



Australian Government

Department of Agriculture, Fisheries and Forestry

EXPOSURE DRAFT

Explanatory Guide

DRAFT Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011

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the Minister for Agriculture, Fisheries and Forestry,
Senator the Hon. Joe Ludwig)

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About this Guide

The purpose of this explanatory guide (the guide) is to explain the basis for and the purpose of provisions in the DRAFT Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (draft Bill). This explanatory guide has also been prepared to assist readers in navigating through the draft Bill.

Readers should be aware that the proposed legislative amendments may change as a result of consultation and that this would affect the validity of the explanatory material in this guide. While care has been taken to prepare the explanatory information in this guide, readers are invited to form their own view of the provisions in the draft Bill, and not rely solely on the explanation in this guide.

The guide is structured in the same way as the draft Bill with the key reforms grouped into Chapters that reflect the Schedules in the draft Bill. In each chapter of this guide, the key reforms are summarised (Summary) and then provisions in the draft Bill are explained (Detailed explanation) in the context of these reforms.

Throughout this guide the term ‘item’ is used to describe the drafting item numbers in the draft Bill. The drafting items are the bolded numbers at the left of each amendment. For example, in the drafting item below the drafting item number is the bolded number ‘3’ towards the top left of the box. To the right of the drafting item number is the existing provision in the current legislation that relates to the drafting item. In the example below, ‘subsection 14(1) of the Schedule’ is the provision in the current legislation to which the drafting item relates.

13	3 Subsection 14(1) of the Schedule
14	Repeal the subsection, substitute:
15	(1) The APVMA must grant an application made under section 10 if:
16	(a) it is satisfied of all the matters referred to in subsection (3);
17	and
18	(b) in a case where the APVMA considers that the matters
19	referred to in subsection (3A) are relevant to the
20	application—it is satisfied of those matters.

The draft Bill proposes amendments to the *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* (Levy Act).

Invitation to Comment

The government is inviting comment from the community on reforms to agricultural and veterinary medicine (agvet chemical) legislation. This reform Bill is proposed to be introduced to the Commonwealth Parliament as soon as possible following the close of the comment period with passage later in 2012. Address details for submissions are provided below. It would therefore be of assistance if you could provide any comments as soon as possible, but at the latest by **29 February 2012**.

Comments received after this time may not be able to be considered. The government has provided this extended consultation period due to the complex nature of the proposed reforms and in light of the time of year.

If you wish to provide a written statement or submission on this draft legislation you can provide your comments to the Department of Agriculture, Fisheries and Forestry at the addresses below. While submissions may be lodged electronically or by post, electronic lodgement by email is preferred. For accessibility reasons, please email responses in a Word or RTF format. An additional PDF version may also be submitted.

All information (including name and address details) contained in submissions will be made available to the public on the department's website, unless you indicate that you would like all or part of your submission to remain in confidence. Automatically generated confidentiality statements in emails do not suffice for this purpose. Respondents who would like all or part of their submission to remain in confidence should provide this information marked as such in a separate attachment.

A request made under the *Freedom of Information Act 1982* (Commonwealth) for a submission marked 'confidential' to be made available will be determined in accordance with that Act, which was recently amended.

This guide may be updated from time to time. The current version is available from <http://daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>. For clarification of any points in this guide or further information on this process, please contact the department via the following means:

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Glossary

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

<i>Abbreviation</i>	<i>Definition</i>
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 Code	Schedule to the Code Act (see below)
Bill	<i>Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011</i>
CEO	Chief Executive Officer of the APVMA
COAG	Council of Australian Governments
Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
FSA NZ	<i>Food Standards Australia New Zealand</i>
Levy Act	<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>
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 the <i>Acts Interpretation Act 1901</i> . At present a penalty unit is \$110.
PIMC	Primary Industries Ministerial Council
Policy discussion paper	<i>Better Regulation of Agricultural and Veterinary Chemicals Policy Discussion Paper, released November 2010</i>
Reconsideration	A review of a chemical approval and/or registration.

Executive Summary

The Australian Government is committed to reforms to the registration and review of agvet chemicals that improve the efficiency and effectiveness of the current regulatory arrangements, and provide better protection for human health and the environment.

In November 2010, a policy discussion paper, *Better Regulation of Agricultural and Veterinary Chemicals*, was released to assist stakeholders in commenting on reform proposals¹. Stakeholders were invited to comment on the reform proposals from mid-November 2010 to early February 2011. The Department of Agriculture, Fisheries and Forestry received 92 submissions as part of the consultation.

Based on the submissions, the government has developed a number of legislative and administrative reforms to agvet chemical regulation. 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 Assisting on Deregulation.

The government has now developed the necessary amending legislation to implement the proposed reforms. Recognising the complexity of agvet chemical regulation, the government is releasing an exposure draft of the amending legislation for further consultation with stakeholders.

In general terms, the reforms aim to encourage the development of modern and safer chemicals, through cutting unnecessary red tape for business. The reforms also aim to reduce the backlog of chemicals requiring review and remove disincentives for companies to invest in cutting edge technologies. The reforms also enhance the APVMA's business and operational functions.

The reforms would result in a more straightforward assessment process that is easier to understand and more cost effective to administer. In many cases, particularly for low risk products, the reformed system as established by these amendments may be faster, would deliver more predictable outcomes and should also result in improved health and environmental protection for the broader community.

This guide provides further detail about the reforms and the following table (Table 1) summarises the proposed reforms and outlines the basis for each. The reforms have been arranged into particular chapters that reflect the amendment schedules in the draft Bill e.g. Chapter 1 relates to Schedule 1 in the draft Bill.

There will also be a need to amend regulations arising from the legislative amendments in the draft Bill. The amendments to the regulations will be consulted on separately.

¹ <http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>

Table 1: Table of Reforms and Reasons

Chapter	Proposed Reform	Reasons for Reform
Chapter 1 – Decision-making using a risk based framework	Develop, publish and implement a risk framework for decisions about approvals, registrations and reviews of agvet chemicals.	Enhance the consistency, efficiency and transparency of decision making about approvals, registrations and reviews of agvet chemicals
Chapter 2 – Enhancing chemical review arrangements for existing approvals and registrations	Implement a mandatory scheme for the continuation of approvals for active constituents and registrations of chemical products.	Consistent with international practice, implement a systematic approach to regular safety reviews of chemical products through application to the APVMA confirming the previously evaluated details.
Chapter 3 – Improving quality and efficiency of assessment and registration processes	Facilitate electronic submission of information and the refusal of defective applications at preliminary assessment, and provide for regulations to prescribe timeframes for reconsiderations (chemical reviews) of approvals of active constituents or registrations of products. Ensure overseas data can be used to its appropriate extent.	Improve the APVMA’s performance through electronic receipt of applications/information, focussing the APVMA’s resources on complete applications, limiting the preliminary assessment to an administrative check of details, and introducing timeframes to reduce the backlog of chemical reviews. Addition of measurement of timeframes by elapsed time to increase certainty around when applications will be finalised.
Chapter 4 - Enforcement	Provide the APVMA with a graduated range of investigative, compliance and enforcement powers, including improved evidence collection authority, the ability to give enforceable directions and the inclusion of civil penalty provisions, including penalty infringement notices.	Improve compliance with the APVMA’s regulatory decisions, allow a proportionate approach to managing non-compliance (including counterfeit products), and maintain public confidence in agvet chemical regulation.
Chapter 5- Data protection	Improve existing data protection provisions.	Improve consistency in data protection requirements and remove disincentives for industry to provide data in support of ongoing registration of agvet chemicals.
Chapter 6 – Arrangements for collecting levy	Provide for any Commonwealth agency to be able to issue notices regarding levy assessments and receive levy payments. No change to the levy structure or rate is proposed by the draft Bill itself.	Remove the possibility of a perception of a conflict of interest arising from the current arrangements for collection of levies on the sale of chemical products.
Chapter 7 - Miscellaneous	A number of specific amendments that assist in the operation of the Code Act and the Levy Act.	Remove out-of-date provisions.

Structure and Content of the draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011

The draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011 (draft Bill) proposes amendments to the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act) and the *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act). These proposed amendments would improve the efficiency and effectiveness of the current regulatory arrangements for agricultural and veterinary chemicals, and provide better protection for human health and the environment. The draft Bill also includes amendments to the *Agricultural and Veterinary Chemical Products (Collection of Levy)* (Levy Act) to improve administrative efficiency.

The draft Bill has three introductory sections and seven schedules that deal with the key elements of the proposed reforms. Table 2 below provides an outline of the schedules and provides a general description of the content of each schedule in the draft Bill.

Section 1 of the draft Bill is a formal provision specifying the short title of the Act as the ‘Agricultural and Veterinary Chemicals Legislation Amendment Act 2011’. Section 2 of the Bill specifies when the amendments commence. Some Schedules commence later than others to allow time for any administrative arrangements and subordinate legislation to be developed and consulted upon. Section 3 of the draft Bill specifies that the items set out in the Schedules amend or repeal items in the Admin Act, Code Act or Levy Act.

Table 2: Structure of the draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2011

Schedule	Title	Description
Schedule 1	Decision-making using a risk based framework	Schedule 1 provides for the APVMA to develop and use a risk based framework in considering approvals, registrations and reconsiderations (reviews) of agvet chemicals.
Schedule 2	Continuation of approvals and registrations	Schedule 2 provides for a scheme for continuation of approvals for active constituents and registrations of chemical products (including listed registered products).
Schedule 3	Streamlining processes for giving and receiving information	Schedule 3 sets out provisions to facilitate the electronic submission of information, to mandate refusal of defective applications at preliminary assessment, and to provide for regulations to prescribe timeframes for evaluation of applications and reconsiderations (reviews) of an approval or registration. Ensure overseas data can be used to its appropriate extent.
Schedule 4	Enforcement	Schedule 4 includes provisions that provide the APVMA with a graduated and contemporary range of compliance and enforcement powers, as well as measures for counterfeit active constituents/products.
Schedule 5	Data protection	Schedule 5 sets out a number of improvements to existing data protection provisions.
Schedule 6	Arrangements for collecting levy	Schedule 6 provides for any Commonwealth agency to be able to issue notices regarding levy assessments and receive levy payments.
Schedule 7	Miscellaneous	Schedule 7 provides for a range of matters which facilitate the operation of the Code Act and the Levy Act.

Regulations

There will be a need to amend regulations arising from the legislative amendments in the draft Bill. The amendments to the regulations will be consulted on separately and the following points outline the principal changes required to the regulations.

- New regulations that prescribe conditions for the approval of active constituent or registration of a chemical product.
- New regulations to prescribe timeframes or the method for determining timeframes for reconsiderations (chemical reviews).
- New regulations that relate to new compliance and enforcement provisions e.g. offences for which infringement notices and warnings may be issued in the Code Act regulations.
- Amendments to regulations to remove redundant regulations e.g. removing out of date provisions from the Levy regulations.
- Machinery changes to regulations to reflect updated or new sections in the legislation e.g. deletion of regulations that relate to protection periods; circumstances where late applications may be accepted by the APVMA.
- Elapsed time used for measurement of registration and variation applications.

1. Chapter 1 – Decision-making using a risk based framework

1.1 Summary

Schedule 1 of the draft Bill includes amendments to the Code Act to enhance consistency, efficiency and transparency through the development and application of a risk framework for the assessment (including reconsideration) of agvet chemicals. The risk framework would allow the APVMA to determine the scale of an assessment appropriate to the application or reconsideration, and result in more efficient and timely decision-making. The framework will increase certainty for applicants, provide a comprehensive reference to the risk assessment process and improve the predictability of regulatory decisions.

The APVMA and its regulatory partners will develop, publish and apply an overarching risk framework for agvet chemicals. The framework will include all relevant guidelines, standards and methods which guide regulatory decisions made under the agvet chemicals legislation.

Legislation is not required to develop the framework. However, legislation is required to ensure the risk framework is taken into account when the APVMA makes decisions, and to formalise the current discretion the APVMA uses in the modular assessments of applications and reconsiderations. This would ensure that the APVMA and its regulatory partners match the level of assessment effort with the level of risk. For example, the APVMA would consider efficacy or trade components for applications if the APVMA considers that these matters are relevant. However, public health, occupational health and safety and environment would continue to be assessed for all applications.

The amendments:

- alter existing provisions to allow the APVMA to determine for itself whether it needs to be satisfied about some matters before granting an application or determining a reconsideration. This would align the level of assessment with the hazards of the active constituent or the risks associated with the chemical product use (e.g. items 6, 7, 8 and 9)
- clarify those matters which the APVMA must have regard to and those matters which the APVMA may have regard to in making certain decisions, including considering an application or reconsideration (item 11), recalls (item 58), suspending and cancelling permits (items 67 and 68) and reserving chemical products (item 57)
- in considering an application or reconsideration, the APVMA would have some discretion in relation to considering whether use of a product would unduly prejudice trade or commerce between Australia and places outside Australia (e.g. items 4 and 9). Other than for applications for permits, the APVMA would also have discretion in relation to considering whether the use of a chemical product would be effective
- these amendments do not change the requirements for the APVMA to consider matters relating to human health or the environment
- amend some existing provisions to improve their readability
- include application provisions (item 69) that ensure an orderly introduction of the new requirements

1.2 Detailed explanation

Item 1

This item amends the definition of relevant particulars as a result of changes made to subsection 29(1) (see below).

