Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

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Law and Bills Digest Section

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The Bills Digest at a glance

Policy Commitment and Reform Developments

This Bill is a response to the Government’s 2010 election promise to improve the regulation of agricultural and veterinary chemicals in Australia—based on recommendations of the Australian National Audit Office and the Productivity Commission.

Key Features

The Bill primarily amends the Agricultural and Veterinary Chemicals Code (the Agvet Code) which is a Schedule to the Agricultural and Veterinary Chemicals Code Act 1994 to:

- through a risk-based approach, improve:
  - the consistency and transparency of the process for making, and assessing, applications for approval of an active constituent for a proposed, or existing, chemical product and
  - the registration of a chemical product and approval of a label for the containers of a chemical product
- insert a new requirement that existing approvals and registrations operate for a finite period and, when that period has elapsed, a new application must be lodged for re-approval or re-registration and
- update existing offences, create new offences and insert civil penalty provisions.

The Bill also amends the Agvet Code and the Agricultural and Veterinary Chemicals (Administration) Act 1992 to insert extensive monitoring and investigation powers, and include updates to entry, search and seizure provisions to bring them into line with contemporary standards.

In addition, the amendments will create a graduated range of compliance and enforcement powers, such as infringement notices and enforceable undertakings, which will allow the regulatory sanctions to be tailored to the seriousness of the noncompliance.

The Bill also amends the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 to allow any Commonwealth agency to issue notices regarding levy assessments and receive levy payments—in response to perceptions of a conflict of interest arising from the current arrangements.

Key Issues

Whilst the Bill is directed towards increasing the effectiveness and efficiency of agvet chemical regulation, stakeholders have questioned whether it, in fact, delivers increased complexity and higher costs for those seeking approval or registration and a greater regulatory burden for chemical and pesticide users.

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The underlying tension in the Bill is that applicants for approvals and registrations will also have to become more effective and efficient in the preparation of their applications or risk having them refused at the outset. There is also the risk that low value but widely used generic products will not be re-registered.

To promote compliance with the revised Agvet Code, the Bill overlays the existing regime of warning letters and criminal prosecution with updated civil penalty provisions. However, concern has been raised about the legal nature of these provisions (by both the Standing Committee for the Scrutiny of Bills and the Parliamentary Joint Committee on Human Rights) and whether the penalties that may be imposed are consistent with the Commonwealth Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers.
Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Date introduced: 28 November 2012

House: House of Representatives

Portfolio: Agriculture, Fisheries and Forestry

Commencement: Sections 1–4 on Royal Assent; Schedules 1–6 on 1 July 2013.

Links: The links to the Bill, its Explanatory Memorandum and second reading speech can be found on the Bill's home page, or through http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation. When Bills have been passed and have received Royal Assent, they become Acts, which can be found at the ComLaw website at http://www.comlaw.gov.au/.

Purpose of the Bill

The primary purpose of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill) is to implement reforms to processes for the approval, registration and reconsideration of agricultural and veterinary (agvet) chemicals by amending:

- the Agricultural and Veterinary Chemicals Act 1994 (Agvet Act)\(^1\)
- the Agricultural and Veterinary Chemicals (Administration) Act 1992 (Agvet Administration Act)\(^2\)
- the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code Act)\(^3\) and
- the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 (Agvet Levy Act).\(^4\)

Structure of the Bill

This Bill contains six schedules as follows:

- Schedule 1 amends the Agvet Code Act in relation to approvals, registrations, permits and licences


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Schedule 2 amends the Agvet Code Act in relation to re-approvals and re-registrations. Proposed Division 3A of Part 2 of the Agvet Code sets out the application process and proposed Division 6 of Part 2 of the Agvet Code deals with the duration of approvals and registrations, and with renewing registrations.

Schedule 3 amends the Agvet Code Act, the Agvet Administration Act and the Agvet Levy Act in relation to enforcement.

Schedule 4 amends the Agvet Code Act in relation to data protection.

Schedule 5 amends the Agvet Levy Act in relation to the arrangements for collecting the levy and

Schedule 6 amends the Agvet Levy Act, the Agvet Act, the Agvet Administration Act and the Agvet Code Act to make miscellaneous amendments.

Although this Bill amends a number of statutes, it is the Agvet Code which is the primary focus. The Agvet Code, set out in Schedule 1 to the Agvet Code Act, consists of eleven parts. Annexure 1 of this Bills Digest contains a table outlining the parts of the Agvet Code and the corresponding location of relevant amendments.

Background

Regulation of agricultural and veterinary chemicals

The regulatory framework for managing pesticides and veterinary medicines in Australia is collectively referred to as the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS). The NRS is a partnership between the Commonwealth and the states and territories. Assessment and registration of agricultural and veterinary (agvet) chemicals, as well as control of supply activities up to the point of retail sale, is undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of the use of agvet chemicals after sale is the responsibility of individual states and territories.

According to the Explanatory Memorandum:

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

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5. Registrants are required to pay levies based on the dollar value of sales on their registered products. A levy is payable on all sales for each product greater than $5000. Source: Australian Pesticides and Veterinary Medicines Authority website, ‘Fees and levies’, accessed on 12 March 2013, http://www.apvma.gov.au/registration/fees/index.php#levies


7. The APVMA is established under the Agricultural and Veterinary Chemicals (Administration) Act 1992.


The APVMA is a statutory authority established in 1993 to centralise the registration of all agricultural and veterinary chemical products into the Australian marketplace. Previously each state and territory government had its own system of registration.\(^{10}\)

The role of the APVMA is to independently evaluate the safety and performance of agvet chemicals intended for supply within Australia, ensuring that the health and safety of people, animals, crops, the environment and trade are protected. All registered products must be shown to work and be safe for people and the environment. Registered products also must not unduly jeopardise Australia’s trade with other nations.\(^{11}\)

**Reviews of APVMA and its processes**

**Australian National Audit Office**

In 2006, the Australian National Audit Office (ANAO) carried out an audit of the APVMA which examined the APVMA’s arrangements for, amongst other things, planning and overseeing the delivery of its regulatory functions and for administering its cost recovery framework.\(^{12}\) The ANAO took the view that:

> To underpin the integrity of its decision making processes, and to provide confidence to stakeholders, the APVMA needs to better manage the risk of actual or perceived conflict of interest. The APVMA’s arrangements for managing potential conflict of interest for some external service providers have, until recently, been inadequate. Aspects of the current arrangements also require strengthening.\(^{13}\)


\(^{13}\) Ibid., recommendation 12, p. 15.
Productivity Commission

In 2008, the Productivity Commission was tasked to undertake a research study examining the existing arrangements for the regulation of chemicals and plastics in Australia and to:

... assess the impact of current regulation on the productivity and competitiveness of the chemicals and plastics industry, Australian industry and the economy as a whole, together with the effectiveness of the regulations in addressing public health, environmental, and occupational health and safety issues, and substances of national security interest.\(^\text{14}\)

Amongst other things, the Productivity Commission concluded that:

The efficiency of APVMA assessments could be ... improved by rectifying the currently dysfunctional arrangements for registering low regulatory concern products and through greater use of international assessment data.\(^\text{15}\)

Policy commitment to better regulation

In response to these reviews and to complaints about the performance of the APVMA—particularly in relation to the cost and dilatory nature of the registration and review processes—the Australian Labor Party (ALP) promised in the lead-up to the 2010 election that it would:

... improve the regulation of agricultural and veterinary chemicals in Australia through the APVMA [and that] ... A key focus will be on the efficient assessment of lower-risk agricultural and veterinary (agvet) chemicals while ensuring that higher-risk agvet chemicals are assessed appropriately.\(^\text{17}\)

In making that election commitment, it was acknowledged that ‘inefficiencies in the system have led to a backlog of chemicals requiring review and a disincentive for companies to invest in cutting-edge Australian technology’.\(^\text{18}\)


\(^\text{15}\) Ibid., p. 199.


\(^\text{17}\) Minister for Agriculture, Fisheries and Forestry, \textit{Gillard Labor Government will support Australia’s agricultural industries into the future}, campaign media statement, 11 August 2010, p. 6, accessed on 12 December 2012, \url{http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22library%2Fpartypol%2F1DPX6%22}

\(^\text{18}\) Ibid.
Reform process

Following the 2010 federal election the Gillard Government released a policy discussion paper and sought public comment noting that:

The Australian Government recognises the system is not working as effectively as it should and is looking at options for reform, to better protect human health and the environment; and increase the authority’s efficiency and effectiveness.\(^{19}\)

The reforms outlined in the discussion paper were aimed at reducing the regulatory burdens on industry and businesses, and enhancing the APVMA’s business and operational functions.\(^{20}\)

Following the 2010 stakeholder consultation, a range of measures was developed and considered by the Australian Government.\(^{21}\) Prior to the introduction of this Bill, the Government issued both an initial exposure draft\(^{22}\) and a revised exposure draft\(^{23}\) of its proposed legislation for public comment. Announcing the release of the initial exposure draft of the legislation, the Minister for Agriculture, Fisheries and Forestry stated that the measures would improve the efficiency and effectiveness of agvet chemicals regulation by:

- making it simpler to know what is required before applying and lodging with the APVMA, while at the same time, making it easier and more efficient for the regulator to operate
- improving the APVMA’s procedures, timelines and quality requirements, for all stages of the assessment and registration process
- addressing stakeholder concerns about human health and the environment, by
  - introducing a requirement for chemicals companies to regularly demonstrate that their chemicals meet appropriate health and safety standards and
  - improving chemical review by encouraging more data to be submitted by improving intellectual property (that is, data) protection and placing time limits on the APVMA

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20. Ibid., p. 5.
• establishing an independent science panel to provide advice on the chemical re-registration regime and on chemicals assessment generally
• updating the APVMA’s compliance regime to improve the APVMA’s ability to effectively ensure compliance with its decisions and
• making it easier to understand the roles and responsibilities of government in agvet chemical regulation by codifying and publishing the risk framework for agvet chemicals regulation.24

The Bill as introduced has been subject to extensive consultation with key stakeholders with resultant refinements over a period of some two years. Under section 4 of the Bill the Minister must cause a review of the operation of the amendments to be conducted and for the report of the review to be tabled in each House of the Parliament within 15 sitting days of that House after 1 July 2018.

Committee consideration

Agriculture, Resources, Fisheries and Forestry Committee

The Bill has been referred to the House of Representatives Standing Committee for Agriculture, Resources, Fisheries and Forestry (the Agriculture, Resources, Fisheries and Forestry Committee) for inquiry and report.25 That report was tabled on 28 February 2013.26 The majority report of the Agriculture, Resources, Fisheries and Forestry Committee recommended that the Bill be passed.27 However the Coalition members provided a dissenting report which stated that the:

... Bill as is drafted provides a substantial increase in regulatory burden and costs that will have a negative impact on industry without significantly improving the efficiency of regulation and the re-registration process will slow down rather than increase the review of suspect chemistries. To achieve genuine efficiencies within the system that allow for a more timely review of suspect chemistries it is vital that the proposed re-registration process be removed from the bill.28

24. J Ludwig (Minister for Agriculture, Fisheries and Forestry) and N Sherry (Minister Assisting on Deregulation), Reforms a boost for agriculture and veterinary chemicals, joint media release, 15 November 2011, accessed on 12 December 2012, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22media%2Fpressrel%2F1230099%22
27. Ibid., p. 42.
28. Ibid., p. 52.
Rural and Regional Affairs and Transport Legislation Committee

The provisions of the Bill also have been referred to the Senate Rural and Regional Affairs and Transport Legislation Committee (Rural and Regional Affairs and Transport Committee) for inquiry and report. The Rural and Regional Affairs and Transport Committee published its report on 27 February 2013. The majority report of the Rural and Regional Affairs and Transport Committee recommended that the Bill be passed. However, both the Coalition Senators and the Australian Greens (the Greens) Senator provided dissenting reports. Essentially, the Coalition Senators were of the view that the Bill should not be passed in its present form. The Greens Senator considered that the Bill could be passed with the following amendments:

- a definition of unmanageable risk be included in the objects and the assessment triggers of the Bill
- a reference to the degradation products and metabolites as part of any reference to toxicity within the safety assessment criteria of the Bill be included
- the relationship between actions taken by foreign jurisdictions and Australian decision making be strengthened in the Bill and the regulations
- the onus of proof in the Bill be reversed so that chemical companies have to address data gaps in order to maintain registration.

Detailed comments from the dissenting reports are discussed under the ‘Key issues and provisions’ section of this Bills Digest.

Senate Standing Committee for the Scrutiny of Bills

The Senate Standing Committee for the Scrutiny of Bills (Scrutiny of Bills Committee) has published comments about the Bill in relation to those amendments which are perceived to trespass on personal rights and liberties. The Scrutiny of Bills Committee comments are directed at:

31. Ibid., pp. 27–30.
32. Ibid., pp. 31–35.
33. Ibid., p. 30.
34. Ibid., p. 35.
35. Senate Standing Committee for the Scrutiny of Bills, Alert digest no. 1 of 2013, 6 February 2013, accessed on 7 February 2013,
• trespass on personal rights and liberties arising from offences of strict liability which rely on a reversed onus of proof in items 54 and 58 in Schedule 1 of the Bill and item 7 in Schedule 2 of the Bill

• trespass on personal rights and liberties arising from the abrogation of the privilege against self-incrimination in proposed sections 34 and 130C, inserted by items 14 and 283 in Schedule 3 of the Bill respectively

• rights and liberties are dependent on administrative discretion arising from the power to make regulations to provide for a scale of amounts which may apply for alleged contraventions under the infringement notice scheme in proposed subsections 69EKA(3) and 145DB(3) inserted by items 66 and 306 in Schedule 3 of the Bill respectively

• trespass on personal rights and liberties arising from the reversal of onus of proof in proposed subsection 45C(4), inserted by item 120 in Schedule 3 of the Bill

• trespass on personal rights and liberties arising from the exercise of entry powers without warrant under proposed section 131AA, inserted by item 284 in Schedule 3 of the Bill

• Trespass on personal rights and liberties arising from the retrospective validation of legislation by item 36 of Schedule 5 and item 58 of Schedule 6 of the Bill.

Where relevant these comments are outlined in the ‘Issues and provisions’ section of this Bills Digest.

**Compatibility with Human Rights**

As required under Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011 (Cth), the Government has assessed the Bill’s compatibility with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of that Act. The Government considers that the Bill is compatible.


36. The Scrutiny of Bills Committee has sought the Minister’s advice as to the justification for placing strict liability and an evidential burden of proof on defendants in relation to these provisions.

37. The Scrutiny of Bills Committee has sought the Minister’s advice as to the justification of why an evidential burden is not sufficient to support the objective of promoting human health and the environment in relation to this defence.

38. The Statement of Compatibility with Human Rights can be found at pages 10–16 of the Explanatory Memorandum to the Bill.

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Parliamentary Joint Committee on Human Rights

The Parliamentary Joint Committee on Human Rights (Human Rights Committee) has published comments about the Bill. The Human Rights Committee comments are directed at:

- the right to protection against arbitrary or unlawful interferences with privacy—the use of extensive investigation and monitoring powers including entry, search and seizure
- the right not to incriminate oneself
- criminal offences, civil penalty provisions and criminal process rights
- double jeopardy and
- civil penalty provisions and reverse onus of proof provisions.

