



**Australian Government**  
**Department of Agriculture**  
**and Water Resources**

# **Consultation on Streamlining Regulation of Agricultural and Veterinary Chemicals**

Agvet Chemicals Branch

Sustainable Agriculture, Fisheries and Forestry Division

# Contents

<b>Contents.....</b>	<b>ii</b>
<b>Submissions .....</b>	<b>iv</b>
How to have your say .....	v
Publishing of submissions.....	vi
Next steps .....	vi
<b>Streamlining Regulation of Agricultural and Veterinary Chemicals.....</b>	<b>1</b>
Links to agvet chemical legislation.....	1
<b>Context.....</b>	<b>3</b>
Regulatory framework.....	3
Other reforms .....	4
<b>Our proposals for change.....</b>	<b>5</b>
Proposal 1 – Provisional registration or variation with conditions for efficacy ( <i>provisional registration of chemical products</i> ).....	5
Proposal 2 – An accreditation scheme for assessors in the future ( <i>accreditation of assessors</i> ).....	12
Proposal 3 – Prescribed approvals and registrations ( <i>approval and registration for active constituents, chemical products or labels</i> ) .....	15
Proposal 4 – Data protection incentives for certain uses of chemical products ( <i>limits on use of information</i> ) .....	19
Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment ( <i>information to be taken into account in determining applications</i> ).....	24
Proposal 6 – Provide for computerised decision-making ( <i>computerised decision-making</i> ) .....	26
Proposal 7 – Improve the transparency of voluntary recalls ( <i>voluntary recalls</i> ).....	28
Proposal 8 – Require relevant information to be provided in relation to label approvals and variations ( <i>notification of new information</i> ) .....	32
Proposal 9 – Standards for registered chemical product constituents ( <i>definition of registered chemical product</i> ).....	34
Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval ( <i>suspension or cancellation of approval or registration for provision of false or misleading information</i> ) .....	37
Proposal 11 – Addressing an inconsistency in label particulars ( <i>supply of registered chemical products with unapproved label</i> ).....	40
Proposal 12 – Improving dealings with suspended approvals and registrations ( <i>variation of approval or registration during suspension</i> ).....	41
Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria ( <i>safety, efficacy, trade and labelling criteria</i> ) .....	43
Proposal 14 – Simplifying APVMA corporate reporting requirements ( <i>annual operational plans</i> )	45
Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation ( <i>other amendments</i> ).....	47

Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (*other amendments*)..... 48

Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (*other amendments*)..... 51

# Submissions

The Department of Agriculture and Water Resources (the department) is seeking submissions on proposed legislative changes to the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act)
- *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act)
- Schedule to the Code Act (Agvet Code).

The proposed changes would help streamline the regulation of agricultural and veterinary (agvet) chemicals by making systems changes to enable the use of new, simpler regulation processes for chemical product assessment based on risk. These changes would support improved access to safe and effective chemical products, reduce costs associated with registration, better align regulatory effort with risk and reduce red tape.

The draft Bill also includes proposed measures to optimise risk communication about chemical products by improving the transparency of voluntary recalls. A further measure would provide for a legislative instrument to prescribe a scheme (in the future) to allow applicants and the APVMA to use accredited third party providers to undertake assessment services.

Additional measures would address deficiencies or inconsistencies in the regulation of agvet chemicals that currently detract from the operational efficiency and regulatory role of the APVMA.

Collectively, the measures in the Bill would improve the effectiveness and efficiency of the national system for regulating agvet chemical products.

Your submissions will help us assess whether we need to amend these proposals to better meet the needs of stakeholders while retaining protections for the health and safety of humans, animals and the environment.

## How to have your say

**The deadline for receipt of all submissions is 5 pm on 22 August 2018.**

The department will consider all relevant material provided in submissions. While there is no set format for a submission, please make sure you include at least the following information:

- the title of this consultation document
- your name and title
- your organisation's name if submitting on behalf of an organisation
- your contact details.

Please ensure your comments can be clearly read as copies may be made to help with assessment and evaluation. We would appreciate your assistance by identifying the relevant section when making a comment on a specific section of this consultation document or the associated draft Bill.

You can return your submission in the following ways:

Post to:

Streamlining Regulation of Agricultural and Veterinary Chemicals  
Agvet Chemicals Branch  
Department of Agriculture and Water Resources  
GPO Box 858  
Canberra ACT 2601

Email: [agvetreform@agriculture.gov.au](mailto:agvetreform@agriculture.gov.au)

If submitted by email (the department's preferred method), a hard copy of your submission is not needed. The department will endeavour to formally acknowledge receipt of submissions within three business days.

We may not be able to consider submissions received after the closing date of 22 August 2018. However, suggestions for additional reform measures received after the submission deadline can be considered as part of future phases of reform.

**Privacy:** The department will only use the personal information collected about you to enable us to contact you about your submission and may (where the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*) disclose it to specialists; other Commonwealth government agencies; state and territory government agencies or foreign government departments.

The department requests that, at minimum, you provide your name and contact details with your submission. Please indicate if you do not wish to have identifying information published with your submission or disclosed to third parties.

The department will use and store all personal information it collects in accordance with the Australian Privacy Principles as outlined in the department's [Privacy Policy](#) available on the department's website.

**Confidentiality:** Subject to the *Freedom of Information Act 1982* and the *Privacy Act 1988*, the content of submissions may be made public, unless you state you want all or part of your submission to be treated as confidential material. A claim for confidentiality must be justified and provided as an attachment, marked 'Confidential'. Confidential material will not be made public.

No breach of confidence will occur if the department shares your submission with a third party referred to under 'Privacy' in seeking advice in response to your submission.

## Publishing of submissions

All non-confidential submissions will be published on [the department's website](#), although the department may redact parts of submissions. We will not publish confidential material but will record that such information is held. Confidential submissions may be subject to release under the provisions of the *Freedom of Information Act 1991* (FOI Act). Submissions will be published as soon as possible after the end of the public comment period.

If you are making a confidential submission, you may wish to indicate any grounds for withholding information it contains. Reasons could include that the information is commercially sensitive or that you wish personal information, such as names and contact details, to be withheld. An automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information if the department receives an FOI Act request.

We will take your indications into account when determining whether to release information under an FOI Act request. Any decisions to withhold information requested under the FOI Act may be reviewed by the Commonwealth Ombudsman.

The department reserves the right not to publish submissions.

## Next steps

After the consultation period has closed, the department will assess all submissions and consider the requirement for further amendments to address the issues raised.

The finalised policy for legislative amendments will then be recommended to the Minister for Agriculture and Water Resources.

# Streamlining Regulation of Agricultural and Veterinary Chemicals

Agvet chemicals are regulated under a cooperative national registration scheme involving the Australian, state and territory governments.

This scheme is given effect through agvet chemical legislation that includes the:

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act)

The Administration Act establishes the Australian Pesticides and Veterinary Medicines Authority (APVMA) and sets out its role as an independent regulator of agricultural and veterinary (agvet) chemical products. The Code Act and the Schedule to it (the Agvet Code) contain the detailed provisions allowing the APVMA to evaluate, approve, register or review active constituents and chemical products (and their labels).

The government is proposing legislative changes to improve regulation of agvet chemicals. These proposed changes for the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (Streamlining Regulation Bill) are detailed in this document.

The government proposes that these measures commence at different times to provide for their orderly introduction. The proposed commencement provisions are described later in this document under 'Our Proposals for Change'.

Some proposals provide for regulations to specify the details of the particular requirements. This document provides examples or particulars that could be included in these regulations. The government will consult separately on any such regulations when they are developed.

This public consultation will allow the department to receive submissions that will inform part of the government's process for considering the legislative changes. Any changes recommended will be subject to government consideration and agreement.

