of resources through a reduction in APVMA staff time and travel. The *Environment Protection and Biodiversity Conservation Act 1999*, Division 15A has similar provisions.

These requirements would be implemented by a notice served on a person where there are reasonable grounds to believe that this person has the documents or knowledge. Any notice must allow at least 14 days for the person to comply with the requirements in the notice and must be signed by the Chief Executive Officer of the APVMA. If the notice requires a person to appear before an inspector then the notice must also state that a person may be accompanied by a lawyer. This provides a person with sufficient time to comply and organise access to representation.

Section 130A provides that the APVMA may take copies or retain documents or things provided to it in accordance with a notice served under section 130. However, section 130A also requires the

APVMA to make documents and things available to a person who would be entitled to view the document or thing at times they would ordinarily be able to. This ensures that a person has reasonable access to documents or things that have been provided to the APVMA.

Section 130B includes the offence provisions for failing to comply with a notice served under section 130. This includes refusing to answer a question put to a person where the person is required to appear before an inspector. Consistent with the *Guide*, a maximum penalty of 30 penalty units or six months imprisonment or both has been included.

The new division aligns with old section 144 but includes a new section 130C that abrogates the privilege against self-incrimination for the purposes of a notice under section 130. New section 130C is similar to old section 34 of the Collection Act. Section 130C requires persons to give information, produce a document or thing or answer a question in relation to a notice under section 130, even though this information, document or things might tend to incriminate the person or expose the person to a penalty. In other situations in the Agvet Code, the privilege against self-incrimination would continue to be available for natural persons.

The abrogation of the privilege against self-incrimination is necessary because based on past experience with existing provisions in the Agvet Code that require persons to provide information (for example, sections 160A and 161), the APVMA has had difficulty in obtaining the necessary information from persons because they are concerned that the information may incriminate them or expose them to a penalty, or because of a concern about 'brand damage' or a lack of awareness of relevant compliance requirements in the first place.

New section 130C provides a use and derivative use immunity in that any information or documents provided, including any information, document or thing obtained directly or indirectly as a consequence of the provided information, are not admissible in evidence against an individual in:

- civil proceedings for contravention of a civil penalty provision
- criminal proceedings, unless the proceedings are for an offence that relates to investigation by the APVMA, including the provision of false or misleading information or documents, or obstructing Commonwealth public officials.

The provision related to obstruction of Commonwealth officials is appropriate as hindering or resisting APVMA inspectors may have serious consequences for the health of the community or the environment if information is not provided or actions not taken that will enable chemical products to be made harmless or destroyed. For example, knowledge of the constituents of a chemical product is important information to enable an APVMA inspector to determine how a product may be made harmless or destroyed and adequately inform other persons involved in any appropriate disposal (for example, about personal protective equipment requirements). Actions that thwart investigations may have serious consequences where dangerous agricultural and veterinary chemicals are provided to the community and where complete information is needed to develop response measures to protect public health and the environment. Examples of obstructing investigations include destroying all electronic, paper and physical records relating to distribution of a chemical, as well as hiding or manipulating records relating to distribution of the chemical. In any of these types of scenarios the APVMA must be able to obtain information to find out what happened and recover the dangerous chemical, while still being able to pursue some sanction for thwarting the investigation.

Items 284 and 285 – new sections 131, 131AA, 131A, 131B, 131C, 131D, 131E, 131F, 131G, 132, 132A, 132B, 132C, 132D, 132E, 132F, 132G, 132H, 133 of the Agvet Code

Monitoring and investigation powers

These items introduce Divisions 3, 4 and 5 into Part 9 of the Agvet Code that deal with investigative powers. These new divisions replace the previous sections in the Agvet Code that related to monitoring and investigation powers. The amendments modernise the monitoring and investigation

powers to bring them into line with contemporary standards. The powers, as amended, are similar to those available to other Commonwealth regulatory agencies (for example, Therapeutic Goods Administration) and the provisions mirror those in other contemporary Commonwealth legislation. Except where indicated, the provisions are also consistent with the *Guide*. The amendments align with those in the Admin Act.

The new Divisions 3 and 4 authorise the APVMA to exercise a range of monitoring and investigation powers. Division 5 includes obligations and incidental powers of inspectors. The occupier of the premises also has specific rights and responsibilities in relation to how the monitoring and investigation powers are exercised.

The APVMA currently appoints inspectors under the Admin Act (section 69F) and must issue them with an identity card that includes a photograph. An inspector must comply with any direction given by the APVMA. Inspectors have powers to enter premises to monitor activities, and to investigate potential contraventions. However, these activities are subject to specific rules about how these inspectors enter premises and how they conduct themselves.

The new provisions allow an inspector to enter any premises (including private residential premises) with consent or, if there is not consent, with a warrant to determine whether agvet law is being complied with (sections 131 and 132). In addition, the APVMA can enforce agvet law where a business operates from a residence, and where a magistrate agrees access to residential premises is reasonable.

The monitoring and investigation powers include the ability for online purchasing, the results of which can be used as evidence for the purposes of the provisions in the Agvet Code that regulate supply, in particular the offences relating to supply of unregistered chemical products or unapproved active constituents.

Except as provided for in section 131AA, an inspector requires consent or a warrant to enter premises. Section 133 outlines the conditions that apply when an occupier of premises gives consent to an inspector seeking to enter and search the premises without a warrant. The inspector must tell the occupier that they may refuse consent, and must not coerce the occupier into giving consent, as the consent has no effect unless it is voluntary. The occupier can limit their consent to a particular period. The inspector and anyone assisting them can enter the premises until a consent period ends, or until consent is withdrawn. They must leave once consent is withdrawn or, if consent is given for a particular period of time, at the end of that time. If consent is given without any limitations, it will continue to have effect until it is withdrawn.

The exception to this is where there is imminent risk to persons of death, serious illness or serious injury and an inspector may enter or remain on premises without a warrant or consent and exercise monitoring powers (section 131AA). This authority is necessary to protect the community. Reporting arrangements for the use of this authority have been provided for in the Admin Act. This approach is consistent with the *Guide*. In addition, this authority is consistent with the authority provided to inspectors in other similar Commonwealth legislation (for example, therapeutic goods legislation).

Having entered the premises, an inspector may exercise a range of monitoring (section 131A) and investigation (section 132A) powers including to examine or test anything, photograph or record anything and copy documents for relevant information. As with other chemical product regulators, APVMA inspectors may take samples of these products when exercising monitoring and investigation powers. In order to ensure appropriate disposal of sampled containers, the monitoring and investigation powers have been extended to authorise an inspector to give directions about sampled containers, and to require a person to comply with these directions. As provided for in the previous section 131 of the Agvet Code, a strict liability offence of 30 penalty units has been included in sections 131A and 132A for not complying with a direction. These are also civil penalty provisions and therefore pecuniary penalties may apply for contraventions of the provisions. This authority is to be used to ensure that directions to make chemical products harmless are complied

with. These powers also provide for sampled containers to be supplied to the market (with appropriate labelling) and not have to be disposed of through less practical or more costly mechanisms such as recalls or landfill disposal.

The monitoring powers include the authority to operate electronic equipment (sections 131B and 132B) and to secure (section 131C) or seize (section 132C) things and to exercise supervisory powers over seized things (section 132D). Evidence may be secured for up to seven days and electronic equipment (that is not evidence) may be secured for up to 72 hours. These represent longer periods than are usually provided to other regulators and are necessary to allow the APVMA to practically exercise its investigative powers in remote, rural and regional areas of Australia where chemical products are used. Undertaking these activities in remote areas requires APVMA inspectors (and electronic equipment experts) to travel long distances to and from implicated premises and securing authorities need to provide for these operational requirements.

New section 132C provides for seizure of evidential material or things that an inspector believes on reasonable grounds to be evidence of an offence or contravention. This new section also provides for inspectors to give directions in relation to seized things. As provided for in the previous section 131 of the Agvet Code, a strict liability offence of 30 penalty units has been included for not complying with a direction. The authority is to be used to ensure that directions are complied with in order to cause the least danger to the health of the public or any person.

An inspector may be assisted by other persons, for example, an interpreter or information technology specialist (sections 131D and 132E). Assistants may do anything the relevant inspector reasonably requires them to do to assist in the exercise of his or her compliance powers and must not do anything that the inspector does not have power to do. This section ensures that assistants are always subject to directions from inspectors and the same restrictions that apply to inspectors. The inspector is accountable for the actions of the assistant and persons assisting an inspector must act in accordance with any direction given by the inspector. A written direction is not a legislative instrument, as it is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Provisions stating this have been included in the relevant sections to indicate that an exemption from the LI Act is not sought or required.

The powers authorise the use of force when executing a warrant but only force against things and no more than is reasonable and necessary (sections 131E and 132F). This authority for use of force is considered necessary as agricultural and veterinary chemical products may be secured in storage cabinets or transported in wooden crates that require physical actions to identify and take custody of these products.

The powers also include the authority to require people to provide information or produce documents (sections 131F and 132G). These powers are consistent with those in the Admin Act and are to be used to respond only to non-compliance and not for the purpose of compelling information to assist the conduct of a reconsideration.

