Chapter 2

Key provisions

2.1 The bill comprises two schedules, with the first containing 14 parts and the second, two parts.

2.2 A key feature of the bill is that it transfers several aspects of APVMA responsibility to regulations. Section 6 of the Code Act contains broad regulation-making powers. This section allows the Governor-General to make regulations in relation to any matter required or permitted by the Code Act to be so prescribed.

2.3 The following summarises the bill's key provisions.

Schedule 1—Main amendments

Part 1—Approval and registration for prescribed active constituents, chemical products or labels

2.4 Part 1 proposes amendments to the Code Act Schedule (primarily to subsections 9A(2) to (5); and by inserting new sections 14C, 14D and 14E) that would create a streamlined assessment process for a new category of applications: prescribed applications for active constituents, chemical products and container labels. It is anticipated this process will be quicker and less costly than the current approval and registration processes.[1]

2.5 Under the proposed streamlined process, there would be no preliminary assessment procedure. The APVMA would be required to approve an application if:

- it meets application requirements (including safety, efficacy, trade and labelling criteria);
- it is a 'prescribed' application; and
- no disqualifying criteria apply.

2.6 The types of applications that would be prescribed applications are to be determined in regulations. The EM anticipates that they would be applications of 'sufficiently low associated risk as to warrant reduced supporting information requirements'.[2] These would be cases where minimal or no assessment of technical information occurs. The EM states that as it is conceivable no technical information may be required, the prescribed process could support the introduction of a means of self-approval or self-registration.[3] The EM provides the following examples:

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1 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 8.

2 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 8.

3 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 7–8.

- applications involving well-characterised chemistry or existing pharmacopoeial active constituents;
- products with a history of safe use; and
- applications with assessments conducted by accredited third party providers.[4]

2.7 Although prescribed applications would be subject to less scrutiny, the APVMA could consider the trustworthiness of an applicant as a 'disqualifying criteria'. However, if an applicant is disqualified on the basis of this criterion, they would still be eligible to submit an application under the standard process. According to the EM, an applicant may be disqualified on the basis of trustworthiness if they have:

- been convicted of an offence;
- been ordered to pay a civil pecuniary penalty; or
- had a registration or approval cancelled or suspended for breaching a condition or providing false or misleading information.[5]

Part 2—Information to be taken into account in determining applications

2.8 Under section 8C of the Code, the APVMA is restricted from considering new information provided by, or on behalf of, an applicant during the assessment period for an application.

2.9 The proposed amendments in Part 2 of Schedule 1 of the bill would amend section 8C to provide the APVMA with greater flexibility in dealing with certain types of information when determining an application. Under the proposal, the types of information to be taken into account would be prescribed in regulation, but may include the provision of an updated good manufacturing practice certificate.[6]

2.10 These changes would allow applicants to provide information during the application process without having to face delays, or having to make a variation application after the initial application has been assessed, approved and the product registered.

Part 3—Limits on use of information

2.11 There are currently two forms of data protection recognised under the Code. The first is that of limits on the use of information. Under this category, information that is provided to the APVMA as part of an application under the Code and relied on by the APVMA in making a decision receives a 'limitation period'. During this limitation period, the APVMA may not use the information to assess or make a

4 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 7–8.

5 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 9.

6 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 12.

decision on another application or a reconsideration unless an exemption applies. The current limitation period for this information as prescribed by the Code ranges from three years to 10 years.

2.12 The second form of data protection is for 'protected information'. This information relates to either an active constituent that has been approved or a chemical product that has been registered and then provided as part of a reconsideration. A protection period of eight years applies to this information.

2.13 Part 3 of Schedule 1 of the bill (proposing new sections 34KA and 34MA, and other consequential amendments to the Code Act Schedule), aims to extend the period of time that information used to assess an application or reconsideration for a chemical product or active constituent, is protected from use by other applicants for a period of up to five years.[7]

2.14 The EM describes the purpose of the proposed provisions:

> An innovator funds the production of information to support a new active constituent (or improved characteristics for an existing active constituent) or a new use of a chemical product. Limiting the use of information prevents competitors from using innovators' data or allows innovators to seek compensation from the competitors for use of the innovators' information. This benefits the innovator, who has incurred the cost of generating this information, and promotes innovation.[8]

2.15 The proposed provision is expected to be of particular benefit in situations of minor use, where only a low economic return is expected. In addition, the proposed amendments aim to increase the number of applications made to the APVMA for certain kinds of active constituents with new, desirable features (such as new modes of action to manage resistance) or to register certain uses (priority uses) of chemical products.[9]

Part 4—Computerised decision making

2.16 Part 4 of Schedule 1 of the bill (proposing a new section 5F; various amendments to sections 166(1), 166(1A) and 167(2A); and other consequential amendments to the Code Act Schedule), seeks to amend the Code to enable the APVMA to use computerised decision-making as part of its processes.