## Links to agvet chemical legislation

[\*Agricultural and Veterinary Chemicals \(Administration\) Act 1992\*](#)

[\*Agricultural and Veterinary Chemicals Code Act 1994 \(including the Agvet Code\)\*](#)

[\*Agricultural and Veterinary Chemicals Code Regulations 1995\*](#)

[\*Agricultural and Veterinary Chemicals Legislation Amendment Act 2013\*](#)

[\*Agricultural and Veterinary Chemicals Legislation Amendment \(Removing Re-approval and Re-registration\) Act 2014\*](#)

## ACRONYMS, ABBREVIATIONS AND COMMONLY USED TERMS

<b>Term</b>	<b>Meaning</b>
AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
Administration Act	<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
Administration Regulations	<i>Agricultural and Veterinary Chemicals (Administration) Regulations 1995</i>
agvet	agricultural and veterinary
Agvet Code	the Agricultural and Veterinary Chemicals Code, as set out in the Schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
APVMA	Australian Pesticides and Veterinary Medicines Authority
Code Regulations	<i>Agricultural and Veterinary Chemicals Code Regulations 1995</i>
Code Act	<i>Agricultural and Veterinary Chemicals Code Act 1994</i>
FSANZ	Food Standards Australia New Zealand
the minister	the minister administering the <i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>
NRS	the National Registration Scheme
Omnibus Bill	Agriculture and Water Resources Legislation Amendment Bill 2016
PGPA Act	<i>Public Governance, Performance and Accountability Act 2013</i> )
the record	Record of Approved Active Constituents for Chemical Products kept under section 17 of the Agvet Code
the register	Register of Agricultural and Veterinary Chemical Products kept under section 18 of the Agvet Code
Streamlining Regulation Bill	The Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill, which is the subject of this consultation paper)



# Context

The Australian Government is committed to improving agvet chemical regulation.

Recent reforms have already delivered a \$9.1 million reduction of agvet chemical red tape, by removing duplicative re-registration and reforming pet food and stock food regulation. The government wants to further reduce red tape and safely improve access to agvet chemicals, including for farmers who need to improve their competitiveness, sustainability or farm gate returns.

The 2016–17 budget included a \$17.1 million measure, over four years, to streamline agvet chemical regulation under the *Agricultural Competitiveness White Paper*.

The department is working with the APVMA, and consulting the farm industry, chemicals sector and government agencies, to identify further priority changes to agvet chemical legislation.

The APVMA is also implementing a suite of operational changes to improve its efficiency and reduce regulatory burden. This includes work to fast-track registration for products of low regulatory concern and its recently-published guide on the use of international data, standards and assessments to support registration.

The government will build on this by streamlining the approval of agvet chemicals to reduce industry and user costs. This will provide more timely access to productivity-enhancing chemicals, while continuing to ensure appropriate safeguards are in place.

## Regulatory framework

Agvet chemicals are regulated through a cooperative National Registration Scheme (the NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities.

The APVMA assesses and registers agvet chemicals for use in Australia and controls supply activities, including retail sale. The control of use of agvet chemicals after supply is the responsibility of individual states and territories.

The APVMA is established under section 6 of the Administration Act. The APVMA is the national regulator for the supply of agvet chemicals under the NRS.

The NRS is implemented, in part, through the Code Act. The Code Act contains, as a schedule, the Agvet Code. The Agvet Code operates in each state, the Northern Territory and each participating territory (the Australian Capital Territory and Norfolk Island) to constitute a single national Agvet Code applying throughout Australia.

The Administration Act and the Code Act, including the Agvet Code and any regulations or legislative instruments made under these laws, are collectively described as agvet legislation.

The Agvet Code includes detailed provisions allowing the APVMA to evaluate, approve, register and reconsider active constituents and agvet chemical products (and their associated labels). The provisions in the Agvet Code also allow the APVMA to issue permits and to issue licences for 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, including suspending and cancelling registration of chemical products.

## **Other reforms**

The government is also considering further improvements to agvet chemical regulation.

These other reforms include measures that can be implemented through regulations. The government will consult separately on these when developing the measures.

In the meantime, the government is pursuing reforms to the Code Act (including the Agvet Code) and the Administration Act that:

- the APVMA can implement within its current resources and processes
- will improve efficiency and reduce the administrative and regulatory burden on industry and the APVMA
- will allow the APVMA to more effectively regulate agvet chemicals.

# Our proposals for change

## Proposal 1 – Provisional registration or variation with conditions for efficacy (*provisional registration of chemical products*)

Provide the APVMA with discretion to provisionally register products, or provisionally register new uses of existing chemical products (vary product registrations), by allowing information about the efficacy of a product to be provided after registration, as a condition of registration.

### Background

The APVMA assesses applications to register chemical products (or vary registrations) against the statutory safety, efficacy, trade and labelling criteria in sections 5A, 5B, 5C and 5D of the Agvet Code. This assessment includes chemistry, toxicology, residues, efficacy, work health and safety and environmental matters, as well as administrative matters such as trade issues.

The outcome of an assessment determines whether an active constituent and label are approved and a product is registered in Australia (or registration or approval is varied). It also determines the conditions and labelling requirements that apply to these approvals and registrations.

### Current approach

The APVMA cannot register a chemical product, or vary its registration, unless it is satisfied that the product meets the safety criteria, efficacy criteria and trade criteria. If it is not satisfied that the product meets the statutory criteria—and the applicant does not withdraw the application—the APVMA must refuse it, approve it in a way other than as set out in the application (e.g. for fewer uses) or seek additional information from an applicant.

Importantly, the APVMA is prevented from taking into account information from the applicant unless the information is:

- provided in the application, or
- required to be provided to the APVMA under sections 157, 159 or 160A of the Agvet Code, or
- provided in a submission responding to an invitation given by the APVMA.

While Australia typically receives most agvet chemical products available in overseas markets, there may be a delay—sometimes several years—before the product is available locally. In addition, products may be registered for fewer uses in Australia than in some overseas markets.

Given the relatively small size of the market, the cost and time associated with generating the information to satisfy the statutory criteria in Australia can be obstacles to registering innovative chemical products for some uses—particularly where such data must be generated specifically for Australia.

## **Proposed approach**

These obstacles could be reduced by providing for the APVMA to 'provisionally' register a chemical product, pending confirmatory information to satisfy the efficacy criteria being provided in a defined period following registration.

The approach could also provide for provisional variation to registration, to provide for new uses of an existing product. For example, if a product was registered for use on wheat and an applicant applied to register it for use on other cereals, the APVMA could consider provisionally varying the registration to accommodate the additional uses, pending confirmatory efficacy information being provided.

The government proposes that provisional registration or variation would only apply to a product for a limited period of time. The applicant would need to agree to provide the additional efficacy information at a later date, to allow the APVMA to confirm the product meets the efficacy criteria.

Regulations would prescribe the types of chemical products that would not be eligible for provisional registration or variation (for example, restricted chemical products). The regulations could also prescribe other criteria, such as the kinds of applicants for which provisional registration or variation would be suitable (e.g. fit and proper person requirements) and the kinds of uses of chemical products that could be provisionally registered. For example, uses for new chemistries, new modes of action, minor uses, uses for which there are currently no registered chemical products or products used to control weeds of national significance. The government would consult on the detail of these regulations when they are developed.

Importantly, the APVMA would need to be satisfied that the chemical product meets the safety and trade criteria, as per current arrangements. That is, approved use of the product would not pose an unacceptable risk to humans, animals, plants, the environment or other things, and would not unduly prejudice Australia's trade or commerce.

With these safeguards, the proposed measures would enable innovative products to be supplied to the Australian market while the confirmatory information about the efficacy of the product is generated in Australia. It could also be used to encourage registration of innovative uses of existing (and new) products, such as a broader range of priority and minor uses of established products, or products with new modes of action.

This measure would be at the discretion of the APVMA and preserve its decision-making role in registering chemical products, while providing some flexibility to reduce the obstacles for introducing innovative chemical products and uses where appropriate. The APVMA would be required to cancel the registration or variation if the confirmatory efficacy information was not provided in the required timeframe. This cancellation could then affect the ability for the holder to seek provisional registration or variation in the future, as it may affect the 'fit and proper person' status of the applicant for future applications.

Importantly, provisional registration or variation is not intended to provide a second tier pathway for a product where there is no evidence to support the efficacy of the product. Neither is it intended as a means for dealing with poor quality applications.

The approach would be similar in concept to one used in the United States of America, where the United States Environmental Protection Agency may conditionally register a product if the application lacks some required data and the use of the product would not have unreasonable adverse effects while this data is generated (noting that the US approach applies to matters other than efficacy, such as product safety).

#### *Key elements of the proposal*

The key elements of the proposal are:

- amending the Agvet Code to provide for:
  - the APVMA to register a chemical product, or vary a registration, without being satisfied that the chemical product meets the efficacy criteria—but only if the APVMA is satisfied the applicant can provide additional information that would allow the APVMA to confirm that the chemical product meets the efficacy criteria
  - the applicant to agree to provide the additional information in a specified timeframe, as a condition of registration
- providing for a subsequent application (under section 27 of the Agvet Code) to allow for the assessment of the additional information—this will ensure:
  - the APVMA can impose a fee for considering the additional information
  - the register is updated and notification requirements to the public are triggered
  - that limits on the use of the efficacy information could be imposed (i.e. a limitation period could apply to the additional efficacy information).