If an inspector enters premises with the occupier's permission, the inspector is permitted to ask the occupier to answer questions and produce documents that relate to the inspector's reasons for entering the premises. However, as the inspector's right to be present on the premises is based on the consent of the occupier, it is not an offence to refuse to comply with an inspector's request.

If the inspector enters premises under a warrant, he or she may require any person on the premises to answer any questions or produce any documents that relate to the inspector's reasons for entering the premises. A person who fails to comply with any such request will have committed an offence. A penalty of 50 penalty units (not strict liability) is included for not complying with this requirement. This penalty amount is consistent with other offence provisions in the Agvet Code and is considered necessary to ensure that when executing a warrant, the inspector is provided with information necessary to determine if legislation is being complied with and to protect public health and the environment.

Items 286 to 290 – sections 134, 135, 136, 137, 138, 138A, 138B, 138C and 138D of the Agvet Code

These items introduce new sections into Division 5 of Part 9 of the Agvet Code that deal with obligations and incidental powers of inspectors, including where an investigation warrant is interrupted. The amendments mean that these obligations in the Agvet Code are the same as those in the Admin Act and generally consistent with other Commonwealth laws.

In the exercise of their functions, inspectors are subject to a range of obligations aimed at protecting the rights and interests of the occupiers of premises. These include:

- where a monitoring warrant has been obtained, the inspector must, before entering the premises, announce that he or she is authorised to enter the premises, show his or her identity card and give the occupier of the premises the opportunity to permit entry into the premises (section 134)
- when executing a monitoring warrant, the inspector must be in possession of the warrant (section 135)
- the inspector must provide a copy of the monitoring warrant to the occupier who is present and inform him or her of the rights and responsibilities of the occupier (section 136)
- specific requirements for securing electronic equipment (for example, computers containing relevant data) until an expert assistant is able to attend and operate the equipment (section 137)
- the Commonwealth must provide compensation for damage to electronic equipment due to a failure to exercise sufficient care (section 138)

Specific provisions have been included in a new Division 6 to deal with when the execution of an investigation warrant has been interrupted (sections 138A and 138B).

The monitoring powers include the authority to secure electronic equipment (that is not evidence) for up to 72 hours (section 137). These represent longer periods than are usually provided to other regulators and are necessary to allow the APVMA to practically exercise its investigative powers in remote, rural and regional areas of Australia where chemical products are used. Undertaking these activities in remote areas requires APVMA inspectors (and electronic equipment experts) to travel long distances to and from implicated premises and securing authorities need to provide for these operational requirements.

Rights and responsibilities of occupiers

The occupiers of premises have rights and responsibilities provided by the new Division 7 of Part 9 of the Agvet Code (sections 138C and 138D). These include providing reasonable facilities and assistance to an inspector to execute a warrant, for example, to enable access to business records held off-site on remote servers and password protected devices. Consistent with other Commonwealth legislation and the *Guide*, an offence with a penalty of 30 penalty units is included for not complying with this requirement. This is considered necessary to ensure that the occupier of the premises assists the inspector with equipment or access that enables the warrant to be effectively and efficiently executed.

Items 291 to 302 – sections 139, 139A, 140, 141, 141A of the Agvet Code

Seizure

These items update the provisions relating to seizure of things by inspectors and include amendments to existing seizure matters in sections 139 and 140 and new provisions in a new Division 8 in Part 9 of the Agvet Code. The amendments update the previous provisions to align them with other Commonwealth legislation (for example, therapeutic goods legislation). The amendments mean that the obligations in the Agvet Code are the same as those in the Admin Act.

The amendments provide that an inspector does not need to return a seized thing if the possession of the thing would be an offence (item 292) and require the return of seized things, where this is appropriate (item 294). The amendments also provide for consideration by a magistrate if an inspector requires a seized thing for longer than 60 days (items 300 and 301). The amendments retain requirements for inspectors to provide a receipt for seized things in new section 139A (item 293). In addition, new section 141A includes specific requirements for the disposal of seized things by the APVMA in a manner it considers appropriate (item 302). This recognises that some agvet chemical products may require special disposal arrangements. However, an APVMA inspector must take reasonable steps to return the seized item before arranging disposal. Items 291 and 298 are consequential amendments that reflect other amendments to the Agvet Code.

Items 303, 304 and 305 – section 142 of the Agvet Code

These items amend section 142 which deals with when certain expenses are recoverable by the APVMA. Items 303 and 304 are consequential amendments to reflect the changes made to the updating of the investigation powers. Item 305 inserts a new provision that allows the APVMA to offset expenses associated with the disposal of a thing seized under an investigation warrant.

Item 306 – sections 143, 143A, 143B, 143C, 143D, 143E, 143F of the Agvet Code

Warrants

This item inserts new divisions that deal with warrants and the powers of magistrates when issuing warrants. The new divisions replace the previous provisions (sections 143 to 145) with more contemporary requirements for applying for monitoring warrants (section 143) and investigation warrants (section 143A).

Warrants are essential tools for furthering investigations as they authorise the regulator to enter premises to gather evidence. Monitoring powers and investigation powers may be exercised with consent or with a warrant issued by a magistrate

Warrants were previously referred to as ‘offence related warrants’ in the Agvet Code. However, as civil penalty provisions are being included in the Agvet Code, it is no longer appropriate to refer to the warrants as ‘offence-related warrants’. For this reason and consistent with other Commonwealth legislation, provisions for ‘monitoring warrants’ and ‘investigation warrants’ have been included.

An inspector may apply to a magistrate for a monitoring warrant (section 143) or an investigation warrant (section 143A), which must contain specified information. The magistrate may issue a warrant if he or she is satisfied, based on information given under oath or affirmation (including further information sought by the magistrate), that access to the premises is necessary.

Reflecting the modernised provisions, further provisions specify that warrants may also be issued by electronic means (for example, telephone) (section 143B), although there are specific requirements that apply to these warrants (sections 143C and 143D). Consistent with other Commonwealth legislation, these requirements include an offence that would apply to an APVMA inspector in relation to the form of a warrant and its presentation to a magistrate or other persons (section 143D). Further provisions have been incorporated to reflect the powers of magistrates in issuing warrants (section 143F).

A new section 143E provides that a warrant issued in one jurisdiction has effect and may be executed in another jurisdiction. In such circumstances the warrant would state the location and jurisdiction in which it would be taken to have effect and be executed. This allows for cross-jurisdictional execution of warrants and avoids the need to obtain multiple warrants from particular jurisdictions.

Items 307 and 308 – new Part 9A, sections 145, 145A, 145AA, 145AB, 145AC, 145AD, 145AE, 145AF, 145AG, 145B, 145BA, 145BB, 145BC, 145C, 145CA, 145CB, 145CC, 145CD, 145CE,

145CF, 145CG, 145DA, 145DB, 145DC, 145DD, 145DE, 145DF, 145E, 145EA, 145F, 145FA, 145FB, 145FC, 145G, 145GA, 145GB, 145H, 145J.

These items insert a new Part 9A that deals with enforcement. Enforcement powers range in seriousness from formal warnings to criminal sanctions and include:

- the use of civil penalties to enforce civil penalty provisions (sections 145A to 145CG)
- the use of infringement notices to enforce certain strict liability offences and civil penalty provisions (sections 145DA to 145DF)
- the acceptance and enforcement of undertakings to comply with provisions (sections 145E to 145EA)
- the use of injunctions in the enforcement of provisions (sections 145F to 145FC);
- the issue of substantiation notices in relation to certain claims and representations (sections 145G to 145GB)
- giving enforceable directions where a person is not complying with this Code, and it is necessary to protect the health and safety of human beings, or to protect animals, plants or things, or the environment (section 145H)
- the issue of formal warnings in relation to suspected contraventions (section 145J)

These inserted provisions introduce modern compliance and enforcement provisions so that the APVMA can effectively manage and deter non-compliance. These improve the ability of the APVMA to efficiently administer its regulatory decisions, and protect public health and safety and the environment. The measures are similar to those available to other regulators under other Commonwealth laws.

The new provisions also provide the APVMA with the capacity to tailor its response to the seriousness of the non-compliance through a graduated range of compliance and enforcement measures. The measures are consistent with the *Guide*.

Civil penalty provisions and orders

New section 145A provides that pecuniary penalties may be imposed for contraventions of civil penalty provisions. These penalties may only be imposed on persons who have obligations under agvet chemical legislation. They cannot otherwise be imposed on members of the public more generally.

The APVMA may apply to the court for a civil penalty order against a person who has contravened a civil penalty provision (section 145A). The APVMA must seek the order no later than six years after the contravention. Courts with sufficient jurisdiction may make civil penalty orders (section 145A). A State and Territory court is a court with jurisdiction to decide matters covered by the provisions relating to civil penalty orders. This is generally determined by any limits on the amount of pecuniary orders that may be made by a court. If a court is satisfied that a person has contravened a civil penalty provision it may then order the person to pay a civil penalty.

