

Chapter 2

Background

Current regulatory environment

2.1 Only registered agricultural chemicals and veterinary medicines (agvet chemicals) may be used in Australia. Registration and other aspects of their regulation are administered through a cooperative National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) which was agreed to by the Australian Agriculture Council in 1991.

2.2 The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. The assessment and registration of agvet chemicals and the control of supply activities up to the point of retail sale are undertaken on behalf of the states by a Commonwealth Government authority, the Australian Pesticides and Veterinary Medicines Authority (APVMA). Control of use of agvet chemicals after sale is the responsibility of the states and territories.¹

2.3 The APVMA's operations were described by the Department of Agriculture, Fisheries and Forestry (DAFF) as follows:

With input from other government agencies, the APVMA approves active constituents and agvet chemical products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's processes provide assurance, through rigorous science based risk assessments, that agvet chemical use is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9900 separate agvet chemical products registered, each of which contains one or more of around 1883 approved active constituents.²

2.4 In addition to approving, reviewing, registering and monitoring compliance of registrants of agvet chemicals, the APVMA may also issue permits and license manufacture. The APVMA's procedures are determined in great detail by the provisions of the Agvet Code, which is set out in a schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.³

Proposed amendments

2.5 In the Explanatory Memorandum to the bill the Government stated that the proposed amendments would:

1 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 2.

2 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 3.

3 Department of Agriculture, Fisheries and Forestry, *Submission 32*, p. 2.

- Enhance the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, which the APVMA must have regard to and legislative amendments to align regulatory effort with chemical risk;
- Ensure the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration regime, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses;
- Improve the efficiency and effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations;
- Improve the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals;
- Improve consistency in data protection provisions and remove disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals; and
- Address perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so.⁴

The Bill also includes other amendments to remove redundant provisions and amend out of date provisions.⁵

2.6 In this regard, the Government has identified six areas for improvement, as follows:

- Approvals, registrations, permits and licences;
- Re-approval and re-registration;
- Enforcement;

4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 1–2.

5 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Bill 2012, pp 1–2.

- Data protection;
- Levy collection; and
- Other amendments.⁶

Each of these areas is addressed in turn below.

Approvals, registrations, permits and licences

2.7 The approvals process is to be reformed to ensure that applications for approvals or registration are of the required standard to be assessed. The amendments require the APVMA to refuse inferior or deficient applications.

2.8 Applicants would be assisted by the APVMA's principles and processes being made transparent by the publication of a risk framework or compendium. Applicants would also be offered assistance with their applications, for a fee, before they are submitted. It is expected that the new processes will improve the predictability of regulatory decisions.

2.9 The amendments also introduce timeframes for assessment and reconsideration that include the total time elapsed, including the time taken to provide additional information, so that assessments are not frustrated by the late provision of sometimes inadequate information.⁷

Re-approvals and Re-registrations

2.10 The Government has stated that there is now no mandatory requirement for agvet chemicals, once approved or registered, to be reviewed. The amendments will provide for such a scheme.⁸ The Explanatory Memorandum states that:

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.⁹

2.11 The provisions surrounding the re-approval and re-registration process are canvassed in some detail in Chapter 3 of this report.

Enforcement

2.12 The intent of the amendments relating to enforcement is to provide the APVMA with a range of penalties more appropriate to its regulatory role. New provisions would allow the Authority to impose penalties other than a warning letter or criminal prosecution as is the case at present. The amendments also create new offences, for example, failing to comply with directions of inspectors and failing to

6 Explanatory Memorandum, pp 2–8.

7 Explanatory Memorandum, p. 3.

8 Explanatory Memorandum, p. 3.

9 Explanatory Memorandum, p. 3.

comply with a notice to produce documents or things or attend an interview to answer questions.

2.13 The Government has stated that the new offences either align with existing offences or are consistent with the Government's *A Guide to Framing Commonwealth Offence, Infringement Notices and Enforcement Powers*.¹⁰

2.14 The amendments relating to enforcement have been considered in some detail by other Parliamentary committees – in Alert Digest No. 1 of the Senate Standing Committee for the Scrutiny of Bills and in the First Report of 2013 of the Parliamentary Joint Committee on Human Rights.¹¹ See Chapter 3 for further discussion.

Data protection

2.15 Data protection is stated to be a common feature of agvet chemical regulation in countries that have comparable registration systems to that of Australia. According to the Explanatory Memorandum:

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.¹²

Levy collection

2.16 The APVMA is funded by the industry through fees, charges and levies on the wholesale sale of agvet chemicals, which are collected by the Authority. The bill would allow for another Australian Government agency to collect the levies if that were cost effective. The amendments are intended to address any perception of a conflict of interest given that the APVMA is both the regulator and collector of fees.

Other amendments

2.17 Other amendments to the current legislation include those that preserve Parliamentary oversight of legislative instruments made under the legislation.

Recent developments in regulation

2.18 In 2006, the Council for Australian Governments (COAG) identified the need for regulatory reform in relation to chemicals and established a Ministerial Taskforce, to 'develop a streamlined and harmonised national system of chemicals and plastics regulation'.¹³ COAG also referred the matter to the Productivity Commission for

10 Explanatory Memorandum, p. 4.

11 Senate Standing Committee for the Scrutiny of Bills, *Alert Digest No. 1 of 2013*, 6 February 2013; and Parliamentary Joint Committee on Human Rights, *First Report of 2013*, February 2013.

12 Explanatory Memorandum, p. 6.

13 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. III.

advice. In 2008, the Commission published a report, *Chemicals and Plastics Regulation*, that found:

...the current institutional and regulatory arrangements are broadly effective in managing the risks to health and safety, but are less effective in managing risks to the environment and national security. Efficiency could be enhanced by: national uniformity in some regulatory areas; reducing costs and delays in obtaining regulatory approvals; and attaining economies of scale in regulatory administration.¹⁴

2.19 In 2009, COAG announced that a Memorandum of Understanding for Chemicals and Plastics Regulatory Reform had been agreed to, and established the Standing Committee on Chemicals, whose role was to co-ordinate, monitor and advise governments on the implementation of reforms identified by the Productivity Commission as necessary.¹⁵

2.20 The Australian Government's response, a discussion paper entitled *Better Regulation of Agricultural and Veterinary Chemicals*, was published in November 2010.¹⁶ That document identified the need for the development of a Regulatory Impact Statement (RIS) to assess the effect of the proposed reforms. A RIS was published in November 2011.

2.21 The Government published an exposure draft of the bill in November 2011 and a revised draft of the bill in September 2012.

Consultation

2.22 DAFF invited public comment on the discussion paper and on the exposure drafts and received many submissions from industry groups, environmental groups, primary producer associations and Commonwealth, state and territory governments. The submissions were considered and the drafts of the bill addressed many of the issues raised in the consultation process.¹⁷

14 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne, p. XXV.

15 Memorandum of Understanding for Chemicals and Plastics Regulatory Reform, Council of Australian Governments, www.coag.gov.au/node/93, (accessed 4 February 2013).

16 Better Regulation of Agricultural and Veterinary Chemicals, Policy Discussion Paper, Australian Government, Department of Agriculture, Fisheries and Forestry, www.daff.gov.au/_data/assets/pdf_file/0009/1853973/agvet-chemicals-discussion-paper-191110.pdf (accessed 4 February 2013).

17 Department of Agriculture, Forestry and Fisheries, *Submission 32*, p. 8.