Applicants would apply for registration (or variation to registration) as they would normally. An applicant could not apply for ‘provisional registration or variation’. The decision to provisionally register a product or vary a registration would rest with the APVMA and be at the APVMA’s discretion. However, an applicant would not be prevented from indicating their agreement to provisional registration or variation in an application. This could, for example, be based on advice received from the APVMA as part of pre-application assistance. The APVMA may develop guidelines to inform stakeholders and assessors about the circumstances under which it may consider provisional registration or variation to be suitable.

If the APVMA chose to provisionally register or vary a registration, it would impose a condition that additional information would be provided within a period of up to three years. This additional information condition would have the same status as any other condition of registration and the APVMA would not be prevented from imposing other conditions it considered necessary. Holders could then supply their products and comply with all the usual requirements for a conditional registration.

The provisional registration or variation would be for a period of no more than three years. However, the APVMA may provide for a further two years of registration if an extraordinary event or circumstance beyond the control of the holder prevents the holder from providing the additional information within the three year timeframe. This would allow for some flexibility where problems may occur when conducting the efficacy trials (for example, adverse weather events or natural disasters).

It is anticipated that a further condition of registration could include a requirement for the label of the provisionally registered or varied product to include a conspicuous statement or other

mark (or a sticker) adjacent to the space set aside for the APVMA approval number. This statement would inform the user that the product is provisionally registered. The government proposes this labelling requirement would be a statutory condition of registration set out in regulations. The government would consult on the requirement and form of such a statement or mark when this regulation was developed.

As required now for any other kinds of conditions of registration, the APVMA would need to ensure the record, register and relevant APVMA file include the condition that the holder must provide additional information by a specified timeframe.

The chemical product would remain provisionally registered while any application to assess the additional efficacy information was considered by the APVMA.

If additional information is provided but this does not satisfy the APVMA, the APVMA could consider suspension or cancellation through existing pathways. However, the APVMA would not be prevented from provisionally registering or varying the product again if different additional information is required (i.e. information other than that required through the initial condition of registration; for example, a further confirmatory trial). A decision to suspend, cancel, or provisionally register on the condition that additional information is provided would be subject to merits review, including internal reconsideration by the APVMA.

In order to ensure the applicant or holder complies with the condition, the APVMA would be required to cancel a registration, or cease a variation to a registration, if the additional information is not provided in the specified timeframe (unless an extension of up to two years has been provided due to an extraordinary event or circumstance).

If a provisional registration is cancelled, existing provisions in the Agvet Code provide that a permit would be taken to be issued for supply of the provisionally registered chemical product for up to one year (section 45B of the Agvet Code). This would allow for an orderly removal of the product from the market, where a period for dealing with 'stock in trade' was appropriate. Similarly, where a variation to registration is ceased, the APVMA would be able to authorise 'trade-out' of the product through existing statutory powers in section 81 of the Agvet Code. Shorter 'trade-out' periods or immediate recall would also be available to the APVMA in both cases if the APVMA considered this was warranted.

If provisional registration is cancelled, the holder would be informed (consistent with existing section 45A). Similarly, a holder would be informed when the APVMA ceases a variation (new section 29C). These decisions would be subject to internal reconsideration and an application to the Administrative Appeals Tribunal (AAT).

Limits on the use of information would apply for provisional registration. These periods would be consistent with those currently set out in Division 4A of Part 2 of the Agvet Code. For the information provided in the application, the limitation period would apply from when the product is provisionally registered (or provisionally varied). The limitation period for the efficacy information provided in the subsequent variation application would commence when the subsequent variation application is determined.

*The holder's additional responsibilities*

The holder would remain responsible for the supply of the provisionally registered product and taking corrective action if a problem is identified with the product, in the same way a holder must take corrective action if a problem is identified with any other registered chemical product. The holder would also remain liable for any damages caused by the product, as is currently the case with other registered chemical products.

While the product is supplied, the holder of provisional registration would have the responsibility to comply with all the usual requirements of a registered chemical product. This would include providing to the APVMA any relevant information the holder becomes aware of that shows the chemical product may not meet the efficacy criteria.

Despite having been issued with provisional registration, the holder would retain discretion over whether or not to supply the product, and the extent of any supply.

*Comment*

The government invites comment on this proposal, including about:

- any benefits of providing for provisional registration and variation, in particular whether users support access to provisionally registered products—recognising that the status of a product's use may change depending on the additional information provided by the holder and the APVMA's assessment of that additional information
- whether other kinds of information could be provided after provisional registration or provisional variation to registration (for example, crop safety or product stability)
- whether this measure should apply to variations of existing registrations of chemical products (new uses of existing products) as proposed or whether it should be limited to new products only
- whether this measure should be limited to particular kinds of products or kinds of uses that could be provisionally registered (for example, new chemistries, new modes of action, minor uses, uses for which there are currently no registered chemical products or products used to control weeds of national significance)
- the potential impacts that provisional registration or variation may have on the information generated to demonstrate that other products meet the efficacy criteria (for example, a provisionally registered chemical product could compete in the market with other registered chemical products, thereby reducing the value of the efficacy information that was generated by the holders of the other registered chemical products)
- any additional safeguards that are necessary for this measure (for example, whether the prospective holder should have a history of holding registration of chemical products or be a 'fit and proper person'—having not had a registration cancelled for contravening conditions of registration or for providing false or misleading information)
- whether three years is enough time in which to provide additional efficacy information or whether a longer period (e.g. five years) may be more appropriate
- whether the applicant should be required to agree a project plan with the APVMA to provide additional efficacy information (similar to provisional registration in therapeutic goods legislation) or whether the use of an undertaking is sufficient
- what labelling requirements should apply so users are aware of the provisional registration status of the chemical product and that the product may not be effective

- whether the product registration or variation must be cancelled if the holder does not provide the additional efficacy information in the specified timeframe (and if suspension of the registration or variation was considered the more proportionate response for a potentially inefficacious product, what should the APVMA do at the end of the period of suspension)
- whether provisional registration or variation should be ‘offered’ at the APVMA’s discretion following discussion with the applicant, or whether the applicant should be able to specifically apply for provisional registration or variation (which would require a new application type)
- what measures should apply to other chemical products that are registered on the basis of the provisionally registered chemical product (for example, whether it should be possible to register other chemical products using a provisionally registered chemical product as a reference product subject to the same condition to provide information, and whether these registrations also be cancelled if the registration of the provisionally registered chemical product is cancelled).

### **Exposure draft explanatory notes**

Part 1 of the exposure draft deals with provisional registration. This part would commence 12 months after royal assent to allow sufficient time to develop the necessary regulations. The measure would only apply to applications made after this 12 month commencement period (item 30).

Items 4 and 14 would, respectively, amend sections 14 and 29 of the Agvet Code to allow the APVMA to provisionally register or provisionally vary a registration of a chemical product. These measures would only apply to chemical products prescribed in the regulations (see new paragraphs 14(1A)(a) and 29(1B)(a)) and for uses and other criteria prescribed in the regulations (see new paragraphs 14(1A)(g) and 29(1B)(g)).

Item 6 would amend the Agvet Code to provide for the condition requiring the holder to provide the efficacy information within three years or within a further two years that the APVMA may allow. Item 24 would amend the Agvet Code to require the APVMA to cancel a registration if these conditions are contravened (that is, the required efficacy information is not provided in a variation application). Item 22 would amend the Agvet Code to provide that a notice of a proposed suspension or cancellation is not required to be given to a holder in this circumstance, as the APVMA is required to cancel the registration under new subsection 36(3). Item 23 would be a consequential amendment to section 36 to reflect the addition of new subsection 36(3). (Section 41 of the Agvet Code already provides that the APVMA may suspend or cancel a registration where having considered the efficacy information from the holder, the APVMA is not satisfied that the product meets the efficacy criteria. In this circumstance, a notice of a proposed suspension or cancellation must be given to the holder by the APVMA.)

Items 25 and 26 would amend section 43 to allow a person to apply to vary the relevant particulars and conditions for a product registration that is suspended pending an application under new subsection 27(2A) to provide additional efficacy information.