The Human Rights Committee has written to the Minister to seek clarification about these issues.

Further discussion of these concerns is outlined in the ‘Key issue—offences’ section of this Bills Digest.

Policy position of non-government parties/independents

The position of the Coalition and the Australian Greens can be gleaned from the minority reports by members of the Rural and Regional Affairs and Transport Committee which are outlined above.

Position of major interest groups

The submissions to the House of Representatives Standing Committee for Agriculture, Resources, Fisheries and Forestry and the Rural and Regional Affairs and Transport Committee can be broadly described as originating from three groups:

- chemical users—such as farmers who are seeking ‘a system of chemical registration that facilitates the introduction of new chemicals onto the Australian market in a timely and cost efficient manner’

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• chemical companies—who have expressed concern that the proposed reforms ‘will significantly increase the cost to agricultural chemical producers by as much as 30 per cent each year’. They fear that ‘this increase in cost recovery from the industry may have a detrimental effect on the availability of accessible chemicals for Australian production systems’ \footnote{41} and

• environmentally-focused groups—who have urged that the legislation should reflect, not the risk management model which is proposed, but the ‘precautionary principle’ \footnote{42} which is one of the leading principles of environmental law. \footnote{43}

The concerns raised by each of these three broad groups highlight the major issues that the Bill is seeking to address. Accordingly, further details of stakeholder comments are included in the ‘Issues and provisions’ section of this Bills Digest.

Financial implications

According to the Explanatory Memorandum, the Bill ‘has no impact for the Budget’. \footnote{44} It should be noted that the APVMA operates on a cost recovery basis.

In 2010–11, payments of application fees, levies and annual fees by the agvet chemical industry represented 96 per cent of the APVMA’s total revenue (excluding ‘one-off’ reform funds). It was 94 per cent in 2009–10 and 96 per cent in 2008–09.

In its 2010–11 mid-year economic and fiscal outlook statement, the government announced $8.75 million of funding over four years to implement reforms to the regulation of agvet chemicals in Australia as part of the Reform Agenda. This funding is not ‘ongoing’, rather it relates only to the initial establishment and implementation of the reforms. \footnote{45}


\footnote{42}{Application of the \textit{precautionary principle} requires taking decisions on what is considered an ‘acceptable’ level of risk for society, identifying gaps in knowledge that result in uncertainty concerning the nature of a potentially unacceptable risk, and managing that risk in the face of uncertainty. \textbf{Source}: Milieu Ltd, the TMC Asser Institute and Pace, \textit{Considerations on the application of the precautionary principle in the chemicals sector}, Final report, August 2011, accessed 4 February 2013, \url{http://ec.europa.eu/environment/chemicals/reach/pdf/Final%20report%20PP.pdf}}


\footnote{44}{Explanatory Memorandum, p. 9.}

\footnote{45}{Australian Pesticides and Veterinary Medicines Authority, \textit{Cost recovery discussion paper}, op. cit., p. 8.}

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Key issue—offences

A key issue arising from this Bill is the creation of offences and the penalties which flow from them.

Problem with the existing Agvet Code

Under the current Agvet Code all of the offences which arise from conduct which contravenes the Agvet Code are criminal offences—most (but not all) of which are strict liability offences. The standard of proof in a criminal case is ‘beyond a reasonable doubt’. To establish an offence of strict liability it is only necessary to prove that the relevant conduct or event took place. However the defence of ‘mistake of fact’, (honest and reasonable mistake) is open to those who mistakenly but reasonably believe certain facts to exist which, if true, would have shielded them from liability. The existing offences, if proven, generally (but not in all cases) allow for financial penalties to be paid rather than imposing a term of imprisonment.

To date, the APVMA has had limited success in prosecuting holders of registrations and approvals in circumstances where alleged breaches of the Agvet Code have occurred.46

In the alternative, under the current Agvet Code, the APVMA’s only other enforcement tool is the power to issue notices which warn of the consequences of non-compliance.47

Approach to offences in this Bill

This Bill takes a multi-phased approach to compliance and enforcement as follows:

- it creates new offences such as offences for not complying with the directions of APVMA inspectors
- it provides for existing offence provisions to also be civil penalty provisions so that the APVMA can apply to the court for a civil penalty order against a person who has contravened a civil penalty provision
- it makes minimal changes to existing offences ‘so as not to disturb the existing provisions’48 and
- it provides the APVMA with a suite of powers to issue infringement notices, formal warnings and substantiation notices, to seek enforceable undertakings and to apply to the court for injunctions, including injunctions to undertake, or to cease from undertaking, certain actions.

Committee comments

The Scrutiny of Bills Committee drew attention to certain of the offence provisions in the Bill both in relation to the size of the penalty for the strict liability offence—that is, it is higher than the

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47. Explanatory Memorandum, p. 3.
48. Ibid., p. 4.
maximum of 60 penalty units recommended by the Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement powers (the Guide to Framing Offences) 49—and because the Explanatory Memorandum does not provide a justification for the reversal of the onus of proof in respect of these provisions. 50 The Scrutiny of Bills Committee has sought the Minister’s advice in relation to these matters. 51

**Two standards of proof**

The Human Rights Committee also commented on the offence provisions. Essentially, the Bill prohibits certain conduct. That conduct may give rise to a criminal offence as well as being a civil penalty provision. The Human Rights Committee considered the factors which international jurisprudence has identified should be taken into account in deciding whether conduct is criminal noting that:

> In the present case, there appears to be no difference in the conduct involved or in the rationale of the provisions – the only differences are the increased penalty to which a person is subject in civil penalty proceedings, and the lesser standard of proof that is required. The choice of which type of proceedings takes place appears to be at the discretion of the APVMA. 52

**Amount of penalties**

The Bill provides for the APVMA to apply to a civil court for an order that a person pay to the Commonwealth a pecuniary penalty. According to the Human Rights Committee, the pecuniary penalty ‘could be up to three times higher than an amount payable as a fine were the person prosecuted under a criminal offence’. According to the Explanatory Memorandum:

> The financial disincentives to misconduct provided by civil penalties are a more proportionate and effective enforcement tool, reflecting the practice of other areas of (particularly, corporate) regulation under Commonwealth legislation. 53

The issue is, however, whether conduct which is considered to be so egregious as to attract a penalty in excess of the limit set out in the Guide to Framing Offences should, in fact, give rise to a civil offence to which the court applies the civil rules of evidence and procedure and a lesser standard of proof. According to the Human Rights Committee:

> Notwithstanding the new provisions are not criminal offences, this is not determinative of the issue as to whether the conduct and penalties are ‘criminal’ for the purposes of article 14 of the ICCPR. If they do


51. The comments made by the Scrutiny of Bills Committee on this point are also referred to above under the heading ‘Committee Consideration’.

52. Parliamentary Joint Committee on Human Rights, op. cit., p. 12.

53. Explanatory Memorandum, p. 4.

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involve the determination of a criminal charge, then the rights set out in article 14 as applicable to criminal
proceedings would apply – including the requirement that the case be proved beyond reasonable doubt. 54

And further:

In civil penalty proceedings a person may be subject to triple the pecuniary penalty that could be imposed
by fine if the matter were dealt with as a criminal offence ... Thus, a person may be subject to a much larger
penalty, imposed in proceedings in which the civil standard of proof ... is employed ... While incarceration is
not an option under civil penalties, these are still a serious form of punishment that can have serious
financial implications and cause reputational damage to an offender. 55

Double jeopardy

According to the Human Rights Committee under the new provisions ‘a person may be proceeded
against for a criminal offence after the person has been the subject of a civil penalty order’. This
raises questions ‘around double punishment for the same conduct’. 56 This is contrary to article 14(7)
of the ICCPR which provides that no one shall be liable to be tried or punished again for an offence
for which he has already been finally convicted or acquitted in accordance with the law and penal
procedure of each country.

Whilst the Bill provides that the same evidence cannot be used in criminal proceedings against an
individual if already used in civil penalty proceedings, according to the Human Rights Committee, ‘it
is not clear whether the practical effect of this provision is to rule out the possibility of a criminal
conviction where a civil penalty order has already been made’. 57

Accordingly, the Human Rights Committee has stated that it intends to write to the Minister seeking
clarification of these issues.

Comments

The Australian Law Reform Commission’s Statement of Principle is:

The distinction between criminal and non-criminal (civil) penalty law and procedure is significant and adds
to the subtlety of regulatory law. This distinction should be maintained and, where necessary, reinforced.
Parliament should exercise caution about extending the criminal law into regulatory areas unless the
conduct being proscribed clearly merits the moral and social censure and stigma that attaches to conduct
regarded as criminal. 58

Other Bills which have been considered by the Parliament have similar provisions to those in this
Bill. 59 It appears, then, that it will be for the APVMA to use the cascading enforcement powers such

55. Ibid., p. 8.
56. Ibid., p. 9.
57. Ibid., p. 10.
58. Australian Law Reform Commission, Principled regulation: federal civil and administrative penalties in Australia,
59. For example, the Greenhouse and Energy Minimum Standards Bill 2012 the details of which are available on the Bill
homepage:
as warnings, infringement notices and substantiation notices rather than resort to criminal proceedings at the first instance. Undoubtedly where the relevant conduct continues and the APVMA brings criminal proceedings, a defendant will be less able to rely on a ‘mistake of fact’ defence.

**Issues and provisions**

Although this Bill amends a number of statutes, it is the Agvet Code which is the primary focus. The Agvet Code, set out in Schedule 1 to the Agvet Code Act, consists of eleven parts. Annexure 1 of this Bills Digest contains a table outlining the parts of the Agvet Code and the corresponding location of relevant amendments.

**Pre-application consultation**

This Bill provides for the making, and assessment, of applications for approval of an active constituent for a proposed, or existing, chemical product, the registration of a chemical product and approval of a label for the containers of a chemical product. A general explanation of the Part of the Agvet Code that contains these provisions is outlined under **proposed section 9**.

If an application does not comply with certain application requirements (which are discussed below) the APVMA must refuse the application.60

**Issue—the cost of ensuring compliance with application requirements**

When the initial draft of the Bill was released for community consultation, the relevant explanatory material indicated that ‘applicants would continue to be provided with assistance in understanding the requirements that apply to their applications. This would be achieved with ... formalisation of arrangements for pre-application assistance’.61

Importantly, the Bill does not contain any provisions relating to pre-application consultation. Instead this is contained in the APVMA Risk Compendium.62 According to a cost recovery impact statement prepared by the APVMA:

> The initial fee payable for pre-application advice is $350 reflecting staff time to review, research and attend meetings. Additional cost units of $175/person/hour will be added to the initial fee, based on the time

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60. Proposed subsection 11(3) of the Agvet Code.


Some submitters expressed concern that this consultation process is to be delivered on a cost-recovery basis. For example, the Australian Mushroom Growers’ Association expressed the view that ‘given the uncertain nature of the guidance to be sought prior to application, the cost of seeking a pre-application consultation will be unknown creating a significant disincentive to pursue such a provision’. Biopharm Australia considered that ‘further pre-registration assistance on a cost-recovery fee basis places the APVMA in the position of being an industry consultant and risks a conflict of interest’.

At the hearings before the Rural and Regional Affairs and Transport Committee the Department of Agriculture, Fisheries and Forestry (DAFF) stated that the rationale for providing this assistance was that some applicants ‘try to use the APVMA, essentially, as an unpaid consultant’ and that the ‘charge [for] the initial phase [is to be] rebated.’

The majority view of the Agriculture, Resources, Fisheries and Forestry Committee was that the implementation of preliminary assessment to achieve higher quality applications is a positive step on the grounds that ‘it will allow the APVMA to concentrate its resources on evaluating applications and reducing assessment timeframes’.

Part 1 of the Agvet Code

Whilst existing section 1 of Part 1 of the Agvet Code already sets out the objects of the Agvet Code, item 2 of Schedule 1 of the Bill inserts proposed section 1A which ‘explicitly states the purpose and framework for regulatory decision making for agvet chemicals’. In particular, proposed subsection 1A(2) provides that the Agvet Code is to be implemented in a manner that, amongst other things:

66. T Parnell (Assistant Secretary, Department of Agriculture, Fisheries and Forestry), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, Senate, Debates, 4 February 2013, p. 62, accessed on 8 February 2013, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22committees%2Fcomm%2Fcommons%2F6f98e75b-2431-4f58-a080-3d786c7de3e9%2F0000%22
68. Explanatory Memorandum, p. 18.
• reflects established best-practice principles for the assessment and management of risk, based on science\(^{69}\) and
• recognises that the use of chemical products that pose unmanageable risks to the health and safety of human beings, animals and the environment is not appropriate in Australia.\(^{70}\)

Issue—manageable and unmanageable risk

The terms ‘risk’ and ‘unmanageable risk’ are not defined in the Bill. Some of the stakeholders were concerned that the Bill does not require the APVMA to ‘define highly hazardous pesticides (HHPs) in line with international definitions’ with the result that HHPs can be removed from regulation.\(^{71}\) In support of this view Future Fisheries stated:

> ... the community of Australia has already clearly articulated that persistent, bio-accumulative and toxic (carcinogens, chemicals that produce reproductive and developmental harm) agricultural chemicals have no place in the Australian market and should not be registered for any use. Substitution by less harmful chemicals is severely hindered by the current approach to HHP.\(^{72}\)

The Rural and Regional Affairs and Transport Committee sought clarification from relevant stakeholders as to what is meant by the term ‘unmanageable risk’. Joana Immig of the National Toxics Network explained that the term highly hazardous chemicals as defined by the Food and Agriculture Organisation of the United Nations and the World Health Organization ought to be incorporated into the Bill.\(^{73}\) She pointed out that ‘there are some chemicals that fall into the category of being unmanageable’ citing the Stockholm Convention on Persistent Organic Pollutants to which Australia is a signatory.\(^{74}\)

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69. Proposed paragraph 1A(2)(b) of the Agvet Code.
70. Proposed paragraph 1A(2)(d) of the Agvet Code.
74. Ibid., p. 9.

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CropLife Australia commented that ‘new concepts such as “unmanageable risks” and poorly defined requirements around “undue hazards” are vague, unnecessary and are likely to build in additional uncertainty into the registration and approval processes’.  

Other stakeholders supported the APVMA’s ‘current risk management approach’ and the commitment ‘to continuing to regulate agricultural chemical constituents and their associated products according to their risk.’ However there was some concern that the ‘content, detail and transparency of the Risk Management Framework have not been developed’ and that ‘without a clear understanding of the content and parameters that form a Risk Assessment Framework, stakeholders are not able to assess the potential impacts’ on chemical product registration and end use.

The Greens member of the Rural and Regional Affairs and Transport Committee also commented on this aspect of the Bill in their minority report on the Bill—recommending that a definition of unmanageable risk be inserted into the objects of the Bill and into the various assessment triggers contained in the Bill.