2.17 The bill contains a number of amendments to align the treatment of computer-made decisions with existing procedures and to provide for a review of computerised decisions.

2.18 Safeguards include proposed provisions to:

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7 This provision would extend both the 'limitation period' of three to 10 years, and the protected information period of eight years, up to a further five years.

8 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 13.

9 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 13.

- allow the APVMA to substitute a decision for a computerised decision if it is satisfied that the computerised decision is incorrect;
- ensure that a computerised decision is subject to the same reconsideration process as a decision made by an APVMA staff member; and
- provide that a substituted decision may be reviewed by the Administrative Appeals Tribunal.[10]

2.19 The EM states the intent of the amendments is to increase the efficiency of the APVMA by establishing a 'flexible legislative regime that will support future developments in information technology and business processes'.[11]

2.20 According to the EM, the APVMA will develop procedures and guidance for the implementation of computerised decision-making in accordance with the best practice principles developed by the Administrative Review Council in its report No. 46 of 2004, *Automated Decision Making*.[12]

Part 5—Accreditation of third party assessors

2.21 The proposed amendments under Part 5 of Schedule 1 of the bill (a new section 6G and other consequential amendments to the Code Act Schedule), would allow the APVMA to recognise assessments from accredited third party providers. Through a disallowable legislative instrument, the APVMA would be able to prescribe matters relating to the accreditation of persons, and the roles such accredited persons might perform. Proposed subsection 6G(2) details some of the matters that the disallowable legislative instrument might consider, including:

- criteria to be met by persons seeking accreditation;
- how accreditation is to be recognised, and for how long;
- the certificates, assessments or reports accredited persons may or must provide and the circumstances in which they must be provided;
- standards and other obligations persons must continue to meet to remain accredited;
- monitoring of compliance with conditions of accreditation;
- circumstances in which an accredited person may have the person's accreditation varied, suspended or revoked, and the review process; and
- who may deliver training to accredited persons.

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10 However, if the initial decision was not reviewable by the Administrative Appeals Tribunal (AAT), then the proposed amendment in item 35 has the result that the substituted decision is also not reviewable by the AAT. Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 18.

11 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 17.

12 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 17.

2.22 The proposed amendments also allow for regulations to prescribe a method of calculating fees, with the intention the accreditation scheme will run on a cost recovery model in the future.[13]

2.23 The EM explains that the proposed accreditation scheme would have broad application to support the APVMA to accredit persons for a range of purposes.

2.24 An accredited person might prepare assessment reports either directly with or for industry for inclusion in applications made to the APVMA. Alternatively, an accredited person might undertake work that the APVMA currently undertakes, such as conducting assessments of information in applications made to the APVMA.[14]

2.25 Under the proposed amendments, accredited assessors need not be persons, and can include a 'body politic or corporate as well as an individual'. Neither do they need to be Australian citizens or located in Australia.[15] Further, accreditation would not be mandatory—the requirements only relate to particular persons who voluntarily apply to be accredited under the scheme.[16]

2.26 The EM suggests that there are a number of potential benefits that will flow from the proposed accreditation scheme. These include:

- providing applicants with greater flexibility over data assessment timeframes and cost;
- simplifying administration processes within the APVMA;
- increasing the efficiency of application processing; and
- opening data assessment to greater competition.[17]

Part 6—Voluntary recalls of chemical product

2.27 Part 6 of Schedule 1 of the bill (primarily a substitution of section 106 of the Code Act Schedule), intends to improve the voluntary recalls process by introducing specific provisions that require persons to inform the APVMA when undertaking certain voluntary recalls and requires the APVMA to publish information about such recalls.

2.28 Item 50 of the bill replaces section 106 of the Code to specify the requirements for a voluntary recall. It states that a voluntary recall applies if a person

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13 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 23.

14 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 19.

15 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 19, 21.

16 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 22.

17 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 19.

(who does not need to be a holder of the registration) voluntarily proposes to take action to recall a chemical product because it appears to the person that:

- the chemical product does not meet the safety, trade or efficacy criteria, or the label does not meet the labelling criteria; or
- the chemical product is not a registered chemical product (for example, where the concentration, composition or purity of constituents in a batch of the chemical product vary by more than the prescribed extent set out in the Register of Chemical Products).[18]

2.29 Under the proposed amendments, a person who recalls a chemical product must notify the APVMA within two days of the recall. In turn, the APVMA must publish a copy of the notice about the voluntary recall on its website within three working days and in the APVMA Gazette within 14 days. The APVMA may also publish the recall in any other manner it deems appropriate.