Items 27, 28 and 29 would provide for an application to be made to the AAT if the APVMA provisionally registers or varies a registration, or ceases a provisional variation of a registration



because a holder does not provide the required efficacy information for the variation (that is, contravenes the conditions to provide the efficacy information in the appropriate timeframe).

Items 1 and 2 would amend the definition of relevant particulars so the definition includes any relevant particulars varied under new sections 29AA or 29C.

Item 9 would amend section 27 of the Agvet Code to insert a new subsection 27(2A) that would provide for a holder to apply to the APVMA for assessment of the additional efficacy information, which the holder must provide to comply with the new conditions for provisional registration or variation. Items 10 to 13 would be consequential amendments to sections 27, 28 and 29 of the Agvet Code to reflect the application the holder may make under new subsection 27(2A) (as inserted by item 9).

Item 16 would insert a new section 29AA that authorises the APVMA to vary relevant particulars and conditions of registration of a chemical product after it has considered the additional efficacy information provided in the application made under subsection 27(2A).

Item 17 would insert new section 29C that requires the APVMA to determine that a variation ceases to have effect if the holder contravenes the condition to provide the additional efficacy information. This measure allows a provisional variation to registration to be 'undone' if the additional efficacy information is not provided, similar to the requirement that a provisional registration of a chemical product must be cancelled if the additional efficacy information is not provided. New section 29C also requires the APVMA to update the register and inform the applicant of the determination that ceases the variation to registration. New section 29C specifically requires the APVMA not to update the register until 14 days have elapsed since the notice of the determination was given to the holder.

Items 18 and 19 would amend the Agvet Code to provide that additional efficacy information be subject to limits on its use, and that information subject to limitation cannot be used to provisionally vary a registration. Item 20 amends subsection 34MA(5) (inserted in Part 4 of the Bill) to provide for the limitation period for the additional efficacy information to be extended.

Items 5 and 15 would be consequential amendments to subsections 14(2) and 29(2) to reflect the new subsections inserted by items 4 and 14.

Items 7 and 8 would amend the explanation section for varying relevant particulars and conditions to include references to new sections 29AA and 29C. Item 21 would amend the explanation section of the Agvet Code for suspensions and cancellations to reflect the new requirement for a registration to be cancelled under subsection 36(3) if the holder contravenes the condition in new subsection 23(4) (set out above).

Item 3 would be an editorial amendment to align the expression about labels so that it refers to 'containers' like elsewhere in the Agvet Code.

## Proposal 2 – An accreditation scheme for assessors in the future (*accreditation of assessors*)

Provide for a disallowable APVMA legislative instrument to prescribe an accreditation scheme for assessors in the future, including charges for accreditation, and provide for sanctions for contravening conditions of accreditation.

### Background

The APVMA outsources elements of its technical assessments to third party external assessors who are experts in the fields of human health, environment, efficacy and target animal and crop safety risk assessment (these assessors are used for applications lodged with the APVMA). In addition, the APVMA is conducting an efficacy contestability pilot project in which third party external assessors conduct pre-application assessment of efficacy and target animal and crop safety (that is, the assessors are engaged by applicants, not by the APVMA). The APVMA anticipates that this pre-application approach to assessments may be expanded in the future to assessments other than efficacy and target animal and crop safety.

Moving the function of conducting or commissioning data assessments from the APVMA to third-party providers has the potential to:

- provide applicants with more control over data assessment timeframes and costs
- simplify administration processes within the APVMA
- increase efficiency of application processing
- open data assessment to competition.

Stakeholders have noted the need for rigour in the quality of external assessors and their assessments.

### Current approach

The administrative scheme operated by the APVMA can apply some sanctions to third-party assessors (for example, removal from the list of assessment providers). However, there are no direct civil or criminal sanctions that the APVMA can apply to an external assessor (e.g. for contravening the conditions of an accreditation scheme, should one be established in the future).

### Proposed approach

The government proposes that the Agvet Code be amended to provide for a legislative instrument to be made, setting out an accreditation scheme for assessors. This would enable the APVMA to establish a framework for assessors in the future which could, for example, specify requirements about professional experience, insurance, conflict of interest measures and data handling protocols for assessors.

The legislative instrument setting out the accreditation scheme could also include requirements for an audit and compliance program, overseen by the APVMA. This would help ensure quality and consistency, and safeguard the integrity of the third party assessment process.

The scheme would need to provide for charges for functions the APVMA would perform, consistent with cost-recovery principles. The specific charges would need to be developed following consultation on the details of the accreditation scheme and would be set out in the

legislative instrument the APVMA would make (potentially supplemented by separate levy legislation, if appropriate). Any charges for the accreditation scheme (either fees or levies) would need to be consistent with the Australian Government Charging Framework and the Australian Government Cost Recovery Guidelines. Fees for service must reflect efficient costs of the effort required to deliver a specific good or service.

The scheme would have broad application to support the APVMA and could potentially be used to accredit persons for a range of purposes in the future, such as:

- roles that accredited persons might undertake directly with industry, including preparing assessment reports for applicants that would then be included in applications made to the APVMA (similar to the approach used in New Zealand)
- roles the APVMA currently undertakes, but which could potentially be undertaken by accredited assessors in the future, such as conducting assessments of information in applications made to the APVMA (APVMA-initiated assessments by accredited external assessors).

Recognising the technical nature of an accreditation scheme and the expertise required to establish and oversee it, the government proposes that the APVMA would develop the accreditation scheme through a legislative instrument. This would provide a suitable legislative basis for the scheme (and would be disallowable in parliament, and hence subject to parliamentary oversight), while ensuring the scheme can be sufficiently responsive to the needs of the APVMA.

Furthermore, the government anticipates that persons overseas may wish to become accredited persons. For this reason, the offences for non-compliance with conditions of accreditation would extend to an overseas person.

The government invites comment on this proposed measure. The exposure draft specifies that fees for the accreditation scheme would not amount to taxation and all fees for the accreditation scheme would therefore be limited to fees for service (subsection 69GA(5)). However, subsection 69GA(2) specifies examples of some matters that could be included in the legislative instrument that the APVMA could make about the accreditation of persons. The examples of matters in paragraphs 69GA(2)(j) to (o) and paragraph 69GA(2)(q) could potentially be recovered as a levy on accredited persons (that is a tax) rather than a fee for service. Such a levy could potentially be through an annual accreditation renewal fee. If there is stakeholder support for the legislative instrument to deal with the matters in paragraphs 69GA(2)(j) to (o) and paragraph 69GA(2)(q) then further legislation would be required to authorise levies for these matters.

### **Exposure draft explanatory notes**

Part 2 of the exposure draft deals with the accreditation of assessors. Part 2 would not commence until 12 months after royal assent.

Item 34 would insert a new section 69GA into the Administration Act to allow the APVMA to make a legislative instrument prescribing matters for the accreditation of persons and the roles they would perform. New section 69GA includes examples of the kinds of matters that the APVMA legislative instrument could deal with (noting its operation would not be limited to these examples). New section 69GA also provides for the APVMA legislative instrument to set

out fees for accreditation. Item 32 would amend the Administration Act to provide that fees received by the Commonwealth in relation to an instrument under section 69GA must be paid to the APVMA by the Commonwealth.

Item 34 would also insert new section 69GB, which includes offences and civil penalties for contravening conditions of accreditation. New section 69GB includes both an aggravated offence and aggravated civil penalty provision (subsections 69GB(1) and (2)), as well as a strict liability offence and civil penalty provision (subsections 69GB(4) and (5)). New subsection 69GB(7) extends the geographic jurisdiction of the offences in subsections 69GB(1) and (4).

Items 31, 33, 35 and 36 would be consequential amendments to add a definition for 'accredited person' and reflect that the 'accredited person' has a similar status to a 'consultant'.

## **Proposal 3 –Prescribed approvals and registrations (*approval and registration for active constituents, chemical products or labels*)**

Provide for prescribed approvals and registrations to simplify the approval of active constituents and labels, and the registration of certain products (to be set out in regulations or other instruments).

### **Background**

The Agvet Code provides for streamlined variations to approvals of active constituents and labels, and registrations of chemical products, through ‘notifiable’ and ‘prescribed’ variations. However, it does not provide a similar mechanism to streamline new approvals and registrations. This means that while regulatory effort and risk can be aligned for variations to approvals or registrations, there is no means of adopting a similar approach for approvals and registrations in the Agvet Code.