**Part 2 of the Agvet Code**

Part 2 of the Agvet Code contains provisions relating to:

- approval of active constituents for proposed or existing chemical products
- registration of chemical products and
- approval of labels for containers for chemical products.

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78. Rural and Regional Affairs and Transport Legislation Committee, op. cit., p. 32.

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Lodging an application

Items 31 and 32 of Schedule 1 of the Bill amend Division 2 of Part 2 of the Agvet Code in relation to the approval and registration process. A person may apply to the APVMA for:

- approval of an active constituent for a proposed or existing chemical product
- registration of a chemical product and
- approval of a label for the containers of a chemical product. 79

The application must meet the ‘application requirements’ which are described in proposed section 8A in Schedule 1 of the Bill. 80 To meet the application requirements, all of the following conditions must be satisfied:

- the application must be in writing in the approved form and signed by the applicant, be accompanied by so much of the prescribed fee as is required to be paid, be lodged with the APVMA and contain, or be accompanied by, any information which has been specified by legislative instrument (which is not a disallowable instrument81) in accordance with proposed section 8B82
- the constituent, product or label complies, or will comply, with any requirement prescribed by the regulations
- any requirement to provide a sample for analysis83 or to provide additional information, report or sample84 has been complied with
- any other requirement prescribed by the Agvet Code in relation to the application has been complied with and
- any amount (including an amount in respect of a tax or penalty) that is payable by the applicant to the APVMA (including under a law of another jurisdiction or the agvet law) has been paid.

If the application is for an active constituent or chemical product, the application must also include instructions for the use of the constituent or product.85 The use of certain information given to the

79. Proposed subsection 10(1) of the Agvet Code inserted by item 32 of Schedule 1 of the Bill.
80. Proposed paragraph 10(2)(a) of the Agvet Code.
81. Proposed subsection 163A(2) of the Agvet Code, inserted by item 44 of Schedule 6 of the Bill, provides that a legislative instrument made under section 88 is not a disallowable instrument in accordance with section 42 of the Legislative Instruments Act 2003. The text of the Legislative Instruments Act 2003 can be viewed at:
82. Proposed subsection 156A(2) of the Agvet Code (inserted by item 161 of Schedule 1 of the Bill) provides that regulations may require that information which is required to be given to the APVMA be given only electronically, and in accordance with particular information technology requirements, by means of a particular kind of electronic communication (proposed subsection 156A(3)).
83. Section 157 of the Agvet Code.
84. Section 159 of the Agvet Code.
85. Proposed paragraph 10(2)(b) of the Agvet Code.
APVMA in respect of an application is subject to the limitation periods set out in proposed section 34M (which is inserted by item 29 of Schedule 4 of the Bill).

**Preliminary assessment**

Under proposed section 11 of the Agvet Code the APVMA has one month to complete a preliminary assessment of the application (proposed subsection 11(1)). If it appears that the application meets the application requirements, within 14 days of making that preliminary assessment the APVMA must notify the applicant in writing (that it will be determined under section 14 and setting out any matters prescribed by the regulations), and publish a summary of the application that includes any details prescribed by the regulations (proposed subsection 11(2)).

Otherwise the APVMA must refuse the application. Proposed section 8G sets out the formal requirements for giving notice to an applicant of that decision, including the amount of any fee that is repayable to the applicant because of the refusal.

**Issue—introduction of preliminary assessments**

The requirement that an application must pass a preliminary assessment or be refused is a significant departure from the current procedure which was described by DAFF as follows:

> In preliminary assessments under the Agvet Code as it exists now, the APVMA has to go back to registrants with every small defect it finds with an application … They have to continually do this and it takes an inordinate amount of time, and lots of letters back and forth to be able to accept the application, because of these small deficiencies. So the legislation … removes the back and forth step.

Importantly, the requirement for an application to undergo a preliminary assessment is a key feature of the Bill—an application for a variation of an approval or registration (proposed section 28 of the Agvet Code), re-approval or re-registration (proposed section 29E of the Agvet Code inserted by item 5 of Schedule 2 of the Bill) or an application for a minor use permit (proposed section 110A of the Agvet Code) are all subject to a preliminary assessment process.

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86. Proposed subsection 156A(4) of the Agvet Code (inserted by item 161 of Schedule 1 of the Bill) provides that if the APVMA is required to give a person information in writing, the requirement will be taken to have been met if the person consents to the information being given electronically and it is so given, the information includes the Chief Executive Officer’s electronic signature and, in the event of a breach of a civil penalty provision (arising from a person’s failure to do, or not do, a thing set out in the information), the APVMA has in place systems for proving the person received the information.


88. M Kelly (Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, Senate, Debates, 4 February 2013, p. 56, accessed on 8 February 2013, [http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22committees%2Fcommsen%2F6f98e75b-2431-4f88-a080-3d786c7d8e98%2F0000%22](http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22committees%2Fcommsen%2F6f98e75b-2431-4f88-a080-3d786c7d8e98%2F0000%22)

89. Proposed section 27 of the Agvet Code allows the holder of an application to apply for a variation of the approval or registration, proposed section 29D allows for re-approval or re-registration of an active constituent or chemical

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Decision to approve and register

Subject to the restrictions imposed on the APVMA to register products and approve labels by proposed section 15 of the Agvet Code, proposed section 14 (inserted by item 32 of Schedule 1 of the Bill) provides that the APVMA must approve the active constituent or label, or register the chemical product where it is satisfied that the application meets the application requirements and the additional criteria outlined below.

<table>
<thead>
<tr>
<th>Application type</th>
<th>Criteria for approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>For an active constituent</td>
<td>meet the safety criteria</td>
</tr>
<tr>
<td>For a chemical product</td>
<td>meet the safety criteria and</td>
</tr>
<tr>
<td></td>
<td>meet the trade criteria and</td>
</tr>
<tr>
<td></td>
<td>meet the efficacy criteria or</td>
</tr>
<tr>
<td></td>
<td>comply with the standard</td>
</tr>
<tr>
<td>For a label of a chemical product</td>
<td>meet the labelling criteria or</td>
</tr>
<tr>
<td></td>
<td>comply with the standard</td>
</tr>
</tbody>
</table>

Safety criteria

Under proposed section 5A of the Agvet Code (inserted by item 27 of Schedule 1 of the Bill), an active constituent or chemical product meets the safety criteria if use of the constituent or product, in accordance with any instructions approved (or to be approved) by the APVMA, or contained in an established standard:

- would not be an undue hazard to the safety of people who are exposed to it during handling
- would not be an undue hazard to the safety of people using anything containing its residues
- would not be likely to have an effect that is harmful to human beings and
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

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90. Proposed section 15 the Agvet Code provides that the APVMA must not register a chemical product unless each active constituent of the product, as well as a label for the container of the product, have been approved. The APVMA must not approve a label for the container of a chemical product unless it also registers the product.

91. Proposed sections 12 and 13 of the Agvet Code (inserted by item 32 of Schedule 1 of the Bill) require the APVMA to publish a notice and invite written submissions before a new active ingredient is approved and registered.

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Proposed subsections 5A(2) and (3) set out the matters which the APVMA must have regard to in making the decision about whether an active constituent or a chemical product respectively meets the safety criteria.

These criteria are consistent with the manner in which the Code is to be implemented as set out in proposed section 1A—that is, there is to be recognition that the health and safety of human beings, animals and the environment is the first priority of the system for regulating chemical products and their constituents and it reflects established best-practice principles for the assessment and management of risk, based on science.

Trade criteria

Under proposed section 5C of the Agvet Code (inserted by item 27 of Schedule 1 of the Bill), a chemical product meets the trade criteria if use of the product, in accordance with instructions approved (or to be approved) by the APVMA or contained in an established standard, does not unduly prejudice trade or commerce between Australia and places outside Australia. Proposed subsections 5C(2) and (3) list those matters which the APVMA must have regard to in order to be satisfied that a chemical product meets the trade criteria.

Efficacy criteria

According to proposed section 5B of the Agvet Code (inserted by item 27 of Schedule 1 of the Bill), a chemical product meets the efficacy criteria if use of the product, in accordance with instructions approved (or to be approved) by the APVMA for the product, would be effective according to criteria determined by the APVMA by legislative instrument (which is not a disallowable instrument92) or contained in an established standard. Proposed subsections 5B(2) and (3) list those matters which the APVMA must have regard to in order to be satisfied that a chemical product meets the efficacy criteria.

Labelling criteria

A label for containers for a chemical product meets the labelling criteria in accordance with proposed section 5D of the Agvet Code (inserted by item 27 of Schedule 1 of the Bill), if the label contains adequate instructions about the following matters, where appropriate:

- the circumstances in which the product should be used and how it should be used
- the times when the product should be used and the frequency of the use
- the withholding and re-entry period after the use of the product
- the disposal of the product and containers of the product

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92. Proposed subsection 163A(2) of the Agvet Code, inserted by item 44 of Schedule 6 of the Bill, provides that a legislative instrument made under section 5B is not disallowable in accordance with section 42 of the Legislative Instruments Act 2003.
• the safe handling of the product and first aid in the event of an accident caused by the handling of the product and
• any matters prescribed by the regulations.

Proposed subsection 5D(2) sets out those matters which the APVMA must have regard to in order to be satisfied that a label meets the labelling criteria. Annexure 2 of this Bills Digests contains an example of a label.

Standards

Proposed section 8U of the Agvet Code requires the APVMA (inserted by item 29 of Schedule 1 of the Bill), by legislative instrument, to make a standard for each listed chemical product. This requirement applies whether or not the product is the subject of a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary) or in a similar publication. The matters which may be included in a standard for a listed chemical product are set out in proposed subsections 8U(4) and (5). However, proposed subsection 8U(3) provides that the standard for a listed chemical product must require that the product is labelled in a manner, or kept in containers that comply with requirements, specified in the standard.

Issue—requirement to provide new information to the APVMA

The requirement that an active constituent of a chemical product, a chemical product or the label for the container of a chemical product must meet the approval criteria or the appropriate standard is a key feature of this Bill. Wherever the requirement is specified in the Bill, the APVMA must be satisfied that the relevant criteria are met. However, section 161 of the Agvet Code (as amended by items 192–197 of Schedule 1 of the Bill) requires the holder of a registration or approval to notify the APVMA as soon as they become aware of any information about a product or its constituents which indicates that it may no longer meet the safety, efficacy or trade criteria. The maximum penalty for contravening this provision is 300 penalty units.

The exception to this rule is listed chemical products which are discussed below.

93. A legislative instrument can be subject to disallowance if either a Senator or Member of the House of Representatives moves a motion of disallowance within 15 sitting days of the day that the legislative instrument is tabled. The motion to disallow must be resolved or withdrawn within a further 15 sitting days of the day that the notice of motion is given. However, it should be noted that if there is no notice of motion to disallow a legislative instrument, then there is no debate about its contents.

94. Proposed section 8T of the Agvet Code provides that regulations may include a schedule specifying chemical products, or classes of chemical products, that are listed chemical products for the purpose of the Code.


96. This is equivalent to $51 000.
Approval and registration

The APVMA is responsible for three official documents:

- the Record of Approved Active Constituents for Chemical Products (the *Record*)
- the *Record of Permits* and
- the Register of Agricultural and Veterinary Chemical Products (the *Register*).

**Item 43 of Schedule 1** of the Bill repeals and substitutes sections 19–26 of the Agvet Code which deal with formal approval and registration. Approval of an active constituent takes place when the APVMA enters the details set out in **proposed subsection 19(1)** into the *Record*. These details include the date the approval ends. The approval end date is to be worked out as required by the regulations and is the last day of a calendar month at least seven years—but not more than 15 years—after the approval takes place. Once the approval time has elapsed, a new application must be submitted for the active constituent to be re-approved.

Registration of a chemical product takes place when the APVMA enters the details set out in **proposed subsection 20(1)** in the *Register*. The date the registration ends, is the last day of a calendar month not more than 12 months after the registration takes place. This date, as well as the date after which the registration cannot be renewed (last renewal date) must be entered into the Register. Under **proposed subsection 20(2)** the last renewal date is to be worked out as required by the regulations and is the last day of a calendar month at least seven years—but not more than 15 years—after the initial registration, or a variation of a registration, takes place. These sections operate so that registration of a chemical product is to be renewed annually until the last renewal date occurs, at which time the chemical product must be formally re-registered.

**Under proposed section 21** of the Agvet Code, approval of a label takes place when the APVMA determines which of the particulars prescribed by the regulations that are to be contained on the label, gives a distinguishing number to the label and records the information set out in **proposed paragraph 21(c)** in the APVMA file.

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97. The definition of the term *Record* is inserted by **item 20** of Schedule 1 of the Bill.
98. The definition of the term *Record of Permits* is contained in section 3 of the Agvet Code and is unchanged by this Bill.
99. The definition of the term *Register* is inserted by **item 22** of Schedule 1 of the Bill.
100. **Proposed subsection 19(3)** of the Agvet Code allows the APVMA to approve an active constituent for less than seven years so that the end of the approval coincides with that of another active constituent.
101. Explanatory Memorandum, p. 3.
102. **Proposed section 50**, inserted by **item 12** of Schedule 2 of the Bill provides that registrations are to be renewed annually.
103. **Proposed paragraph 20(1)(g)** of the Agvet Code provides that where the product is a listed chemical product, and the product and each label comply with the established standard for the product the last renewal date will not be required to be entered on the Register.
104. **Proposed subsection 20(3)** of the Agvet Code allows the APVMA to enter a last renewal date in the Register of less than seven years so that the last renewal date coincides with that of another chemical product which contains one or more of the same active constituents.
Importantly proposed section 23 provides that the approval of an active constituent for proposed or existing chemical products, registration of a chemical product and approval of a label for the containers for a chemical product may be subject to two types of conditions.

The first type of condition is one prescribed by regulation—even if the conditions have not been prescribed at the time of approval or registration. This is new to the Agvet Code. According to the Explanatory Memorandum, at present the APVMA is able to apply conditions at the time of approval or registration. If new information becomes available, the APVMA is required to undertake a chemical review of the active constituent or chemical product. This provision ‘addresses this by allowing for conditions to be imposed after approval or registration with these conditions to be prescribed in regulations’.

The second type of condition is one imposed by the APVMA where it is considered to be appropriate. This may include a condition that the approval or registration is for a period of not more than one year. This conditional approval may be extended for a further period of no longer than one year.

The holder of an approval of an active constituent, the registration of a chemical product or the approval of a label for containers of a chemical product must notify the APVMA in writing within 28 days if the holder has reasonable cause to believe that a particular, or condition, which has been entered in the Record or Register, or recorded in the relevant APVMA file, is incorrect as a result of inaccurate recording. A holder who contravenes the requirement commits an offence of strict liability. The penalty attributable to the offence is 30 penalty units.

Proposed subsections 26(1) and (2) of the Agvet Code authorise the APVMA to vary an entry or record, if the APVMA is satisfied that the information that has been entered in the Record or Register, or recorded in the relevant APVMA file, is incorrect in a material respect.