2.30 In its submission to the exposure draft of the bill, the Australian Competition and Consumer Commission (ACCC) had raised concerns about the duplication of notification requirements with regard to the recall of an avget product. It noted that in instances where an agvet product also met the definition of a consumer good, a supplier would have to meet the requirements of both the bill and section 128 of the Australian Consumer Law when conducting a voluntary recall.

2.31 Following the consultation period, DAWR amended the bill to ensure that voluntary recalls were aligned more closely with the Australian Consumer Law.[19]

Part 7—Notification of new information

2.32 Part 7 of Schedule 1 of the bill (various amendments to paragraphs and subparagraphs of sections 160A and 161 of the Code Act Schedule), seeks to amend the Code to provide consistency with regard to the notification of new information.

2.33 This will be achieved by provisions which oblige holders of label approvals, and applicants for both label approvals and variations to approvals or registrations, to provide 'relevant information' to the APVMA. These obligations already apply to holders of active constituent approvals and product registrations under sections 160A and 161 of the Code.[20]

2.34 Relevant information is defined as information that contradicts any information that was given in an application; and information that shows the

18 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 24.

19 Department of Agriculture and Water Resources, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/streamlining/public-consultation (accessed 7 December 2018).

20 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

constituent or product may not meet the safety criteria, trade criteria, efficacy criteria, or labelling criteria.[21]

2.35 The proposed amendments are intended to ensure the regulator is aware of the latest available information and provide safeguards to protect public, animal and plant health, and the environment from potential damage, where new information about an agvet chemical comes to light.[22]

Part 8—Definition of registered chemical product

2.36 Part 8 of Schedule 1 of the bill (inserting a new section 5AA to the Code Act Schedule), seeks to amend the Code's definition of a registered chemical product to provide prescribed standards for the:

- concentration range of constituents of a chemical product; and
- composition and purity of constituents of a chemical product.

2.37 These amendments seek to address an anomaly in the Code whereby the regulations can provide concentration ranges for constituents in chemical products to allow for the routine variation in constituent concentration arising in manufacturing. However, offences and civil penalty provisions in Part 4 of the Code operate in a way that prohibits the supply of a product if it is formulated differently to the registered formulation.[23]

2.38 According to the EM, this inconsistency places an unreasonable burden on the APVMA and industry because the only recourse available is for a holder to make an application to the APVMA to include more detail about a product's composition in the register. The regulatory effort associated with this task is considered inconsistent with the risks, particularly given that some provisions of the Code already provide for reasonable variations in a product's composition.[24]

2.39 The EM notes that the proposed amendments are intended to allow reasonable variations in the composition of a product and that any fundamental changes would still require the holder to submit a variation application to the APVMA.[25]

Part 9—Suspension or cancellation of approval or registration

2.40 Part 9 of Schedule 1 of the bill (substitution of section 38A of the Code Act Schedule), proposes to expand the grounds upon which the APVMA may suspend or

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21 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

22 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 28.

23 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 31.

24 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 31.

25 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 31–32.

cancel approvals or registrations where information is provided that is false or misleading.

2.41 Under current provisions in the Code, the APVMA has the power to suspend or cancel an active constituent approval or product registration where false or misleading information has been provided. The proposed amendments would enable the APVMA to suspend or cancel an approval or registration if any person (not just the holder of the registration) has given false or misleading information in relation to any of the following:

- an application for approval or registration;
- an application for a variation of approval or registration;
- in response to a notice to provide information under subsection 32(1) or section 33 or 159 of the Code; or
- in the event that new information has come to light, either before or after, the APVMA has made an approval or registration decision.[26]

Part 10—Supply of registered chemical products with unapproved label

2.42 Part 10 of Schedule 1 of the bill (primarily a substitution of paragraphs 81(3)(a), (b) and (c) of the Code Act Schedule), proposes to address an inconsistency in the Code by clarifying what information must be included in a product label. The proposed amendments will specify the minimum information requirements for inclusion on a label to reduce the need for unnecessary information.

2.43 In recognition of the fact that the information on labels will change in accordance with the proposed provisions, the bill provides for a period of two years (or as determined by the APVMA) to trade out a product with previously required information on the label. Amendments in the bill will allow the APVMA to manage this transition by allowing a product (with the previously required information on the label) to be supplied, where considered appropriate.[27]

Part 11—Variation of approval or registration during suspension

2.44 Part 11 of the bill (various amendments to sections 42, 43 and 45 of the Code Act Schedule), proposes to introduce measures into the Code to deal with suspended registrations and to address the reason for a suspension. It would also allow holders to request a suspension of an approval or registration, in addition to the current option of requesting a cancellation of an approval or registration.