The court may order a civil penalty if it is satisfied a person has contravened a civil penalty provision. Section 145AB provides that a pecuniary penalty is a debt payable to the Commonwealth. However, section 145AC(2) provides a double jeopardy provision which states that a person cannot be liable for two or more pecuniary penalties for the same conduct.

The court may have regard to all relevant matters in determining the amount of the penalty. To assist the court, section 145A specifies matters to which it may have regard, including the nature and extent of the contravention and the loss or damage it resulted in, the circumstances in which the contravention took place, whether the person has engaged in similar conduct and whether they have cooperated with the authorities, and, if the person is a body corporate, the seniority of the involved

officers and employees, whether any due diligence was undertaken and whether the corporation has a corporate culture conducive to compliance.

The integrity of the regulatory system for agvet chemicals could be compromised by persons failing to comply with agvet chemicals legislation, and there may be significant impacts on public health or the environment arising from this non-compliance. Furthermore, a person who does not comply could obtain substantial financial gains (for example, through providing unregistered chemical products or breaching registration conditions). On this basis and consistent with other Commonwealth legislation, the legislation provides for pecuniary penalty orders.

A number of provisions in the Agvet Code are civil penalty provisions in addition to being offence provisions. Ancillary contraventions, such as aiding a contravention, are also civil penalty provisions (section 145CA). The financial disincentives to misconduct provided by civil penalties and pecuniary penalty orders are a more proportionate and effective enforcement tool, reflecting the practice of other areas of (particularly, corporate) regulation.

Except for multiple contraventions of civil penalty provisions, section 145AA limits the pecuniary penalty for contravening a civil penalty provision. For a body corporate this is limited to five times the amount that would apply if the body corporate were convicted of an offence for the same contravening conduct. For an individual, the maximum penalty is three times the amount that would apply if the person were convicted of an offence for the same contravening conduct. For example, if a body corporate contravenes the civil penalty provision in section 76 (supply of unapproved active constituent), the maximum penalty that a court could impose would be 7500 penalty units (that is, 5 times 1500 penalty units) as 1500 penalty units is the maximum penalty (that is, 5 times 300 penalty units) that could be imposed for committing an offence against that provision. For an individual the maximum penalty would be 900 penalty units (that is, 3 times 300 penalty units).

Section 145AD deals with multiple contraventions of civil penalty provisions. A court may make a single civil penalty order for multiple contraventions of a civil penalty provision where the contraventions are founded on similar facts, or are part of a series of contraventions of the same or similar character. Provisions in section 145AD clarify that the penalty imposed for multiple contraventions must not exceed the maximum sum for separate penalties that could be ordered for each contravention. This is consistent with other Commonwealth legislation.

Section 145AE provides that a court may direct that two or more proceedings for a civil penalty may be heard together. For example, the court may do this for proceedings concerning multiple contraventions by a single entity or members of a corporate group. This will streamline the process for civil proceedings, remove the need for a person to be subject to multiple proceedings, and thereby reduce legal costs for the person and the Commonwealth.

Section 145B provides that if a person has been convicted of a criminal offence concerning conduct which is substantially the same as that to which the alleged contravention relates, then the court must not make a civil pecuniary penalty order against the person. Section 145BA provides that civil proceedings for a contravention must be stayed if criminal proceedings are commenced concerning conduct which is substantially the same as that to which the alleged contravention relates. If the criminal proceedings result in a conviction, this section will ensure that civil proceedings related to the same conduct are dismissed and costs for the civil proceedings are not awarded. However, section 145BB provides that criminal proceedings may be commenced even if a civil penalty has been imposed for substantially similar conduct. Section 145BC provides that evidence given in civil proceedings is not admissible in subsequent criminal proceedings, unless that evidence concerns the question of whether the evidence in the civil proceedings was false.

Civil penalty provisions - evidential burden

Civil penalties are imposed by the courts according to civil standard of proof (section 145AF). A matter brought to the court seeking a civil pecuniary penalty is subject to the ‘on the balance of probabilities’ standard of proof.

Section 145CB provides that a person is not liable to have a civil penalty order made against them if the person considered whether or not facts existed and was under a mistaken but reasonable belief about those facts and had those facts existed, the conduct would not have constituted a contravention of the civil penalty provision. This has an effect on civil proceedings similar to the effect strict liability has on criminal proceedings. To ensure that liability does not result for simple errors of fact, this section provides a ‘defence’ to civil penalty proceedings on the grounds that a person’s conduct was the result of a considered but reasonable error of fact. The person who asserts that a particular course of action resulted from a mistake of fact bears an evidential burden in relation to that matter.

The evidential or legal burden for offence provisions has not changed but some have been co-located for clarity. Where the defendant currently bears an evidential or legal burden in these offence provisions, the same evidential or legal burden applies in proceedings for civil penalty orders where these offence provisions are also civil penalty provisions. Section 145CD has only been included to deal with evidential burden for civil penalty provisions throughout the Agvet Code and to reduce duplication. It does not change the evidential burden for any civil penalty provision.

In seeking a civil penalty order, section 145CC provides that the APVMA does not need to prove the person’s intention, knowledge, recklessness, negligence or any other state of mind with regard to specified civil penalty provisions. This provision makes it clear that it is not necessary to prove a matter concerning a person’s state of mind at the time the conduct occurred. It is only necessary to prove whether the relevant provision has been contravened. Where a person’s state of mind is relevant to the issue, then this is specifically dealt with in the relevant provision.

Civil penalty provisions - liability for executive officers of body corporate

Section 145CF provides that executive officers of bodies corporate are liable for a contravention of a civil penalty provision by that body corporate in certain circumstances. An ‘executive officer’ of a body corporate is a person, by whatever name called and whether or not a director of the body, who is concerned in, or takes part in, the management of the body (for example, a director or chief executive officer).

It is appropriate that extended accessorial liability applies to such officers, given the importance of ensuring compliance with agvet chemical legislation. Liability is not being imposed simply because the person is an office holder at the relevant time, but requires a degree of responsibility on the part of the officer concerned before a civil penalty may be imposed.

Where a body corporate contravenes a civil penalty provision, and one of its executive officers knew that the contravention would occur, then the officer is subject to a civil penalty if he or she was in a position to influence the conduct of the body corporate concerning the contravention, but failed to take all reasonable steps to prevent it (section 145CF).

Section 145CG provides that executive officers have a defence that they took reasonable steps to prevent the contravention. In considering whether an officer failed to take reasonable steps, the court may have regard to all relevant matters. These matters may include what action (if any) the officer took towards ensuring (to the extent that the action is relevant to the contravention) that the body corporate’s agents, employees and contractors had a reasonable understanding of the requirements in the Agvet Code. This takes into account that the actions of an employee are attributable to the body corporate (section 145CE).

These provisions take the same approach as the liability imposed on executive officers in other Commonwealth laws, including section 494 of the *Environmental Protection and Biodiversity*

Conservation Act 1999. It ensures compliance with obligations under the mechanism is taken seriously at a high level within liable entities. However, it includes measures that allow executive officers to demonstrate that they took reasonable steps to ensure compliance and prevent contraventions. This approach ensures fairness and offers some protection to the individuals involved. It is also consistent with the recommendations of the Australian Law Reform Commission in *Report 95: Principled Regulation: Federal Civil and Administrative Penalties in Australia*.¹

Infringement notices

Section 145DA authorises an inspector to issue penalty infringement notices (PINs) for alleged contraventions of civil penalty provisions that are prescribed in the regulations, and specifies that infringement notices must be issued within 12 months of the alleged contravention. These infringement notices may only be issued to persons who are covered by the agvet chemical legislation and they cannot be issued to members of the public more generally.

The ability to issue infringement notices represents a means for rapid conclusion to instances of non-compliance without the expense associated with court proceedings. The ability to issue PINs would align the APVMA's regulatory control options with those of other comparable regulators. PINs provide the greatest flexibility for tailoring a proportionate response to instances of non-compliance.

Section 145DB specifies the information to be included in a PIN, including that non-payment would lead to exposure to further proceedings, specifically civil proceedings. This provision also specifies that the infringement notice penalty must be less than one-fifth of the maximum that a court could impose and provision is also made for a scale of amounts that may apply for alleged contraventions to be detailed in the regulations. While the provision for a scale of amounts for infringement notices is not consistent with the *Guide*, a scale is intended to provide for a proportionate response to contraventions based, for example, on the amount of substance concerned or the number of containers implicated in an alleged contravention. These provisions also specify that the infringement notice penalty must be less than one-fifth of the maximum that a court could impose and this provides a safeguard as to the maximum amount that could be imposed.

Sections 145DC and 145DD provide that the time to pay an amount may be extended and a PIN may be withdrawn by the APVMA. These sections also detail the requirements for arranging an extension or withdrawal. Subsection 145DD(5) provides that if a person has already paid the infringement notice amount and then it is withdrawn, the Commonwealth must refund the amount to the person. Section 145DE provides that the payment of the PIN discharges liability. This section provides that if a person pays the infringement notice amount before the end of the period referred to in paragraph 145DB(1)(h), then any liability of the person is discharged and no further proceedings may be brought against them for that alleged contravention. By paying the infringement notice, the person is not regarded as having admitted liability. However, non-payment would lead to exposure to further proceedings.