105. Proposed paragraph 23(1)(a) of the Agvet Code.
106. Explanatory Memorandum, p. 32.
107. Proposed subsection 23(2) of the Agvet Code.
108. Proposed subsection 23(3) of the Agvet Code.
109. The term holder is repealed and replaced by item 10 of Schedule 1 of the Bill and is defined as (a) in relation to an approval or registration, means the person entered in the Record, Register or relevant APVMA file as the holder of the approval or registration or, if the holder was an individual who has died or is an individual whose affairs are being lawfully administered by another person—the legal personal representative of the individual or the person administering the individual’s affairs or, if the holder was a body corporate—a successor in law of the body corporate; or (b) in relation to a permit or licence, means the person to whom the permit or licence was issued.
110. Proposed subsection 26(3) of the Agvet Code, inserted by item 43 of Schedule 1 of the Bill.
111. The imposition of strict liability means that a fault element does not need to be satisfied, but the offence will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations.
112. Under section 4AA of the Crimes Act 1914, a penalty unit is equivalent to $170. This means that the penalty is equivalent to $5100. The text of the Crimes Act 1914 can be viewed at: http://www.comlaw.gov.au/Details/C2013C00031/Download
Variation of an entry or record

Item 44 of Schedule 1 of the Bill repeals and replaces the existing Division 2A and Division 3 of Part 2 of the Agvet Code. New Division 2A provides for relevant particulars of an approval or registration to be varied—if the relevant particular is set out in a legislative instrument made under section 26B. Only holders of approvals or registrations may apply under new Division 2A. The use of certain information given to the APVMA in respect of an application for a variation of an entry or records is subject to the limitation periods set out in proposed section 34M (which is inserted by item 29 of Schedule 4 of the Bill). According to the Explanatory Memorandum:

A legislative instrument made by the APVMA is the most appropriate mechanism to identify permissible low regulatory concern variations as such an instrument can be varied at short notice and APVMA has the technical expertise to know what variations are appropriate. The legislative instrument is disallowable.

New Division 3 of Part 2 of the Agvet Code provides more generally for variation of relevant particulars or conditions of approvals and registrations. The holder, or a third party with the consent of the holder, may apply to the APVMA for a variation of the particulars or conditions of an approval of an active constituent, the registration of a chemical product or the approval of a label for containers of a chemical product. Where such an application is received the APVMA must complete a preliminary assessment within one month after the application is lodged, formally notify the applicant that it is to be assessed under section 29 of the Agvet Code and set out any matters prescribed by regulations.

Applications under both new Division 2A and new Division 3 of Part 2 of the Agvet Code must meet the application requirements. The APVMA must vary the particular (or condition) if the application meets the application requirements and if the variation would meet the relevant safety, trade or efficacy criteria and/or established standard for approval. Otherwise the APVMA must refuse the application. Where an application is accepted and a variation is made, the APVMA must take steps to ensure that the Record, Register or relevant APVMA file are updated.

113. Subsection 26A(1) of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill.
114. Proposed subsection 9(3) of the Agvet Code, inserted by item 30 of Schedule 1 of the Bill and proposed subsection 26A(2) inserted by item 44 of Schedule 1 of the Bill.
115. Explanatory Memorandum, p. 33.
116. Proposed subsection 9(4) of the Agvet Code, inserted by item 30 of Schedule 1 of the Bill and proposed subsection 26E(1) of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill.
117. Proposed section 28 of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill. Also see above in the text of the Bills Digest the comment about the common features of the Bill in relation to applications and preliminary assessments.
118. Proposed subsection 26B(2) and proposed subsection 27(3) of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill.
119. Proposed subsection 26C(1) and proposed subsection 29(1) of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill.
120. Proposed subsection 26C(2) and proposed subsection 29(2) of the Agvet Code. This will trigger the notification requirements in proposed section 8G of the Agvet Code.
121. Proposed section 26D and proposed section 29B of the Agvet Code, inserted by item 44 of Schedule 1 of the Bill.
Re-approvals and re-registrations

Item 5 of Schedule 2 of the Bill inserts new Division 3A into Part 2 of the Agvet Code. The new Division consists of proposed sections 29C–29K to provide for re-approval and re-registration of active constituents and chemical products.

The re-approval and re-registration takes place in equivalent terms to an original approval and registration as set out in proposed sections 10–14 as outlined above.

Importantly under proposed section 29D the application by the holder of the approval of an active constituent or the registration of a chemical product must meet the application requirements and be made:

- for re-approval—not earlier than six calendar months, and not later than three calendar months, before the date entered in the Record as the date the approval ends
- for re-registration—not earlier than six calendar months, and not later than three calendar months, before the date entered in the Register as the date after which the registration cannot be renewed under Division 6 (which consists of proposed section 46A, proposed sections 47–47D and existing sections 48—51 as amended).

The APVMA may accept a late application made on, or before, the day the approval ends or the day after which registration cannot be renewed in circumstances prescribed by the regulations and upon payment of the prescribed fee (if any).

Once an applicant for re-approval and re-registration has been lodged, the APVMA has two months to complete a preliminary assessment. If it appears that the application meets the application requirements, the APVMA must notify the applicant in writing within 14 days that the application will be determined under proposed section 29F. Otherwise the APVMA must refuse the application.

Under proposed section 29F:

- for re-approval of an active constituent—the APVMA must re-approve the constituent unless it appears that there are reasonable grounds to believe that the constituent does not meet the safety criteria
- for re-registration of a chemical product—the APVMA must re-register the product unless it appears that there are reasonable grounds to believe that the product does not meet the safety criteria, the trade criteria and/or the efficacy criteria.

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122. As noted in the text above in this Bills Digest, the application requirements are set out in proposed section 8A in Schedule 1 of the Bill.
123. Proposed subsection 29D(3) of the Agvet Code, inserted by item 5 of Schedule 2 of the Bill.
124. Proposed subsection 29E(1) of the Agvet Code, inserted by item 5 of Schedule 2 of the Bill.
125. This will trigger the notice requirements in proposed section 8G in Schedule 1 of the Bill.
Where the APVMA does not re-approve or re-register the active constituent or chemical product it must reconsider the existing approval or registration as set out in Division 4—that is, it must undertake a chemical review (see further discussion below).

**Issue—need to apply for re-approval or re-registration**

Australia is unusual compared to the 30-odd countries in the EU and the US in that, basically, pesticides can be used in Australia forever, with no sunset clause. The only way pesticides fall out of the system is where the burden of proof falls to communities and to the government to try and prove that chemicals are unsafe, whereas in other countries they regularly become deregistered and need to be re-registered and have to prove to the communities and the government they are safe.

The requirement in this Bill that the holder of an approval or registration must apply for re-approval or re-registration after a certain period is a significant change to the current regulatory regime and is one of the more contentious amendments in the Bill. It was of particular concern to the Coalition members of the Rural and Regional Affairs and Transport Committee who considered that it is seen as expensive and developed without a compelling cost/benefit analysis.

**Arguments for re-approval and re-registration**

The rationale for the requirement is set out in the Explanatory Memorandum which states:

Re-approval and re-registration will increase the scrutiny of chemical constituents and products through a scheme that minimises impacts on industry. The scheme provides a greater level of assurance that existing chemicals and products do not pose an undue risk to human health or the environment, and further promotes public confidence in agvet chemical regulation.

DAFF explained the difference between Australia’s proposed re-approval and re-registration scheme and that used overseas as follows:

Overseas companies have to come in to the regulator and prove that their chemical is safe, again and again. This system requires that the APVMA demonstrate that there are reasonable grounds to believe that it might be unsafe, and if there are no reasonable grounds to believe that it is unsafe then the product should be re-registered.

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127. N Heath (National Manager, Freshwater, WWF Australia), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, *Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012*, Senate, Debates, 4 February 2013, p. 2, accessed on 18 February 2013, [http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=id%3A%22committees%2Fcommsen%2FF6f98e75b-2431-4f58-a080-3d786c7d8e98%2F0000%22](http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=id%3A%22committees%2Fcommsen%2FF6f98e75b-2431-4f58-a080-3d786c7d8e98%2F0000%22)
128. Rural and Regional Affairs and Transport Legislation Committee, op. cit., p. 27.
129. Explanatory Memorandum, p. 3.
130. M Kelly (Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, *Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012*, op. cit., p. 65.
Arguments against re-approval and re-registration

Many stakeholders, however, did not agree with the proposed re-approval and re-registration requirement. For example, Agforce Queensland considered that it would ‘result in delays for new crop and animal protection products’.131 CropLife described the measures as ‘expensive, unfair and will not deliver any better protection of workers, consumers or the environment’.132

The National Farmers’ Federation expressed its concern that the new process ‘may duplicate, add minimal value or reduce flexibility in the existing processes and mechanisms in place’.133

By far the greatest concern of stakeholders is that products which are ‘off patent’ will be lost to users. The problem arises with a product which has been on the market for an extended period with no reports of adverse events or questions of its safety. When the registration or approval period ends, an application for re-registration or re-approval must be lodged. However, when a product is no longer under patent, the commercial value of the product is diminished for the holder of the registration or approval. That being the case, there is concern that there will be no incentive for a new application to be lodged—leading to the loss of products from the market.134

Matthew Cossey of CropLife Australia advised, in addition, that ‘generating data packages to get through a re-registration process ... becomes an expensive situation ... Getting one company to put up the money is very difficult if it then means that they all piggyback off it’.135

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134. B Gardiner (President of the Australian Veterinary Association) and B Twentyman (Deputy Veterinary Director, Australian Veterinary Association), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, Senate, Debates, 4 February 2013, pp. 31 and 33, accessed on 18 February 2013, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22committees%2Fcommsen%2F6f9fe75b-2431-4f58-a080-3d786c7de8e98%2F0000%22

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However, the evidence by DAFF to the Rural and Regional Affairs and Transport Committee may go some way to allay these concerns. DAFF described the distinction between the existing system of chemical reviews and the proposed requirement for re-approval and re-registration as follows:

The reregistration scheme is a scheme that operates to filter the entire chemical inventory on the market and decide whether a chemical needs to be reviewed. So the system is relatively simple. It assesses whether there are any reasonable grounds for doubt that the product would not meet the safety criteria, the trade criteria or the efficacy criteria.

It looks at an application from the holder of the registration and decides whether there are any doubts. If there is a sniff of a doubt then it can assess that doubt through the full, longer chemical review system ... the reregistration scheme is a much less involved process than that. And the drafting in the bill now makes a specific requirement of the APVMA that they cannot require information in that application for reregistration that the applicant cannot reasonably be expected to have. That means that the costs of reregistration do not include costs of generating new data—and that is where the big cost in the chemical review system is.\(^\text{136}\)

### Reconsidering approvals and registrations (‘chemical reviews’)

Existing section 31 of the Agvet Code provides that the APVMA may, at any time, reconsider an approval of an active constituent for a proposed or existing chemical product, the registration of a chemical product or the approval of a label for containers of a chemical product.\(^\text{137}\) In addition, the APVMA may invite the public to propose active constituents of chemical products, or their labels, the approval or registration of which the APVMA might reconsider.\(^\text{138}\)

Items 45–59 of Schedule 1 of the Bill amend existing Division 4 of the Agvet Code to set out the system for reconsideration of approvals and registrations by the APVMA in order to decide whether they should remain in force.\(^\text{139}\) These are known as ‘chemical reviews’. Proposed section 29L provides an explanation of the operation of this Division.

First the APVMA must give notice in writing to the holder of the registration or approval setting out the matters it proposes to deal with (and the reasons for doing so), requiring the holder to provide specified information within a period of no less than 28 days and inviting the holder within that period to make a written submission about the matters under reconsideration.\(^\text{140}\) This information, when received, will be protected information. (A discussion about protected information is set out

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136. M Kelly (Director, Reform Development and Implementation, Department of Agriculture, Fisheries and Forestry), Evidence to the Rural and Regional Affairs and Transport Legislation Committee, Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, op. cit., p. 55.
138. Section 30 of the Agvet Code.
139. Proposed subsection 9(6) of the Agvet Code, inserted by item 30 of Schedule 1 of the Bill. See also item 218 of Schedule 1 of the Bill inserts proposed section 165A into the Agvet Code to set the period within which the APVMA is to conclude its reconsideration. This period is to be determined in accordance with regulations.
140. Proposed subsection 32(1) of the Agvet Code, inserted by item 52 in Schedule 1 of the Bill. This information, when received, will be protected information. A discussion about protected information is set out under the heading Data protection in this Bills Digest.
below under the heading Data protection). The APVMA may also inform any other person that it proposes to reconsider, or is reconsidering, an approval or registration and invite that person to make submissions within a specified time about the matters which are the subject of the reconsideration.141

**Second** the APVMA may, by written notice, require the holder to provide specified information (this will be *protected information*); to carry out a search of the published literature and give the APVMA a report on the results of the search; and to conduct trials or laboratory experiments and give the results to the APVMA and/or give to the APVMA a sample of an active constituent or a chemical product for analysis (this will be *protected information*). The information required by the APVMA from the holder must be relevant to the reconsideration. The APVMA must give the holder a reasonable period to comply with the request.142 That period must not be longer than a period which is specified in the regulations.143

The APVMA may suspend or cancel the registration—after giving the appropriate notice—if the information is not provided, or if the holder provides information which is false or misleading in a material particular.144

**Third** the APVMA must affirm the approval or the registration—to the extent of the reconsideration—only if it is satisfied that the relevant approval criteria are met and that the constituent, product or label complies with any requirement prescribed by the regulations.145

*Proposed paragraph 34(3)(a) of the Agvet Code* (inserted by *item 59 of Schedule 1* of the Bill) sets out the matters to which the APVMA must have regard in making its decision. This includes, but is not limited to, any information which has been provided to the APVMA by the holder of a registration or approval under section 161 of the Agvet Code that contradicts the information that has been entered into the Register or on to the Record or which shows that the constituent or product may not meet the trade, safety or efficacy criteria.

If the approval or registration is not affirmed, the APVMA may, in limited circumstances146, vary a particular or condition of an approval or registration to allow the approval or registration to be

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141. Proposed subsections 32(2) and (2A) of the Agvet Code, inserted by *item 52 in Schedule 1* of the Bill.

142. Proposed subsection 33(1) of the Agvet Code, inserted by *item 56 in Schedule 1* of the Bill.

143. Proposed subsection 33(1A) of the Agvet Code. *Proposed subsection 33(1B)* of the Agvet Code allows for a further period in circumstances prescribed by the regulations.

144. Proposed subsection 38(1) inserted by *item 108 of Schedule 3* of the Bill and *proposed section 38A* inserted by *item 110 of the Schedule 3* of the Bill respectively.

145. Proposed subsections 34(1) and (2) of the Agvet Code, inserted by *item 59 in Schedule 1* of the Bill. *Proposed section 34AC* of the Agvet Code sets out the requirement that the APVMA give written affirmation to the holder and publish a notice of the affirmation in the Gazette.