Items 2 and 3

These items amend the notice requirements as a result of changes to subsection 14(3) (see below).

Items 4

This item amends the existing subsection 14(1) to allow the APVMA to consider certain matters only if the APVMA considers that they are relevant to the application. These matters would be in a new subsection (see item 9 below).

Item 5

This item amends the current requirement as a result of changes to subsection 14(1).

Items 6, 7, 8, 9

These items modify the matters that the APVMA must be satisfied of in granting or refusing an application for approvals and registrations (Division 2 of Part 2). The amendments remove the need for the APVMA to consider efficacy and prejudice to international trade or commerce when approving active constituent applications. For applications for product registrations, the amendments remove the requirement for the APVMA to consider certain other matters unless the APVMA considers that these matters are relevant. These certain other matters are whether the use of a chemical product would unduly prejudice trade or commerce between Australia and places outside Australia, as well as whether the use of the chemical product would be effective. The amendments insert a new subsection 14(3A) that specifies these matters. The APVMA would have discretion to consider these matters where the APVMA considers that these matters are relevant to the application. However, the APVMA would continue to consider the other specified matters, including human health, occupational health and safety and unintended effects to the environment, in granting or refusing an application.

Item 10

This item amends the current requirement as a result of changes to subsection 14(1).

Item 11

This item amends the current requirements to clarify the specific matters that the APVMA must have regard to and those other matters the APVMA may have regard to in satisfying itself about the use of a chemical product.

Item 12, 13 and 14

These items are consequential amendments arising from changes to subsection 14(1).

Items 15, 16, 17, 18 and 19

These items deal with applications to change certain relevant particulars for an approved active constituent, a registered chemical product or an approved label for containers (Division 2A of Part 2). The items modify the matters that the APVMA must be satisfied of in granting or refusing an application. The amendments mirror the changes above (items 6 to 9) for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers.

Item 15 amends the existing subsection 26A(3) to allow the APVMA to consider certain matters only if the APVMA considers that they are relevant to the application. These matters would be in a new subsection 26A(3A).

Items 20 and 21

These items amend the existing requirements for applications to change certain relevant particulars for an approved label for chemical product containers (Division 2A of Part 2). The amendments require the APVMA to consider whether the label of a chemical product container includes adequate instructions for these applications. This corrects an anomaly and aligns the requirements for applications relating to changing relevant particulars in labels with the requirements for other applications that relate to labels [e.g. paragraph 14(3)(g)].

Items 22, 23 and 24

These items amend the existing provisions relating to granting and refusing applications to change certain relevant particulars for an approved active constituent, a registered chemical product or an approved label for containers. The amendments clarify that the actions of the APVMA relate to when the APVMA grants or refuses an application, rather than when the APVMA is satisfied or not satisfied in relation to an application. This aligns the actions of the APVMA with the decisions that the APVMA makes in relation to an application. The amendments do not affect the actions that the APVMA is to undertake when considering these applications (e.g. issuing written notices).

Item 25, 26, 27, 28, 29, 30, 31 and 32

These items deal with applications to change relevant particulars or conditions for an approved active constituent, a registered chemical product or an approved label for containers (Division 3 of Part 2). The items modify the matters that the APVMA must be satisfied of in granting or refusing an application. The amendments mirror the changes above (items 6 to 9) for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers. Similar to the items above, item 25 amends the existing subsection 29(1) to allow the APVMA to consider certain matters only if the APVMA considers that they are relevant to the application. These matters would be in a new subsection 29(1B).

Items 33 and 34

These items modify the existing subsection 29(2) to reflect the changes made to subsection 14(5) (see above) and to include the existing requirements in paragraphs 29(1)(h) and 29(1)(i) in their own subsection, namely subsection 29(2B).

The changes made to subsection 14(5) are to clarify the specific matters that the APVMA must have regard to and those matters the APVMA may have regard to in satisfying itself about the use of a chemical product. The matters the APVMA must have regard to include whether the use of the chemical product would not be undue hazard to the safety of people and would not be likely to have an unintended harmful effect to the environment.

There are no changes to the existing requirements arising from including paragraphs 29(1)(h) and 29(1)(i) into the new subsection 29(2A). However, the inclusion of these requirements in their own subsection is intended to make the requirements clearer to readers of the legislation.

Item 35

This item amends the current requirements for refusing an application as a result of changes to subsection 29(1) (see items above).

Items 36, 37 and 38

These items deal with the reconsideration of approvals or registrations (Division 4 of Part 2). The amendments mirror the changes above for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers. Similar to items above (Items 6 to 9), items 36 and 37 amend the existing subsection 34(1) so that the APVMA has discretion in considering certain matters in relation to the reconsideration.

These matters are whether the use of a chemical product would unduly prejudice to trade or commerce between Australia and places outside Australia, as well as whether the use of the chemical product would be effective.

Item 39

This item amends the current requirements for identifying information that the APVMA has relied on in making certain decisions. The amendment only alters the existing requirements because of changes made to subsection 29(1) (see items above).

Item 40

This item amends the current requirements for the suspension or cancellation of approval of an active constituent or registration of a chemical product. The amendments are required to align with the changes made to subsection 14(5) (see items above). The amendments combine the existing criteria of trade and commerce between Australia and places outside of Australia with the criteria relating to efficacy, and allow the APVMA to decide if these criteria are relevant to their consideration for a suspension or cancellation of the registration of a chemical product.

Items 41 and 42

These items deal with standards for listable chemical products in Division 3 of Part 2A of the Code Act. The amendments mirror the changes above for applications relating to active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers. Similar to items above, the existing requirements have been amended so that the APVMA has discretion in considering certain matters in relation to the standards for listable chemical products. These matters are whether the use of a chemical product would unduly prejudice to trade or commerce between Australia and places outside Australia, as well as whether the use of the chemical product would be effective. However, the APVMA must continue to consider human health, occupational health and safety, and unintended effects to the environment in any standards for listable chemical products.

Items 43, 44, 45, 46, 47, 48, 49, 50, 51, and 52

These items deal with applications to change relevant particulars or conditions for registered listed chemical products (Division 5 of Part 2A). The amendments mirror the changes above for applications relating to active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers. Similar to items above (items 6 to 9), the existing section 56U is amended to allow the APVMA to consider certain matters only if the APVMA considers that they are relevant to the application. These matters would be in a new subsection 56U(1B).

Items 53, 54, 55 and 56

These items deal with the suspension or cancellation of listed registration of chemical products (Division 7 of Part 2A). The amendments mirror the changes above for active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers (item 40). Similar to item 40, the amendments combine the existing criteria of trade and commerce between Australia and places outside of Australia with the criteria relating to efficacy, and allow the APVMA to decide if these criteria are relevant to their consideration for a suspension or cancellation of the listed registration of a chemical product.

Item 57

This item deals with reserved chemical products. The amendment mirrors the changes above for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers. Similar to items above, the item amends the existing requirements so that the APVMA has discretion in considering certain matters in relation to reserved chemical products.

Item 58

This item amends the requirements for the recall of products. The amendment only alters the existing requirements because of changes made to subsection 14(5) (see item 11 above).

Items 59 and 60

These items deal with applications for permits relating to the use of chemical products (Part 7). The amendments mirror the changes above (items 6 to 9) for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers.

Item 61

This item amends the requirements for applications for permits (Part 7). The amendment only alters the existing requirements because of changes made to subsection 14(5) (see item 11 above).

Items 62, 63, 64, 65 and 66

These items relate to applications for permits relating to the use of chemical products (Part 7). The amendments mirror the changes above for applications about active constituent approvals, registrations of chemical products and approvals of labels for chemical product containers.

Items 67 and 68

These items amend the requirements for suspending or cancelling permits. The amendment only alters the existing requirements because of changes made to subsection 14(5) (see item 11 above).

Item 69

This item specifies when the amendments in Schedule 1 apply. Most requirements apply on or after the day that the item commences. To ensure an orderly application of new requirements, there are some exceptions, including for certain applications and reconsiderations at certain stages of consideration.

Item 70

This item introduces a savings provision to ensure that applications which are made before the proposed legislative changes are considered under the regulations that existed at the time the application was made.

2. Chapter 2 – Enhancing chemical review arrangements for existing approvals and registrations

2.1 Summary

In contrast to other comparable regulators, particularly in Europe and the United States, Australia currently has no requirement for agvet chemicals currently in use to be regularly reviewed. Instead, Australia's approach relies on an *ad hoc* 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. These chemicals are then made the subject of a reconsideration (chemical review) of their status. The government considers that there is a need to implement a mandatory scheme for the continuation of approvals and registrations to complement the existing chemical review system.

Schedule 2 of the draft Bill includes amendments to the Agvet Code that provide greater assurance of the ongoing safety of agvet chemicals through a scheme for the mandatory consideration of the continuation of approvals and registrations. Under the scheme, the registration or approval of chemical products would expire after a limited time. Registrants or approval holders would need to apply to continue approvals for active constituents and registrations of chemical products (including listed registration) after a set period of time. This period would be determined on the basis of risk (taking into account the APVMA's published risk framework).

Consistent with international practice², the scheme would be a systematic approach with regular safety reviews of chemical products. The scheme would be based on the principle that registration and approval should be continued where there are no reasonable grounds, founded in evidence, to doubt that the product or active constituent poses an unacceptable risk to human or environmental health.

The scheme is intended to be robust and rigorous enough to ensure currently available chemicals continue to meet appropriate standards for safety, while minimising the potential for the administration of the scheme to reduce the availability of safe and useful chemicals to the community. The continuation of approvals and registrations scheme would therefore promote public confidence in agvet chemicals while minimising impacts on industry. The scheme adds to the existing requirements for the renewal of chemical product registration in Division 6 of Part 2.

The amendments:

- introduce provisions to require chemical product registrations and active constituent approvals to be continued, with differing expiry periods depending on the risk associated with the active constituent and the risk associated with the product use, as provided for in the APVMA's published risk framework (item 12)
- introduce an opportunity to apply (a *continuation application*) for continuation of approval of an active constituent or registration of a chemical product (including listed registration) and provide certain information in support of the application (item 15)
- require the APVMA to undertake a preliminary assessment of the continuation application and refuse applications where identified defects either cannot be, or are not, rectified (item 15)
- require the APVMA to continue the approval of an active constituent or registration of a chemical product where the APVMA is satisfied that it has no doubts that the chemical is safe or that it would not be an undue hazard to people, animals, plants or the environment, or would not be effective, or would unduly prejudice trade or commerce (item 15)
- refer an application for reconsideration (chemical review) or amend the particulars or conditions of the registration or approval where the APVMA is not satisfied (item 15)

² International Code of Conduct on the Distribution and Use of Pesticides

2.2 Detailed Explanation

Items 1, 2 and 3

These items introduce the concept of an application to continue the approval of an active constituent or the registration of a chemical product. The items insert a new definition of ‘continuation application’ and update the current definition of ‘interested person’ for use throughout the Code Act. The amendments also update the explanation of Part 2 of the Code Act to refer to continuations of approvals and registrations.

Items 4 and 5

These items ensure that the APVMA notifies FSANZ about any continuation application that is likely to require an amendment to the Maximum Residue Limits Standard in the Australia New Zealand Food Standards Code. The provisions mirror requirements that apply to other applications.

Items 6 and 7

These items update the details for effecting the approval of an active constituent and the registration of a chemical product. The amendments require the date that either approval or registration ends to be publicly available. The amendments also require that these dates must be the last day of a calendar month and require the APVMA specify the year in which a continuation application is due. The year in which a continuation application for an active constituent approval is required must be at least seven years and not later than 15 years after the previous approval of the active constituent. Except for where a condition exists to prevent a continuation application (item 8 below), the year in which a continuation application is required for registration of a chemical product must be at least seven years and not later than 15 years after the previous registration of the chemical product.

Items 8 and 9

These items amend the provisions to provide for additional conditions that may be applied to the registration of chemical products to allow for a condition to be imposed that prevents a continuation application from being made. The amendments also allow the APVMA to vary conditions of registration that relate to continuation applications in specified circumstances and for specified timeframes.

Items 10 and 11

These items amend the existing provisions for incorrectly recorded or registered particulars. The purpose of the amendments is to allow the APVMA to amend the Record of Approved Active Constituents, the Register of Chemical Products or the relevant APVMA file where the recorded details are not correct. Where the APVMA amends recorded details it must inform the interested person.

Item 12

This item complements the scheme for the continuation of approvals and registration (item 15 below) by specifying when approvals and registrations commence and expire. The amendments remove the perpetual approval of active constituents and provide for these approvals to expire on a particular day. This provides for the requirement that these approvals be continued on a regular basis by application to the APVMA. Based on risk and within 2 years of commencement of the proposed legislation (see item 36), the APVMA would determine the period after which a continuation application is required for the approval of an active constituent. The period of approval of an active constituent would be publicly available.