Section 145DF includes specific provisions that state the effect of the infringement notice provisions, including specifying that two or more PINs may be issued and that the issuing of an infringement notice is discretionary. Division 3 also does not limit the option to take enforcement action in other ways, limit liability in any way unless an infringement notice is paid, and does not limit a court's ability to determine the amount of a penalty if a person is found to have contravened a civil penalty provision (except when an infringement notice penalty has been paid).

Enforceable undertakings

Section 145E provides that the APVMA may accept undertakings from a person about their compliance with the Agvet Code. A person may, for example, undertake to take specific action to

¹ Available at <http://www.alrc.gov.au/report-95>. See pages 324-325.

comply with their obligations under the legislation, or stop doing something which is not in compliance with the legislation. This provides the APVMA with an avenue to formalise agreed remedial actions between the APVMA and parties seeking to actively address instances of non-compliance. This would allow for ongoing compliance where the APVMA agrees that an individual or a company in breach is genuinely committed to correcting their behaviour. Enforceable undertakings are a useful tool to promote compliance, without the need to take court action. They are used extensively by other Commonwealth regulators.

These undertakings may be accepted from persons who are regulated by the Agvet Code (for example, holders of registration). They cannot be imposed on persons that are not regulated by the legislation, for example, members of the public or persons who do not have compliance obligations under the legislation. Subsection 145E(6) requires the APVMA to publish these undertakings to encourage compliance through increased transparency. However, this must not include confidential commercial information, personal information (within the meaning of the *Privacy Act 1988*) or information for which disclosure would not be in the public interest.

A person may withdraw or vary the accepted undertakings at any time, but only with the written consent of the CEO. In addition, the CEO can cancel the undertaking. The written consent of the APVMA CEO to withdraw or vary an undertaking is not a legislative instrument, as it is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Provisions stating this have been included to indicate that an exemption from the LI Act is not sought or required.

Where the APVMA considers that a person has breached any of the terms of the undertaking, section 145EA allows the APVMA to apply to the court for an order that includes any or all of the following:

- directing the person to comply with the undertaking
- directing the person to pay the Commonwealth an amount up to the amount of any financial benefit reasonably attributable to the breach of the undertaking
- directing the person to compensate any other person who has suffered loss or damage as a result of the breach
- any other order the court considers appropriate.

Injunctions

Section 145F authorises the APVMA to apply to the court for an injunction in circumstances where a person has engaged or is proposing to engage in conduct that either constitutes or would constitute a contravention of the Agvet Code. The terms of the injunction would be determined by the court but may include an order to undertake particular actions. Sections 145F, 145FA and 145FB and 145FC maintain the effect of the previous section 130 of the Agvet Code which specified requirements for injunctions.

Substantiation notices

Section 145G provides the APVMA with the ability to seek evidence, with substantiation notices, to support claims made about a product. The use of these notices is limited to information, including documents, about the supply or possible supply of a chemical product, the manufacture of a chemical product or the safety or efficacy of a chemical product. These notices do not apply to a person who publishes claims made by another person and where there is no commercial relationship between these persons (other than the role of publishing the claims) (for example, advertising agencies that merely publish claims on behalf of others).

The authority to issue substantiation notices is intended as a preliminary investigative tool where the APVMA suspects a representation may not be able to be substantiated and subsequently in breach of the agvet chemical legislation. Their use would mean that the APVMA would not have to attempt to establish the veracity of the claims itself but would be able to seek information, including documents,

from relevant persons about such claims. It therefore promotes a more efficient resolution of instances of alleged non-compliance (for example, claims about products). Notices may relate to information or documents which could be capable of substantiating the representations either generally and in relation to specific matters.

Section 145GA requires a person given a substantiation notice to provide information, including documents within 21 days of the notice being issued. With the agreement of the APVMA the notice period may be extended. An offence and civil penalty provision for non-compliance with a substantiation notice of 50 penalty units has been included (section 145GB). This penalty is more than is specified in the *Guide* (for example, failure to keep records). This is considered justified given the importance of protecting public health and the environment and the need for the APVMA to be fully informed of the potential implications of agvet chemical supply.

Given the timeframe for response, the provisions are framed in such a way that a genuine attempt to provide information which may support a claim would be sufficient; recognising that more time may be required for the material that would be capable of fully substantiating the claim or representation. A person is also able to refuse to provide particular documents or information on the grounds they might incriminate the person (section 145GA).

Enforceable directions

Section 145H provides for the APVMA to give an enforceable direction to anyone who must comply with the Agvet Code. This authority applies where the APVMA has information indicating that a person is not complying with the Agvet Code and action is necessary to either protect the health and safety of human beings, or to protect animals, plants, things or the environment, or to prevent significant prejudice to trade or commerce. Directions would include a direction to cease non-compliant behaviour or to take remedial action necessary to comply.

The APVMA has found that with its previous authority it could be cost prohibitive to bring some companies into compliance and best practice is often not achieved in most cases where businesses choose not to comply. Directions are intended to act as means for rapid resolution and avoid the need for lengthy court proceedings on low regulatory concern matters. Directions would be in relation to specific behaviour (for example, supply of an unregistered product or claims made in advertising). Non-compliance with the direction would be used as evidence of that offence only.

An offence for non-compliance of 30 penalty units is included for standard offences and 120 penalty units for aggravated offences. Subsection 145H(9) describes aggravated offences. These offences are also civil penalty provisions and therefore provides for civil penalty orders and pecuniary penalties for contravening section 145H. The amounts for these penalties are considered acceptable because they align with the penalty amounts for other directions (for example, section 132C) and for other offences and civil penalty provisions that relate to potentially harmful situations (for example, section 94 - supply of restricted chemical products). In addition, if the person does not comply with steps in the direction then the APVMA may arrange for these steps to be undertaken and the costs offset.

Warnings

Section 145J provides for the APVMA to issue formal warnings to a person which states the APVMA's belief that the person's specific actions may constitute non-compliance with the Agvet Code. The APVMA would use these notices in instances where it believed the non-compliant behaviour was inadvertent. The APVMA may use this option at its discretion. Warnings would be considered in the context of any future compliance and enforcement and penalty considerations. Non-compliance may result in a matter being escalated to investigation and used to support increased penalty for the same offence at a later stage. Warnings may be issued generally or to address possible breaches or contraventions against specific offence or civil penalty provisions in the Agvet Code.

Item 309 – new sections 146 and 147 of the Agvet Code

This item reinserts the offences in relation to false or misleading information from the previous section 145 (new section 146). The item also amends the previous section 147 which dealt with when prosecutions may begin (new section 147 inserted) and repeals the previous provision relating to copying of documents.

The reinserted offences relating to false or misleading information (new section 146) are the same as those in the previous section 145 and no change has been made to the penalty units. The offences in the previous section 145 are not strict liability offences and similarly, the reinserted offences are not strict liability offences.

The item also repeals the previous section 146 that related to the privilege of self-incrimination. This is because an updated provision relating to the only situation where the privilege against self-incrimination is abrogated has been included in new section 130C (which deals with the production of documents and information).

The item also repeals the previous provision that authorised an inspector to copy documents. New provisions have been included under monitoring and investigation powers that authorise the copying of documents (new sections 131G and 132H).

New section 147 relates to when prosecutions must begin. The previous provision allowed for a prosecution for an offence to begin within two years after the commission of the offence. As offences may be concealed there can be significant timeframes between the commissioning of an offence and when the APVMA becomes aware of the offence. Therefore, the new provision allows a prosecution for an offence to begin within two years from the date of discovery (instead of the commission of the offence). In addition and similar to therapeutic goods legislation, the new section 147 also allows for prosecutions to be brought within three years of the commissioning of an offence (instead of the current two years). These amendments would allow the APVMA to more effectively manage its compliance response.

Item 310 - new section 149A in the Agvet Code

This item includes a new section 149A that allows the APVMA to offset costs and expenses in certain circumstances. The APVMA expends considerable resources in the analytical study of material relevant to court proceedings and appeals (including testing of chemical products). While this provision is not consistent with the *Guide*, a provision to allow for offsetting costs in particular situations ensures effective use of the APVMA's resources (which are fully cost recovered from industry). The measure minimises the impact on complying industry participants by providing for convicted industry participants to be responsible for reasonable costs and expenses. Sufficient safeguards have been included and the new provision only provides for the APVMA's costs of chemical analysis and related activities to be offset upon a conviction or a decision in favour of the APVMA. Only the court may make an order for reasonable costs and expenses that the court considers just and equitable. These provisions are similar to those in the *Fisheries Management Act 1991* which allows for recouping of pursuit costs where an illegal foreign fishing boat is forfeited. These costs are in addition to certain expenses that the APVMA may recover under section 142 for example, debts.

Items 311 to 314 – sections 160A and 161 of the Agvet Code

These items amend sections 160A and 161 which respectively deal with providing new information to the APVMA in respect of a pending application, or providing new information to the APVMA generally. The amendments provide that the previous offence provisions in these sections are also civil penalty provisions and that therefore pecuniary penalties may apply for contraventions of the provision. The level of the penalty (300 penalty units) is unchanged.