### **Current approach**

Section 27 of the Agvet Code provides for variations to the conditions and relevant particulars of approvals and registrations. Divisions 2AA (notifiable variations) and 2A (prescribed variations) of Part 2 of the Agvet Code provide for streamlined variations to the relevant particulars of approvals and registrations. These streamlined application processes were provided to reduce the supporting information requirements and the time and effort for industry to make—and for the APVMA to assess—variations to registrations or approvals.

The types of variations to approvals and registrations that can be made as notifiable variations and prescribed variations are set out in the Agricultural and Veterinary Chemicals Code Regulations 1995 (Code Regulations) and a legislative instrument made by the APVMA.

The Agvet Code currently provides for a person to apply for new registration of a chemical product, or an approval of an active constituent or label for containers for a chemical product (section 10). However, there is currently no means to provide for approvals and registrations to be made by the APVMA through a simplified self-declaration or self-registration model, similar to the approach currently used for notifiable or prescribed variations.

### **Proposed approach**

Similar to the approach currently used for prescribed variations (in Division 2A of Part 2 of the Agvet Code), the government proposes to provide for a streamlined means of approving active constituents and labels and registering chemical products. This would provide for:

- prescribed approvals of active constituents and labels
- prescribed registrations of chemical products.

#### *Prescribed approvals and registrations*

Prescribed approvals and registrations would represent a new approval or registration process that would be quicker and less costly than the current approval or registration process. This new process would apply for those active constituents, chemical products and labels where minimal or no assessment of technical information was required.

As is the case for notifiable and prescribed variations, this new process for prescribed approvals and registrations would only apply where an approval or registration is of a kind determined by the APVMA in a legislative instrument or prescribed in the regulations.

An application for a prescribed approval or registration would need to meet the application requirements. If the application does not meet the application requirements, the APVMA would notify the applicant of the reasons the application does not meet the application requirements. The streamlined process would mean that applications would not be subjected to preliminary assessment. However, the APVMA may alter the application with the written consent of the applicant.

The APVMA would be required to approve an active constituent, register a chemical product or approve a label if it was satisfied the application meets the application requirements, the active constituent, product or label is of a prescribed kind, and no prescribed disqualifying criteria for the applicant apply (see below). Where this was not the case the APVMA would be required to refuse the application (subject to a notice being issued under section 8S of the Agvet Code).

For prescribed approvals and registrations, the APVMA must make a decision to approve or register, or refuse the application, within the assessment period prescribed in the regulations (as currently required for prescribed variations). Different assessment periods and different fees could be prescribed for different kinds of approvals of active constituents and labels, and different kinds of registrations of chemical products, so the assessment periods and fees reflect the regulatory effort.

If the APVMA does not make a decision within the prescribed timeframe then the usual process in section 165 of the Agvet Code would apply. That is, the applicant could notify the APVMA to have their application taken to be refused. Unlike for prescribed variations, the government proposes that a 'deemed' approval not occur because this would be impractical to implement for a new active constituent, product or label. A 'deemed' refusal would also be inappropriate because of the reputational risks for applicants.

A prescribed approval or registration would be in effect only when the APVMA updates the record, the register or relevant APVMA file (as is the case now). This difference in approach from prescribed variations is considered necessary to ensure that only safe and effective products continue to be available in Australia.

Information with a limitation period could not be used for prescribed approvals and registrations. Information in applications for prescribed approvals and registrations would not be eligible for a limitation period.

### *Implementation*

This measure would provide for a streamlined means of dealing with certain chemical products (e.g. those that are the same as an existing chemical product or those of lower regulatory concern). This would reduce the APVMA's workload in assessing these kinds of applications and limit pre-market assessments of low- and medium-risk products, to focus on high-risk products.

The government proposes that the measure apply to particular kinds of chemical products that would be set out in a disallowable legislative instrument made by the APVMA or prescribed in the regulations. This measure would need to be implemented incrementally with the number of

kinds of products so prescribed growing over time. The government would consult on the legislative instrument or regulations when they are developed.

A key element of prescribed approvals and registrations is the greater reliance on the applicant and information provided by the applicant. Therefore, prescribed approvals and registrations would be subject to prescribed disqualifying criteria that could include criteria about the applicant. It is anticipated that the disqualifying criteria may refer to applicants that have been convicted of an offence or ordered to pay a civil pecuniary penalty (within the previous 10 years) or that have had a registration or approval suspended or cancelled under sections 36 (contravening a condition of approval or registration) or 38A (providing false or misleading information) of the Agvet Code. This would be consistent with the current approach for permits and licences to manufacture chemical products and would better enable the APVMA to rely on certain applicants and the information they provide. This would provide flexibility for applicants while continuing to provide confidence in the regulatory scheme.

Applicants that met the disqualifying criteria would still be able to apply for approvals and registrations, as is currently the case. However, these applications may not be able to be dealt with as prescribed approvals or registrations, and may need to be dealt with in the same manner as they are now through the usual section 10 application pathway.

To implement prescribed approvals and registrations, the APVMA will also need increased flexibility to act on false or misleading information that it may receive in an application for a prescribed approval or registration. These measures are described later in this document and include:

- more scope to respond to false or misleading information provided in applications, including in variation applications and applications for label approval
- additional obligations on applicants and holders to provide relevant information for their applications, approvals and registrations
- greater flexibility for holders to deal with suspended, and seek suspension of, product registrations.

The government invites comment on this measure and the additional kinds of approvals and registrations that could be specified as prescribed approvals and registrations. In particular, the government invites comment on whether a longer lead time of 12 months (instead of six months) should apply to the introduction of this measure. Furthermore, the government requests comment on whether the APVMA should be required to cancel an approval or registration if given false, misleading or incorrect information in an application for prescribed approval or registration (for example, requiring the APVMA to cancel a registration of a chemical product where the application contains incorrect information and the APVMA relied on that information to register the chemical product).

### **Exposure draft explanatory notes**

Part 3 of the exposure draft deals with prescribed approvals and registrations. Part 3 would commence six months after royal assent to allow the regulations or APVMA legislative instruments for this measure to be developed.

Item 41 would insert new sections 14C, 14D and 14E. These new sections would provide for the regulations or APVMA legislative instruments to specify certain kinds of active constituents,

chemical products and labels that could be approved or registered through a simplified approval or registration process. These sections also provide for the APVMA to make a legislative instrument setting out disqualifying criteria for this pathway in respect to applicants, and set out the criteria on which the APVMA is to approve an active constituent or label or register a chemical product or refuse an application. The new sections would be similar to those that currently provide for prescribed variations to approvals and registrations.

Items 45, 46 and 47 would provide for internal reconsideration and an application to the AAT where applications for prescribed approvals and registrations are refused, or where an approval or registration is subject to conditions, or where instructions or relevant particulars are different from those provided in the application.

Item 39 would amend the current explanation section to include reference to prescribed approvals and registrations. Items 37, 38, 40, 42, 43 and 44 would be consequential amendments to reflect the insertion of new sections 14C, 14D and 14E about prescribed approvals and registrations.



## **Proposal 4 – Data protection incentives for certain uses of chemical products (*limits on use of information*)**

Provide for extensions to limitation and protection periods (to be set out in regulations or other instruments) as an incentive for registration holders to include certain uses of chemical products on labels and reduce the need for permits.

### **Background**

An innovator funds the production of information to support the new use of a chemical product (innovator product). If there were no limits on the use of this information then another person could seek to rely on this information to register a generic version of the product. This would allow the generic product to compete with the innovator product without incurring the cost of producing the information or taking the financial risks of ‘testing’ the market with a new product, use or claim.

Limiting the use of information prevents generic competitors from using innovators’ information for a period of time or allows innovators to seek compensation from the generic competitors for use of the innovators’ information during the period the information is protected. This benefits the innovator, who has incurred the cost of generating this information, and promotes innovation.

### **Current approach**

The Agvet Code provides for two kinds of periods in which the use of information provided to the APVMA can be protected.

‘Limits on use of information’ relates to information provided to the APVMA as part of an application or as relevant information under section 161 of the Agvet Code. (Section 161 of the Agvet Code requires the holder of an active constituent approval or chemical product registration to provide certain new information to the APVMA that would affect the approval or registration; this must be done when the holder becomes aware of that new information.) If the information is relied on by APVMA in making a decision, it receives a ‘limitation period’. The limitation periods for this information are set out in Division 4A of Part 2 of the Agvet Code. During the limitation period the APVMA may not use the information to assess or make a decision on another application or on information given under section 161 unless an exception applies (for example, the authorising party has provided consent for the information to be used).

