

Background

Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

2.1 This chapter provides background information to the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (“the Bill”). In particular, it highlights:

- the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) used to regulate agricultural and veterinary chemicals;
- the reform context and development of the Bill; and
- a description of the key provisions of the Bill.

2.2 Agricultural and veterinary chemicals encompass a vast array of chemicals and products. Agricultural chemicals and products have a variety of uses including the protection of crops from weeds, insects and pathogens; the protection of buildings, parks, infrastructure and houses from pests; and the protection of human and environmental health.¹ Veterinary chemicals and medicines encompass vaccines, antibiotics, worm treatments, lice treatments, vitamins and minerals and those used to protect livestock and domestic or companion animals from a wide range of diseases and illnesses.²

1 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

2 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

- 2.3 The Australian Pesticides and Veterinary Medicines Authority (APVMA) is a statutory agency charged with the 'registration of all agricultural and veterinary chemical products into the Australian marketplace'.³ The APVMA, formed in 1993, has oversight of the NRS, being the mechanism by which such chemicals are registered.
- 2.4 The Bill seeks to amend various legislation overseeing the agricultural and veterinary (AgVet) chemicals sector and in particular, makes a range of changes to how AgVet chemicals are regulated and registered. The Bill aims to amend the following Commonwealth Acts:
- *Agricultural and Veterinary Chemicals (Administration) Act 1992;*
 - *the Agricultural and Veterinary Chemicals Act 1994;*
 - *the Agricultural and Veterinary Chemicals Code Act 1994;* and
 - *the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994.*
- 2.5 The Bill's Explanatory Memorandum states that:
- The Bill implements reforms to the approval, registration and reconsideration of agvet chemicals to improve the efficiency and effectiveness of the current regulatory arrangements and provide greater certainty to the community that chemicals approved for use in Australia are safe. The Bill makes it clear that the health and safety of human beings, animals and the environment is the first priority of the regulatory system.⁴

The current National Registration Scheme

- 2.6 The NRS 'is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities'.⁵
- 2.7 The Explanatory Memorandum states that:
- The Code Act contains as a schedule to it, the Agvet Code. Under the NRS, the Agvet Code operates, together with the Agvet Code

3 Australian Pesticides and Veterinary Medicines Authority, *About the APVMA* (7 February 2013) <<http://www.apvma.gov.au/about/index.php>>

4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 8.

5 Australian Pesticides and Veterinary Medicines Authority, *National Registration Scheme* (19 February 2013) <<http://www.apvma.gov.au/about/nrs/index.php>>

of each participating territory (that is, each State and the Northern Territory) to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agricultural and veterinary chemical products, (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products; and ensure compliance with and enforcement of the Agvet Code.⁶

Reform context and development of the Bill

2.8 This section will provide a brief history of the reports and consultations that led to the present Bill. Independent reports highlighting the need for reform were released beginning in 2006 and culminated in the development of the current Bill. Commenting on the reforms, the Department of Agriculture, Resources, Fisheries and Forestry's submission to the inquiry stated:

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

Three rounds of public consultation were conducted on the reforms and associated Bill. The first round of public consultation occurred from mid November 2010 to early February 2011 about the policy discussion paper, Better Regulation of Agricultural and Veterinary Chemicals ...

Further public consultation with an exposure draft of the legislation occurred from 15 November 2011 to 29 February 2012 ...

6 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012, 9.

The Bill was revised and released again as a revised exposure draft in September 2012. The revised Bill included amendments to address issues raised during the previous round of consultation.⁷

- 2.9 In brief, the reports and consultations leading to the development to the development of the Bill have been as follows:
- ⇒ In 2006, the Australian National Audit Office (ANAO) released a Performance Audit on the Regulation of Pesticides and Veterinary Medicines, making a number of recommendations.
 - ⇒ In 2006, the Council of Australian Governments (COAG) identified the need for regulatory reform in the chemicals and plastics area.⁸ It subsequently tasked the Productivity Commission to study the area and identify potential reforms.
 - ⇒ In 2008, the Productivity Commission presented its report into Chemicals and Plastics Regulation. It proposed a governance framework to address a number of system failures.
 - ⇒ These outcomes were translated into a National Framework for Chemicals and Plastics Regulatory Reform, from which a COAG-backed Standing Committee emerged.
 - ⇒ Following this, the Australian Government released the Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper to inform the reform agenda.
 - ⇒ Several draft Bills were issued and consulted upon. These consultations have formed the basis of the Bill before the Committee.
 - ⇒ The Department of Agriculture, Fisheries and Forestry (DAFF) recently completed a consultation on the regulations associated with the legislation. Their findings are yet to be released.
- 2.10 Each of these major steps are discussed in further detail below. It should also be noted that in addition to these reports and consultations, a Regulation Impact Statement (RIS) was prepared to assist the Australian Government's consideration of the issues.⁹ This is discussed later in this report.