Item 315 – sections 162 of the Agvet Code

This item is a consequential amendment to section 162 to reflect that notice requirements are now specified in new sections 8H, 8J, 45A and 47C, as sections 52, 53, 54 and 55 have been repealed.

Item 316 – subsection 170A(1) of the Agvet Code

This item increases the penalty for using the APVMA's protected name or protected symbol. It increases the penalty from 30 penalty units to 50 penalty units. While this amount is less than described in the *Guide* (false representations), it is consistent with the penalty amounts in other provisions.

SCHEDULE 4 – DATA PROTECTION

Summary

Schedule 4 includes amendments to the Agvet Code to improve consistency in data protection provisions, and remove disincentives for industry to generate and provide data to support the ongoing registration of agvet chemicals. Amendments balance the desire to encourage newer, safer chemicals while allowing access to the market for generic products.

Investment in regulatory data can require significant resources and the protection of these data encourages innovation in new and existing agvet chemicals, and supports the ongoing registration of existing chemical products. For these reasons, data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. Australia also has international obligations to provide data protection in certain circumstances.

Where data protection applies, the APVMA is prevented from using data generated or owned by one person or company when determining, including assessing, an application from another person or company. This restriction on the use of data is for a specific period of time and protects the data owner's investment from competitors gaining unfair commercial advantage over those who have been involved in the generation of those data. The amendments:

- consolidate data protection provisions into a more contemporary format without changing the effect
- significantly improve the protection for data submitted in relation to a reconsideration (chemical review) and provide an additional incentive to submitting data as part of reconsiderations
- extend data protection eligibility to efficacy data and data relating to the use of products on non-food-producing animals (for example, companion animals), and therefore remove disincentives to generating and providing data for these situations
- maintain data protection eligibility where data are provided as part of an application and that application is withdrawn or refused, as well as where data is provided as part of a permit application and these data are provided in relation to a future application
- provide for any information received in response to the notice of draft decision given for the re-approval or re-registration process to be protected if it is later submitted with an application or in response to a requirement made by the APVMA in the reconsideration (chemical review) process
- partially address 'springboarding'² by preventing the APVMA from using protected information when assessing a second application and making a decision on the second application.

Detailed Explanation

Agricultural and Veterinary Chemicals Code Act 1994

Items 1 to 11 - subsection 3(1) of the Agvet Code

Item 1 repeals the definition of 'companion animal product' as it is no longer required. Item 2 inserts a new definition for 'continue' for Part 3 of the Agvet Code to clarify that it includes to affirm an approval or registration for Division 4 of Part 2 (reconsiderations) and to vary relevant particulars or conditions of an approval or registration, other than where the variation takes place under Division 3A of Part 2 (re-approval or re-registration). Item 3 inserts a new definition for 'limitation period' to

² 'springboarding' relates to the effective loss of patent or other intellectual property protection due to the time required for the regulator to assess data to address regulatory requirements.

be used in Division 4A of Part 2 of the Agvet Code. Items 4 and 5 replace the previous definition of ‘primary applicant’ with ‘primary holder’.

Items 6, 7, 8, 9, 10 and 11 amend the definitions of ‘protected active constituent’ and ‘protected chemical product’ to omit unnecessary words, improve the wording and clarify that active constituents are approved and chemical products are registered under Part 2 of the Agvet Code.

Item 12 amends the definition of ‘protected chemical product’ to remove the exclusions for uses that relate to non-food producing species. The purpose of the amendment is to extend the scope of the definition of ‘protected chemical product’ and therefore the data protection eligibility for data relating to non-food producing species (for example, companion animals). This removes disincentives for investment in these data and reduces the complexity of administering data protection requirements for specific types of chemical product uses.

Item 13 - subsection 3(1) of the Agvet Code

This item amends the definition of ‘protected information’ so that it is now applicable to information generally, rather than being limited to data relating to the interaction of the environment or living organisms. The amendment also removes the exemption that applied to efficacy data (that is, performance of the constituent or product) and allows these data to be eligible for data protection. These amendments mean that more of the data submitted in relation to a notice of a proposed reconsideration or is otherwise required by the APVMA will be eligible for protection. This removes disincentives to generating and providing data for these situations.

Item 14 - subsection 3(1) of the Agvet Code

This item amends the definition of ‘protection period’ to make effective the data protection period for information provided as part of a reconsideration (chemical review).

The protection period for data submitted in relation to a reconsideration currently commences when the data are accepted by the APVMA and is determined by a formula detailed in the regulations or for a maximum of seven years. Due to the duration of past chemical reviews, the protection period has often expired prior to the conclusion of the review, so data was rarely protected and the originator was not eligible for compensation. This represented a disincentive to providing data as part of reconsiderations.

The amendment to the definition of ‘protection period’ means that the data protection period for data provided as part of a reconsideration commences when the information is provided for a reconsideration and ends eight years after the APVMA concludes the reconsideration (that is, where the APVMA affirms an approval or registration for subsections 34(1) or 34A(1), or suspends or cancels the approval or registration for 34AA(1) or (2)). This extended data protection period removes disincentives for investment in data to support reconsiderations. It also means that data generators are more likely to be eligible for compensation if other applicants need to rely on these data for their products and provides data generators with an opportunity to obtain a return on their data generation investment. It also encourages more participants to ‘pool’ their resources in providing data for a reconsideration through slightly revised compensation arrangements.

Items 15, 16 and 17 - subsection 3(1) of the Agvet Code

These items replace the previous definition of secondary applicant with new definitions of secondary holder (for both a secondary active constituent and a secondary chemical product). These changes are necessary to reflect the new terminology of ‘holder’.

Item 18 – new section 34F of the Agvet Code

This item replaces the current explanation of Division 4A of the Agvet Code which deals with limitations on the use the APVMA can make of certain information provided to it.

Items 19 to 28 – new sections 34G and 34H of the Agvet Code

These items amend the previous section 34C to provide for the general rules about the APVMA using certain information and the exceptions to these rules. Items 19 and 20 insert new headings to reflect the subject matter of the provisions under them and change the section numbering from 34C to 34G.

Item 21 inserts three new subsections that restrict the use of certain information by the APVMA in determining (including evaluating or assessing) another application or making a decision on a reconsideration of an approval or registration. Subsection 34G(1) specifies that the information in paragraphs 34G(1)(a) and (b) must not be used by the APVMA to determine an application made under sections 10 and 27. The wording of this provision, along with subsection 34G(1B), is such that the APVMA may not use information given with an application under sections 10 or 27 or information given under section 161 to assess another application under sections 10 or 27 as well as make a decision on the application. This, along with new section 34L, prevents ‘springboarding’³ of applications for approval or registration, preventing the effective loss of data protection for the time it takes to assess a subsequent application that relies on information given with the first application.

Subsection 34G(1A) specifies that the information in paragraphs 34G(1A)(a) and (b) must not be used by the APVMA to vary relevant particulars or conditions under sections 26C, 29A (where the APVMA varies these with the holder’s consent) or 29G (where the APVMA varies particulars or conditions to allow re-approval or re-registration).

Subsection 34G(1A) also specifies that the information in paragraphs 34G(1A)(a) and (b) must not be used by the APVMA to reconsider an approval or registration under Division 4 of Part 2 of the Agvet Code. This measure does not prevent the APVMA from using the information to assess the reconsideration.

Together, subsections 34G(1) and (1A) allow the APVMA to use information given with an application under sections 10 or 27 or information given under section 161 to re-approve an active constituent or re-register a chemical product but not to re-approve or re-register with varied particulars or conditions.

Subsection 34G(1B) clarifies that the use of information includes applying a decision or a conclusion reached based on the information, as well as the use of knowledge or understanding gained from the information. This clarification means that using information includes using any conclusion, knowledge or understanding arising from the information.

Item 22 inserts a new subsection that provides for a person or body consulted by the APVMA to be subject to the same restrictions on use of information as the APVMA when it provides information or advice about an application or reconsideration. Items 23, 24, 25, 26 and 27 create a new section 34H that retains the previous provisions that specify that the validity of the decision and that no action lies against the Commonwealth, the APVMA or other specified persons because of the use of the information in contravention of the requirements in section 34G. Item 28 omits an unnecessary subparagraph that referred to directors of the APVMA.

Item 29 – new sections 34J, 34K, 34L and 34M of the Agvet Code

These items insert four new sections that deal with the use of information for determining applications or reconsidering approvals or registrations, including use in the public interest and limitation periods. Consistent with the previous section 34D, new section 34J sets out a suite of exceptions to the limits on use of information established by section 34G. Specifically, when:

- an authorising party provides a written statement authorising its use (subsection 34J(2))

³ ‘Springboarding’ relates to the effective loss of patent or other intellectual property protection due to the time required to address regulatory requirements.