Currently, all chemical product registrations need to be renewed on 30 June each year. The amendments do not affect the current annual renewal of chemical product registrations. However, the amendments provide for the registration of chemical products to expire on a date set by APVMA and to be continued on a regular basis by application to the APVMA (continuation application). This enables the APVMA to consider the continued registration of all products, containing the same active

constituent, in the same year as the continuation application for that active constituent. Based on risk and within 2 years of commencement (see item 36), the APVMA would determine the period after which a continuation application is required for the registration of the chemical product. The expiry date would form part of the particulars of each chemical product registration and the period of registration of a chemical product or approved active constituent.

Item 13

This is a consequential amendment arising from the redrafting of section 54 (see below).

Item 14

This item clarifies that a renewal application is not required where a continuation application is required. This provision means applicants do not need to make a renewal application in the same year a continuation application is already required.

Item 15

This item introduces a new Division in the Code Act for a scheme about applications for the continuation of approvals and registrations. The scheme does not apply to permits. Consistent with international practice, the scheme would implement a systematic approach with regular safety reviews of chemical products to ensure that recorded details and conditions for approvals and registrations remain current, and that their products remain safe and meet appropriate standards. The scheme is based on the principle that approval and registration should be continued where there are no reasonable grounds, founded in evidence, to doubt that the active constituent or product would not meet contemporary standards.

The new scheme allows approval holders and registrants to apply to continue approvals of an active constituent or to continue registration of a chemical product. The scheme also applies to suspended active constituents and chemical products. Applications would need to be made between three and six months before registration or approval expires and be accompanied by any prescribed fee (sections 51A and 51B).

Once the application is received the APVMA must conduct a preliminary assessment within two months. If there are defects that can reasonably be corrected, the applicant will be given 14 days to do so. Otherwise the application will be refused. Should an application be refused any fee payable is not to be refunded. The interested person would need to apply again for continuation of approval or registration should they wish the approval or registration to not expire.

The APVMA will provide at least 14 days notice of the impending expiry of the approval or registration. If an application is not received by the required date then approval or registration would not continue. The APVMA would publish a notice if an approval or registration is not continued. While an application is under consideration the registration or approval would continue until that application is decided.

The APVMA must grant the application if it is satisfied that it has no doubt that the use of the chemical would not be an undue hazard to the safety of people and would not be likely to have a harmful unintended effect on the environment, that there is no outstanding debt in relation to the chemical product, and that the APVMA has no doubt that the use of the product in accordance with the instructions is effective. If a continuation application for approval of an active constituent is granted, the period of approval would be publicly available and the applicant notified. If a continuation application for registration is granted, the period of registration of a chemical product would be publicly available and the applicant notified.

Where the APVMA is not satisfied, it may decide to reconsider the approval or registration or to vary the conditions or particulars of the existing approval or registration. Before reconsidering or varying the approval or registration, the APVMA must provide the applicant with a notice of this draft

decision and reasons for it. The APVMA must also consult coordinators in jurisdictions about any variations that would require a change to the use instructions for a chemical product [Section 51G]. An applicant would have a minimum of 28 days to provide a written submission to the APVMA about the draft decision.

After the submission period, the APVMA must consider the views of the applicant and make a decision to reconsider the approval or registration or to vary the conditions or particulars of the approval or registration. The APVMA is to notify the applicant. A decision to vary particulars or conditions is reviewable by the Administrative Appeals Tribunal.

Item 16

This item updates the existing section 52 that deals with notices about approvals of active constituents and registrations of chemical products. The section has been amended to include requirements for continued approvals and continued registrations and to mirror the notice requirements for other applications that relate to approvals for active constituents and registrations of chemical products. This includes the publication of a material safety data sheet if the registration of a chemical product is continued.

Item 17

This item updates the existing section 54 that deals with notices about the end of registration of a chemical product. The section has been amended to include requirements for when the approval of an active constituent ends and to apply the same requirements that currently apply for when the registration of a chemical product ends. The amendments also update the existing offence provision to a more contemporary form and provide that it is also a civil penalty provision. The criminal penalty unit amount is unchanged.

Items 18, 19, 20, 21, 22, 23, 24, 25, 26, 27 and 28

These items amend the requirements for listed registered chemical products to mirror those for registered chemical products. The amendments introduce a new Division in the Code Act for a scheme for the continuation of listed registration, and include notice requirements that complement those for the continuation of registration for chemical products.

Item 29

This item updates the existing section 152 that deals with the liability of person acting on behalf of non-residents. The section has been amended to include requirements for the continuation of approvals or registrations.

Items 30 and 31

These items update the existing section 160A that deals with the notification of new information to the APVMA in respect of a pending application. The amendments extend the situations where an appropriate person must provide relevant information to the APVMA to include continuation applications.

Items 32, 33, 34 and 35

These items introduce the opportunity for review of decisions about continuation applications by the Administrative Appeals Tribunal (AAT), including where conditions or particulars are varied. While reviewable by the AAT, the amendments provide that a decision about a continuation application cannot be reconsidered under section 166 by the APVMA, given the draft decision and opportunity for comment process.

Item 36

This item specifies the transitional provisions for this Schedule and allows the APVMA two years to notify approved persons of the day on which a continuation application is required. The amendments

provide that the first continuation date be not later than 15 years from commencement and not less than 7 years from the original registration date.

Item 37

This item is a transitional provision that allows existing conditions to remain in force in accordance with any period in those conditions.

3. Chapter 3 – Improving quality and efficiency of assessment and registration processes

3.1 Summary

Schedule 3 of the draft Bill includes amendments to the Code Act to streamline application processes. It is in two parts with the first part dealing with electronic communication and the second part dealing with other amendments for streamlining application processes. Electronic lodgement would reduce the amount of time and effort applicants spend preparing and submitting applications and reduce the opportunity to make an incorrect or incomplete application that would subsequently be refused.

Aspects of the current approval and registration system can lead to delays in assessing and finalising applications for agvet chemicals. In some cases, delays occur as a result of processes that require the APVMA to focus its resources on aspects of the system that do not result in improved regulatory outcomes. In other cases delays occur because applicants submit inferior applications that the APVMA then provides assistance on improving. In addition, the reconsideration process for approvals and registrations (commonly called chemical reviews) can be unnecessarily delayed through misuse of the provisions that enable applicants to provide data at any time. This can require the APVMA to delay the outcome of a reconsideration while it continually assesses new information and while chemicals under review remain on the market.

The government considers that there is a need to implement a number of measures to improve the quality of applications for approval or registration and improve timeliness of application assessment. The proposed measures would require the APVMA to only assess applications that are of the required standard and to refuse inferior or deficient applications. The proposed measures preserve access to data protection where applications are refused. The measures would also provide for the consistent and predictable completion of assessments within appropriate timeframes, and better align regulatory effort with the assessment required for the particular application. In addition the government has decided to implement measures to address the timeliness of chemical review to reduce the current backlog and provide for consistent completion of assessments within appropriate timeframes.

Overseas data, assessments and regulatory decisions are currently used in Australia's agvet chemicals regulatory system. The government has decided to encourage the APVMA and its regulatory partners to make more effective use of data from trials and experiments conducted overseas and the work conducted by comparable overseas agencies, which have applied a compatible approach, to the extent possible considering Australian conditions. The changes would ensure that there is no undue impediment to the increased use of overseas data and assessments (where conducted by comparable agencies) by the APVMA and its regulatory partners in their consideration of agvet chemical use in Australia.

The amendments:

- facilitate electronic lodgement of applications and supporting documentation to the APVMA
- prevent an applicant from amending an application after it has been accepted by the APVMA (item 13)
- limit the APVMA's preliminary assessment to administrative criteria and require the APVMA to refuse applications that are found to be deficient at preliminary assessment (without refund of fees). This would focus the APVMA's resources on complete applications
- require the APVMA to refuse applications where applicants do not provide information, reports or samples within set timeframes, with no refund of fees
- set a time limit (in regulations) for the APVMA consideration of the total elapsed time for the application assessment process, including the time between when the APVMA makes a requirement of an applicant and the applicant complies. Any extensions to set timeframes would be mutually agreed by the APVMA and the applicant

- introduce timeframes (in regulations) for reconsiderations of an approval or registration (chemical reviews) to reduce the backlog of chemical reviews (item 30)
- modify the provisions relating to reconsideration of decisions (section 166) to limit the reconsideration and review to particular circumstances and to those decisions where the APVMA is required to consider only specified administrative criteria when making a decision
- amend the Code Act to ensure no impediment to the appropriate use of overseas data, including information, assessments and decisions (item 31)

3.2 Detailed explanation

3.2.1 Part 1 – Electronic Communication

Item 1

This item inserts a definition of ‘electronic signature’ which refers to a new section that specifies the requirements for the giving of information in electronic form (section 156AA).

Item 2

This item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. The electronic lodgement of applications would result in administrative efficiencies.

Item 3

This item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. These measures mirror item 2 but relate specifically to applications for the variation of relevant particulars in a legislative instrument made by the APVMA (Division 2A of Part 2). The electronic lodgement of applications would result in administrative efficiencies.

Item 4

Consistent with item 2, this item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. These measures relate specifically to applications for the variation of relevant particulars or conditions of existing approvals or registrations (Division 3 of Part 2). The electronic lodgement of applications would result in administrative efficiencies.

Item 5

Consistent with item 2, this item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. These measures mirror requirements for other applications but relate specifically to applications for registration of listable chemical products (Division 4 of Part 2A). The electronic lodgement of applications would result in administrative efficiencies.

Item 6

Consistent with item 2, this item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. The item relates specifically to applications to vary relevant particulars or conditions of listed registration (Division 5 of Part 2A). These measures mirror requirements for other applications. The electronic lodgement of applications would result in administrative efficiencies.

Item 7

Consistent with item 2, this item inserts a new note identifying the option for electronic lodgement of applications if the APVMA consents, and directing the reader to section 156AA which deals with giving information in electronic form. The item relates specifically to applications for a permit for a

chemical product or an active constituent for an existing or proposed chemical product (Part 7). These measures mirror requirements for other applications. The electronic lodgement of applications would result in administrative efficiencies.

Item 8

This item inserts a new provision (section 156AA) providing for the provision of information to and from the APVMA in electronic form. Electronic provision of information reduces administrative costs e.g. the electronic lodgement of applications has resulted in administrative efficiencies.

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.

Item 9

Consistent with item 2, this item inserts a new note directing the reader to section 156AA which deals with giving information in electronic form, including information, a report or a sample of an active constituent or chemical product that the APVMA or another prescribed authority may request from an applicant, an interested person, an approved person or the holder of a permit (section 159). The purpose is to allow the optional lodgement of this information or reports in electronic form. These measures mirror requirements for applications. The electronic lodgement of information or reports would result in administrative efficiencies.

Item 10

Consistent with item 2, this item relates to information that an appropriate person must give to the APVMA if an application has been lodged with the APVMA (section 160A). The purpose is to direct the reader to section 156AA which deals with giving this information in electronic form. The electronic lodgement of information would result in administrative efficiencies.

Item 11

Consistent with item 2, this item relates to information that an interested person or holder of a permit must give to the APVMA if they become aware of relevant information about a constituent or chemical product (section 161). The purpose is to direct the reader to section 156AA which deals with giving this information in electronic form. The electronic lodgement of information would result in administrative efficiencies.

3.2.2 Part 2 – Improvements to Processes

Item 12

This item amends the definition of ‘acknowledge’ to remove the references to circumstances where defects in an application have been rectified and where an application is deferred. These circumstances are being removed from the definition because it is proposed the APVMA would refuse defective applications in the future and would therefore not need to require applications to be rectified or be deferred. The changes to the definition complement the proposed amendments to the consideration of applications changes in the items below.

Item 13

This item replaces an existing provision and has the effect of removing the option for an applicant to give the APVMA additional information after the application is made and before the APVMA has determined the application. This would mean that once an application is lodged, an applicant would not be permitted to provide additional or varying information about the application.

Applicants would continue to be provided with assistance in understanding the requirements that apply to their applications. This would be achieved with a transparent risk framework (see Chapter 1) and formalisation of arrangements for pre-application assistance.

Applicants would also retain the option of withdrawing applications at any time before the APVMA has determined the application. In addition, the APVMA would still be able to request a sample (section 157) or additional information of the applicant (section 159), and would be able to alter the application with the consent of the applicant (section 11(2)).

The amendments do not have any effect on section 160A (Notification of new information to the APVMA in respect of pending application) or section 161 (Notification of new information to APVMA) of the Code Act. For example, appropriate persons would still need to provide information to the APVMA which contradicts information previously given or which raises doubts about the safety or efficacy of the active constituent or chemical product.

Items 14, 15, 16, 17, 18, 19

These items amend section 11A of the Code Act to remove those provisions that relate to rectifying defects in applications or deferring consideration of applications following preliminary assessment. The removal of these provisions means that the APVMA must refuse an application that has defects and the APVMA would no longer have the option of requiring defects to be rectified or deferring consideration of an application.