146. Proposed subsection 34A(2) of the Agvet Code, inserted by *item 59 in Schedule 1* of the Bill, limits the material to which the APVMA may have regard in making this decision.
affirmed following reconsideration. Otherwise the APVMA must suspend or cancel the approval or registration.\textsuperscript{147}

\textbf{Proposed section 34AF} (inserted by item 59 of Schedule 1 of the Bill) authorises the APVMA to reconsider the approval of a label at any time in order to ensure that the label meets the labelling criteria.

The holder commits an offence of strict liability if the holder contravenes the requirement to provide the information specified in the types of notices outlined above within the specified period.\textsuperscript{148} These are civil penalty provisions with a maximum penalty of 120 penalty units.\textsuperscript{149} In both cases the evidential burden lies with the defendant.\textsuperscript{150}

Comments in relation to the criminal offences and civil penalty provisions which are contained in this Bill are under the heading ‘Key issue—offences’ above.

\section*{Data protection}

The submission by DAFF to the Rural and Regional Affairs and Transport Committee puts the amendments under this heading into context as follows:

Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. Regulatory data is required to be protected from unfair commercial use by the World Trade Organisation under its Trade Related Aspects of Intellectual Property Rights Agreement and the data should not be disclosed in an inappropriate manner.\textsuperscript{151}

\textbf{Items 13 and 14 of Schedule 4} of the Bill insert new definitions of \textit{protected information} and \textit{protection period} respectively into subsection 3(1) of the Agvet Code. \textit{Protected information} is information or results given to the APVMA as required under specified paragraphs\textsuperscript{152} of the Agvet Code.

\begin{itemize}
  \item \textbf{Proposed section 34AA} of the Agvet Code, inserted by item 59 in Schedule 1 of the Bill. The APVMA must give written notice of the proposal in accordance with \textbf{proposed section 34AB} as outlined above.
  \item \textbf{Proposed subsections 32(5)} (inserted by item 54 of Schedule 1 of the Bill) and \textbf{33(4)} (inserted by item 58 of Schedule 1 of the Bill) of the Agvet Code respectively. The imposition of strict liability means that a fault element does not need to be satisfied, but the offence will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations.
  \item The penalty is equivalent to $20 400.
  \item Note 2 to each of these subsections states that: ‘A defendant bears an evidential burden in relation to a matter in this subsection’. Under subsection 13.3(3) of the Criminal Code Act ‘a defendant who wishes to rely on any exception provided by the law creating an offence bears an evidential burden in relation to that matter.’ Also under section 13.3 of the Code, \textit{evidential burden}, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist’.
  \item That is, paragraph 32(1)(b), paragraph 33(1)(a) or (c) and subparagraphs 159(2)(d)(i), (ii) or (iii) of the Agvet Code.
\end{itemize}
Code that have been obtained because of a trial or laboratory experiment and relate to an active constituent that has been approved or a chemical product that has been registered.

The protection period for protected information is the period that begins when the information is first given to the APVMA in relation to a reconsideration (that is, a chemical review) and ends eight years after the APVMA makes its decision on the reconsideration. (Part 3 of the Agvet Code provides for payment of compensation from a person who wishes the information to be used by the APVMA in connection with an application for the approval, or continued approval, of another active constituent or the registration, or continued registration, of another chemical product).

Items 18—29 of Schedule 4 of the Bill amend existing Division 4A of Part 2 of the Agvet Code which limits the use of information which has been given to the APVMA.

Proposed section 34G sets out general rules about the use of information by the APVMA. It prohibits the APVMA from using certain information in assessing or making a decision about an application for the approval of an active constituent, a proposed, or existing, chemical product, registration of a chemical product, the approval of a label for containers for a chemical product or an application has been made to vary the terms of such an approval or registration. That information is:

- information that has been given to the APVMA in connection with another application by the applicant for the other application and

- information from the holder of a registration or approval which has been given because the holder has become aware of information that contradicts any information that has been entered in the Record, Register or Record of Permits or which shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria.

Similarly, the APVMA must not use the information listed above to vary relevant particulars or conditions or reconsider an approval or registration.

However item 29 of Schedule 4 of the Bill inserts proposed sections 34J and 34K which contain exceptions to the general rules. The APVMA will be able to use information if any of the following conditions are met:

- the authorising party gives written consent to the use of the information—even if the consent is subsequently withdrawn

153. Proposed subsection 34G(1B) inserted by item 21 of Schedule 4 of the Bill provides that the use of information includes (a) applying a decision made, or a conclusion reached, based on the information and (b) the use of knowledge or understanding gained from the information.
154. Section 10 of the Agvet Code.
155. Section 27 of the Agvet Code.
156. Items 192–196 of Schedule 1 of the Bill amend section 161 of the Agvet Code to this effect.
158. Division 4 of Part 2 of the Agvet Code refers.
• the use of the information is in the public interest in accordance with prescribed regulations\textsuperscript{160}

• the information relates to a proposed or existing approval or registration of an active constituent for a proposed or existing chemical product and the information shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria\textsuperscript{161}

• the information has already been given to the APVMA in relation to the application\textsuperscript{162}

• the information is protected information\textsuperscript{163} whose protection period\textsuperscript{164} has expired

• the information is publicly available\textsuperscript{165}

• the information was given in connection with an application for approval, or variation of an approval, as an active constituent for a chemical product, of a substance that was a previously endorsed.\textsuperscript{166}

\textit{Proposed section 34M} (which is inserted by item 29 of Schedule 4 of the Bill) contains a table setting out the \textit{limitation periods} for various types of information. These periods range from three years to ten years.

**Suspending and cancelling approvals and registrations**

\textit{Items 101–122 of Schedule 3} of the Bill amend Division 5 of Part 2 of the Agvet Code in relation to the suspension or cancellation of approvals and registrations. \textit{Proposed section 34N} provides a general explanation of the operation of this Division.

Under Division 5 as amended, the APVMA is given broad powers to suspend or cancel an approval or registration. These powers are in addition to existing powers if:

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159. Proposed subsection 34J(2) of the Agvet Code, inserted by item 29 of Schedule 4 of the Bill.
160. Proposed subsection 34J(3) of the Agvet Code. Proposed section 34K provides further rules about the public interest exception.
162. Proposed subsection 34J(5) of the Agvet Code, inserted by item 29 of Schedule 4 of the Bill.
163. Item 13 of Schedule 4 of the Bill repeals and replaces the definition of protected information in subsection 3(1) of the Agvet Code. The term refers to information or a result given to the APVMA as required under paragraph 32(1)(b) or 33(1)(a) or (c), or subparagraph 159(1)(d)(i), (ii) or (iii), that (a) have been obtained because of a trial or laboratory experiment and (b) relate to an active constituent that has been approved or a chemical product that has been registered.
164. Item 14 of Schedule 4 of the Bill repeals and replaces the definition of protection period in subsection 3(1) of the Agvet Code. The term, in relation to protected information, means the period that begins when the information is first given to the APVMA in relation to a reconsideration, and ends eight years after the APVMA makes its decision on the reconsideration.
165. Proposed subsection 34J(5B) of the Agvet Code.
166. Proposed subsection 34J(6) of the Agvet Code

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• it is necessary to prevent imminent risk to persons of death, serious injury or serious illness—whether or not it is being used in accordance with the instructions that the APVMA has approved\textsuperscript{167}

• the holder does not comply with a requirement under the Agvet Code to give the APVMA information, a report or a sample when requested\textsuperscript{168}

• the holder has given information that is false or misleading\textsuperscript{169}

• it appears to the APVMA that the criteria for approval or registration are not, or are no longer, satisfied.\textsuperscript{170}

Generally, the APVMA must not suspend or cancel an approval or registration without giving notice to the holder outlining the reasons for the proposed suspension or cancellation and inviting the holder to make submissions to the APVMA within the period specified in the notice about the proposed action. The APVMA must not make its decision without considering the submission that has been made.\textsuperscript{171}

Under existing section 43 of the Agvet Code, a suspension must be for a stated period, and does not prevent cancellation. Suspensions and cancellations can be revoked.\textsuperscript{172} Under proposed section 45A of the Agvet Code, a notice of suspension and cancellation must be given to the holder of the registration or approval and any other person whom the APVMA considers should be given a notice. In addition, a formal notice of the suspension or cancellation must be published in the Gazette.\textsuperscript{173}

The consequence of suspension or cancellation of the approval of a constituent or the registration of a product, is that certain persons are taken to have a permit to possess, have custody of or use of the constituent or product for a limited period\textsuperscript{174} and those persons may only supply the constituent or product in accordance with instructions contained in the notice provided by the APVMA under section 45A.\textsuperscript{175}

**Issue—reversal of onus of proof and civil penalty amount**

\textsuperscript{167} Proposed section 35A of the Agvet Code inserted by item 105 of Schedule 3 of the Bill.

\textsuperscript{168} Proposed subsection 38(1) of the Agvet Code inserted by item 108 of Schedule 3 of the Bill.

\textsuperscript{169} Proposed section 38A of the Agvet Code inserted by item 110 of Schedule 3 of the Bill.

\textsuperscript{170} Proposed section 41 of the Agvet Code inserted by item 113 of Schedule 3 of the Bill.

\textsuperscript{171} Proposed section 34P of the Agvet Code inserted by item 101 of Schedule 3 of the Bill. The exceptions to this general rule are where the suspension or cancellation is made under section 34AA (reconsideration), section 35A (suspension or cancellation of registration if imminent risk to persons of death, serious injury or serious illness), section 39 (suspension of approval or registration if compensation for use of protected information cannot be arbitrated) or section 42 (cancellation of approval or registration at the request of the holder).

\textsuperscript{172} Proposed subsection 46(2) inserted by item 122 of Schedule 3 of the Bill sets out the action which the APVMA must take in circumstances where a suspension or cancellation is revoked.

\textsuperscript{173} Inserted by item 120 of Schedule 3 of the Bill.

\textsuperscript{174} Proposed section 45B inserted by item 120 of Schedule 3 of the Bill.

\textsuperscript{175} Proposed section 45C inserted by item 120 of Schedule 3 of the Bill.
Proposed subsection 45C(1) of the Agvet Code applies if a person has possession or custody of the constituent or product with the intention of supplying it. According to proposed subsection 45C(2), once the notice of the suspension or cancellation is given to the person or published in the Gazette, the person must not possess, have custody of, or deal with the constituent or product other than in accordance with the instructions contained in the notice. A person commits an offence of strict liability, the penalty for which is 300 penalty units, if the person contravenes this section. The provision is a civil penalty provision.\(^{177}\)

However proposed subsections 45C(3) and (4) contain exceptions to that rule. In particular, proposed subsection 45C(4) provides that the requirement to act in accordance with the instructions in the notice does not apply to a person who was not given a notice if they prove that they did not know, and could not reasonably be expected to have known, of the existence of the notice published in the Gazette or that their possession, custody or dealing was not in accordance with the instructions contained in the Gazette notice.

According to the Explanatory Memorandum:

> This is an additional defence to the defence of honest and reasonable mistake of fact and, although the defendant bears the legal burden, is broader in scope. This is because it is not concerned with the requisite state of mistaken belief but is judged against the standard of what could be reasonably expected. The provision imposes the legal burden of proof on the defendant and this must be discharged on the balance of probabilities.\(^{178}\)

It is this reversal of the onus of proof about which the Scrutiny of Bills Committee has commented on the grounds that ‘it is not clear why a legal burden, as opposed to an evidential burden is necessary’.\(^{179}\) That being the case, the Committee has sought further justification for this provision.

Duration of approvals and registrations and renewal of registrations

Item 7 of Schedule 2 of the Bill inserts proposed sections 46A and 47–47E. Proposed section 47A provides a general explanation of the operation of proposed Division 6 of Part 2 of the Agvet Code.

Proposed section 47 provides for an extension of the period of approval in circumstances where an application for re-approval or re-registration has been received up to the day that the application has been determined. Importantly, the registration of a chemical product will end if the approval of an active constituent for the product ends and the approval of a label for containers for a chemical product ends when the registration of the product ends.

The APVMA is required to vary the date entered in the Record or Register as the day the approval or registration ends, where regulators of agricultural or veterinary chemicals of two or more foreign countries have decided to prohibit all uses of the same active constituent, or one or more chemical

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176. Proposed subsection 45C(5) of the Agvet Code, inserted by item 120 of Schedule 3 of the Bill.
177. Proposed subsection 45C(7) of the Agvet Code, inserted by item 120 of Schedule 3 of the Bill.
products containing the same active constituent, on safety grounds within a seven year period. In that case the APVMA must vary the end date and the last renewal date in the Record or Register and give the holder of the approval or registration written notice of the date as varied at least six months before it occurs.  

End of approval or registration

In all other circumstances, twelve months before either the end of the approval of an active constituent or the date after which the registration of a chemical product cannot be renewed the APVMA must do two things:

- publish a notice in the Gazette to that effect inviting submissions as to whether the active constituent should be re-approved or the chemical product should be re-registered. The notice must specify the time within which the submission must be received. This should be a period of no later than six months before the existing approval or registration ends

- give the holder a notice setting out the relevant particulars and conditions of the approval or registration, specifying the relevant end date and any information prescribed by regulations.

As soon as practicable after an approval or registration ends, the APVMA must publish in the Gazette a notice to that effect—unless it deems that in the circumstances it is unnecessary. That notice must also contain instructions in relation to possessing or using the product, warnings about the consequences of failing to comply with the instructions and any other warnings which the APVMA considers appropriate. The APVMA must give a copy of the notice to the holder and any other person who the APVMA considers should be given notice of the end of the approval or registration.

Persons who possess, have custody of, or use, the constituent or product which has been the subject of such a notice are deemed to have been issued a permit for that purpose until one year after the day on which the approval or registration ended, or an earlier date specified by the APVMA in the Gazette, provided that the person uses the constituent or product in accordance with the instructions contained in the notice.

If the APVMA has published a notice to the effect that an approval has ended, a person who has possession or custody of the constituent or product with the intention of supplying it must deal with the constituent or product only in the manner set out in the notice. A person who contravenes that requirement commits an offence of strict liability. Importantly, the imposition of strict liability

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180. Proposed section 47A inserted by item 7 of Schedule 2 of the Bill.
181. Proposed subsections 47B(1) and (2) inserted by item 7 of Schedule 2 of the Bill.
182. Proposed subsections 47B(3) and (4) inserted by item 7 of Schedule 2 of the Bill.
183. Proposed subsections 47C(1) and (3) inserted by item 7 of Schedule 2 of the Bill.
184. Proposed subsection 47C(2) inserted by item 7 of Schedule 2 of the Bill.
185. Proposed subsection 47C(4) inserted by item 7 of Schedule 2 of the Bill.
186. Proposed subsection 47D(1) inserted by item 7 of Schedule 2 of the Bill.
187. Proposed subsections 47E(1) and (2) inserted by item 7 of Schedule 2 of the Bill.
will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations. The penalty for the offence is 300 penalty units. This is also a civil penalty provision.

Issue—decisions of foreign regulators

The purpose of proposed section 47A is to provide for an automatic trigger for re-approval and re-registrations:

… where prescribed regulators in two or more foreign countries have prohibited all the uses of an active constituent or chemical product to prevent harm to humans or prevent unintended harm to animals, plant, things or to the environment.