- use of the information is in the public interest (under rules and requirements specified in subsection 34J(3) and section 34K) (subsection 34J(3))
- information does not favour the applicant or holder in the circumstances where the information shows that the constituent or product may not meet the safety criteria, trade criteria or efficacy criteria (subsection 34J(4))
- the information is given to the APVMA in connection with the application that is being assessed (that is, the current application), or for a reconsideration of an approval or registration and is used for the reconsideration (that is, use of the information is not prevented by Part 3) (subsection 34J(5))
- the protection period for the information has expired (that is, it is no longer protected) (subsection 34J(5A))
- the information is publicly available (subsection 34J(5B))
- the information was given for an application for approval of an active constituent that was previously endorsed when Division 4A commenced on 1 January 2005 (paragraph 34J(6)(a))
- the information was given for an application for the variation of the relevant particulars of the approval of an active constituent for a chemical product, consistent with the previous subsection 34D(6)(b) (paragraph 34J(6)(b)).

New section 34K places conditions on the public interest exemption at new subsection 34J(3). If subsection 37J(3) applies, the APVMA must give a notice to the applicant and the person that the APVMA believes is the authorising party for the relevant information. The APVMA must not use the information before the end of 28 days after the day on which it gives notice. This ensures that the applicant or authorising party is aware of the APVMA's intentions. Despite this, subsection 34K(4) provides that the APVMA may use the information if it believes it is necessary to use the information before the end of the 28 days to prevent imminent risk to persons of death, serious injury or serious illness and it states that belief in the notice to the applicant and authorising party.

New section 34L specifies that the APVMA may use information after the limitation period has ended. The effect of new section 34L is to prevent the APVMA from using information to determine (including assess) an application until after the limitation period has ended. New section 34L specifies that the APVMA may use information to reconsider an approval or registration, provided that the decision on the reconsideration is made after the limitation period has ended. This allows the APVMA to use information for a reconsideration but prevents the APVMA from making a decision on a reconsideration until after the limitation period has ended. These measures partially address springboarding by preventing the APVMA from using information given with an application when assessing a subsequent application as well as making a decision on the subsequent application. Protection against springboarding is not relevant for a reconsideration.

The limitation periods in new section 34M apply to information given in connection with a section 10 or 27 application that is relied on to assess or make a decision to approve a constituent or label or register a product or to vary the relevant particulars or conditions of a registration. Information given in connection with applications under sections 10 or 27 that are withdrawn or refused or information which is not relied on is protected indefinitely. However, if information previously given with these (refused etc) other applications is supplied again for a subsequent section 10 or 27 application it may get a limitation period if the information is relied on to approve or register or to vary particulars or conditions of a registration or label approval. The limitation periods in new section 34M also apply to information provided under section 161 for a registered chemical product in the same way section 34M applies to information given in connection with certain applications.

Limitation periods do not apply for information given in connection with applications other than those under sections 10 or 27, for example, permit applications or re-registration applications. However, new sections 34L and 34M maintain data protection eligibility for information given with these applications and provide for limitation periods to apply if this information is provided in a

subsequent section 10 or 27 application which results in an approval or registration or variation and is relied on.

The period of the limitation ends, in relation to approve or register, either 10, five or three years after the active constituent is approved or after the chemical product is registered or the label approved. The period of the limitation ends, in relation to the variation of relevant particulars or conditions of an approval or registration, either 5 or 3 years after the particulars or conditions are varied.

These limitation periods in new section 34M align with those in the previous section 34F, with exceptions for the periods in items 1 and 2 of the table after new subsection 34M(1). The limitation period has been increased from eight to 10 years for applications for approvals of active constituents that have not been previously endorsed (that is, new active constituents) and chemical products (and label approvals) containing these active constituents. These measures promote research into innovative chemistry for active constituents and encourage development of products that contain this new chemistry.

New section 34M retains the limitation period for information provided for other section 10 and 27 applications (items 3 to 6 of the table in section 34M) and relied on for the registration or label approval, as well as information given under section 161 (items 1 and 2 of the table to subsection 34M(2)). For applications, the period of the limitation starts after the product is registered or the label is approved. For information given for section 161 the limitation period starts after the information is given. The limitation period is different depending on whether the product is an agricultural chemical product (5 years) or a veterinary chemical product (3 years).

Items 30, 31 and 32 – section 57 of the Agvet Code

Items 30 and 31 are consequential amendments to the provisions in section 57 to align the paragraph with the new definition of protected information. Item 32 repeals subsection 57(3). Together, these amendments extend data protection eligibility to data relating to assessing the performance of an active constituent or chemical product and data relating to non-food producing species, including companion animals. This removes disincentives for generating and providing these data.

Item 33 – section 58 of the Agvet Code

This item is a consequential amendment as the matter previously dealt with in this section is now included in section 6C.

Items 34 to 44 – section 59 of the Agvet Code

These items update the previous section 59 which prohibits APVMA use of protected information given for a reconsideration or for deciding whether to suspend or cancel a registration for another purpose and provides some exceptions to the prohibition.

Item 34 is consequential to amendments to the definition of ‘protected information’ (item 13) to make full use of the definition and to section 33 (item 56 of Schedule 1) to reflect that information for reconsiderations gathered under the previous paragraph 159(1)(c) is instead now gathered under section 33. Item 34 also corrects an anomaly with the previous paragraph 59(1)(b) which provided protection for information given in relation to deciding whether to suspend or cancel a permit. Information provided with an application for a permit is not protected when it is given with the permit application. It is inconsistent to provide protection for similar information given in relation to a decision to suspend or cancel a permit.

Items 35 and 36 renumber the section to reflect the deletion of previous paragraphs 59(1)(a) and (b). Item 37 inserts a note to advise that in Part 3 the terms ‘approve’ and ‘register’ do not include ‘re-approve’ or ‘re-register’ respectively.

Items 38 and 40 improves the readability of section 59 and, consistent with the old Part 3 and Division 4A of Part 2, provide that the APVMA is not prevented from using certain protected

information that was also given in relation to a reconsideration or a decision to suspend or cancel an approval or registration. This certain information includes information that is publicly available (paragraph 59(2)(g)) and information that shows the constituent or product may not meet the safety criteria, trade criteria or efficacy criteria (paragraph 59(2)(f)).

This certain information also includes information that has previously been given to the APVMA other than as protected information (paragraph 59(2)(e)), except if that information was provided in responding to a proposed decision notice for section 8S for a re-registration or re-approval application or is information for which use is already limited under Division 4A of Part 2. Information given in response to a proposed decision notice in re-approval or re-registration is thus not prevented from receiving protection under Part 3. Information given in connection with an application under sections 10 or 27 that is prevented from use by the relevant protection provisions in Division 4A of Part 2 is also prevented from use if given again for a reconsideration or decision to suspend or cancel an approval or registration. In this case, the information may be used by the APVMA once the information is no longer prevented from use by Division 4A of Part 2, for example, once any limitation period has expired.

Items 39, 41 and 43 replace applicant with 'holder' to reflect the new 'holder' terminology. Item 42 removes an unnecessary reference to section 168 which applies anyway.

Item 44 inserts a new provision to clarify that where the expression 'continue' is used in Part 3, it includes to vary relevant particulars or conditions of an approval or registration, other than where the variation takes place under Division 3A of Part 2 (re-approval or re-registration) and to affirm an approval or registration for Division 4 of Part 2 (reconsiderations).

Items 45 to 67 – sections 60, 61, 62, 69, 70 and 71 of the Agvet Code

Items 46 and 49 provide for the APVMA to issue notices to all primary holders and the secondary holder about use of protected information. Item 50 amends section 60 to provide that the APVMA must take action as specified in subsection 60(3) within 14 days as the current time period for taking action is not specified. Item 48 amends paragraph 60(2)(c) to specify that the notice recipient must tell the APVMA within 60 days of whether it wants the APVMA to take further action in relation to the use of protection information (instead of the current 'reasonable period'). Item 58 amends section 61 to provide that the primary holder must within 28 days of receiving a notice under subsection 60(3) give a written notice to a secondary holder setting out the information in paragraphs 61(1)(a) to (e). This replaces the previous 'as soon as practicable' and provides for more certainty of arrangements for dealings with protected information. These items amend the provisions about notices that are provided to parties which are involved in, or may potentially be involved in, mediation or arbitration about protected information compensation. The purpose of the items is to ensure that the primary holder is also informed when the APVMA notifies a secondary holder that it cannot complete an application without using protected information. This is intended to improve the transparency for protected information compensation arrangements and facilitate negotiation on access to protected data.

These items also include editorial amendments to replace applicant with holder or notice recipient to reflect the new 'holder' terminology or that the measures apply to notice recipients generally (items 51, 52, 53, 54, , 56, 57, 59, 61, 62, 64, 65 and 66). Items 47 and 55 remove an unnecessary reference to paragraph 59(2)(d) as it is unnecessary for notices to include detail about circumstances where information use is in the public interest. Item 60 is an editorial amendment to clarify that the notice under section 60 is the notice under subsection 60(3). Item 63 clarifies that subsection 62(1) applies to any applicant. Item 67 is an editorial amendment to clarify that the reference to a section should be a division, as the intent is for regulations to be made for rules governing the conduct of an arbitration under Division 3 of Part 3 of the Agvet Code.