The amendments remove subsection 11A(3) and amend subsection 11A(4). Together, these amendments require the APVMA to refuse an application if it does not comply with the application requirements currently set out in subsection 11(1). If an application is refused, then the application fees would be repayable, less any component of the fee that would be payable for the preliminary assessment. In addition, subparagraph 11A(5)(a)(iii) is amended so that the APVMA is no longer required to provide reasons as to why an application cannot reasonably be rectified. This does not affect the current subparagraph 11A(5)(a)(ii) which requires the APVMA to notify an approved person of the defects in the application. The amendments to subsection 11A(5) is necessary to ensure consistent use of the term ‘refuses’ or ‘refused’ throughout the section.

These changes work together with the other amendments in item 13 to place an onus on applicants to ensure that their applications are complete and suitable for assessment. It reduces the administrative burden on the APVMA and its partner agencies, and potentially improves the timeliness of their assessment.

Items 20 and 21

These items specify the information the APVMA is required to consider when considering applications for approvals of active constituents, registrations of chemical products, variations to relevant particulars or conditions of existing approvals or registrations. The purpose of these amendments is to confine the APVMA to the information specified in the new subsections and to specify that the APVMA need not consider other information provided to it. These amendments mean that the APVMA can complete the application consideration without more information continuing to be provided and continuing to delay the finalisation of the application. In turn, this would enable the APVMA to complete applications in accordance with prescribed timeframes (see below).

Items 22 and 23

These items specify the information the APVMA is required to consider when undertaking reconsiderations (chemical reviews). The purpose of these amendments is to confine the APVMA to the information specified in the new subsection 34(2A) and that the APVMA need not consider other information provided to it. These amendments mean that the APVMA can complete the reconsideration without more information continuing to be provided and continuing to delay the finalisation of the reconsideration. In turn, this would enable the APVMA to complete these reconsiderations in accordance with prescribed timeframes for reconsiderations (see below).

Item 24, 25, 26 and 27

These items mirror the above items 13 and 20, but apply for applications for and reconsiderations of registration of listable chemical products (Part 2A). The amendments would remove the opportunity for an applicant to give the APVMA additional information after the application is made and before the APVMA has determined the application. This would mean that once an application is lodged, an applicant would not be permitted to provide additional or varying information about the application. Applicants would retain the option of withdrawing applications at any time before the APVMA has determined the application. In addition, the APVMA would still be able to request a sample or additional information of the applicant (section 159), and would be able to alter the application with the consent of the applicant (section 56J(2)).

The amendments do not have any effect on section 160A (Notification of new information to the APVMA in respect of pending application) or section 161 (Notification of new information to APVMA) of the Code Act. For example, appropriate persons would still need to provide information to the APVMA which contradicts information previously given or which raises doubts about the safety or efficacy of the active constituent or chemical product.

Item 28

This item specifies the information the APVMA is required to consider for applications for permits. The purpose of these amendments is to confine the APVMA to the information specified in the new subsection 112(2B) and that the APVMA need not consider other information provided to it. These amendments mean that the APVMA can complete the permit application without more information continuing to be provided and continuing to delay the finalisation of the application.

Items 29 and 30

These items amend subsection 159(3) and delete subsection 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 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. The amendments would 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. This would reduce the administrative burden on the APVMA and its partner agencies, and improve the timeliness of their assessment.

Item 31

This item amends the existing provision that relates to the use of overseas trials and experiments by the APVMA (and its partner agencies) in assessing applications, reconsidering approvals and registrations and deciding whether to suspend or cancel permits. The purpose is to encourage the APVMA and its regulatory partners to make more effective use of work conducted by comparable overseas agencies, which have applied a compatible approach, and to the extent possible considering Australian conditions.

The circumstances where the section applies and where overseas data may be used are unaffected e.g. applications for a proposed chemical product, reconsideration of the approval of an active constituent, continuation application. The amended provision now specifically refers to information, decisions and assessments undertaken by relevant foreign regulatory authorities. The amended provision therefore specifies that the APVMA may take these matters into account when performing its functions and exercising its powers. However, the amended provision also requires the APVMA to take into account 'any significant differences in the way decisions or assessments 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.

Item 32

This item relates to time periods in which the APVMA must determine an application (section 165). The purpose of the item is to allow the regulations to specify time periods that take account of the total elapsed time for all components of the assessment process, including the time between when the APVMA makes a requirement of an applicant and the applicant complies. These time periods would take into account any extended time period for an applicant to comply with an APVMA requirement that is imposed during the assessment of the application.

The current provisions have resulted in a situation where the APVMA makes an assessment of the completeness of the application to comply with section 11A and combines this with a preliminary technical assessment of application components. Current legislation requires that the defects found in preliminary assessment are addressed before the time period provided by section 165 can commence. It is intended to replace this current approach with a model which takes account of the total elapsed time for all components of the assessment process but which commences only after the application is accepted by the APVMA following preliminary assessment. The time periods for full evaluation of the application would be included in regulations. The regulations would specify an assessment period (where the APVMA does not make a requirement of an applicant) and a maximum assessment period (where the APVMA makes any requirement of an applicant). These time periods would include time required for public consultation.

Should the APVMA make a requirement of the applicant, the applicant must address the requirement within a stated period. The period would be agreed by both the applicant and the APVMA (agreed period). Should agreement not be reached and should the applicant not withdraw the application, the APVMA is to determine the application as it stands, with the possibility of its being refused. The agreed period will take account of the time the APVMA would require to assess the new information and finalise the application. The APVMA must refuse an application if, after reaching agreement, the applicant does not satisfactorily meet the requirements.

Item 33

This item relates to time periods in which the APVMA must reconsider approvals and registrations (known as chemical reviews). The purpose of the item is to allow the regulations to specify time periods for the APVMA to conclude chemical reviews. The time periods would exclude the public consultation time periods (section 32) and where the APVMA has required trials or laboratory experiments (section 33). Where a reconsideration arises from a continuation application (see Chapter 2), the time period would commence at a time to be determined by the APVMA.

At present, there is no requirement for the APVMA to determine a reconsideration of approval or registration within a particular period. In addition, approval holders or registrants submit new information to the reconsideration at any point in the process, and prolong registrations or approvals. Stipulating time frames would reduce the backlog of chemical reviews.

Item 34

This item amends the provisions relating to reconsideration of decisions (section 166) to reflect the changes made to the consideration of applications by the APVMA. The purpose of this item is to specify the reconsideration of decisions to those decisions that are reviewable by the Administrative Appeals Tribunal and those decisions where the APVMA is required to consider only particular matters when making a decision about an application.

Items 35 to 44

These items amend the provisions relating to review of decisions (section 167) to reflect the changes made to the consideration of applications by the APVMA, including where the APVMA must refuse

an application and where it may no longer defer an application. The purpose of these items is to ensure the opportunity to review decisions does not include those decisions where the APVMA is required to consider only particular matters when making a decision (recognising that a person may seek to have the APVMA reconsider its decision in these circumstances).

Item 45

This item specifies when the amendments in Schedule 3 apply. Most new requirements apply on or after the day that the item commences. To ensure an orderly application of new requirements, there are some exceptions, including for certain applications and reconsiderations at certain stages of consideration.

4. Chapter 4 – Enforcement

4.1 Summary

Schedule 4 of the draft Bill includes amendments to the Admin Act, the Code Act and the Levy Act (agvet chemical legislation) to improve the ability of the APVMA to efficiently administer its regulatory decisions, and to protect public health and safety and the environment.

Compliance enforcement involves the assessment of the risk posed by the non-compliant behaviour and the application of enforcement responses to breaches of agvet chemical legislation that are appropriate in the circumstances. The APVMA currently employs three distinct strategies in its efforts to ensure compliance. The strategies involve prevention (awareness and understanding of obligations), quality facilitation (publication of standards and guidelines, licensing scheme for manufacture of veterinary chemical products and an adverse experience reporting program) and monitoring and enforcement (through recalls, warnings, injunctions and in extreme circumstances criminal prosecution).

The government considers that the existing statutory framework for the APVMA limits its capacity to manage compliance through both monitoring and enforcement, and is insufficient to deter non-compliance. For example, all offences currently described in agvet chemical legislation are criminal offences. Criminal prosecution is not a suitable response option in many instances, and there is a concern that some individuals and companies deliberately flout the legal requirements in the knowledge that such prosecution is considered a disproportionate response to lesser scale non-compliant behaviour.

More options are needed to allow the APVMA to respond in a proportionate and graduated manner to the risk posed by non-compliant behaviour. The inclusion of civil penalties is an example of providing the APVMA with alternatives to deal with breaches when criminal prosecution is not warranted. Civil penalties can also be a more appropriate mechanism for addressing improper corporate behaviour. Civil penalties would not apply for all offences under agvet chemical legislation as criminal penalties are more appropriate in certain cases.

Although some breaches may be minor in terms of risk, the financial gain that companies may derive from certain behaviour can vary widely depending on the nature of the breach and the size of the market involved. Therefore, the level of some penalties currently provided in the Code Act, the Admin Act and the Levy Act need to be increased to provide a penalty proportionate to the potential gain.

The amendments provide the APVMA with a range of measures to use to effectively manage and deter non-compliance. The measures are similar to those available to other regulators under Commonwealth laws. The inclusion of these measures does not prevent the APVMA from continuing its existing strategies for maximising voluntary compliance, including continual improvement of the awareness and understanding of obligations, as well as the publication of standards and guidelines.

The amendments:

- provide the APVMA with a range of compliance and enforcement powers to improve and streamline evidence collection, provide the ability to direct improvements in compliance, divert less serious non-compliance from the court system and strengthen penalties for serious non-compliance (see below).
- enhance existing controls on active constituents and products to ensure their ongoing quality and integrity by providing for statutory conditions of approval or registration to be varied
- include specific provisions for regulating counterfeit products
- provide for the APVMA to suspend or cancel approvals, registrations and permits, including where there is an imminent risk to public health and safety (including without notice) or where false or misleading information has been provided
- include new offences for breaching conditions of a permit
- allow a prosecution for an offence to be brought within two years from the date of discovery or

- within three years of the commissioning of an offence (instead of the current two years)
- provide for a court to award that the APVMA's costs of chemical analysis and related activities to be offset upon a conviction or a decision in favour of the APVMA

Attachment A contains general information about the changes to compliance and enforcement.

4.2 Detailed explanation

Items 1 and 2

These items remove the definitions of 'occupier' and 'premises' as these are no longer required in the Levy Act. These definitions are only relevant for monitoring and investigation powers. Monitoring and investigation powers are in the Admin Act and these would apply for the purposes of the Levy Act, and there is therefore no need to duplicate them in the Levy Act.

Items 3 and 4

These items update an existing offence provision under the Levy 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 Levy Act (section 15). The update to the offence provision maintains the existing strict liability of the offences but increases the penalty from 30 penalty units to 50 penalty units. A 'penalty unit' is defined by reference to the *Acts Interpretation Act 1901*.³ At present, a penalty unit is \$110. This brings the penalty in line with other penalties in agvet chemical legislation. 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 Levy Act, including monitoring and investigation powers, warnings and enforceable undertakings.

Item 5

This item removes reference to a redundant provision (reference to a section in Division 1 of Part 2 of the Levy Act) and updates the existing offence provision in the Levy Act that relates to failing or refusing to comply with a requirement to provide information to the APVMA about disposals of chemical products. The update to the offence provision maintains the existing strict liability of the offence and specifies that the physical elements of the offence are set out in the existing subsection 20(1) (e.g. give information to the APVMA).

The amendments also provide that civil penalties may be imposed against a person who contravenes subsection 20(1)(civil penalty provision), as provided for in Part 9A of the Code Act and section 69EK of the Admin Act. A civil penalty provision provides the APVMA with more flexibility in requiring information about disposals of chemical products, and subsequently the levies that are payable. This includes providing for civil penalty orders to be made for contravening a civil penalty provision, including pecuniary penalty orders.

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.

Item 6 and 7

These items repeal the monitoring and investigation powers in the Levy Act as these are no longer required in the Levy Act. Monitoring and investigation powers are in the Admin Act and these would apply for the purposes of the Levy Act. The co-location of these powers makes it easier to maintain them in a consistent and contemporary form, including making them easier to amend as required.

³ The *Acts Interpretation Act 1901* was amended by the *Acts Interpretation Amendment Act 2011* to define 'penalty unit' in section 2B by reference to section 4AA of the *Crimes Act 1914*. This bill is expected commence after the *Acts Interpretation Amendment Act 2011*.

Item 8 and 9

These items update an existing offence provision under the Levy 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 existing 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. 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 Levy Act, including monitoring and investigation powers, warnings and enforceable undertakings.

Items 10 to 24

These items introduce new definitions into the Admin Act including for ‘civil penalty order’, ‘civil penalty provision’, ‘Collection Act’ and ‘evidential burden’. These definitions relate to later provisions which introduce civil penalty provisions into the Admin Act.