‘Protected information’ is certain kinds of information provided as part of a reconsideration (sometimes referred to as a chemical review) that relates to either an active constituent that has been approved or a chemical product that has been registered. The protection period commences from the time the information is provided and ends eight years after the APVMA makes its decision on the reconsideration.

These limitations on the use of information are sometimes known as ‘data protection’ and the period during which the information cannot be used is sometimes known as a ‘data protection period’.

## **Proposed approach**

The government is proposing to provide incentives for product registration holders to register priority uses of chemical products, by providing extensions to limitation and protection periods, similar to approaches applied internationally. The government anticipates that this would encourage more uses to be included on product labels and could reduce the need for permits.

The incentives would operate by providing for any existing limitation and protection periods to be extended for up to five years if certain conditions are met.

The requirements for extending these periods will include technical detail (see 'Implementation' below). For this reason, the government proposes that the Agvet Code be amended to provide that the regulations would specify most of the details for extending limitation and protection periods.

### *Extension of the limitation and protection periods*

The table to section 34M of the Agvet Code sets out the current limitation periods for information given for different kinds of applications and for information given under section 161 of the Agvet Code. The provisions in the table apply where that information is relied on for making decisions about applications or as a result of giving that information to the APVMA for section 161. The regulations would prescribe circumstances where the limitation periods in section 34M of the Agvet Code may be extended—that is, the extension would apply to the information used for the initial registration, and not only to the information for the additional use(s). The regulations would also provide for the eight year protection period for 'protected information' to be extended. The government would consult on these regulations when they are developed.

While most of the technical details would be set out in the regulations, the Agvet Code would specify the following restrictions on extensions to the limitation or protection period:

- a limitation or protection period cannot be extended beyond a maximum of five years (in total)
- a limitation or protection period can only be extended for a use that is specified in an order made by the minister or prescribed in the regulations (priority uses)
- a limitation or protection period can only be extended if the application to vary an existing registration is made at least three years before the limitation or protection period for the information associated with the existing registration expires (to prevent generic manufacturers prematurely preparing for, and investing in, market entry).

These extensions to limitation and protection periods would provide incentives for industry to include certain uses on the labels of chemical products. The government anticipates that these uses could include broad crop groups (see below) or other uses needed to support agricultural productivity. Uses might also include those needed to control weeds and pests of national significance.

### *Implementation*

To practically implement this measure:

- a limitation or protection period for the information should already exist, or
- the registration of the product and active constituent or label approval would result in the information in the application for registration or approval being subject to a limitation period.

An extension to the limitation or protection period would be provided for information the APVMA relies on to:

- register a chemical product or approve a label as set out in item 2 of the table in section 34M of the Agvet Code
- vary the registration of a chemical product or vary a label approval as set out in items 3, 4, 5 and 6 of the table in section 34M of the Agvet Code.

A limitation or protection period extension would also be provided for prescribed kinds of active constituents in relation to an active constituent approval as set out in item 1 of the table in section 34M of the Agvet Code, e.g. biological pesticides.

The specific uses and extension periods would be subject to consultation when the regulations or ministerial order that prescribe them are made. However, as an example, the government anticipates the regulations could prescribe extensions of the limitation and protection periods such as:

- three months additional limitation or protection period for the use of a chemical product for:
  - each use specified in an order made by the minister or the regulations (other than a use on a food or fibre producing animal species) or
  - individual representative crops of a crop group
- six months additional limitation or protection period for the use of a chemical product for:
  - each use on an animal species specified in an order made by the minister or the regulations or
  - each additional food or fibre producing animal species on a representative commodity of an animal commodity
- twelve months additional limitation or protection period for the use of a chemical product on:
  - each entire crop group or
  - each animal commodity group.

Longer periods of protection could potentially be provided for animal species because of the smaller number of animal commodity groups. The references above to an 'entire crop group' and a 'representative crop' of a crop group would be consistent with the APVMA's guidelines on these crops and groups (<https://apvma.gov.au/node/18851>).

These additional limitation and protection period extensions would be cumulative and could provide for up to five years extension in total. Based on the above, a possible example would be where a chemical product was registered for use on:

- pome fruit (a crop group) (12 months extension)
- stone fruit (a crop group) (12 months extension)
- grapes (a representative crop of a crop group) (three months extension)
- three uses specified in an order made by the minister or the regulations (nine months extension).

In this circumstance, the product would be eligible for a total of three years' extension to the limitation or protection period for the information relied on by the APVMA to register the chemical product and approve the label for the above mentioned uses of the product.

#### *Implications and benefits*

Providing such incentives may benefit users by encouraging more holders to include additional uses on labels. However, this may also exclude generic manufacturers from the market for a longer period of time, which may have an effect on the cost of these chemicals during the extension period. The extent of these benefits and impacts is difficult to gauge. It would depend on the degree to which holders include uses on labels in response to the proposed limitation or protection period extensions.

While access to safe and effective chemical products can already be provided through permits, this measure could encourage more uses on to the labels of chemical products and therefore promote transparency about the uses of chemical products.

The government invites comment on this proposed measure, including:

- the likelihood that industry will use these extensions—for example, whether the benefits of longer limitation and protection periods is likely to outweigh the costs of registering chemical products and approving the active constituent and labels for particular uses
- the potential impacts on users of chemical products, particularly the potential for increased access to innovative products or uses, with potentially reduced access to generic products
- the extensions to limitation and protection periods and appropriate circumstances for these extensions, as suggested in the examples above
- whether the extensions should apply to both limits on use information given in relation to an application (the kinds of information in section 34M of the Agvet Code) and protected information given in relation to a chemical reconsideration, or if the extensions should only apply to the kinds of information in section 34M of the Agvet Code
- the kinds of uses that should be incentivised for inclusion on product labels, recognising that permits can already provide access to the use of a product
- whether the incentives should be limited to agricultural chemical products, with alternative approaches to apply for veterinary chemical products (for example, extending the current three year limitation period for information used for a variation to five years instead of extending the limitation period for information used to register the product).

### **Exposure draft explanatory notes**

Part 4 of the exposure draft deals with encouraging uses on to the labels of products by allowing limitation and protection periods to be extended. Part 4 would commence six months after royal assent and item 60 provides that the extensions only apply to limitation and protection periods beginning after commencement.

Items 55 and 58 would insert new sections 34KA and 34MA to provide that the regulations may provide for the protection period and limitation period to be extended. These new sections would provide that these periods could only be extended for a maximum period of five years (in total), and that at least three years of the existing period must remain for a limitation or protection period to be extended.

Items 48, 49, 50, 51, 52, 53, 54, 56, 57 and 59 would be consequential amendments to reflect the insertion of new sections 34KA and 34MA.

## **Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment (*information to be taken into account in determining applications*)**

Provide the APVMA and industry with more flexibility to deal with certain prescribed types of information (to be set out in regulations or other instruments) given while the APVMA is determining an application.

### **Background**

Prior to 2014, applicants could provide information to the APVMA while an assessment was underway, for example, information to support registration of additional uses or a longer shelf life. This frequently resulted in the APVMA managing sub-standard or incomplete applications (which is not appropriate for a cost-recovered agency). It also meant the APVMA would sometimes have to undertake additional technical assessments that were not foreseen when the application was made. Changes to the Agvet Code now prevent the APVMA from considering new information provided by an applicant after an application has been made, except where the information is provided in response to a notice (that is, unless the APVMA specifically requests the information). This encourages applicants to lodge complete applications and improves the efficiency of APVMA's assessments.

### **Current approach**

Section 8C of the Agvet Code prohibits some kinds of new information from being considered during the assessment period for an application. This includes both data requiring technical assessment, and simple, non-technical information.

As the APVMA cannot consider information provided by, or on behalf of, the applicant during the assessment period for the application, the only option for an applicant to provide additional information, is to do so in a variation application. This cannot be made until the original application has been determined. In some cases, such as where good manufacturing practice certification may have expired while an assessment was underway, this creates inefficiencies for both the APVMA and the applicant, and is an unintended consequence of the reforms that commenced in 2014.

In addition, it is sometimes necessary to clarify information during an assessment. Despite section 8C, the APVMA may, at its discretion, issue a notice to an applicant under section 159 of the Agvet Code seeking additional clarifying information. The first such notice issued during an assessment triggers a compulsory one-off extension to the statutory time period in which the application must be assessed, as set out in the table at Part 2, Schedule 6 of the Code Regulations. This extension period is typically equivalent to one-third of the statutory assessment period for the original application (rounded up to the nearest whole month) plus an additional month. While the fixed extension period is intended to provide certainty to the applicant about when the application will be determined, the defined period may be excessive for some requests for simple clarifying information.