Items 68 and 69 – section 169 of the Agvet Code

These items insert a new subsection to provide that when a document or sample is given to the APVMA it becomes the property of the APVMA and nothing in section 14B, Division 4A of Part 2 or Part 3 affect this. This clarifies that the documents and samples provided to the APVMA can be retained by the APVMA.

SCHEDULE 5 – ARRANGEMENTS FOR COLLECTING LEVY

Summary

Schedule 5 includes amendments to the Collection Act to enable any Commonwealth agency to collect the levy on product sales on behalf of the APVMA. The amendments would address the possible perception for a conflict of interest created by the APVMA collecting this levy itself and provide an opportunity to improve efficiency. No change to the levy structure or rate is proposed.

The amendments:

- authorise the Minister to specify a collection agency in place of the APVMA in a written instrument, where the Minister responsible for that agency agrees
- authorise collecting agencies generally to issue notices, collect information, undertake assessments and collect levies payable under the Collection Act.

Detailed Explanation

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

Items 1, 2 and 3 - subsection 3(1)

Item 1 inserts a new definition of ‘Agency’ that describes the term ‘collecting agency’ throughout the Collection Act. The definition relies on an existing definition in Commonwealth of Australia legislation, namely the *Financial Management and Accountability Act 1997*. The new definition limits the scope of possible collecting agencies to those Commonwealth agencies that are defined in the *Financial Management and Accountability Act 1997*. It is only these agencies that would therefore be able to issue notices regarding levy assessments and receive levy payments.

Item 2 inserts a new definition of ‘collecting agency’ to be used throughout the Collection Act. The definition includes the APVMA and any other Agency that is specified in a written instrument. Item 3 amends the definition of ‘notional wholesale value’ to reflect that other agencies other than the APVMA could be a collecting agency.

Item 4 – section 3A

This item inserts a new section that authorises the Minister to specify a collecting agency in a written instrument. The purpose of the item is to ensure transparency in relation to the agencies that are collecting agencies and allow agencies other than the APVMA to collect levies. The new section also requires the Minister to obtain the agreement from the potential collecting agency before that agency is specified in a written instrument as a collecting agency.

A written instrument appointing another agency is not a legislative instrument and subsection 3A(3) has been included to make this clear. A written instrument of appointment is not legislative in character and therefore not within the meaning of section 5 of the LI Act. Subsection 3A(3) has been included to indicate that an exemption from the LI Act is not sought or required.

Items 5 to 21 – section 6, subsections 6(1), 14(2), 14A(1), 14A(3), 15(1), (3), (4), (5), (6), section 16, subsections 16(1), (4), (5), (6), (12), 17(1), 17(2), 18(1), (3), (4), (5), (7) and (8)

These items are consequential amendments of provisions that refer to the APVMA in relation to levy collection. The new provisions refer more generally to a ‘collecting agency’. The purpose of these amendments is to provide any specified collecting agency with the same authority as the APVMA to

make determinations, remit an amount of a late levy payment or understatement penalty, calculate the levy, issue notices, undertake assessment, reconsider and review assessments.

Item 22 – new sections 18A and 18B

This item inserts new provisions that require a specified collecting agency to provide information to the APVMA about levies that the agency has assessed, determined and collected. This allows the APVMA to be informed of any outstanding levies so that any compliance action can be initiated in relation to collection of these levies.

Items 23 to 33 – sections 20, 33, 38, 38A, 38B and 38C

These items amend provisions that refer to the APVMA to instead refer more generally to a 'collecting agency'. The purpose of these amendments is to provide any collecting agency with the same authority as the APVMA in collecting levies. Item 26 clarifies that the APVMA may still provide notices to persons to provide information about disposals of chemical products, irrespective of whether another agency has been specified to be a collection agency.

Item 34 – new sections 38D and 38E

This item inserts a new section 38D that allows a collecting agency to be reimbursed by the APVMA for its costs in collecting the levy. This item also inserts a new section 38E that deals with delegation of a Chief Executive Officer's authority to make an assessment of payable levies. It provides that the Chief Executive Officer may delegate his or her authority. However, the provision specifies that this delegation only extends to Senior Executive Service (SES) employees or Acting SES officers of the appointed collecting agencies for the purposes of subsection 16(12) of the Collection Act.

Item 35 – subsection 39(1)

This item amends a provision that refers to the APVMA to instead refer more generally to a 'collecting agency'. The purpose of this amendment is to provide any collecting agency with the same authority as the APVMA in collecting levies.

Item 36 – validation of delegations

This item validates past actions in relation to signing notices of assessment for levies payable under the Collection Act that is, subsection 16(12). Together with new section 38E, this amendment corrects an anomaly in the Collection Act for delegations and provides for additional limited delegations that were understood to apply because of section 44 of the Admin Act (which provides that the Chief Executive Officer may delegate all or any of his or her powers). This provision only applies where the notice was signed by a person on behalf of the APVMA and as a purported delegate of the Chief Executive Officer. The item specifies that these notices are valid and effective, irrespective of whether these notices were issued by a person with the authority to sign these notices. However, a further provision has been included to ensure that rights and liabilities of parties are not affected where a court has heard and determined proceedings between parties before this item commences.

SCHEDULE 6 – MISCELLANEOUS

Summary

Part 1 of Schedule 6 includes amendments to the Admin Act, Agvet Act, Collection Act and the Code Act (including the Agvet Code) to deal with legislative instruments, provide for reviews of agvet chemical legislation and remove redundant provisions.

Part 2 of Schedule 6 deals with the transitional, application and savings provisions.

Detailed Explanation

Part 1 – Miscellaneous amendments

Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994

Items 1 to 5 - subsection 3(1)

Item 1 amends the definition for the ‘prescribed date of payment’ to remove the redundant elements of the definition. The redundant elements (namely subparagraphs 3(1)(b)(i), (ii), (iii) of the previous definition) refer to sections in the redundant Division 1 – Liability for levy from 1 January 1994 to 30 June 2005 of Part 2 of the Collection Act. Item 2 amends the definition for the ‘rate of levy’ to remove reference to redundant provisions in Division 1 of Part 2 of the Collection Act. Item 5 repeals the definition of ‘relevant calendar year’ as it is no longer necessary (the definition is only used in Division 1 of Part 2 of the Collection Act and this is to be repealed). Items 3 and 4 amend the definitions of ‘registered’ and ‘registration law’ to remove the unnecessary reference to ‘listed registration’ and Part 2A (which has been repealed).

Item 6 – Division 1 of Part 2

This item repeals Division 1 of Part 2 of the Collection Act as it no longer applies (this Division only applied up until 30 June 2005). The ongoing liability for levies is contained in Division 2 of Part 2 of the Collection Act.

Items 7 and 8 – section 12C

Item 7 is an editorial amendment and Item 8 repeals subsections 12C(2) and (3) because they are no longer necessary as a result of the application of new subsection 33(3AB) of the Acts Interpretation Act (which provides for prescribing matters by reference to a class or classes of matters).

Items 9, 10, 11 and 12 – subsection 20(1), sections 36 and 39

These items amend subsections 20(1) and 39(2) to remove reference to redundant sections. The redundant sections are contained in Division 1 of Part 2 of the Collection Act and have been repealed. Item 10 amends the heading of section 36 to better reflect the content of the section. Item 11 is a consequential amendment to section 36 to include the new re-approval and re-registration applications that may be made to the APVMA.

Agricultural and Veterinary Chemicals Act 1994

Item 13 – section 7 of the Agvet Act

This item repeals an unnecessary subsection about providing brief particulars of reasons for decisions, which is already required by other Commonwealth legislation.

Items 14, 15, 16 and 17 – new section 8A and section 23 of the Agvet Act

Item 14 inserts a new section 8A to clarify the status of legislative instruments made under the Code Act and that they apply for the purposes of the Agvet Code. Item 15 clarifies that the manufacturing principles determined by the APVMA are legislative instruments. Item 16 amends section 23 to correctly refer to the manufacturing principles that are the subject of the section. Item 17 replaces the previous subsection 23(3) to preserve the disallowance of manufacturing principles determined by the APVMA but to refer to the more contemporary legislation for legislative instruments (that is, the LI Act).

Agricultural and Veterinary Chemicals (Administration) Act 1992

Item 18 – section 7 of the Admin Act

This item amends to remove the unnecessary reference to ‘listed chemical products’ which are now covered by the more general term ‘registered chemical products’.

Items 19, 20, 21 and 22 – section 8 and 8A of the Admin Act

Item 20 includes certain national regulatory authorities of a foreign country as bodies that the APVMA may consult. This amendment complements the amendments to section 160 of the Agvet Code to ensure that there is no impediment to the appropriate use of decisions or evaluations undertaken by overseas agencies. Items 19 and 21 amend section 8 to remove specific reference to ‘government’ as that is already encompassed in the term ‘body’. Item 22 removes an unnecessary reference to ‘listed registration’ as this is now part of ‘registration’ of a chemical product.