Item 25

This item stipulates that the authority to issue notices to attend, give information or produce documents under the Code Act 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 *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*⁴.

Item 26

This item amends provisions in the Admin Act to introduce a new amount that may be credited to the APVMA Special Account (see Division 1 of Part 7 of the Admin Act). The purpose of this amendment is to allow the APVMA to credit costs and expenses that the APVMA incurs in taking samples, inspections or analysis during the investigation of an offence or civil penalty provision (new section 149A) to the APVMA Special Account.

Item 27 and 28

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

Items 29 to 35

In addition to allowing for the existing offence provision to be a civil penalty provision (see Attachment A as it relates to civil penalty provisions), these items introduce the option for the APVMA to apply conditions to any exemption relating to the importation of an active constituent or chemical product, including an existing exemption. Provisions allowing for conditions to be applied to the import of unregistered or unapproved chemicals via the existing permit system would facilitate a more efficient and effective control of otherwise prohibited material (e.g. in emergencies).

Items 36, 37, 38 and 39

These items introduce headings for new subdivisions in the Admin Act to improve readability of the Admin Act.

Item 40, 41 and 42

These items update existing offence provisions under the Admin Act. These provisions relate to providing annual returns about the import or manufacture of active constituents or chemical products, as well as maintaining records of imports, manufacture, use and dealing with active constituents or chemical products. These provisions also refer to complying with directions from inspectors.

The update to the offence provisions maintains the existing strict liability of the offences but increases the penalty from 30 penalty units to 50 penalty units. The amendments also provide that the offence in

⁴ Available from <http://www.ag.gov.au>

relation to providing annual returns is a civil penalty provision. This brings the penalty in line with other penalties in agvet chemical legislation.

Item 43

This item replaces the existing powers of entry, search and seizure in the Admin Act with a new Part that specifically deals with investigative powers. The amendments relate to monitoring and investigation powers, and include updates to existing entry, search and seizure provisions to bring them into line with contemporary standards.

Warrants are essential tools for furthering investigations as they authorise the regulator to enter premises to gather evidence. The amendments include updates to the specific rules about how inspectors enter premises and how they conduct themselves, and the specific rights and responsibilities of the occupier of premises in relation to how the monitoring and investigation powers are exercised.

The powers, as amended, are similar to those available to other Commonwealth regulatory agencies (e.g. Therapeutic Goods Administration). The powers authorise the use of reasonable force when executing an investigation warrant. The powers also include the authority to require people to provide information or produce documents or things, by notice issued to an approved person or interested person. These powers, which will only be used to respond to non-compliance and not for the purpose of compelling information to assist the conduct of a review, are described in Attachment A.

Unlike other Commonwealth legislation, the Admin Act does not currently provide that it is an offence to fail to provide reasonable facilities and assistance to an inspector to execute a warrant e.g. to enable access to business records held off-site on remote servers (e.g. cloud computing) and password protected devices (e.g. smart phones). The amendments address this anomaly by requiring this assistance and including a penalty of 30 penalty units for not complying with this requirement.

The amendments 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 Code Act is being complied with (section 69EB). The introduction of a monitoring warrant provision would ensure that the APVMA can enforce the Code Act where a business operates from a residence, and where a magistrate agrees access to residential premises is reasonable.

An inspector may be assisted by other persons but these persons must act in accordance with any direction given by the inspector (section 69EBD). 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 *Legislative Instruments Act 2003* (LI Act). Provisions stating this have been included in the draft Bill in relevant sections to indicate that an exemption from the LI Act is not sought or required.

Items 44 and 45

These items insert a new Part that deals with enforcement. The relevant provisions are described in more detail in Attachment A. The provisions relate to:

- the use of civil penalties to enforce civil penalty provisions (section 69EK);
- the acceptance and enforcement of undertakings to comply with provisions (sections 69EL and 69ELA);
- the issue of substantiation notices in relation to certain claims and representations (sections 69EM to 69 EMB);
- the issue of formal warnings in relation to suspected contraventions (section 69EN).

Item 46

This item updates existing offence provisions under 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.

Item 47

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

Item 48

This item provides for two new offences in relation to false and misleading information. The new offences are not strict liability offences. 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. This is considered a serious offence and the level of the penalty (300 penalty units) is the same as the current offence for importing an active constituent that is not approved or a chemical product that is not registered, reserved or exempt. The second offence relates to providing false or misleading information to an inspector. The level of penalty (60 penalty units) is consistent with the penalty comparisons relating to false representations in *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*. The amendments also remove a section that relates to the copying of documents by inspectors, as this authority is provided for by the new powers of inspectors.

Items 49 and 50

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

Item 51

This item relates to the function of inspectors that the APVMA CEO may authorise. The deletion of the word 'particular' would allow 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 Levy Act and the Code Act.

Items 52 to 69

These items include new definitions in the Code Act. These definitions are required to make it clear that certain terms have particular meanings in the Code Act.

Items 70 and 71

These items include a table of provisions that identify the physical elements associated with relevant civil penalty provisions. This clearly identifies those matters that need to be considered.

Item 72

This item amends the existing provisions that authorise the APVMA to impose conditions on the approval of active constituents or registrations of chemical products. The amendments allow the APVMA to apply conditions that are either the conditions the APVMA thinks appropriate at the time of the approval or registration, or conditions prescribed by the regulations (whether or not the conditions are prescribed at the time the approval or registration is granted).

While the existing section 23 provides that the APVMA may apply conditions, this is currently only able to be exercised 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 amendment addresses this by allowing for conditions to be imposed after approval or registration with these conditions to be prescribed in regulations.

The conditions are able to be expressed in relation to particular active constituents or products; classes of constituents or products; or all constituents or products. The amendment aligns the conditions that may be imposed for active constituents and chemical products with the conditions that may currently be imposed for approval for chemical product labels (existing section 23A).

Items 73 to 78

These items amend the existing offence provisions to provide that these are civil penalty provisions (see Attachment A as it relates to civil penalty provisions). The level of the criminal penalty is unchanged from the existing offence provision.

Item 79

This item introduces a new provision into the Code Act (section 35A) that allows the APVMA to suspend or cancel an approval or registration without prior notice, where a failure to suspend or cancel this approval or registration would create an imminent risk to public health or occupational health and safety. This measure provides an essential means to take action in those situations where action is necessary to protect people.

Item 80

This item introduces a new provision into the Code Act (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 such a provision would also better protect the community and the environment and limit any commercial benefit obtained through fraud.

Unless the continued approval or registration would create an imminent risk to public health or occupational health and safety, 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 interested person and approved persons to provide submissions on the proposed suspension or cancellation. This approach is similar to that used in section 21N of the *Industrial Chemicals (Notification and Assessment) Act 1989* for commercial evaluation permits.

Any APVMA decision to suspend or cancel approval or registration would be subject to reconsideration of the decision and Administrative Appeals Tribunal review.

Items 81 to 110

These items amend the existing offence provisions to provide that these are now also civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions.

Item 111

This item amends a reference in an existing provision to reflect the changes made to the monitoring powers of inspectors (see below).

Items 112 to 120

These items amend the existing offence provisions to provide that these are civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions.

Items 121 to 131

These items amend the existing offence provisions to provide that these are now also civil penalty provisions. The level of the criminal penalty has been increased from 30 penalty units to 60 penalty units in section 88 and section 89. This brings the penalty in line with other penalties in agvet chemical legislation.

Items 132, 133 and 134

These items amend the existing offence provisions to provide that these are now also civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions. A new section 91A has been created and the existing requirements for supplying a date-controlled chemical product after its expiry date have been included in this section for clarity.

Item 135

This item introduces a new division in the Code Act that deals with counterfeit active constituents and chemical products. A chemical product or active constituent is counterfeit if certain representations about the constituent or product are false, including the name, the source or the name of the manufacturer. While current indications are that there is limited supply of counterfeit products in Australia, counterfeiting of active constituents or chemical products is an emerging worldwide problem. To ensure the widest response options are available to the APVMA civil penalty provisions also apply to counterfeit products. The provisions mirror those currently in therapeutic goods legislation.

Items 136 to 140

These items amend the references in existing provisions to reflect the changes made to the monitoring powers of inspectors (see below).

Items 141 to 144

These items amend the existing offence provisions to provide that these are civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions.

Items 145 to 149

These items amend the definition of ‘permit’ so that it reflects the new civil penalty provisions and the new section 91A (created by splitting the existing section 91 into two separate sections). The amended sections also now refer to sections 121A and 121B. The amendments therefore extend the situations where the APVMA may issue a permit to include the manufacture of chemical products in contravention of sections 121A or 121B, where there are exceptional circumstances.

Item 150

This item updates the existing provision about the duration of permits to include reference to the new sections relating to cancellation of permits (see below).

Item 151

This item inserts a new offence into the Code Act for contravening the conditions of a permit. The APVMA may issue permits that allow the legal use, and with these amendments manufacture, of chemicals in ways that are different to that evaluated and approved or, in certain circumstances, the limited use of an unregistered chemical. Part 7 of Agvet Code describes the circumstances under which permits are issued, how applications are made and the criteria that APVMA considers to grant or refuse 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 agvet legislation. This is inconsistent with the other provisions in the Code Act 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 criminal penalty is 300 penalty units, which is consistent with the penalty for contravening the conditions for chemical products (e.g. section 79A). This item also establishes a civil penalty.

Items 152 to 156

These items introduce new provisions into the Code Act that allow the APVMA to suspend (sections 118 and 118A) or cancel (sections 119 and 119A) a permit. The amendments introduce new provisions into the Code Act (sections 118A and 119A) that allow the APVMA to suspend or cancel a permit where the APVMA considers it is necessary to prevent imminent risk to public health or occupational health or safety, animal welfare or impact on trade or commerce. The permit holder must be notified of any suspension period or when cancellation takes effect. This measure provides an essential means to take action in those situations where action is necessary to protect people, animals or trade.

The amendments also introduce new provisions into the Code Act (sections 118B and 119B) that allow the APVMA to suspend or cancel a permit where false or misleading information was provided as part of the application or subsequently at the request of the APVMA. The amendment provides 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.

Unless the permit would create an imminent risk to public health or occupational health and safety, animal welfare or impact on trade or commerce, the APVMA must give notice of its intention to suspend or cancel a permit in relation to false or misleading information, and provide reasons for its intended action. This provides an opportunity for interested person and approved persons to provide submissions on the proposed suspension or cancellation. Any APVMA decision to suspend or cancel approval or registration would be subject to reconsideration of the decision and Administrative Appeals Tribunal review.

These new provisions mirror those provisions that relate to approvals for active constituents and registrations of chemical products. The amendments update the existing provision about the duration of permits to include reference to the new sections relating to cancellation of permits (see above).

Item 157

This item repeals a provision that is no longer required. The provision related to the commencement of section 121 when the Code Act commenced, and detailed that the section did not commence until 12 months after the commencement of the Code Act. As the Code Act has been in force for nearly twenty years, this provision is no longer necessary.

Item 158

This item amends the existing offence provisions relating to manufacture of prohibited chemical products and licensing for manufacture of certain chemical products. The item provides that the existing offence provisions are also civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions. A new section 121A has been created and the existing requirements as they relate to licensing for manufacture of certain chemical products have been included in this section for clarity. A new section 121B has been created and the existing requirements as they relate to complying with licence conditions have been included in this section for clarity.

The amendments also remove all reference to the commencement provisions for section 121. These provisions related to the commencement of section 121 when the Code Act commenced, and detailed elements of the section that did not commence until a date prescribed in the regulations or 12 months after the commencement of the Code Act. As the Code Act has been in force for nearly twenty years, these provisions are no longer necessary.

Item 159 to 162

These items relate to the licensing of manufacturing of chemical products. The amendments provide for new conditions of manufacturing licences to be imposed where the action is necessary to prevent

imminent risk to animal welfare, as well as update the existing provisions for suspending or cancelling licences as they relate to manufacture of chemical products.

The current paragraph 127(1)(c) provides for cancellation of a licence if the holder has failed on more than two occasions in any 12 months to comply. However, there may be significant timeframes between the committing of an offence and when the regulator becomes aware of it through the regular audit program. The current provisions excessively restrict timely action being taken in relation to breaches of licences. The amendments address this by removing all reference to the number of non-compliance occasions and the timing for these non-compliances. The amendments retain reference to compliance with manufacturing principles in connection with the manufacture of chemical products as a matter that the APVMA may consider is suspending or cancelling a licence. These manufacturing principles are determined by the APVMA and may include codes of good manufacturing practice. To encourage compliant behaviour, the amendments also include that non-compliance in the last five years only is to be taken into account in considering whether to issue, suspend or cancel a licence. This amendment provides greater certainty for businesses compared to the current “two occasions in any 12 months” requirement.