Summerfruit Australia Limited (SAL) has questioned the basis for the review ‘trigger’ stating:

SAL believes that the legislation should be more explicit and specify that the decision of the foreign regulators must be the result of science based risk assessment. SAL is concerned that in some foreign jurisdictions, such decision could be made on the basis of policy … SAL believes a step should be included in which decision by foreign regulators are vetted to ensure they are science-based and comply with the Australian risk framework.

Similarly whilst the NSW Farmers Association believes that the more effective use of overseas data and assessments by the APVMA should improve the efficiency of the registration and approval process, it urged caution stating that ‘in using data generated overseas it is imperative that the Australian climate and environment and Australian farming systems are taken into consideration’.

This was also an issue for the Greens Senator of the Rural and Regional Affairs and Transport Committee who was concerned that ‘Australia still has pesticides registered that have long been banned in other countries because, after risk assessment, they failed to meet contemporary health and safety standards’ and that ‘there is no justification why these same pesticides should be considered safe to use in Australia’.

Issue—strict liability

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The Scrutiny of Bills Committee drew attention to the terms of proposed section 47E, both in relation to the size of the penalty for the strict liability offence—that is, it is higher than the maximum of 60 penalty units\(^{195}\) and because the Explanatory Memorandum does not provide a justification for the reversal of the onus of proof in respect of these provisions.\(^{196}\) The Scrutiny of Bills Committee has sought the Minister’s advice in relation to these matters.

### Renewing registrations

Subject to the amendment in item 9 of Schedule 2 to the Bill, subsection 48(1) of the Code provides that a holder may apply for the renewal, or further renewal, of the registration of a chemical product. This is expected to occur annually.\(^{197}\) Item 10 of Schedule 2 of the Bill repeals and replaces subsection 48(2) of the Agvet Code so that a renewal application must be made not later than one month before the registration ends and before the day which the Register shows as the day after which registration cannot be renewed.

### Parts 2A and 2B of the Agvet Code

#### Listed chemical products and reserved chemical products

At present, Parts 2A and 2B of the Agvet Code provide two tiers of regulation, known as listed registration and reservation of registration respectively, for those agvet chemical products which are considered to be suitable for a lower degree of regulation—that is, they do not warrant the rigorous, individualised assessment process that applies to registered chemical products, particularly given the known risks associated with their use. In that case, the APVMA can grant either:

- listed registration against a pre-determined standard or
- reservation from registration according to pre-determined conditions.\(^{198}\)

Item 63 of Schedule 1 of the Bill repeals Part 2A of the Agvet Code as the ‘process for what was called listed registration is now included in provisions dealing with registration of a chemical product’.\(^{199}\) Item 29 of Schedule 1 of the Bill inserts proposed section 8T which provides that the

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197. Explanatory Memorandum, p. 31.
199. Explanatory Memorandum, p. 38.
regulations may include a schedule specifying chemical products, or classes of chemical products, that are listed chemical products for the purposes of the Agvet Code.\textsuperscript{200}

Items 64 and 65 of Schedule 1 of the Bill amend Part 2B of the Agvet Code so that the APVMA must give the Minister a written explanation about its satisfaction that a product or class of products meets the safety criteria, the trade criteria and the efficacy criteria before any regulation is made specifying that the product, or class of products are reserved chemical products for the purposes of the Agvet Code.

Part 3 of the Agvet Code

Compensation for the provider of information

Part 3 of the Agvet Code contains provisions that entitle a person who has provided protected information to the APVMA in relation to a protected active constituent or in relation to a protected chemical product, in compliance with a requirement made of the person by the APVMA, to receive compensation from anyone else who wishes the information to be used by the APVMA in connection with an application for the approval, or continued approval, of another active constituent or the registration, or continued registration, of another chemical product.\textsuperscript{201}

Items 30–32 of Schedule 4 of the Bill amend subsection 57(2) of the Agvet Code to clarify the circumstances in which compensation is not payable, that is where the protected active constituent or the protected chemical product is, or includes, a patentable invention and the term of the patent has ended or is about to end\textsuperscript{202}; and the information was obtained because of a trial or laboratory experiment, information about which was given to the APVMA in compliance with a specified provision in the Agvet Code.\textsuperscript{203}

Items 34–44 of Schedule 4 of the Bill amend section 59 of the Agvet Code which sets out the rights of the originator of protected information\textsuperscript{204} to compensation for its use in relation to other applications. (See also the discussion under the heading Data protection above.) The effect of the amendments is that if protected information has been given to the APVMA about an active constituent for a proposed or existing chemical product (called the primary active constituent) or a protected chemical product (called the primary chemical product) the APVMA must not use the information in determining whether to approve, or to continue the approval of, another active constituent for a proposed or existing chemical product (called the secondary active constituent), or whether to register, or to continue the registration of, another chemical product (called the

\textsuperscript{200} Item 15 of Schedule 1 of the Bill inserts the definition of listed chemical product into subsection 3(1) of the Agvet Code so that a listed chemical product is one that is, or is included in, a class of chemical products that is listed by regulation under section 8T.

\textsuperscript{201} Existing subsection 57(1) of the Agvet Code.

\textsuperscript{202} The Agvet Code does not define the term patentable invention or patent. However the Patents Act 1990 regulates the granting of patents. Section 18 of the Patents Act 1990 sets out the meaning of the term patentable invention. The text of the Patents Act 1990 can be viewed at: http://www.comlaw.gov.au/Details/C2012C00423/Download

\textsuperscript{203} Those provisions are proposed paragraph 32(1)(b), proposed section 33 and proposed subsection 159(1) of the Agvet Code.

\textsuperscript{204} The definition of protected information is inserted into the Agvet Code by item 13 of Schedule 4 of the Bill.

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secondary chemical product. There are a number of exceptions to this rule (which have been added to by item 40 of Schedule 4 of the Bill. The exceptions under proposed subsection 59(2) of the Agvet Code include:

- the primary holder and the secondary holder have agreed that compensation will be paid by the secondary holder to the primary holder for the information and have notified the APVMA in writing about the terms of the compensation
- the APVMA has appointed an arbitrator to determine the compensation and the secondary holder agrees, in writing, to comply with the determination
- the protection period has elapsed since that information was given to the APVMA
- the APVMA is satisfied, having regard to any criteria that are prescribed by regulation, that it is in the public interest for the information to be used
- the information was previously given to the APVMA other than as protected information
- the information shows that the secondary active constituent or secondary chemical product may not meet the safety criteria, the trade criteria or the efficacy criteria or
- the information is publicly available.

**Part 4 of the Agvet Code**

**Control of chemical products**

Part 4 of the Agvet Code deals with the control of chemical products. Item 66 of Schedule 1 of the Bill repeals and replaces paragraphs 72(2)(a)–(c) to make clear that Part 4 restricts:

- the supply of unapproved active constituents for chemical products and unregistered chemical products
- their possession for the purposes of supply and
- the supply of active constituents for chemical products that have been approved and the supply of chemical products that have been registered or reserved in contravention of the conditions of their approval, registration or reservation.

Items 67–91 of Schedule 1 of the Bill make consequential amendments to Part 4 to ensure consistency of terms.

Items 123–229 of Schedule 3 of the Bill amend Part 4 to create offences in a manner that is consistent with the terms of the Guide to Framing Offences. In addition, the amendments clarify that contraventions of the requirements of Part 4 of the Agvet Code are also civil penalty provisions.
Part 5 of the Agvet Code

Analysis of samples and substances

Part 5 of the Agvet Code sets out the procedure by which samples or substances are to be analysed and states how evidence of the results of the analysis may be given in proceedings under the Code. Inspectors are appointed under subsection 69F(1) of the Agvet Administration Act or authorised under subsection 69F(2) for the purposes of the Agvet Administration Act. Section 97 of the Agvet Code (as amended) provides that an inspector may give a portion of a sample taken under the monitoring powers (in proposed section 131A which is inserted by item 285 of Schedule 3 of the Bill) or the investigation powers (in proposed section 132A which is inserted by item 285 of Schedule 3 of the Bill) to an approved analyst for analysis.

In addition, existing section 99 empowers the APVMA to give a notice to a person who has possession or custody of a substance (or mixture of substances) to be supplied as a chemical product under a particular name requiring the person to have the substance or mixture analysed. The impetus for such a notice is advice that an inspector reasonably suspects that the constituents, or concentration of the constituents, of the substance or mixture, or the composition or purity of a constituent of a substance or mixture is inconsistent with the information on the Register.

Item 237 of Schedule 3 of the Bill inserts proposed subsections 99(3A) and(3B) into the Agvet Code so that the APVMA is empowered to give a notice to a person requiring the analysis of an active constituent for a proposed or existing chemical product. A person to whom a notice is given under section 99 must comply with the notice and must give the analyst’s certificate to the APVMA not later than five working days after the person received the certificate. Item 241 of Schedule 3 of the Bill inserts proposed subsection 99(5AA) so that a person who fails to comply with the notice and provide the analyst’s certificate within the required time commits an offence of strict liability, the penalty for which is 120 penalty units. This is a civil penalty provision.

Part 6 of the Agvet Code

Recall notices

Part 6 of the Agvet Code deals with recall notices. Under existing section 100 of the Agvet Code the APVMA may issue recall notices requiring persons who have, or have had, stocks of chemical products in their possession to stop supplying the products and to take any other action in relation to the products that the APVMA directs.

205. Section 96 of the Agvet Code.
207. This is equivalent to $20 400.
208. Proposed subsection 99(5B) inserted by item 243 of Schedule 3 of the Bill.

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Items 101–115 of Schedule 1 of the Bill amend Part 6 of the Agvet Code. In particular, item 116 repeals and replaces subsection 104(1) to require the APVMA to publish a notice in the Gazette (and in any other manner it deems appropriate) that it has issued a recall notice within 14 days of the day of issuing the notice. This replaces the current requirement that the APVMA publish a notice ‘as soon as practicable’ after the issue of the recall notice.

Items 244–247 of Schedule 3 of the Bill amend section 105 of the Agvet Code to redraft the offence provision, consistent with the other offence provisions in the Code.

Part 7 of the Agvet Code

Permits

All agricultural and veterinary chemical products sold in Australia must be registered by the APVMA.

In most States, registered products must only be used for purposes that are specified on the label. In practice, situations often arise where chemicals are needed for a use not specified on the label, these are often termed ‘off-label’ uses. The APVMA can consider applications for permits that allow for the legal use of chemicals in ways different to the uses set out on the product label. In certain circumstances, the limited use of an unregistered chemical may also be allowed by permit. 210

Annexure 2 of this Bills Digest illustrates the complexity of the labelling requirements. The use of a product for a purpose which is not consistent with the ‘Directions for Use’ is an ‘off-label’ use.

The basis for issuing permits is contained in Part 7 of the Agvet Code. Items 117–140 amend Part 7 to require that:

- an application for a permit must satisfy the application requirements 211
- the APVMA must conduct a preliminary assessment within one month after the application is lodged. Within 14 days of making that preliminary assessment the APVMA must notify the applicant in writing that it will be determined under section 112 and setting out any other matters prescribed by regulation 212
- if the application has defects that can reasonably be rectified, the APVMA must give written notice to the applicant setting out the defects in the application and requiring those defects to be rectified within one month 213
- otherwise the APVMA must refuse the application 214

211. Proposed section 8A of Schedule 1 to the Bill contains the definition of application requirements. See comments in the text above about the consistent use of these provisions for each of the applications processes provided for in the Agvet Code.
212. Proposed subsections 110A(1) and (2) of the Agvet Code.
213. Proposed subsection 110A(3) of the Agvet Code.

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Having accepted the application following the preliminary assessment process, the APVMA must issue the permit if it is satisfied of all the matters listed in proposed subsection 112(2).215 These include, but are not limited to, the need for the constituent, product and label to meet the safety criteria, trade criteria and efficacy criteria where relevant, as well as any requirements prescribed by regulations.216 In addition, where no application for approval of the constituent or registration of the product has been made, the APVMA must be satisfied that there are reasonable grounds for the application not having been made or for issuing the permit pending determination of an application. The rationale for this requirement is ‘to ensure that permits are not used as a means of allowing users to circumvent seeking active constituent approvals or chemical product registrations’.217

However, proposed subsection 112(4) qualifies the requirement to issue a permit so that a permit must be refused if the APVMA is satisfied that the applicant will be unable to comply with the permit or where the applicant or a person who makes, or participates in making, decisions that affect the applicant’s affairs has, within the 10 years immediately before the application, been convicted of an offence of the types listed, been ordered to pay a pecuniary penalty of the types listed or held a permit that was subsequently cancelled. Despite these conditions for the issuing of permits, proposed subsection 112(6) allows the APVMA to issue the permit if the APVMA is of the opinion that special circumstances make it appropriate to do so. The Explanatory Memorandum gives no guidance as to the nature of the special circumstances.

Proposed section 112A in Schedule 1 of the Bill which is set out in similar terms to proposed section 112 authorises the APVMA to issue a permit in respect of an active constituent for a proposed or existing chemical product or in respect of a chemical product on its own initiative.218

The significant difference lies in proposed subsection 112A(6) which requires the APVMA to first notify the holder of an approval or registration that it intends to issue a permit on its own initiative and to defer the issuing of the permit for a period of 28 days from the date that the notice is given. In any other circumstance there is no requirement to notify the holder of the approval or registration.219 In addition, the requirement does not apply if the APVMA is of the opinion that special circumstances exist. In that case, the permit may be issued without written notice being given to the holder of the approval or registration; or before the end or the 28 days.

Item 130 of Schedule 1 of the Bill amends existing subsection 114(5) so that the APVMA must take action within 14 days of issuing a permit, to place a copy of the permit on the Record of Permits and to notify the co-ordinator that the permit has been issued and tell a prescribed authority that the

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215. Item 126 of Schedule 1 of the Bill repeals existing subsections 112(2)–(5) and inserts proposed subsections 112(2)–(7) of the Agvet Code.
217. Explanatory Memorandum, p. 41.
219. See also proposed section 8F of the Agvet Code which sets out the circumstances in which the APVMA must give written notice to the holder of an approval or registration.
220. The term co-ordinator is defined in section 3 of the Agvet Code and is unchanged by this Bill. A co-ordinator in relation to a jurisdiction, means a person designated to perform the functions of a co-ordinator under the Agvet Code: (a) if the jurisdiction is a State—by a Minister of the State, (b) if there is more than one participating Territory—jointly

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permit has been issued. Under existing subsection 115(1) a permit is in force until it is surrendered or the APVMA cancels it. Items 131–132 operate so that the APVMA may extend a permit for a further period if it is satisfied that the application meets the application requirements and any other requirements prescribed by regulations.

Items 248 and 249 of Schedule 3 of the Bill amend the definition of permit in section 109 of the Agvet Code to also include the new civil penalty provisions and the other amendments to the Agvet Code which extend the circumstances in which the APVMA may issue a permit.