7 DAFF, Submission 2, p. 9.

8 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iii.

9 Department of Agriculture, Fisheries and Forestry (2011) Regulation Impact Statement: Better Regulation of Agricultural and Veterinary Chemicals, p. 46.

Australian National Audit Office report

2.11 In December 2006, the ANAO released an audit report into the regulation of pesticides and veterinary medicines. Findings of the audit included that:

- key programs such as those to monitor the quality of pesticides and veterinary medicines, could have been better administered
- a greater emphasis was required to be placed on the APVMA's compliance program and in completing chemical reviews
- the APVMA was not meeting its obligation to finalise applications within statutory timeframes.

2.12 Overall the ANAO's audit found that the APVMA needed to address some key issues relating to the NRS including reviewing arrangements for sourcing expert scientific advice to inform decisions, and for using state and territory agencies to complete compliance activities on its behalf. The ANAO also suggested improved regulatory arrangements for the chemicals deemed to be low risk.¹⁰

Productivity Commission Research Report

2.13 In July 2008, the Productivity Commission released its study into Chemicals and Plastics Regulation.¹¹ The Commission was asked to 'undertake a research study examining the current arrangements for the regulation of chemicals and plastics in Australia'.¹²

2.14 The Commission's report found that chemicals regulation is generally appended onto a range of state and territory legislation dealing with 'public health, workplace safety, transport safety, environment protection and national security'.¹³ The Commission found that while these regimes are broadly effective, they are less effective in managing environmental and national security risks.

2.15 The Commission proposed that a governance framework that addresses failures at four levels be implemented to include:

- policy development and regime oversight;

10 Australian National Audit Office (2006) Report No 14: Regulation of Pesticides and Veterinary Medicines.

11 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iii.

12 Productivity Commission (2008), Chemicals and Plastics Regulation, p. iv.

13 Productivity Commission (2008), Chemicals and Plastics Regulation, p. xxiv.

- assessment of chemical hazards and risks;
- risk management standards setting; and
- administration and enforcement.

National Framework for Chemical and Plastics Regulatory Reform

2.16 Following the Productivity Commission's report, COAG completed a Memorandum of Understanding (MoU) for Chemicals and Plastics Regulatory Reform.¹⁴ The MoU established the COAG Standing Committee on Chemicals. The Committee's role was as follows:

- co-ordinate the implementation of the new governance framework for the regulation of chemicals and plastics;
- monitor the timeliness, effectiveness and consistency of reforms of chemicals and plastics regulation;
- provide advice and make recommendations as appropriate to BRCWG [Business Regulation and Competition Working Group], COAG and relevant ministerial councils on how chemicals and plastics policy initiatives that have cross-portfolio or cross-jurisdictional implications might be best progressed. Ministerial Councils would include:
 - ⇒ the Australian Health Ministers' Conference;
 - ⇒ the Australian Transport Council;
 - ⇒ the Environment Protection and Heritage Council;
 - ⇒ the Primary Industries Ministerial Council;
 - ⇒ the Workplace Relations Ministers' Council; and
 - ⇒ ministers concerned with the security aspects of chemicals;
- provide an ongoing forum for assessing the consistency of chemicals-specific policy settings across the relevant policy areas, including:
 - ⇒ public health;
 - ⇒ workplace health and safety;
 - ⇒ transport safety;
 - ⇒ environment protection; and
 - ⇒ national security;
- oversee a coordinated national approach to regulatory reform of chemicals and plastics and the consistent application of chemical hazard and risk-assessment methodologies and

14 Council of Australian Governments (2009), National Framework for Chemical and Plastics Regulatory Reform, Memorandum of Understanding for Chemicals and Plastics Regulatory Reform (20 February 2013) <<http://www.coag.gov.au/node/93>>

international standards such as the Globally Harmonised System of Classification and Labelling of Chemicals; and

- support the coordinated development of regulatory proposals that have cross- portfolio or cross-jurisdictional implications, including input into regulatory impact assessments.¹⁵

Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper

2.17 In November 2010 the Australian Government released the Better Regulation of Agricultural and Veterinary Chemicals policy discussion paper.¹⁶ The discussion paper proposed a set of reforms to ‘increase the efficiency and effectiveness of the APVMA and to enable more effective regulation of agricultural and veterinary chemicals’. The reforms were framed around the following objectives:

- protection of human health and the environment;
- alignment of regulatory effort with the degree of risk;
- enabling timely assessments, registrations and reviews;
- addressing gaps in the current regulatory system;
- improving the governance frameworks and operational activities of the APVMA and its regulatory partners;
- improving communication with agvet chemical stakeholders; and
- ensuring the AVPMA’s financial viability for the future.¹⁷

Ongoing regulatory consultations

2.18 Concurrently, DAFF opened consultations on the proposed regulations to accompany the Bill. The proposed regulations include amendments to the:

- Agricultural and Veterinary Chemicals Code Regulations 1995 (Code Regulations)

15 Council of Australian Governments (2009), National Framework for Chemical and Plastics Regulatory Reform, Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Section 5.3 (20 February 2013) <<http://www.coag.gov.au/node/93>>

16 Department of Agriculture, Fisheries and Forestry (2010), Better Regulation of Agricultural and Veterinary Chemicals, Discussion Paper, (20 February 2013) <<http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper>>

17 Department of Agriculture, Fisheries and Forestry (2010), Better Regulation of Agricultural and Veterinary Chemicals, Discussion Paper, p. 7 (20 February 2013) <<http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper>>

- Agricultural and Veterinary Chemicals (Administration) Regulations 1995 (Admin Regulations)
- Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995 (Levy Regulations)

2.19 The consultation document for the proposed regulations notes that:

The details of the proposed regulations include amendments to:

- support measures in the revised Bill;
- refine the scope of agricultural chemical products and veterinary chemical products regulated by the APVMA and to implement Council of Australian Government reforms;
- amend manufacturers' licence conditions, to align with conditions that are currently and routinely applied to licences;
- address other minor issues that have been identified with the regulations, including removing redundant or unnecessary provisions and addressing some errors.

The proposed regulations only include the following fees and charges related matters:

- fees for re-approval and re-registration applications, including late re-approval and re-registration applications;
- global joint reviews and 'timeshift' application fees;
- pre-application assistance fees and rebates;
- providing for the APVMA to charge registrants, approval holders and permit holders for copies and extracts from records and registers (amendment to current regulation 73);
- the removal of a redundant fee provision (current regulation 70A).¹⁸

2.20 This consultation closed on 21 December 2012 and DAFF is in the process of issuing revised regulations based on these consultations.¹⁹

18 Department of Agriculture, Fisheries and Forestry (2012), Agriculture and Veterinary Chemicals Legislation Amendments: Details of Proposed Regulations (20 February 2013) <<http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>>

19 Department of Agriculture, Fisheries and Forestry (2012), Agriculture and Veterinary Chemicals Legislation Amendments: Details of Proposed Regulations (20 February 2013) <<http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals>>

Key Bill provisions

Schedule 1

2.21 Schedule 1 considers the issues of approvals, registrations, permits and licences. The Schedule amends the *Agricultural and Veterinary Chemicals Code Act 1994*. The explanatory memorandum provides:

Simplification, reorganisation and modernisation of the Agvet Code

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

Enhanced consistency and transparency of assessments

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

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

Improving assessment efficiency and effectiveness

The Bill also includes amendments to address concerns about the time taken by the APVMA to complete applications and reconsiderations. The current assessment timeframes do not take into account the total time elapsed for considering an application or finalising a reconsideration (known as chemical review). This does not provide for certainty and predictability in assessment

timeframes for applicants or the APVMA. In addition, applicants may provide data for the APVMA's consideration at any time. These existing arrangements unnecessarily frustrate the finalisation of assessments for applications and reconsiderations.

The amendments require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The reforms also introduce timeframes for assessments that include the total time elapsed, including the time taken to provide more information. This increases certainty around when applications will be finalised.

The reforms introduce timeframes for reconsiderations (also known to the community as chemical reviews). Along with other reforms to reconsiderations, this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes.