In addition, the amendments provide that the APVMA must also consider the likelihood of imminent risk of unintended harm to animals in considering whether to suspend or cancel a licence in relation to manufacture of chemical products. Currently, section 127(2) allows the APVMA to suspend or cancel a licence without prior notice if the failure to suspend or cancel would create an imminent risk to public health or safety or to trade. Section 127 of the Code Act sets out the procedure for suspending or cancelling a licence if the circumstances in s 127(1) apply. However, this procedure does not include imminent risk of unintended harm to animals as a reason for immediate action. This prevents the APVMA from taking prompt action where there is imminent risk to animal health or welfare. The amendments address this anomaly.

Items 163 to 172

These items introduce a new Part into the Code Act that deals with investigative powers. These relate to monitoring and investigation powers. The amendments include updates to existing entry, search and seizure provisions to bring them into line with contemporary standards and comparable regulators. Search warrants are essential tools for furthering investigations as they authorise the regulator to enter premises to gather evidence. The amendments include updates to the specific rules about how inspectors enter premises and how they conduct themselves, and the specific rights and responsibilities of the occupier of premises in relation to how the monitoring and investigation powers are exercised.

The powers, as amended, are similar to those available to other Commonwealth regulatory agencies (e.g. Australian Competition and Consumer Commission, Therapeutic Goods Administration). The powers include the authority to require people to provide information or produce documents or things, by notice issued to an approved person or interested person. These powers are described in Attachment A.

Unlike other Commonwealth legislation, the Code Act does not currently provide that it is an offence to fail to provide reasonable facilities and assistance to an inspector to execute a warrant e.g. to enable access to business records on remote servers and password protected devices. The amendments address this anomaly by requiring this assistance and including a penalty of 30 penalty units for not complying with this requirement.

The amendments also allow an inspector to enter any premises with consent or with a warrant. This extends to private residential premises and allows inspectors to enter these premises to determine whether the Code Act is being complied with (section 131). The introduction of a monitoring warrant provision would ensure that the APVMA can enforce the Code Act where a business operates from a residence, and where a magistrate agrees access to residential premises as reasonable.

An inspector may be assisted by other persons but these persons 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 draft Bill in relevant sections to indicate that an exemption from the LI Act is not sought or required.

Items 173 to 181

These items update the existing provisions relating to seizure of things by inspectors. The provisions update the existing provisions to align them with other Commonwealth legislation (therapeutic goods legislation). In addition, specific requirements for disposal of seized things have been included to authorise the APVMA to dispose of seized things in a manner it considers appropriate. This recognises that some agvet chemical products may require special disposal arrangements.

Items 182 and 183

These items amend references in the existing provisions to reflect the changes made to the updating of the investigation powers.

Item 184

This item updates the existing provisions for certain expenses that the APVMA may recover from persons. It inserts a new provision that allows the APVMA to offset expenses associated with the disposal of a thing seized under an investigation warrant. This provision mirrors the existing provisions in section 142 that authorise the APVMA to recover expenses associated with disposing with things that have been forfeited to the Commonwealth.

Item 185

This item inserts new divisions to replace existing provisions with more contemporary requirements for applying for monitoring warrants (section 143) and investigation warrants (section 143A). These requirements are described in more detail in Attachment A and the requirements are consistent with other Commonwealth legislation (e.g. *Competition and Consumer Act 2010*).

Items 186 and 187

These items insert a new Part that deals with enforcement. The relevant provisions are described in more detail in Attachment A. The provisions relate to:

- the use of civil penalties to enforce civil penalty provisions (sections 145A to 145CE in the draft Bill)
- the use of infringement notices to enforce certain strict liability offences and civil penalty provisions (sections 145D 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 145GA)
- 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)

Item 188

This item provides for two new offences in relation to false and misleading information, removes the existing provision that relates to self-incrimination, amends the existing provisions for when prosecutions may begin and removes the provision relating to copying of documents.

The new offences are not strict liability offences. The first offence relates to providing false or misleading information in an application for approval of active constituent, registration of a chemical product, listed registration or permit. This is a serious offence and the level of the penalty (300 penalty units) is the same as the current offence. The second offence relates to providing false or misleading information to the APVMA in any other circumstance. The level of penalty (60 penalty units) is consistent with the penalty comparisons relating to false representations in *A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers*. The amendments also remove a section that relates to the copying of documents by inspectors, as this authority is provided for by the new powers of inspectors.

The existing provision (section 146) that relates to the privilege of self-incrimination has been removed and replaced with an updated provision (section 130C). The existing provision that authorises an inspector to copy documents (section 148) has been removed and included in a new provision under monitoring powers (section 131G).

The existing provision (section 147) that relates to when prosecutions must begin has been amended. The Code Act currently allows for a prosecution for an offence to begin within two (2) 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 existing provision has been amended to allow 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 existing provision has been amended to allow 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 189

This item includes a new provision in the Code Act (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). A provision to allow for offsetting costs in particular situations would ensure effective use of the APVMA's resources. The new provision 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. 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 costs that the APVMA may recover (section 142).

Item 190 to 193

These items relate to the existing provisions for providing new information to the APVMA in respect of a pending application, or providing new information to the APVMA generally. They amend the existing offence provisions to provide that these are civil penalty provisions. The level of the criminal penalty is unchanged from the existing offence provisions.

Items 194 and 195

These items update the provisions relating to review of decisions to reflect the other changes made to the Code Act. The amendments relate to decisions to suspend or cancel a permit because false or misleading information was provided as part of the application or information subsequently requested by the APVMA. The amendments provide that these decisions are reviewable by the Administrative Appeals Tribunal.

Item 196

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. This brings the penalty in line with other penalties in agvet chemical legislation.

Item 197

This item updates existing provisions in section 181 arising from the creation of the new section 91A (created by splitting the existing section 91 into two separate sections).

Items 198 to 202

These items deal specifically with when certain provisions commence, and are necessary to provide for an orderly introduction of new requirements. The amendments provide that the provisions relating to when proceedings must begin only apply to criminal proceedings that commence after the provisions commence i.e. they do not apply to current proceedings. In addition, the amendments provide that the provisions relating to offsetting costs and expenses only apply to criminal proceedings or proceedings for a civil penalty order that commence after the provisions commence i.e. they do not apply to current proceedings.

In determining the application of the reforms to give effect to the commitment to introduce a graduated compliance regime two broad categories were determined; one relating to conduct on or after the date of commencement and one applying to all conduct regardless of relationship in time to the commencement date.

The reforms are significant in that they introduce new offences, including for counterfeit active constituents and chemical products, as well as conformance with permit conditions. Other reforms include alternatives to criminal proceedings with civil penalty provisions and penalty infringement notices; alternatives to court proceedings; and enhanced evidence gathering tools. To ensure fairness, all civil penalty provisions would only apply for conduct after the date of commencement. Similarly, all offences relating to counterfeit active constituents and chemical products material and conformance with permit conditions, would only apply for conduct after the date of commencement.

Given the scope of reform, 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 these reforms from the day they come into force.

The reforms 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 give effect to an enhanced agvet regulation and improved efficiency within the APVMA compliance and enforcement activities.

Item 203

This item ensures that existing authorisations and regulations remain in effect.

5. Chapter 5 – Data protection

5.1 Summary

Schedule 5 of the draft Bill includes amendments to the Code Act to further protect data submitted for regulatory purposes and provide extra encouragement for innovation in the development of new agvet chemicals and protect data generators from unfair commercial use by competitors.

The research required for an agvet product registration or reconsideration is very detailed and requires investment of significant resources. The Agvet Code currently contains provisions that protect information submitted to the APVMA, by limiting the circumstances in which the APVMA can use the information. This is known as data protection and is an additional form of intellectual property protection to that available under the *Patents Act 1990*.

Data protection is a common feature of agvet regulation in countries that have comparable regulatory systems to Australia. The protection of regulatory data provides extra encouragement for innovation in development of new agvet chemicals. It does so by preventing the APVMA from making decisions that rely on the information while it is protected to support other registrations and approvals. This protects the data owner from unauthorised use by competitors.

The government has decided to implement a number of measures to improve data protection in relation to applications, expand the range of data that is eligible for protection (data provided in relation to chemical reviews and permits). The government has also decided to improve the protection for information submitted in relation to chemical review by changing the point at which protection will commence (from decision instead of from submission) and increasing the maximum protection period from 7 years to 8 years. Proposed amendments would also extend the notification requirements where access for protected information is required for reconsiderations.

The amendments:

- extend data protection compensation eligibility to data relating to use of products on animals that are not food producing animals (e.g. companion animals) and to efficacy data
- extend the period (to eight years) and point of commencement (from decision instead of from submission) of data protection for data provided as part of chemical reviews to remove disincentives for companies to invest in cutting edge technologies
- maintain data protection eligibility for data where an application including that data was withdrawn or where the APVMA decided not to grant the application
- maintain data protection eligibility for data that have been provided in relation to an application for a permit
- improve notification requirements to assist in the negotiation of access to data in relation to protected information relied on in a reconsideration

5.2 Detailed explanation

Items 1 and 2

These items amend 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 data protection eligibility to data relating to non-food producing species (e.g. 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 3

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 (performance of the constituent or product). 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.

Item 4

This item amends the existing definition of ‘protection period’ to extend the data protection period for data provided as part of a reconsideration (chemical review). The purpose is to extend data protection to eight years from when a chemical review regulatory decision is made.

The protection period for data submitted in relation to a chemical review 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.

The amendment to the definition of ‘protection period’ means that the data protection period for data provided as part of a chemical review is equivalent to data protection period for data provided as part of applications for new active constituents and new chemical products. This removes disincentives for investment in data to support reconsiderations, as data generators are more likely to be eligible for compensation if other applicants need to rely on these data.

Item 5

This item amends data protection eligibility requirements in section 34D. The purpose is to maintain the eligibility of data for data protection, where that data has previously been submitted but has not been protected as a result of a withdrawal of an application or an APVMA decision not to grant the application. Under the existing provisions, data submitted in relation to an application that was subsequently withdrawn or not granted by the APVMA is not eligible for data protection in relation to a subsequent application.

In addition, the amendment provides for data that was submitted in relation to an application for a permit to be eligible for protection when submitted in relation to an application for registration. This amendment does not establish a data protection regime for data submitted in relation to an application for a permit; rather it does not prevent it from being protected in relation to a later application.

Items 6, 7, 8 and 9

These items delete references to applications for companion animal products. Taken with items 1 and 2, the purpose of these items is to extend data protection eligibility to data relating to non-food producing species, including companion animals. The amendments mean that subject to other conditions in section 34D, the APVMA is prevented from using information provided for companion animal product applications in other applications or a reconsideration. This aligns data protection for companion animal products with data protection for other chemical products.

Item 10

This item amends the provisions in section 57 to align information which is eligible for compensation in relation to the reconsidered registration of an agvet product with the definition of protected information (*Item 3*).

Items 11

This item deletes the reference to information that was obtained merely for the purpose of assessing the performance of the constituent or product. The purpose of this item is to extend data protection eligibility to data relating to assessing the performance of an active constituent or chemical product.

Item 12

This item deletes reference to information for use only in relation to animals that are not food-producing species. Taken with the items above, the purpose of this item is to extend data protection

eligibility to data relating to non-food producing species, including companion animals. This would align data protection arrangements for companion animal products with other agvet chemical products.

Items 13, 14, 15, 16 and 17

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 applicant (the interested person that provided the protected information) is also informed when the APVMA notifies a secondary applicant that it cannot complete an application without using protected information. This would improve the transparency for protected information compensation arrangements. The amendments recognise that more negotiation over access to protected information are likely given the extensions to protection periods (e.g. item 5) and the extended range of information that may be protected (e.g. information relating to companion animals products).

Item 18

This item deals with the application of item 5 above. The amendment made by item 5 of this Schedule applies to an application under Part 2 or 2A of the Schedule to the Agvet Code whether made before, on or after the day this item commences. This means that data submitted in relation to an application that was withdrawn or refused, or a permit application prior to commencement of this amendment are not prevented from protection should a subsequent application be granted.

Item 19

This item deals with the application of items 13, 14, 15 and 17. These items deal with notices that are provided to parties which are involved in, or may potentially be involved in, mediation or arbitration about protected information compensation. The amendments apply in relation to notices given on or after the day this item commences.

Item 20

This item deals with information that is protected information under the current agvet chemical legislation. It provides that the information protected under the current agvet chemical legislation remains protected in accordance with that legislation.

6. Chapter 6 - Arrangements for collecting levy

6.1 Summary

For efficiency, transparency and to improve confidence in the APVMA, the government has decided to amend the Levy Act to provide the Minister for Agriculture, Fisheries and Forestry with the flexibility to nominate another Commonwealth agency to collect the APVMA's sales levy.

Schedule 6 of the draft Bill includes amendments to the Levy Act to enable any Commonwealth agency to collect the levy on product sales on behalf of the APVMA. The amendments would provide an opportunity to improve administrative efficiency and/or address the possible perception for a conflict of interest created by the APVMA collecting this levy itself. No change to the levy structure or rate is proposed by this draft Bill.