## **Proposed approach**

It would be more efficient if certain (limited) types of information could be provided and considered by the APVMA during the assessment period for an application. The government proposes to provide the APVMA and industry with more flexibility in this regard. The kinds of information to which this measure would apply would be prescribed in the regulations.

Examples of the kinds of information that could be provided during an assessment period would include good manufacturing practice certification, as well as technical information that clarifies information the applicant has already provided (for example, clarifying information about an efficacy study that was provided in the initial application). Additional modular assessment fees and extended timeframes may apply for the APVMA to consider this information, as appropriate. The government would consult on the types of information, and on any associated fees and timeframe extensions if these are considered appropriate.

At this time, it is proposed that this additional information would not include information relating to extensions of the shelf-life of a product. Shelf-life extension may require extensive technical assessment—the APVMA has advised that it prefers that new information requiring technical assessment not be accepted and considered under this mechanism. The government is separately exploring greater use of the existing ‘timeshift’ applications to provide the APVMA and industry with more flexibility to deal with information relating to extensions of the shelf-life of a product but notes that this may add administrative burden to both the APVMA and applicant.

It would be appropriate for the regulations to also prescribe the circumstances under which this information is provided. For example, where the applicant advises, at the time of making the application, that the additional information will be provided before a particular time during the assessment period of the application. Prescribing these circumstances may be appropriate for some kinds of data, to ensure the APVMA can manage the application appropriately. This would allow the APVMA to continue to efficiently assess applications, while also being able to take into account the information that may be provided during the assessment period.

The government invites comment on this proposed measure. This includes comment on kinds of new information that would be appropriate for the APVMA to be able to consider during an assessment and the circumstances under which this information could be provided.

## **Exposure draft explanatory notes**

Part 5 of the exposure draft would deal with authorising certain kinds of information to be provided during assessment of an application. This measure would commence six months after royal assent to allow the necessary regulations to be developed. However, this measure would apply to applications which had not been determined at the time of commencement and allow the kinds of information prescribed in the regulations to be provided even though these applications were made before commencement (item 63).

Item 62 would amend section 8C to insert a new subsection 8C(2A) to allow the regulations to prescribe certain kinds information that can be provided during assessment of an application.

Item 61 would be a consequential amendment to reflect the insertion of new subsection 8C(2A).

## Proposal 6 – Provide for computerised decision-making (*computerised decision-making*)

Modernise the Agvet Code by providing for the APVMA to use computerised decision-making.
--

### Background

Computerised decision-making can, where applied properly and with appropriate safeguards, improve administrative efficiency. Section 7C of the *Therapeutic Goods Act 1989* provides for the Secretary of the Department of Health to arrange for the use of computer programs to make decisions. Similarly, section 172 of the Industrial Chemicals Bill 2017 would also provide for the Executive Director of the Australian Industrial Chemicals Introduction Scheme to use computer programs to make decisions.

### Current approach

While the Agvet Code deals with electronic transactions, it does not currently provide for the use of computer programs to make decisions. Accordingly, all decisions, including those of a largely administrative nature, require an APVMA staff member to turn their minds to the matter at hand.

### Proposed approach

The government proposes to provide that the APVMA may choose to use computerised decision-making as part of its approval and registration processes. Where the APVMA considers it appropriate, this power would assist the APVMA to determine applications and improve efficiency. Computerised decision-making could be used for such activities as preliminary assessments, which involve an administrative check that all elements of an application have been provided. The legislation would not constrain the circumstances under which the APVMA may use computerised decisions.

This measure would need to be implemented gradually after a suitable transition period, to allow the APVMA to develop the necessary systems.

A decision made by a computer program could be reconsidered or an application could be made to the AAT for a review of the decision made by a computer program. However, these opportunities for merits review of a decision made by a computer program would not apply to either:

- a decision that currently is not able to be reconsidered
- a decision for which an application for review may not currently be made to the AAT.

The APVMA would be able to substitute a decision for an incorrect decision made by a computer program within 60 days of the original decision being made. This would enable the APVMA to deal with any incorrect decisions. Where the APVMA has substituted a decision for one made by a computer program, it has effectively reconsidered the initial decision, and the government proposes this substituted decision could not be reconsidered. However, where the APVMA substitutes a decision for a decision made by a computer program, an application could be made to the AAT for a review of the substituted decision (provided AAT appeal would be available if the decision was not made by computer).



The government invites comment on this proposed measure, in particular whether an opportunity for reconsideration (internal review) by the APVMA should be provided for a substituted decision.

### **Exposure draft explanatory notes**

Part 6 of the exposure draft would commence on a day to be fixed by Proclamation to allow the APVMA time to put the necessary information technology arrangements in place. However, this Part would commence six months after royal assent if the provisions do not commence on a proclaimed date before this.

Item 64 would insert new section 5F into the Agvet Code to authorise the APVMA to use computer programs to make decisions. New section 5F would also authorise the APVMA to substitute a decision made by the operation of a computer program if the APVMA is satisfied that it was incorrect.

Items 65 and 66 would provide for internal review and an application to be made to the AAT for decisions made by the operation of a computer program.

## Proposal 7 – Improve the transparency of voluntary recalls (*voluntary recalls*)

Improving transparency about recalls of agvet chemicals by requiring persons to inform the APVMA when they are undertaking certain voluntary recalls and requiring the APVMA to publish such recalls.

### Background

Part 6 of the Agvet Code provides for the APVMA to issue recall notices for chemical products (compulsory recalls) and also provides that the *Competition and Consumer Act 2010* applies to voluntary recalls of ‘consumer goods’. These provisions provide for industry to recall products but also provide for the APVMA to issue notices to require persons who have, or have had, stocks of chemical products in their possession to stop supplying the products or to take action in relation to the products as directed by the APVMA.

These provisions already provide for the APVMA to issue notices to persons requiring them to notify other persons about products being recalled, including distributors of chemical products. These notices could be issued, for example, where the APVMA forms a view that the voluntary recall actions are insufficient.

In addition, holders of registration have legal obligations under section 161 of the Agvet Code to advise the APVMA in writing if they become aware of any relevant information in relation to a registered product or any of its constituents. Information is relevant information if it:

- contradicts any information entered in the record, the register or Record of Permits for the constituent or product; or
- shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria (proposal 8 in this document would extend this requirement to the labelling criteria as well).

### Current approach

The APVMA receives notifications from industry about voluntary recalls and publishes this information on its website. However, these notifications from industry are not mandatory. This means that the APVMA (the national regulator) may be placed in an unacceptable position where it is not always aware of a voluntary recall that is being conducted.

In addition, neither the Agvet Code nor the Competition and Consumer Act specify notification and publication requirements if an agvet chemical product is being voluntarily recalled and the product is not a ‘consumer good’ for the purposes of Schedule 2 to the Competition and Consumer Act (Australian Consumer Law). As a result, it is left to the person recalling the product to determine how the recall is conducted and how stakeholders are notified.

This does not mean that safety, efficacy or trade issues cannot currently be addressed, as the APVMA has the power to mandate a recall (by issuing recall notices) if a product may not meet the safety, efficacy or trade criteria. However, where the APVMA has not issued a recall notice (e.g. because there is no outstanding safety, efficacy or trade concern, including in light of any actions taken by the distributor) and a product is being voluntarily recalled, the person recalling

the product determines the information that is published and how that information is provided to distributors and users of chemical products.

### **Proposed approach**

The government proposes a new measure that will apply if a person (a recaller) voluntarily takes action to recall an agvet chemical product. To simplify the introduction of this new measure, the government does not propose changes to the existing recall notices the APVMA can issue under Part 6 of the Agvet Code ('compulsory' recalls). The proposed measure is therefore focussed on voluntary recalls, and will support operational changes the APVMA has introduced for voluntary recalls of agvet chemicals.

The proposed measure would apply to:

- a chemical product (including a reserved chemical product) or label that does not meet the statutory criteria (for safety, efficacy, trade or labelling)
- a chemical product that is not registered (in the case of products that do not meet the chemical product requirements in the register).

(A chemical product is defined in section 3 of the Agvet Code to be an agricultural chemical product or a veterinary chemical product or both.)

Under the proposal, the recaller must, before taking the action to voluntarily recall the product, give the APVMA a notice in a form approved by the APVMA. The notice would include information about the recall, including the reasons for the recall. An offence and civil penalty provision is proposed to be included to ensure there is a suitable sanction for not notifying the APVMA about a voluntary recall.