The reforms would ensure that there is no undue impediment to the use of overseas data and assessments by the APVMA, where conducted by comparable agencies and while recognising differences in national approaches. The reforms enable the APVMA to require electronic communication between it and applicants. This electronic communication would also streamline the APVMA's internal administrative processes.²⁰

Schedule 2

2.22 Schedule 2 considers re-approvals and re-registrations. The Schedule *amends the* Agricultural and Veterinary Chemicals Code Act 1994. The explanatory memorandum of the Bill provides:

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

Consistent with international practice and coupled with Commonwealth funding to mitigate start-up costs, the Bill provides for a mandatory scheme for re-approval and re-registration. Re-approval and re-registration will increase the scrutiny of chemical constituents and products through a scheme

that minimises impacts on industry. The scheme provides a greater level of assurance that existing chemicals and products do not pose an undue risk to human health or the environment, and further promotes public confidence in agvet chemical regulation.²¹

Schedule 3

2.23 Schedule 3 considers issues of enforcement. The Schedule amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*, *Agricultural and Veterinary Chemicals (Administration) Act 1992* and *Agricultural and Veterinary Chemicals Code Act 1994*. The explanatory memorandum to the Bill provides:

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

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2.24 The Bill creates a range of new offence provisions, addresses previous inconsistencies and provides for existing offence provisions to also be civil penalty provisions. The Bill will give the APVMA the power to:

The Bill includes a number of new offence provisions. The new offences either align with existing or previous offences or are consistent with the *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers* (published by the Attorney-General's Department).²³

21 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012.

22 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012.

23 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

2.25 The Bill also:

- Increases penalties in some circumstances 'to ensure that the penalty remains proportionate to the potential gain from non-compliance and to align with the penalties for other similar offences'²⁴
- Inserts a new Division that 'provides for the more efficient collation of information to provide a response that is complete and allows persons to consider their rights and obligations and seek appropriate legal advice before providing information, documents or answers to questions'.²⁵
- Allows the AVPMA to 'to suspend or cancel, respectively, a registration or a permit where it considers this is necessary to prevent imminent risk to persons of death, serious injury or serious illness. The APVMA may exercise this authority whether or not the product is being used in accordance with its instructions for use or conditions of the permit'²⁶
- Provides powers for persons assisting APVMA inspectors
- Allows to APVMA to 'apply to a court to have a person pay certain costs incurred in investigation of the offence or civil penalty provision'²⁷
- Amends matters pertaining to infringement notices.

Schedule 4

2.26 Schedule 4 considers data protection. The Schedule amends the *Agricultural and Veterinary Chemicals Code Act 1994*. The explanatory memorandum to the Bill provides:

Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. As investment in regulatory data can require significant resources and because the time taken to collect such data and have it assessed by the regulator diminishes its value, the protection of these data encourages innovation in agricultural and veterinary chemicals. In the case of new chemical products this

24 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

25 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 4.

26 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 5.

27 Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, p. 6.

means that the APVMA cannot rely on data it holds to register a product without the data owner's permission and before the protection period has elapsed.

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

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

The Bill includes amendments to improve the mechanism by which data owners can obtain compensation for information submitted in relation to a reconsideration. These reforms would more closely align the data protection for new products and reconsiderations, and reduce the disincentive to providing data as part of these reconsiderations.²⁸

Schedule 5

2.27 Schedule 5 considers arrangements for collection of the relevant levy. The Schedule amends the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994*. The explanatory memorandum to the Bill provides that:

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

28 Explanatory Memorandum, *Agricultural and Veterinary Chemicals Amendment Bill 2012*, pp. 6 - 7.

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

Schedule 6

2.28 Schedule 6 considers miscellaneous amendments. The Schedule amends the *Agricultural and Veterinary Chemicals Act 1994*. The explanatory memorandum to the Bill provides that the Bill:

updates the Agvet Act and the Code Act to specifically provide for legislative instruments made under the Agvet Act or the Code Act, including orders, to remain subject to disallowance with two exceptions ...

includes provisions that deal with transitional, application and savings measures for amendments made by the Act. To ensure a comprehensive transitional approach can be adopted the Bill provides for regulations to take effect before they are registered and this may have some retrospective application of certain measures. A safeguard measure has been included to ensure that a court must not convict a person of an offence, or order the person to pay a pecuniary penalty, in relation to the conduct on the grounds that the person contravened a provision because of a retrospective effect of the regulations.²⁹

²⁹ Explanatory Memorandum, Agricultural and Veterinary Chemicals Amendment Bill 2012, pp. 7 - 8.