The amendments:

- authorise the minister to specify a collection agency in place of the APVMA in a legislative 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 Levy Act
- do not change the structure or rate of the levy

6.2 Detailed explanation

Item 1

This item inserts a new definition of 'Agency' that would be used to describe the term 'collecting agency' that is used throughout the Levy 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

This item inserts a new definition of 'collecting agency' that would be used through the Levy Act. The definition includes the APVMA and any other Agency that is specified in a legislative instrument.

Item 3

This item amends the existing definition of 'notional wholesale value' to reflect that other agencies other than the APVMA could be a collecting agency.

Item 4

This item inserts a new section that authorises the Minister to specify a collecting agency in a legislative 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 legislative instrument as a collecting agency.

Item 5 to 21

These items amend the existing provisions that refer to the APVMA to instead refer more generally to a 'collecting agency'. The purpose of these amendments is to provide any specified collecting agency with the same authority 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 as if it were the APVMA.

Items 22 and 23

These items insert a new provision that requires 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 outstanding levies.

Items 24 to 33

These items amend the existing 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 34

This item inserts a new section that allows a collecting agency to be reimbursed by the APVMA for its costs in collecting the levy, as well as a provision that deals with delegation. The provision relating to delegation is necessary to clarify the officers that can calculate, assess and notify about levies. The delegation only extends to Senior Executive Service (SES) employees or Acting SES officers of the appointed collecting agencies.

Item 35

This item amends an existing 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

This item inserts a new provision that validates past actions taken under the Levy Act for notices.

7. Chapter 7 – Miscellaneous

7.1 Summary

Schedule 7 of the draft Bill includes amendments to the Levy Act to remove redundant provisions as well as amendments to the Code Act to update certain provisions and remove redundant provisions. The amendments to the Code Act also include measures to clarify the information to be used in reconsidering decisions made under the Code Act.

Division 1 of Part 2 of the Levy Act dealt with the liability for levy payments from 1 January 1994 to 30 June 2005. This division is no longer relevant and it should be removed from the Levy Act along with other associated provisions in the Levy Act.

Section 166 of the Code Act provides for certain APVMA decisions to be reconsidered. The government has decided to limit the reconsideration of decisions to consideration of the decision based on the information available to the decision maker at the time the decision was made. However, this would not prevent a new application being made where new information can be considered. No changes are proposed to judicial review arrangements.

The amendments:

- amend the Levy Act to remove redundant provisions (items 1 to 6)
- amend the provisions relating to the reconsideration of decisions to clarify information that should be used in reconsidering a decision, specifically information that was available to the decision maker at the time the decision was made (item 19)
- amend the Code Act to remove or amend redundant provisions (items 10 to 12)

7.2 Detailed explanation

Item 1

This item amends the existing definition for the ‘prescribed date of payment’ to remove the redundant elements of the existing definition. The redundant elements [namely subparagraphs 3(1)(b)(i), (ii), (iii) of the existing definition] refer to sections in the redundant Division 1 – Liability for levy from 1 January 2005 to 30 June 2005 of Part 2 of the Levy Act (see item 4 below).

Item 2

This item amends the existing definition for the ‘rate of levy’ to remove reference to redundant provisions in Division 1 of Part 2 of the Levy Act.

Item 3

This item removes the definition of ‘relevant calendar year’ as it is no longer necessary, given that it is only used in Division 1 of Part 2 of the Levy Act, and this would be deleted (see item 4 below).

Item 4

This item removes Division 1 of Part 2 of the Levy Act as it no longer applies (applied till 30 June 2005). The ongoing liability for levies is contained in Division 2 of Part 2 of the Levy Act.

Items 5 and 6

This item removes reference to redundant provisions (reference to a section in Division 1 of Part 2 of the Levy Act).

Items 7, 8 and 9

These items relate to orders that may be made by the Minister under the Code Act, and remove references to redundant legislative instrument provisions and refer to the contemporary provisions for legislative instruments i.e. *Legislative Instruments Act 2003*.

Item 10

This item amends the definition of ‘material safety data sheet’ in the Code Act. The National Occupational Health and Safety Commission is now the Australian Safety and Compensation Council. Rather than continue to name an agency in the definition, the amendments generalise the definition to any material safety data sheet that is prepared in accordance with a national code of practice.

Items 11, 12 and 17

These items remove reference to section 158 from the Code Act. Section 158 was repealed in the *Agricultural and Veterinary Chemicals Code Amendment Act 2010*, so a reference to this section is no longer required.

Items 13 to 16

These items update existing provisions relating to standards for listable chemical products. The amendments clarify that standards prepared by the APVMA for listable chemical products are legislative instruments.

Item 18

This item amends section 166 that deals with the reconsideration of decisions by the APVMA. The purpose is to limit the reconsideration of decisions to the information that was available to the decision maker at the time the decision was made. The amendment does not prevent a new application being made where new information can be considered. The amendment does not affect other review arrangements (e.g. judicial review). The amendment applies to any reconsideration request made to the APVMA from the time the Schedule (and this item) commences.

Items 19 and 20

These items remove sections 173, 175, 177, 179, 182 and paragraph 184(a) from the Code Act as they are no longer necessary. The existing provisions relate to transitional arrangements for applications from before the Code Act commenced. 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.

Item 21

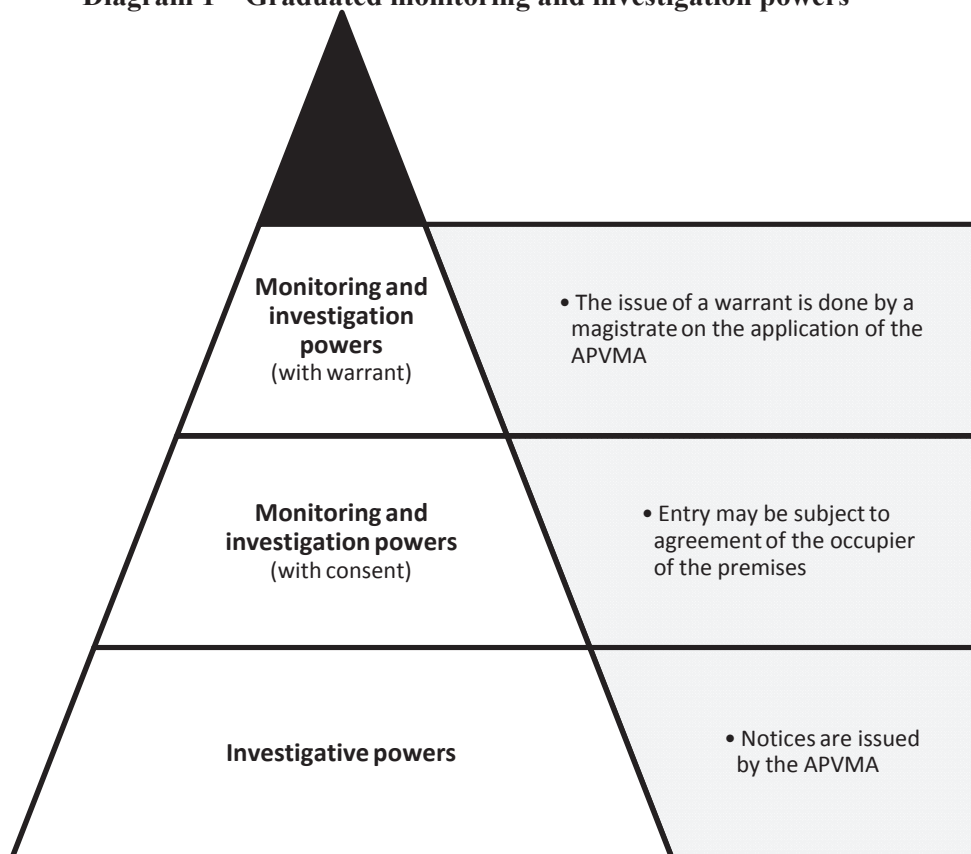
This item deals with the application of item 19 in relation to when the provisions in that item apply. It specifies that the requirements apply from commencement of Schedule 7.

Compliance and Enforcement

This attachment provides further detail about the range of compliance and enforcement measures in Schedule 4. Modern compliance strategies use investigative powers to ensure that relevant information is available and can be obtained. This information is then used to determine the most appropriate and proportionate manner to achieve compliance.

Modern compliance and enforcement can be represented diagrammatically. This is represented in the two following diagrams. The first diagram details the graduated approach for monitoring and investigation. The second diagram details the graduated enforcement powers that regulators may consider to achieve compliance in the particular circumstances. Each circumstance is different and the availability of a range of measures provides flexibility, and allows a regulator (APVMA) to apply the most effective and most appropriate measures in the particular circumstances.

Diagram 1 – Graduated monitoring and investigation powers



1. Monitoring and investigation powers

The draft Bill provides the APVMA with powers to seek and obtain information to ensure compliance with agvet chemical legislation. These replace the existing powers of entry, search and seizure. The powers have been included in both the Admin Act and the Code Act, and the powers in the Admin Act can be exercised for the purposes of the Levy Act. In some cases, the exercise of these powers is subject to court supervision. The relevant parts of the draft Bill are:

- Investigative powers that include the authority to require people to give information and produce documents or things through notices
- Monitoring powers to establish compliance with agvet legislation or correctness of information provided to the APVMA, including the authority to require a person to answer questions or produce documents
- Investigation powers to gather evidential material, with consent or with warrant, including seizure of things

1.1 Investigative powers

The draft Bill includes powers to let the APVMA monitor compliance with agvet chemical legislation, investigate possible contraventions and, where necessary, take enforcement action.

If the APVMA believes on reasonable grounds that a person has information, a document or a thing that is relevant to compliance with agvet chemical legislation, then it may require, by written notice, that person to give information, documents or things, or to provide copies of documents, within at least 14 days of the notice (section 130). A failure to respond to a notice is subject to a penalty of 30 penalty units or 6 months imprisonment or both (section 130B).

Once a person has complied with a notice, the APVMA may inspect the documents or copies produced and make its own copies of or take extracts from those documents. It may retain possession of any copies it makes. The APVMA may take and retain possession of documents produced for as long as is necessary. If a person is otherwise entitled to possess the document (for example, the person who supplied it), then that person is also entitled to a certified copy of the document provided by the APVMA (section 130A).

A person is not excused from giving information or producing a document because it might incriminate them or expose them to a penalty (section 130C) (see *Self-incrimination* below).

1.2 Monitoring powers

The APVMA may appoint inspectors who 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 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.

An inspector can enter premises and exercise monitoring powers to determine whether agvet chemical legislation is or has been complied with. With the consent of the occupier or a warrant issued by a court, this would extend to residential premises and allows inspectors to enter these premises to determine whether agvet chemical legislation is being complied with (section 131). Having entered the premises, an inspector may exercise a range of powers including asking the occupier to answer questions or produce relevant documents (section 131F), examine or test anything, photograph or record anything, copy documents, and operate electronic equipment to see if it contains relevant information (sections 131, 131A, 131B).

An inspector may be assisted by other persons but these persons must act in accordance with any direction given by the inspector. In specific circumstances, an inspector may also secure things for 24 hours (section 131C), and this period can be extended by a magistrate if notice has been given to the occupier of the premises.

The powers of inspectors can be exercised in the public areas of business premises without a warrant, including collecting advertising material, purchasing products and discussing product features with any person, although the occupier of the premises may refuse to allow the inspector on the premises.

In addition, inspectors may gather information and admissible evidence available by mail order or online, including purchasing products online (Section 131D).

1.3 Investigation powers

Specific investigation powers have been included in the draft Bill, including updated provisions relating to seizure of things (sections 139, 139A). These provisions mirror the monitoring powers (see above) but relate to gathering evidential material. The provisions also include existing requirements for inspectors to provide a receipt for seized things (section 139A) and new requirements for the disposal of seized things (section 141A).

If entry is authorised by an investigation warrant, the inspector may require any person on the premises to answer any questions, and produce any document, relating to evidential material specified in the warrant. A person must comply with this requirement and this is consistent with existing provisions. The amendments increase the penalty for non-compliance with this requirement from 30 penalty units to 50 penalty units, as this is consistent with the penalty associated with other similar provisions in agvet chemical legislation.

1.4 Self-incrimination

A person may be required to provide information or a document or thing to the APVMA or to answer questions put to the person by an inspector. A person cannot refuse to produce the information, document or thing, or answer questions because it might incriminate them or expose them to a penalty. However, the information or documents produced are not admissible in evidence against an individual in:

- civil proceedings for contravention of a civil penalty provision; or
- 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.

These provisions are consistent with provisions in other Commonwealth legislation and views expressed by the Senate Standing Committee for the Scrutiny of Bills, as well as the Australian Government's approach regarding the privilege against self-incrimination as set out in *A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers*. They ensure that self-incriminatory disclosures cannot be used against the person who makes the disclosure and enhance the ability of the APVMA to monitor and enforce compliance with agvet chemical legislation.