2.45 The bill provides that whilst a registration or approval is suspended, a person would be allowed to lodge a notice, make an application or seek a variation of the relevant particulars or conditions, provided it is relevant to the reasons for the suspension. These proposed changes would ensure that the matters with a registration

26 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 33.

27 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 35.

or approval that led to its suspension could be rectified prior to the revocation of the suspension.[28]

2.46 Under the Code, the APVMA may suspend an approval or registration. However, the APVMA does not have the power to amend a product registration to address the problem that led to the suspension of the product registration without first revoking the suspension. According to the EM, the proposed amendments correct an unintended administrative barrier which prevents the holder of a registration from dealing with the suspension matter and putting the chemical product back on the market.

2.47 Furthermore, the bill proposes to amend the Code to provide that a holder can request suspension of an approval or registration, in addition to the current option of requesting cancellation of an approval or registration. This will enable the holder to have their approval or registration suspended while they deal with any issues with it. It will ensure that the holder will not have to cancel their registration or approval to deal with administrative matters before having to re-apply for registration or approval at a later time.[29]

2.48 Part 11 of Schedule 1 is drafted on the basis that Part 4 of Schedule 1 to the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017 would have commenced to provide for the variation of relevant particulars and conditions of a label approval that is suspended.[30]

Part 12—Safety, efficacy, trade and labelling criteria

2.49 Part 12 of Schedule 1 to the bill (amendments to section 5D and a new section 5E of the Code Act Schedule), contains two related measures. Item 85 of the bill amends section 5D of the Code to allow the APVMA to make regulations to prescribe matters the APVMA must consider when determining whether a label meets the labelling criteria. As it currently stands, regulation-making powers are only permitted for safety criteria, efficacy criteria and trade criteria.

2.50 Secondly, the amendments will rectify an existing anomaly, and will allow the APVMA the discretion to consider the following when making a decision as to whether an application meets the criteria with regard to safety, efficacy, trade and labelling:

- the results of any trials or experiments already carried out in a foreign country in relation to an active constituent for a proposed or existing chemical product, or in relation to a chemical product or any of its constituents;

28 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 38.

29 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, pp. 37–38.

30 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 37.

- any decisions or evaluations made by regulators of agricultural or veterinary chemicals in a foreign country; and
- any information on which a decision or evaluation mentioned in the dot point above is based.[31]

Part 13—Annual operational plans

2.51 Part 13 (amendments to Part 6, a repeal of sections 55, 56, 57 and substitution of a new paragraph 61(b) to the Administration Act), seeks to remove the need for the APVMA to develop and seek approval for an annual operational plan in addition to the corporate plan.

2.52 Under the Administration Act, the APVMA is required to prepare an annual operational plan. The plan sets out the actions that the APVMA intends to take to comply with the objectives in the corporate plan in the coming year. It provides any performance indicators considered appropriate and any information prescribed by regulations. The plan requires ministerial approval.[32]

2.53 Section 35 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and Part 6 of the Administration Act both require the APVMA's Chief Executive Officer to prepare a corporate plan. The corporate plan is prepared annually, covering a period of four years, and requires ministerial approval. The corporate plan is also presented to the Minister for Finance, and under the PGPA Act must include the following information:

- how the entity will achieve its purposes;
- how the entity's performance will be measured and assessed, including for the purposes of preparing its annual performance statements;
- the key strategies and plans that the entity will implement in each year covered by the plan to achieve its purposes; and
- a summary of the risk oversight and management systems in place for each year of the plan.[33]

2.54 The EM notes that removing the requirement for the APVMA to prepare an annual operational plan would remove a duplication in reporting.

Schedule 2—Other amendments

Part 1—Amendments

2.55 Parts 1 and 2 of Schedule 2 include agvet chemical-related matters from the Agriculture and Water Resources Legislation Amendment Bill 2016. The matters included in the bill include amendments to the Code Act Schedule (subparagraph

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31 *Agricultural and Veterinary Chemicals Code Act 1994*, section 160(2).

32 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 40.

33 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 40.

8E(2)(b)(i) and paragraph 117A(1)(a)) to simplify notices provided by the APVMA to Food Standards Australia New Zealand under section 8E of the Code.[34]

Part 2—Repeals

2.56 Item 4 repeals the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*, as all transitional provisions for this Act are no longer required.

34 Explanatory Memorandum, Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018, p. 45.