Item 252 of Schedule 3 of the Bill inserts proposed subsections 116(3A)–(3C) of the Agvet Code. The effect of these provisions is that a person to whom a permit applies commits an offence if the person contravenes the conditions of the permit. The penalty for the offence is 300 penalty units. Unlike many of the other offences in the Agvet Code, this is not a strict liability offence. Rather it is a civil penalty provision which relates to a non-criminal contravention of the Agvet Code.

Existing sections 118 and 119 of the Agvet Code authorise the APVMA to suspend or cancel a permit respectively. Item 253 of Schedule 3 of the Bill inserts proposed section 117A which requires the APVMA to first notify the permit holder in writing of the intention to suspend or cancel the approval or registration, the reasons for it, and inviting the permit holder to make submissions. The APVMA must not take action to suspend or cancel the approval or registration until it has had regard to any submission from the permit holder.

The general grounds for suspension of a permit are set out in proposed section 118(1) (which is inserted by item 255 of Schedule 3 of the Bill). The APVMA may suspend a permit if it appears to the APVMA that:

- an active constituent or a chemical product do not meet the relevant approval criteria
- the use of an active constituent or a chemical product in accordance with the permit is inappropriate or
- the holder has contravened a condition of the permit.

Items 258 and 259 of Schedule 3 of the Bill amend section 119 of the Agvet Code to update the grounds on which the APVMA may cancel a permit so that the language is consistent with the other provisions of the Agvet Code. Proposed subsections 119A and 119B (inserted by item 261 of Schedule 3 of the Bill) authorise the APVMA to suspend or cancel a permit if the APVMA considers that it is necessary to prevent imminent risk to persons of death, serious injury or serious illness or if the holder of the permit has given information to the APVMA which was false or misleading in a material particular.

by a Minister of the Commonwealth and a Minister of the Australian Capital Territory, otherwise—by a Minister of the Australian Capital Territory.

221. This is equivalent to $51 000.
222. Proposed subsection 117A(2) of the Agvet Code.

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Issue—liability

The Australian Forest Products Association expressed their need of minor use permits, stating that they ‘are essential to ensure chemicals are available to use for forestry applications’. 223

Despite the popularity of minor use permits amongst some stakeholders 224, there was concern about the APVMA granting the limited use of a product by permit on the grounds that ‘it is a risk borne by the registrants’ and that ‘is the reason we do not necessarily approve of the APVMA or any agency being able to extend that risk exposure to that company without the consent of the company’. 225

CropLife Australia recommended that a permit be ‘issued only with the consent of the registrant of that product. That would enable the registrant to refuse a permit to be issued in circumstances in which they were not convinced that that use would be safe’. 226

Part 8 of the Agvet Code

Manufacture of chemical products under licence

The APVMA is required to license manufacturers of veterinary chemical products.

Users of veterinary chemical products expect them to be safe, effective and of a high quality. The best way to meet these expectations is to build quality into the product at the time of manufacture; and to do that products must be manufactured consistently, by a specified method, under adequate supervision and with effective quality control procedures—that is using Good Manufacturing Practices ... To that end the APVMA established the Manufacturers’ Licensing Scheme. 227

Items 141–153 of Schedule 1 of the Bill amend Part 8 of the Agvet Code which relates to the manufacture of chemical products. Item 144 repeals and substitutes subsection 123(1) so that the APVMA must issue a licence unless it is satisfied of certain matters. These include, but are not limited to:

- the application does not meet the common application requirements which are set out in section 8A of the Agvet Code
- the applicant will be unable to comply with the conditions of the licence or the manufacturing principles

224. See also Agforce Queensland, Submission to the Rural and Regional Affairs and Transport Legislation Committee, Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, op. cit., p. 5.
226. Ibid., p. 42.

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- the applicant or a person who makes, or participates in making, decisions that affect the applicant’s affairs has, within the 10 years immediately before the application, been convicted of an offence, been ordered to pay a pecuniary penalty (in equivalent terms to those related to the refusal of a permit), has contravened a condition of a manufacturing licence issued under an agvet law or has held a manufacturing licence or permit that was cancelled under an agvet law.

Proposed subsection 123(1A) provides, for the absence of doubt, that if the APVMA does not issue a licence, it must refuse the application.228

A licence to manufacture may be issued by the APVMA, subject to conditions.229 Proposed paragraphs 126(3)(a) and (b) of the Agvet Code set out the date of effect of the imposition of a condition or a variation of a condition. The date of effect is generally the day stated in the notice that is not earlier than 28 days after the notice is given to the holder—unless the APVMA and the holder agree. The exception to this general provision is where the notice states that the action is necessary to prevent an imminent risk:

- to persons of death, serious injury or serious illness
- of unintended harm to animals, plants or things, or to the environment and/or
- of impact on trade or commerce between Australia and places outside Australia.

In that case, the date of effect is the day that the notice is given to the holder providing that the notice identifies the relevant imminent risk or risks.

Existing section 121 sets out the offences relating to manufacture and licences. Items 263–272 of Schedule 3 of the Bill redraft section 121 to clarify the offences and to insert references to civil penalty provisions. The penalty unit amounts in relation to the offences are unchanged.

Existing section 127 of the Agvet Code authorises the APVMA to suspend or cancel a licence to manufacture chemical products. Items 275–280 of Schedule 3 of the Bill amend section 127 for clarity and consistency with other similar provisions.

228. This will give rise to the requirement to give written notice of the refusal within 14 days in proposed section 8G of the Agvet Code.

229. Existing subsection 126(1) of the Agvet Code. Proposed subsection 120(3) of the Agvet Code, inserted by item 262 of Schedule 3 of the Bill, provides that a licensee is required to comply with conditions imposed on a licence for the manufacture of chemical products.
Part 9 of the Agvet Code

Enforcement

Items 281—306 of Schedule 3 of the Bill repeal and replace much of the existing contents of Part 9 of the Agvet Code which sets out the investigative powers of the APVMA. The amended Part 9 contains the APVMA’s powers to gather information and to search premises with or without a warrant to find out whether an offence against an agvet law has been committed and/or an agvet penalty provision has been contravened. Part 9 consists of 10 Divisions in equivalent terms as the amendments to the Agvet Administration Act which are set out below.

Of particular note, proposed section 130 sets out the APVMA’s power to issue a notice in writing requiring a person to provide information and/or produce documents to an inspector, or to appear before an inspector to answer questions. The notice must specify the period within which the person must comply with the notice (being at least 14 days) and state that the person may be accompanied by a lawyer. Under proposed section 130B, offences (the penalty for which is 30 penalty units or imprisonment for six months or both) are created where a person fails to comply with the notice within the specified time, the person fails to appear before an inspector, a person who is required to provide information under oath refuses or fails to do so and where a person who is required to appear and give answers to an inspector refuses or fails to answer a question put by the inspector.

Importantly, a person is not excused from giving information, providing a document or answering a question on the grounds that doing so might incriminate the person. The Explanatory Memorandum provides the justification for this provision as follows:

The abrogation of the privilege against self-incrimination is necessary because based on past experience with existing provisions in the Agvet Code that require persons to provide information ... the APVMA has had difficulty in obtaining the necessary information from persons because they are concerned that the

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230. The enforcement powers contained in Schedule 3 to the Bill are broadly equivalent to the framework enforcement powers which are outlined in the Regulatory Powers (Standard Provisions) Bill 2012 which is currently before the House of Representatives. The text of the Bill and the explanatory material are at the Bill homepage: http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbillhome%2Fr4912%22

231. Proposed subsections 130(1)–(6) of the Agvet Code Act, inserted by item 283 of Schedule 3 of the Bill.

232. Proposed section 130C of the Agvet Code. ‘The common law privilege against self-incrimination will protect a natural person complying with a notice to disclose information or documents under a notice to produce or attend, unless the privilege is expressly or impliedly overridden’ by legislation. ‘The privilege is relevant for regulatory schemes because it entitles a person to refuse to answer a question put to him or her by an authorised officer under a regulatory scheme on the basis that he or she may incriminate him or herself: Pyneboard Pty Ltd v Trade Practices Commission (1983) 152 CLR 328.’ Legislation should clearly specify if the privilege is to be overridden and if it is removed then at a minimum a ‘use’ immunity provision should be included as some form of protection. If a person claims a ‘use’ immunity, no information or evidence given by them can be directly used against them. A ‘derivative use’ immunity is where no disclosures can be used against the person indirectly to gather other evidence against the person. Source: Commonwealth of Australia, ‘A guide to framing Commonwealth offences, infringement notices and enforcement powers’, op. cit., pp. 94—96.


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information may incriminate them or expose them to a penalty, or because of a concern about ‘brand damage’ or a lack of awareness of relevant compliance requirements in the first place.

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

- civil proceedings for contravention of a civil penalty provision
- criminal proceedings, unless the proceedings are for an offence that relates to investigation by the APVMA, including the provision of false or misleading information or documents, or obstructing Commonwealth public officials.\(^{233}\)

The Human Rights Committee has also commented on the right not to incriminate oneself, but considered that ‘these provisions, which compel disclosure of information or production of documents, but which also provide a use and derivative use immunity, are consistent with the right not to incriminate oneself’.\(^ {234}\)

**Item 285 of Schedule 3** of the Bill inserts updated monitoring powers. In particular, **proposed section 131AA** of the Agvet Code provides that an inspector may, to the extent that it is reasonably necessary for the purpose of preventing imminent risk to persons of death, serious injury or serious illness, enter premises and exercise the monitoring powers which are listed in **proposed section 131A**. However, **proposed subsection 131AA(4)** limits the exercise of this power to circumstances where the inspector has specifically been authorised in writing by the APVMA to do so.

According to the Explanatory Memorandum:

> This authority is necessary to protect the community. Reporting arrangements for the use of this authority have been provided for in the Admin Act. This approach is consistent with the Guide. In addition, this authority is consistent with the authority provided to inspectors in other similar Commonwealth legislation.\(^ {235}\)

However, the Scrutiny of Bills Committee notes that the Guide to Framing Offences states that such powers are only justifiable in rare circumstances which is a higher test than that which is contained in the Bill—although, in mitigation, the exercise of these powers is subject to rigorous reporting arrangements.\(^ {236}\)

Similarly **items 308 and 309** insert **proposed Part 9A** into the Agvet Code Act (**proposed sections 145–147**) to set out updated enforcement procedures. **Proposed section 145** provides a general explanation of this Part. As with the Agvet Administration Act (which is discussed below) these enforcement procedures include seeking civil penalties, issuing infringement notices,

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233. Explanatory Memorandum, p. 77.
235. Explanatory Memorandum, p. 78.
236. Scrutiny of Bills Committee, op. cit., p. 7.
accepting and enforcing undertakings, seeking injunctions, requiring claims to be substantiated and issuing formal warnings.

An additional power is the power for the APVMA to give enforceable directions to a person where it believes on reasonable grounds, that the person is not complying with the Agvet Code requiring the person to take steps to comply.\(^{237}\) A person commits an offence if the person fails to comply with the terms of the notice within the specified time.

Issue—use of administrative discretion

The Scrutiny of Bills Committee raised concerns with the terms of proposed subsection 145DB(3). Proposed section 145DA provides that where an inspector has reasonable grounds to believe that a person has contravened a prescribed civil penalty provision, the inspector may give the person an infringement notice for the alleged contravention. Proposed section 145DB sets out those matters to be included in the infringement notice—including the amount that is payable under the notice. Proposed subsection 145DB(2) of the Agvet Code limits the amount payable to not more than one-fifth of the maximum penalty that a court could impose for the contravention. Proposed subsection 145DB(3) permits regulations to set out the scale of amounts that may apply to an alleged contravention. According to the Scrutiny of Bills Committee ‘the use of a sliding scale can be undesirable as it makes penalties dependent on discretionary judgments’.\(^{238}\) However, the Scrutiny of Bills Committee noted that any such regulation would be disallowable by the Parliament.

Part 10 of the Agvet Code

Overseas trials and experiments

Existing section 160 of the Agvet Code provides that, amongst other things, in making a decision to approve an active constituent of a chemical product, a chemical product or a label for containers of a chemical product, to reconsider an approval or to suspend or cancel a permit, the APVMA may take into account any trials or experiments already carried out in a foreign country.

Items 175–182 of Schedule 1 of the Bill amend section 160 for clarity. The amendments provide that the APVMA may take into account the results of trial and experiments carried out in a foreign country and any decisions or evaluations (and the information on which the decision or evaluation is based) made by regulators of agricultural or veterinary chemicals in a foreign country. In considering such material the APVMA may take into account a range of matters including any significant differences in the way decisions or evaluations are made in Australia and by the national regulatory authority of that foreign country.\(^{239}\) (See the comments under the heading Decisions of foreign regulators above.)

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\(^{237}\) Proposed section 145H of the Agvet Code, inserted by item 308 of Schedule 3 of the Bill.

\(^{238}\) Scrutiny of Bills Committee, op. cit., p. 5.

\(^{239}\) Proposed subsection 160(3) of the Agvet Code.
Reviews and appeals

Existing sections 166 and 167 of the Agvet Code currently provide for ‘reconsideration of decisions’ and for ‘review of decisions’.

Items 219-223 of Schedule 1 of the Bill amend existing section 166 so that:

- what was formerly referred to as a ‘reconsideration’ will be renamed as an ‘internal review’. The matters about which internal review can be undertaken are limited to:
  - a decision that is reviewable by the Administrative Appeals Tribunal (AAT)—these are listed in proposed paragraphs 167(1)(aa) which is inserted by item 225 of Schedule 1 of the Bill—other than a decision to vary relevant particulars and conditions to allow re-approval or re-registration\(^{240}\), a decision to vary particulars or conditions on reconsideration\(^{241}\) and a decision to suspend or cancel an approval or registration\(^{242}\)
  - a decision to refuse an application: for approval or registration\(^{243}\), to vary relevant particulars that are prescribed by regulation\(^{244}\), to vary other relevant particulars\(^{245}\) or for a re-approval or for re-registrations\(^{246}\) because the application does not meet the application requirements set out in proposed paragraphs 8A(a) or (b)
  - a decision to refuse an application to issue a permit\(^{247}\) because the application does not meet the application requirements set out in proposed paragraphs 8A(a) or (b) or because of a failure to provide information as requested by APVMA on behalf of a co-ordinator\(^{248}\)
- where the APVMA has received a request for an internal review of an original decision, the APVMA is to reconsider the decision having regard only to the information that was used to make it\(^{249}\)
- where the APVMA has received a request for an internal review of an original decision it must confirm, vary or set aside the original decision or set aside the original decision and substitute a new decision.\(^ {250}\)

The terms of section 167 have been amended to specify those decisions which may be the subject of an application to the Administrative Appeals Tribunal (AAT), consistent with the other amendments to the Agvet Code.