1.5 Limits on inspectors' powers

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 may be refused, subject to limitations or withdrawn. If consent is withdrawn, the inspector and any person assisting him or her must leave the premises (section 133)
- 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)

1.6 Warrants

Warrants were previously referred to as ‘offence related warrants’. 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’, because the warrants would relate to investigation of potential breaches of the criminal provisions and also potential contraventions of the civil penalty provisions. For this reason ‘monitoring warrants’ and ‘investigation warrants’ have been included in the draft Bill. Monitoring powers and investigation powers may be exercised with consent or with a warrant issued by a magistrate.

An inspector must apply to a magistrate for a monitoring warrant (section 143 – monitor compliance) or investigation warrant (section 143A – gather evidential material), 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.

A new provision has been included to allow a warrant that is issued in one jurisdiction (that is one State or Territory) to have effect and be executed in another jurisdiction (that is a second State or Territory). In such circumstances the warrant would state the location and jurisdiction in which it would be taken to have effect and be executed.

An investigation warrant may also be issued by electronic means (e.g. telephone) (section 143B). Specific provisions have been included to deal with when the execution of an investigation warrant has been interrupted (sections 138A, 138B).

The powers now include the authority for inspectors to use reasonable force against things when executing a warrant (sections 69EAG and 69EBE of the Admin Act and sections 131F and 132 F of the Code Act). 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 occupier of the premises must provide reasonable assistance and facilities to an inspector executing a warrant. A penalty of 30 penalty units has been included in the draft Bill for not providing this assistance or facilities. 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.

2. Enforcement powers, including civil penalties and criminal sanctions

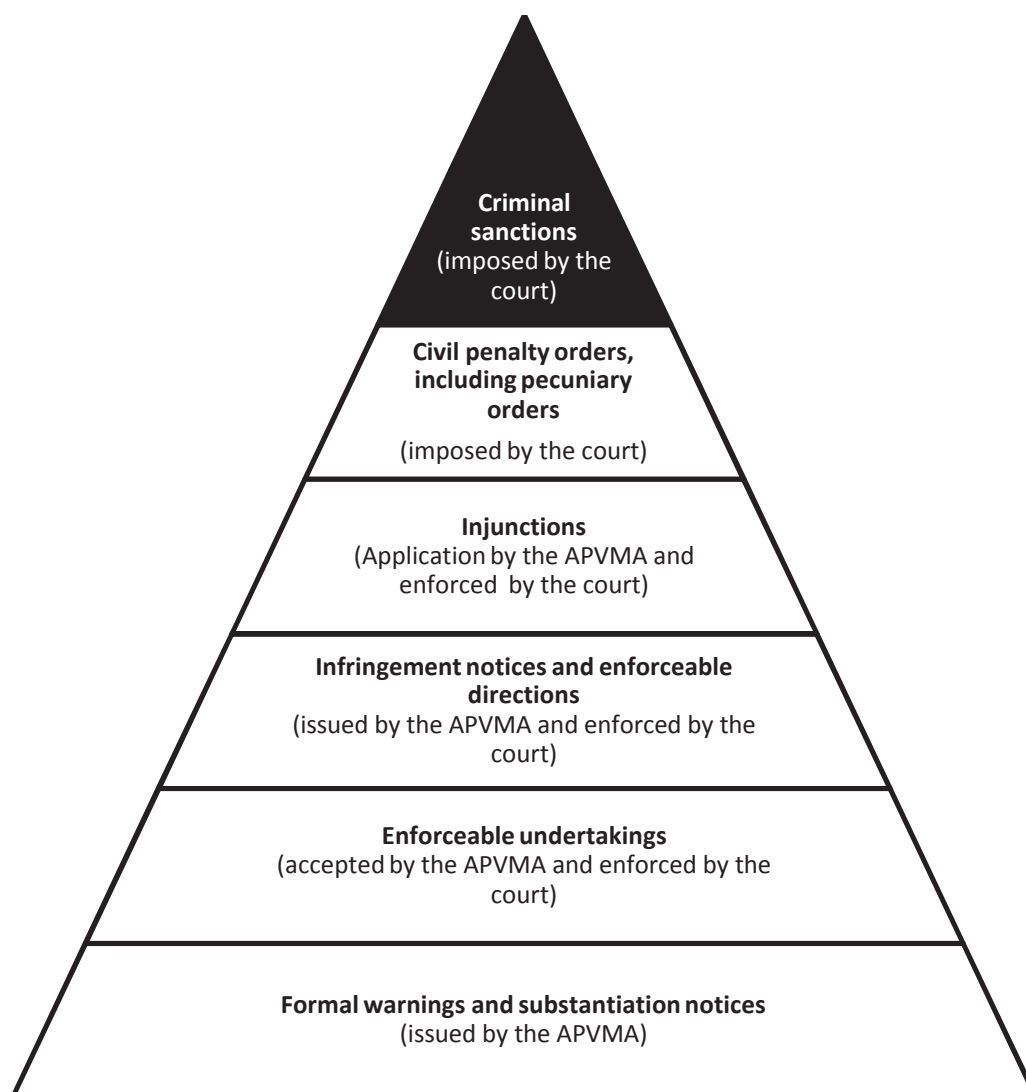
Enforcement powers in the draft Bill range in seriousness from formal warnings to criminal sanctions, including for provision of false or misleading information. The powers also provide for offsetting of reasonable costs and expenses of investigations (by court order).

The relevant parts of the draft Bill are:

- the use of civil penalties to enforce civil penalty provisions (sections 145A to 145CE);
- the use of infringement notices to enforce certain strict liability offences and civil penalty provisions (sections 145D 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);
- 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 substantiation notices in relation to certain claims and representations (sections 145G to 145GA);

- the issue of formal warnings in relation to suspected contraventions (section 145J).

Diagram 2 – Graduated enforcement powers



3. Civil penalty provisions and orders

The draft Bill provides that civil penalties may be imposed for contraventions of certain provisions. These civil 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. 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.

A number of penalty provisions in the draft Bill are civil penalty provisions in addition to being offence provisions. Ancillary contraventions, such as aiding a contravention, are also civil penalty provisions. These offences are also civil penalty provisions because some contraventions may not involve conduct of such serious moral culpability that criminal prosecution and sanctions are warranted. Further, as most liable entities are expected to be bodies corporate, the financial disincentives to misconduct provided by civil penalties are a more proportionate and effective enforcement tool, reflecting the practice of other areas of corporate regulation.

While the reasonable excuse defences have been removed from the offences that are now both offences and civil penalty provisions, a reasonable excuse defence is still available for the offences because the generic defences in Part 2.3 of the Criminal Code would apply.

3.1 The level of civil penalties

The levels of civil penalties in the bill reflect the seriousness of the contraventions, and represent clear and strong disincentives for non-compliance.

The integrity of the National Registration Scheme could be compromised by persons failing to comply with agvet chemical 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 (e.g. through providing unregistered chemical products or breaching registration conditions). In addition, penalties should be adequate for the worst possible case and it should reflect the seriousness of the offence in the legislative scheme. This approach is consistent with *A Guide to Framing Commonwealth Offence, Civil Penalties and Enforcement Powers*. On this basis, the civil penalty provisions are significant and the legislation provides for pecuniary penalty orders.

Except for multiple contraventions of civil penalty provisions, the draft Bill 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 a person other than a body corporate, 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 95A (counterfeit chemical products), the maximum penalty that a court could impose would be 7500 penalty units (i.e. 5 times 1500 penalty units) as 1500 penalty units is the maximum penalty (i.e. 5 times 300 penalty units) that could be imposed for committing an offence against that provision. For a person other than a body corporate the maximum penalty would be 900 penalty units (i.e. 3 times 300 penalty units).

The draft Bill also includes provisions that deal 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 the draft Bill 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.

Other than provisions relating to section 88 (publication of notices) and section 89 (prohibited statements), the criminal penalty provision maximum amounts in the Code Act and the Admin Act are unchanged from the current offence provisions. The penalty maximum has been increased for sections 88 and 89 (from 30 penalty units to 60 penalty units) and section 20 (providing information about chemical products disposals) in the Levy Act (from 30 to 50 penalty units) to more accurately reflect the nature of these offences, which could result in persons failing to comply with agvet chemical legislation.

3.2 The role of the court

Courts with sufficient jurisdiction may make civil penalty orders (section 145A). For these purposes a State and Territory court is a court with jurisdiction to decide matters covered by the draft Bill. 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. The court may have regard to all relevant matters in determining the amount of the penalty. To assist the court, the draft Bill identifies specific 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.

These factors reflect the approach indicated in *A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers* and follow the recommendations of the Australian Law Reform Commission's *Report 95: Principled Regulation: Federal Civil and Administrative Penalties in Australia*.

3.3 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.

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 civil penalty provisions in the draft Bill are framed in such a way as to alter the usual evidential burden, to place it on the defendant in certain circumstances. This approach is consistent with the guidance in *A Guide to Framing Commonwealth Offence, Civil Penalties and Enforcement Powers*, concerning situations where matters are peculiarly within the defendant's knowledge and not available to the prosecution.

In seeking a civil penalty order, 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 in the bill. A provision has been included (section 145CB) that makes it clear, for the avoidance of any doubt, 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.

3.4 Other provisions about civil penalties

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.

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, criminal proceedings may be commenced even if a civil penalty has been imposed for substantially similar conduct.

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, but 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.

4. Infringement notices

The draft Bill provides for the APVMA to issue penalty infringement notices (PINs) for contravention of certain provisions and these would be prescribed in the regulations. These infringement notices may only be issued to persons who are covered by the agvet 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 criminal proceedings. The application of PINs to

both criminal (where warranted) and civil offences would enable the APVMA to enhance the transparency of its compliance activities. The ability to issue PINs would align the APVMA's regulatory control options with those of other comparable regulators. The PIN must include specified information (new section 145DB).

PINs provide the greatest flexibility for tailoring a proportionate response to instances of non-compliance. Notices would be issued within 12 months of the offence and a PIN may be withdrawn by the APVMA. The infringement penalty by an individual must be the lesser of 12 penalty units or one-fifth of the offence maximum and for a body corporate the penalty must be the lesser of 60 penalty units or one-fifth of the offence maximum. The payment of the PIN discharges liability and would not be considered an admission of guilt. Non-payment would lead to exposure to further proceedings, including prosecution or civil proceedings. Provision is also made for a scale of amounts that may apply for alleged contraventions to be detailed in regulation.

5. Enforceable directions

The draft Bill provides for the APVMA to give an enforceable direction to anyone subject to agvet chemical legislation. This authority would be provided where the APVMA has information indicating that a person is not complying with agvet chemical legislation 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 with agvet chemical legislation.

The APVMA has found that with its existing powers it can 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 risk 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. 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.

6. Injunctions

As is the case now, the APVMA may 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 agvet chemical legislation. The terms of the injunction would be determined by the court but may include an order to undertake particular action.

The provisions in the draft Bill maintain the effect of the original section 130 of the Code Act which referred to injunctions.

7. Warnings

The draft Bill 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 agvet legislation. 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 against specific offence provisions in agvet chemical legislation, including the regulations. The regulations are to specify those offence provisions in relation to which a warning may be issued.

8. Substantiation notices

The draft Bill 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) (e.g. 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 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 (e.g. 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. 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. An offence for non-compliance with a substantiation notice of 50 penalty units has been included.

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.

9. Enforceable undertakings

The CEO of the APVMA may accept undertakings from an interested person or an approved person about their compliance with agvet chemical legislation. 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 agvet chemical 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 (e.g. ensuring on-going compliance with Good Manufacturing Principles requirements).

These undertakings may be accepted from persons who are covered by the agvet chemical legislation (e.g. interested persons). They cannot be imposed on persons that are not regulated by the agvet chemical legislation e.g. 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.

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 in the draft Bill in relevant sections 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 national regulators. However, where the APVMA considers that a person has breached any of the terms of the undertaking, it may 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; and
- any other order the court considers appropriate.

10. Liability for executive officers of body corporate

The draft Bill provides that executive officers of bodies corporate are liable for a contravention of a civil penalty provision by that body corporate in certain circumstances (section 145CD and 145CE). 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 (e.g. 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 145CD).

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 Code Act. This takes into account that the actions of an employee are attributable to the body corporate (section 145CC).

The draft Bill takes 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*.⁵

11. Notices to produce or attend

The draft Bill provides for the issuing of notices to produce or attend. Division 3 of Part 9 of the Code Act provides monitoring and enforcement powers for APVMA inspectors only when they are physically present at a location. The introduction of notices to produce or attend to answer specific questions would allow the APVMA to address lesser scale instances of non-compliance without physical attendance at the place of business. These notices would allow the APVMA to access appropriate individuals (e.g. operations manager) at a fixed place and time, while allowing these individuals time to arrange representation (e.g. legal representation), as required.

These notices would 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.

⁵ Available at <http://www.alrc.gov.au/report-95>. See pages 324-325.

These notices identify the inspector; the ‘person’ to whom the notice is issued; the specific information required; and the timeframe in which action is to be taken. The notice must contain all relevant details and generally allow a minimum 14 days for compliance. The existing self-incrimination privilege in section 146 applies in relation to these notices. Non-compliance with the notice is an offence and the maximum penalty is 30 penalty units or six months imprisonment or both (section 130B).