Items 23 and 24 – section 55 of the Admin Act

Item 23 corrects a typographical error in that paragraph 55(2)(a) should refer to ‘objectives’ rather than ‘goals’ to be consistent with paragraph 50(1)(a) which specifies that the APVMA corporate plan define the principal objectives in performing its functions. Item 24 provides for regulations to prescribe specific information that must be included in the APVMA annual operational plan.

Item 25 – section 61 of the Admin Act

This item amends section 61 of the Admin Act which specifies the requirements for the APVMA Annual Report. The amendment amends paragraph 61(2)(c) to provide for regulations to prescribe performance indicators against which the APVMA must evaluate its performance.

Items 26 to 32 - sections 69B, 69E, 69H and 70 of the Admin Act

These items remove reference to ‘listed registration’ or ‘registered listed chemical product’ which is now covered by the more general terms ‘registration’ or ‘registered chemical products’. Item 27 is a consequential amendment to reflect that section 58 is now at section 6C.

Item 33 – new section 72 of the Admin Act

This item inserts a new section that requires a review at least every ten years of all the Commonwealth legislation about agricultural and veterinary chemicals. The purpose of this amendment is to ensure that the legislation is regularly and transparently reviewed to ensure that it remains current and meets community expectations. The Minister may include any related matter in the review and the review must include an independent member among the persons conducting the review. The review must seek and consider public submissions. The report must be tabled before each House of Parliament.

Item 34 – section 77 of the Admin Act

This item repeals a redundant section that dealt with the first period for which estimates were to be prepared for the APVMA after the Admin Act commenced. The Admin Act commenced in June 1993.

Agricultural and Veterinary Chemicals Code Act 1994

Items 35, 36 and 37 – section 7 of the Code Act

These items relate to orders that may be made by the Minister under section 7 of the Code Act. The amendments (items 35 and 37) to subsection 7(1) and paragraph 7(6)(b) are to align with contemporary provisions for legislative instruments in the LI Act. The amendments also repeal subsections 7(3), (4) and (5) as these are no longer necessary given the provisions in the LI Act. Item 36 inserts a new subsection that provides for orders to remain disallowable, despite the provisions in subsection 44(1) of the LI Act and that the Code Act facilitates the operation of an intergovernmental scheme involving the Commonwealth and the states.

Items 38, 39 and 40 – section 9 of the Code Act the table of contents and definitions list of the Agvet Code.

Items 39 and 40 repeal the unnecessary additional table of contents and list of definitions in the Agvet Code. Consequentially, item 38 repeals section 9 which refers to the table of contents and list of definitions.

Items 41, 42 and 43 – section 3 of the Agvet Code

These items repeal the definition of ‘material safety data sheet’ from the Agvet Code as this term is no longer used in the Agvet Code, and consequentially remove an unnecessary subsection number. Item 43 repeals subsection 3(2) because this is already provided for by the LI Act.

Item 44 – new sections 163A and 163B of the Agvet Code

This item inserts a new provision to preserve the disallowance of legislative instruments made under the Agvet Code (section 163A). The provision for disallowance is to apply despite the provisions in subsection 44(1) of the LI Act and that the Agvet Code facilitates the operation of an intergovernmental scheme involving the Commonwealth and the states. This ensures Parliamentary oversight of the legislative instruments made under the Agvet Code.

This provision does not apply to a legislative instrument that the APVMA makes for information to accompany an application (new section 8B) or efficacy criteria (section 5B). These legislative instruments are not subject to disallowance as this may create practical difficulties for applicants in preparing applications.

New section 163B has been included to clarify that provisions in other laws that deal with transitional, application or savings matters in the Agvet Code apply as if these provisions were part of the Agvet Code.

Item 45 – sections 173, 175, 177, 179 and 182 of the Agvet Code

These items repeal sections 173, 175, 177, 179 and 182 from the Agvet Code as they are no longer necessary. The previous provisions related to transitional arrangements for applications from before the Code Act commenced in 1995. These have all been finalised and so the transitional provisions are no longer necessary. This does not affect the ‘grandfathered’ clearance, registration, label approval, varied conditions or permits in sections 172, 174, 176, 178, 180 or 181.

Part 2 – Transitional, application and savings provisions

This Part includes measures for dealing with the transition between the old Agvet Code and the amended Code, particularly in relation to existing applications and reconsiderations and in relation to data protection. These items also deal specifically with when certain provisions are to apply and are necessary to provide for an orderly introduction of new requirements.

Items 46 to 57 – transitional, application and savings provisions

Item 46 specifies the meaning of certain terms in Part 2 of Schedule 6. Item 47 specifies the transitional arrangements for applications and reconsiderations that have already been lodged with the APVMA. It specifies that the requirements in the old Code continue to apply for 12 months to an application lodged with the APVMA before commencement and for which any notice under section 11A has been issued (that is, notice that the application has passed preliminary assessment or notice requiring defects to be rectified in a month or further period that the APVMA allows). After this 12 month period, the requirements in the new Code apply, including the timeframes and that the APVMA must refuse applications if an applicant does not respond in specified timeframes. Similarly, item 47 specifies that the requirements in the old Code continue to apply for 12 months to reconsiderations that have already commenced but that this 12 months is to be calculated from the time after a paragraph 32(1)(b) or 32(2)(c) notice period in the old Code has ended.

Item 48 provides for existing regulations and instruments in force immediately before commencement to remain in force as if they were made under the amended Agvet Code.

Item 49 provides for existing approvals, registrations, licences and permits to remain in force as if issued under the new Code, although this does not prevent these authorisations being varied, suspended or cancelled under the new Code. Similarly, item 50 provides for existing conditions to remain in place and to be valid for approvals, registrations, permit or licences issued under the old Code. The conditions imposed under the Agvet Code before the amendments continue to apply.

Item 51 deals with the end dates for existing approvals and registrations. With exceptions, it provides that the APVMA must assign, and give written notice to a holder of, a date the approval ends for existing approvals and a date after which the registration cannot be renewed (last renewal date) for registrations within two years of commencement. Unless the approval or registration is only in effect for a period of less than a year, these dates must be the last day of a calendar month at least seven years after approval or registration took place and not earlier than six months or later than 15 year after commencement. Despite this, the approval end date or the last renewal date may be less than 7 years (items 51(4) and (5)). This is possible only where the APVMA believes that this is necessary to provide for the end date to be the same as that for another approval of the active constituent or the registration of another chemical product containing one or more of the same active constituent.

Item 52 provides for Division 4A of Part 2 of the old Code to continue to apply to information given before commencement in connection with an application under sections 10 or 27 or for section 161. Division 4A of Part 2 of the old Code continues to apply to information given after commencement provided that the information is given in connection with an application lodged before commencement and that a notice under section 11A of the old Code in relation to the application has not been given to an approved person before the commencement time. This item allows for a single data protection regime to apply for all information given in connection with a particular application.

Item 53 provides for Part 3 of the old Code to continue to apply to information given before commencement in connection with a reconsideration or a decision to suspend or cancel an approval or registration. Information given after commencement will be protected as provided for under the new Code.

Item 54 specifies that new provisions for cancelling permits and licences in paragraphs 119(4)(b) and 127(1)(a) only apply after commencement. This ensures they have no retrospective application.

Item 55 specifies that new section 147 (which deals with the time for bringing proceedings) only applies to acts or omissions after that new section commences. The amended Agvet Code introduces new offences, alternatives to criminal proceedings with civil penalty provisions and penalty infringement notices; alternatives to court proceedings; and enhanced evidence gathering tools. To ensure fairness, the time for bringing proceedings would only apply for conduct after the date of commencement.

The provisions relating to evidence collection and those intended as alternative to court proceedings are considered to be of sufficient net benefit to warrant application to any matter. As such the APVMA would have access to these on the date of commencement to allow for improved efficiency for APVMA compliance and enforcement activities as soon as possible.

Given the scope of the amendments, persons participating in non-compliant behaviour may not have done so under the new arrangements and should be afforded the opportunity to amend their actions. However those persons who choose to continue to undertake practices that endanger the Australian public or undermine the majority of business who operate within the law would be subject to the full weight of the amended provisions from the day they come into force.

Item 56 specifies that new section 149A (which deals with the recovery of investigation costs) only applies to acts or omissions after that new section commences.

Item 57 provides for regulations to be made to deal with transitional, application and savings matters for amendments made by the Act. Item 58 provides that these regulations may apply measures despite the other provisions in Part 2 of Schedule 6 (but they may not affect matters in other Schedules). While item 58 provides for regulations to take effect before they are registered, a safeguard is included to ensure that a court must not convict a person of an offence, or order the person to pay a pecuniary penalty, in relation to the conduct on the grounds that the person contravened a provision because of a retrospective effect of the regulations.

Item 59 provides for regulations to end reconsiderations 12 months after commencement. It may be more efficient for the APVMA to take advantage of reforms to arrangements for reconsiderations and start afresh with a reconsideration than continue the existing reconsideration. This is particularly relevant in relation to reforms to allow the APVMA to set the scope of a reconsideration (see notes about item 59 of Schedule 1).