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\(^{240}\) Proposed subsection 29G(1) of the Agvet Code.
\(^{241}\) Proposed subsection 34A(1) of the Agvet Code.
\(^{242}\) Proposed subsections 34AA(1) and (2) of the Agvet Code.
\(^{243}\) Proposed subsection 14(2) of the Agvet Code.
\(^{244}\) Proposed subsection 26C(2) of the Agvet Code.
\(^{245}\) Proposed subsection 29(2) of the Agvet Code.
\(^{246}\) Proposed subsection 29E(3) of the Agvet Code.
\(^{247}\) Proposed subsection 112(3) of the Agvet Code.
\(^{248}\) Subparagraph 111(1)(b)(iii) of the Agvet Code.
\(^{249}\) Proposed subsection 166(3) of the Agvet Code.
\(^{250}\) Existing paragraphs 166(3)(a)–(d) of the Agvet Code.
Other provisions—enforcement

Agricultural and Veterinary Chemicals (Collection of Levy) Act

Items 1–17 of Schedule 3 to the Bill amend the Agvet Levy Act. That Act:

- empowers the APVMA to give written notice to a person requiring him or her to calculate the total levy payable in respect of a product for a period and to notify the APVMA within a period of not less than one month of the results of those calculations and the basis on which they were made\(^ \text{251} \) and
- empowers the APVMA to require information about disposals of chemical products\(^ \text{252} \) and
- requires applicants for registration of chemical product to keep records.\(^ \text{253} \)

The amendments in items 6–12 and 16–17 of Schedule 3 create offences of strict liability if a person refuses or fails to comply with the requirement.\(^ \text{254} \) These are civil penalty provisions and the penalty is 50 penalty units.\(^ \text{255} \)

Issue—self incrimination

Proposed section 34 of the Agvet Levy Act (inserted by item 14 of Schedule 3 of the Bill) provides that a person is not excused from giving information, producing a document or thing, or answering a question asked by an inspector on the ground that doing so might tend to incriminate the person or expose the person to a penalty.

The Scrutiny of Bills Committee drew attention to this provision noting the comments in the Explanatory Memorandum that ‘this approach aligns with that taken in the Agvet Code and will ensure that the abrogation of this privilege is consistent for regulated entities across agvet chemical legislation’.\(^ \text{256} \)

In addition, the Scrutiny of Bills Committee noted that the statement of compatibility acknowledged the past difficulties faced by the regulator ‘in obtaining the necessary information from persons because they are concerned that the information may incriminate them or expose them to a penalty or because of a concern about “brand damage” or a lack of awareness of relevant compliance requirements in the first place’.\(^ \text{257} \)

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254. Importantly, the imposition of strict liability will not criminalise honest errors and a person cannot be held liable if he, or she, had an honest and reasonable belief that they were complying with relevant obligations.
255. This means that the maximum penalty is $8500.
256. Scrutiny of Bills Committee, op. cit., p. 3.
257. Ibid.

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The Scrutiny of Bills Committee noted that: Both a use and derivative use immunity are provided for those persons who provide information, documents or things in relation to criminal and civil proceedings. While the use and derivative use immunity does not apply in relation to the offence of obstructing Commonwealth officials ... or offences relating to the provision of false and misleading information ... and the explanatory memorandum does not address the point, this is a common exemption from the application of the use and derivative use immunity, at least in relation to the false and misleading information offences.  

Agricultural and Veterinary Chemicals (Administration) Act

Items 18–74 of Schedule 3 of the Bill amend the Agvet Administration Act.

Items 18–63 amend Division 2 of Part 7A of the Agvet Administration Act by inserting new headings which create new subdivisions which will add to the clarity of the Act. In addition, the items amend existing strict liability provisions in Division 2 so that they are expressed in uniform terms as also being civil penalty provisions. The penalty amount for those offences which is currently 30 penalty units is increased to 50 penalty units.  

Existing section 69F of the Agvet Administration Act empowers the APVMA to appoint, in writing, members of its staff who are engaged under the Public Service Act 1999, or other persons having appropriate qualifications, as inspectors. In addition, the Chief Executive may authorise, in writing, officers of a Department or administrative unit of a state or territory which has functions relating to agricultural or veterinary chemicals to perform the functions of inspectors.

Existing Division 3 of Part 7A of the Agvet Administration Act which sets out the existing powers of entry, search and seizure is repealed. Instead proposed Part 7AA which is inserted by item 64 contains the investigative powers of inspectors and a person assisting an inspector. Proposed Part 7AA contains a suite of powers which are written in equivalent terms to those in a number of Bills which have been considered by the Parliament and enacted into legislation in the last year. The characteristics of those powers are set out below.

Monitoring and investigation powers

Under proposed section 69EAB of the Agvet Administration Act, monitoring powers can be exercised by inspectors or persons assisting inspectors if the occupier of the premises consents or if the inspector has a monitoring warrant. The monitoring powers include the power to: search,  

258. Ibid.
260. Proposed section 69EAF sets out the powers, functions and duties of a person assisting an inspector.
261. For example, the Greenhouse and Energy Minimum Standards Bill 2012. Information about the Bill can be viewed on the Bill homepage at: http://parlinfo.aph.gov.au/parlinfo/search/display/display.w3p;query=Id%3A%22legislation%2Fbillhome%2Fr4841%22.  

262. Item 31 of Schedule 3 of the Bill inserts the definition of monitoring warrant into the Agvet Administration Act. Proposed section 69EH of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill sets out the circumstances in which a monitoring warrant is issued and the contents of the warrant.
examine and observe activities conducted on the premises; examine and inspect items; take photographs; and inspect and copy documents.\(^{263}\) The monitoring powers also extend to operating electronic equipment to access and copy the information stored on it.\(^{264}\) However, they do not include the power to seize that electronic equipment. Rather inspectors have the power to secure a thing for a period not exceeding seven days (which may be extended) in circumstances where the inspector believes on reasonable grounds it affords evidence of an offence or contravention of a civil penalty provision and that it is necessary to secure the electronic equipment pending the issue of a warrant for its seizure.\(^{265}\)

Higher level investigation powers are also provided for.\(^{266}\) If an inspector or a person assisting an inspector\(^{267}\) reasonably suspects there may be evidential material on the premises, he or she may enter the premises and use investigation powers so long as the occupier consents or the inspector has an investigation warrant.\(^{268}\) Evidential material is material relevant to offences and civil penalty provisions under the Agvet Administration Act or the Agvet Collection Act.\(^{269}\) Investigation powers include the power to search, inspect items, take pictures and bring in testing equipment, and if there is an investigation warrant, the power to search the premises and seize evidential material.\(^{270}\) The powers extend to electronically-stored material.\(^{271}\) As with monitoring warrants, investigation warrants are issued by a magistrate.\(^{272}\)

Issue—interferences with privacy

The Parliamentary Human Rights Committee noted the extensive investigation and monitoring powers by officers of the APVMA and that these powers are ‘a major encroachment on the right to privacy’. As the use of such powers requires ‘a clear justification as a necessary and proportionate measure’ the Parliamentary Human Rights Committee has sought clarification about the operation of certain of those powers.\(^{273}\)

Giving information to inspectors

The Bill gives an inspector who has entered premises to search for evidential material with the consent of the occupier or under an investigation warrant the power to require any person on the

\(^{263}\) Proposed section 69EAC of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{264}\) Proposed section 69EAD of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{265}\) Proposed section 69EAE of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{266}\) Proposed section 69EAD of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{267}\) Proposed section 69EBD of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{268}\) Proposed section 69EHA of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill sets out the circumstance in which an investigation warrant is issued and the contents of the warrant.

\(^{269}\) Item 26 inserts the definition of evidential material into section 4 of the Agvet Administration Act.

\(^{270}\) Proposed section 69EBA of the Agvet Administration Act inserted by item 64 of Schedule 3 of the Bill.

\(^{271}\) Proposed section 69EBB of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.

\(^{272}\) Proposed subsections 69EH(1) and 69EHA(1) of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.

\(^{273}\) Parliamentary Joint Committee on Human Rights, op. cit., p. 7. Also see the reference to these comments under the heading ‘Committee consideration’.
premises to answer questions or produce any document relating to evidential material. Failure to comply can amount to an offence with a maximum penalty of 50 penalty units.

The ‘coercive power’ granted to an inspector under proposed sections 69EAH and 69EC would appear not to abrogate the common law privilege against self-incrimination.

Occupier’s rights and responsibilities

Where a warrant is being executed in relation to premises, the inspector must, as soon as practicable, make a copy of the warrant available to the occupier or the occupier’s representative and inform that person in writing of the occupier’s rights and responsibilities. The occupier of the premises, or the occupier’s representative, has the right to observe the exercise of the warrant.

The occupier, or the occupier’s representative, must provide reasonable facilities and assistance to the inspector, or a person assisting the inspector, for the effective exercise of their powers. The Bill is silent as to what constitutes ‘reasonable facilities and assistance’. However the Explanatory Memorandum provides, by way of example, that a person may be required to ‘enable access to business records held off-site on remote servers and password protected devices’. Under proposed subsection 69EFA(2) of the Agvet Administration Act (inserted by item 64 of Schedule 3 of the Bill) a person who fails to comply with this responsibility commits an offence. The penalty for the offence is 30 penalty units.

Enforcement

The Bill introduces a range of enforcement options for the APVMA which include seeking civil penalty orders, issuing infringement notices, accepting and enforcing undertakings, seeking injunctions, requiring claims to be substantiated and issuing formal warnings.

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274. Proposed subsections 69EC(1)–(3) of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.
275. Proposed subsection 69EC(4) of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill. The penalty amounts to $8500.
276. ‘The common law privilege against self-incrimination will protect a natural person complying with a notice to disclose information or documents under a notice to produce or attend, unless the privilege is expressly or impliedly overridden’ by legislation. ‘The privilege is relevant for regulatory schemes because it entitles a person to refuse to answer a question put to him or her by an authorised officer under a regulatory scheme on the basis that he or she may incriminate him or herself. Pyneboard Pty Ltd v Trade Practices Commission (1983) 152 CLR 328.’ Legislation should clearly specify if the privilege is to be overridden and if it is removed then at a minimum a ‘use’ immunity provision should be included as some form of protection.
If a person claims a ‘use’ immunity, no information or evidence given by them can be directly used against them. Source: Commonwealth of Australia, ‘A guide to framing Commonwealth offences, infringement notices and enforcement powers’, op. cit., p. 23.
277. Proposed section 69EDC of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.
278. Proposed section 69EF of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.
279. Proposed section 69EFA of the Agvet Administration Act, inserted by item 64 of Schedule 3 of the Bill.
281. The penalty amounts to $5100.

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The APVMA can apply for a civil penalty order within six years of an alleged contravention.\(^{282}\) Under proposed section 69EJA, the maximum penalties for contravention of civil penalty provisions are:

- for a body corporate—not exceeding five times the amount of the maximum monetary penalty that a court could impose if the body corporate were convicted of an offence for conduct that is the same as the conduct constituting the contravention

- for an executive officer of a body corporate\(^{283}\)—not exceeding 12 per cent of the amount of the maximum monetary penalty that could be imposed on the body corporate for the contravention

- for an individual—not exceeding three times the amount of the maximum monetary penalty that a court could impose if the person were convicted of an offence for conduct that is the same as the conduct constituting the contravention.

An inspector can issue an infringement notice setting out details of the alleged infringement, and specifying the amount payable.\(^{284}\) An infringement notice can only be given within 12 months of the alleged contravention.\(^{285}\) If the amount is paid within 28 days proceedings seeking a civil penalty order may not be brought against the person.\(^{286}\) Payment is not to be taken as an admission of liability by the person.\(^{287}\)

The APVMA may accept written undertakings from a person that he or she will take specified action or refrain from taking specified action (as the case may be) to ensure that the person does not commit (or is unlikely to commit) an offence against the Agvet Admin Act or the Agvet Collection Act or to contravene a civil penalty provision.\(^{288}\) If the undertaking is breached, the APVMA may seek a court order that the person complies with the undertaking.\(^{289}\)

Courts also have power to grant restraining injunctions, performance injunctions and interim injunctions to prevent behaviour that is inconsistent with the provisions of the Bill.\(^{290}\)

The APVMA may issue a written notice to a person who has made a claim or representation about the import or export of a chemical product by the person or another person requiring the person who made the claim or representation to give information or produce documents to substantiate the claim or representation.\(^{291}\) Where the person refuses or fails to comply with the terms of the

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282. Proposed section 69EJ of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
283. Proposed section 69EJR of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill, sets out the liability of an executive officer of a body corporate.
284. Proposed sections 69EK and 69EKA of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
285. Proposed subsection 69EK(2) of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
286. Proposed paragraph 69EKD(1)(b) of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
287. Proposed paragraph 69EKD(1)(c) of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
288. Proposed section 69EL of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
289. Proposed section 69ELA of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
290. Proposed section 69EM of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
291. Proposed section 69EN of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
notice he or she commits an offence the penalty for which is 50 penalty units. This is a civil penalty provision. However the person does not contravene this provision if the information may incriminate the individual (proposed paragraph 69ENB(2)(c)).

Finally, the APVMA is empowered to issue a formal warning to a person where it has reasonable grounds to suspect that the person may have contravened the Agvet Administration Act or the Agvet Collection Act. According to the Explanatory Memorandum:

The APVMA would use these notices in instances where it believed the noncompliant behaviour was inadvertent.

The APVMA may use this option at its discretion. Warnings would be considered in the context of any future compliance and enforcement and penalty considerations. Non-compliance may result in a matter being escalated to investigation and used to support an increased penalty for the same offence or contravention at a later stage.

Arrangements for collecting levy

Under the NRS, the APVMA operates on a fully cost recovered basis. This is consistent with Australian Government cost recovery guidelines.

The APVMA’s current cost recovery arrangements were implemented in July 2005. Most of the APVMA’s operational income is collected from registrants of agvet chemicals. Registrants pay application fees to register products and an annual fee to maintain products on the register for the next financial year. Registrants also pay annual levies based on the value of past sales of registered products. Administrative services attract a direct fee.

Item 4 of Schedule 5 of the Bill inserts proposed section 3A into the Agvet Levy Act so that the Minister may, by written instrument, specify an Agency to be the collecting agency. This term is inserted into the Agvet Levy Act by item 2 of Schedule 5 of the Bill so that it refers to the APVMA unless a written instrument has specified another agency.

Where an agency (other than the APVMA) has been specified as the collecting agency, proposed sections 18A and 18B of the Agvet Levy Act require the APVMA to report certain matters to the APVMA which relate to the calculation of the amount of the levy and allow the APVMA to request information from the collecting agency respectively.

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292. This is equivalent to $8500.
293. Proposed section 69EO of the Agvet Administration Act, inserted by item 66 of Schedule 3 of the Bill.
Concluding comments

Despite the lengthy consultation which led to this Bill, it is not without its critics and it is unclear whether the amendments which are contained in the Bill will lead to the greater efficiencies which it is intended to create.

Of greatest concern are the following:

- the potential for increased costs for registrants and applicants
- an increased complexity in the regulatory system which may result in the loss of existing agricultural chemical products and discourage the introduction of newer, modern chemistry and biological products and
- the potential loss from the Australian market of useful products that are safe and effective to use due to the need to obtain re-approval or re-registration of those products.

The Bill requires the Minister to cause a review of the operation of the amendments to be conducted and for the report of the review to be tabled in each House of the Parliament within 15 sitting days of that House after 1 July 2018. At that time, it should be possible to gauge whether these concerns have materialised.

Annexure 1

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Annexure 2


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