If the APVMA receives a notice from a recaller, it must publish the notice on its website, in the Gazette and in any other manner it thinks appropriate. This will ensure transparency about recalls being conducted in Australia.

The requirement for the APVMA to publish the notice would not apply if the chemical product has not been supplied to a person that will use the product. This would mean that where a product has not been distributed to product users, the APVMA need not publish the notice. However, the recaller would still need to notify the APVMA that it is conducting a voluntary recall so the APVMA is aware of the recall and the reasons for it.

Products may be withdrawn from the market for many reasons, some of which are unrelated to a defect with the product. The proposal would only apply where the reasons for the recall relate to the product's compliance with the statutory criteria or to the distribution of a chemical product that is not registered (e.g. it would not apply to products returned to the distributor because they have passed their expiry date, or products recalled for marketing reasons such as changes to label designs).

To provide flexibility, the amendments to the Agvet Code would provide that regulations may exempt suppliers from notifying the APVMA in particular circumstances and exempt the APVMA from publication requirements in particular circumstances (such as those described above).

### *Implementation*

Based on the proposed measure, a voluntary recall process would generally involve a recaller:

- identifying the issue and deciding to conduct a recall of a chemical product
- completing the approved form for the recall of the chemical product (which should include a requirement to provide information on the nature of the recall)
- providing the approved form to the APVMA
- conducting the recall of the chemical product, including contacting customers and any necessary notifications, including advertisements and any notifications to the ACCC
- providing any mandatory reports—for example, if a death or serious injury or illness has been associated with a product, a mandatory report would need to be lodged with the ACCC
- reviewing and assessing the effectiveness of the recall.

The APVMA and the ACCC have produced guidance on conducting a recall and this information is on their websites.

### *Public comment*

The government invites comment on this proposed measure and on the kinds of recalls which should be exempt from notification to the APVMA, as well as circumstances where the APVMA should be exempt from the publication requirements for recalls.

Additionally, the government invites comment on the proposed requirements for disseminating information about recalls and whether additional ‘alert’ mechanisms are required (if so, what these should be).

The government also invites comment on the following aspects of the proposed measure:

- the need to complete an approved form to advise the APVMA of the recall
  - this is proposed to ensure that the APVMA is provided with the information about the recall in a consistent manner and so the APVMA has a clear indication of the issue, the recall parameters and the urgency of the recall and to minimise administrative burden for the APVMA
- the proposed requirement for the recaller to provide the approved form to the APVMA before conducting a recall
  - this is proposed to ensure the APVMA is informed of the recall before public notifications are made; that is, as soon as a recaller is aware that a recall may be required
  - an alternative approach may be to require that the approved form is provided to the APVMA within two days of conducting the recall—similar to section 128 of Schedule 2 to the Competition and Consumer Act

- the requirement for the APVMA to publish the approved form for the recall
  - this is proposed to ensure the APVMA can quickly provide the information about the recall, without having to determine what information in the form should be published
  - there is scope to modify this measure so that the APVMA need only publish a brief statement of the matters to which the recall notice relates, similar to what is required for recall notices issued by the APVMA (see section 104 of the Agvet Code), although this could significantly increase the administrative burden on the APVMA
- the potential for the proposed measures to operate as a disincentive for persons to conduct voluntary recalls.

### **Exposure draft explanatory notes**

Part 7 of the exposure draft would deal with improving transparency about voluntary recalls of agvet chemicals. Part 7 would commence three months after royal assent to allow industry to be informed of its new obligations when conducting voluntary recalls and to allow any supporting regulations to be made.

Item 69 would insert new section 106A into the Agvet Code that would apply to a person proposing to recall a chemical product for certain reasons, specifically where the product or label may not meet the statutory criteria or the product is not a registered chemical product. New subsection 106A(2) requires the person to notify the APVMA of the recall and new subsections 106A(4) and (5) are an offence and civil penalty provision for contravening this notification requirement. New subsection 106A(6) requires the APVMA to publish information about the recall. New subsections 106A(3) and (7) provide for the regulations to exempt persons from the notification requirements and to exempt the APVMA from the publication requirements. Item 70 provides that the obligations in section 106A only apply in relation to action proposed to be taken after commencement.

Items 67 and 68 would be consequential amendments to reflect the insertion of new section 106A about voluntary recalls.

## **Proposal 8 – Require relevant information to be provided in relation to label approvals and variations (*notification of new information*)**

Ensure that obligations to provide relevant information apply to holders of label approvals, and applicants for both label approvals and variations to approvals or registrations; as they do in relation to active constituent approvals and product registrations.

### **Background**

Sections 160A and 161 of the Agvet Code require an applicant or holder (respectively) to provide certain new information to the APVMA that would affect the approval, registration, permit or licence. This must be done when the applicant or holder becomes aware of that new information.

Section 160A applies to applications lodged with the APVMA for:

- approval of an active constituent
- registration of a chemical product
- issue of a permit in respect of an active constituent or chemical product
- issue of a licence in respect of the manufacture of a chemical product.

Section 161 applies to holders of approval for an active constituent, registration of a chemical product and existing permits in relation to an active constituent or chemical product.

### **Current approach**

Currently, the requirements in section 160A (to provide relevant information) do not apply to an applicant for approval of a label for containers for a chemical product. In addition, the section 160A requirements do not apply to applicants seeking to vary an approval or registration. The same public health and environmental protection safeguards for providing relevant information that currently apply under section 160A should also apply to applicants for label approvals and applicants seeking to vary an approval or registration.

Currently the requirements in section 161 (to provide relevant information) do not apply to holders of label approvals. Labels contain instructions for the safe use of a chemical product and any relevant health or safety warnings. Therefore, the same public health and environmental protection safeguards for providing new relevant information that apply under section 161 should apply to holders of label approvals.

### **Proposed approach**

#### *Section 160A of the Agvet Code – applicant obligations*

The government proposes to amend the Agvet Code to require applicants seeking approval of a label for containers for a chemical product to provide new relevant information in relation to the application. Relevant information would be information that contradicts information in the application and relates to certain prescribed particulars, or information that shows the label may not meet the labelling criteria.

The government also proposes to amend the Agvet Code to require applicants seeking variations to approval or registration to provide new relevant information in relation to the application. Relevant information would be information that contradicts information in the application and relates to certain prescribed particulars, or information that shows the active constituent, product or label may not meet the safety criteria, efficacy criteria, trade criteria or labelling criteria.

These new measures would improve post-market compliance and complement the existing measures that apply to applicants seeking approval of an active constituent or registration of a chemical product. It would mean that the same obligations to provide new relevant information would apply to all applicants seeking approval, registration or variation to approval or registration. The government expects that the impact of this measure would be minimal because of the existing obligation to provide relevant information for an application for registration of a chemical product.

#### *Section 161 of the Agvet Code – holder obligations*

The government proposes to amend the Agvet Code to require holders of label approvals to provide relevant information in relation to the approval. This information would be information about the label that contradicts information in the relevant APVMA file for the label or information that shows the label may not meet the labelling criteria. This would mean that holders of label approvals would have the same obligations to provide new relevant information as currently apply to holders of active constituent approvals and holders of chemical product registrations. The government expects that the impact of this measure would be minimal because of the existing obligation to provide relevant information for an approval of an active constituent or registration of a chemical product.

#### *Public comment*

The government invites comment on these proposed measures.

### **Exposure draft explanatory notes**

Part 8 of the exposure draft deals with new information that applicants and holders must provide to the APVMA. Part 8 would commence three months after royal assent to allow industry to be informed of its new obligations to provide relevant information to the APVMA. To avoid retrospective application, item 81 provides that the amended requirements would only apply to applications and information the holder becomes aware of after commencement.

Items 71, 72, 73, 74 and 75 would require applicants for label approvals, and applicants for variations to approval or registration, to provide relevant information to the APVMA. This would align with the similar obligations that currently apply to applicants for approval of an active constituent or registration of a chemical product.

Items 76, 77, 78, 79 and 80 would require holders of a label approval to provide relevant information to the APVMA, to align with the similar obligations that currently apply to holders of an approval of an active constituent and holders of a registration of a chemical product.

## Proposal 9 – Standards for registered chemical product constituents (*definition of registered chemical product*)

Reduce the regulatory burden on industry and the APVMA by allowing defined variations to the constituents in chemical products.

### Background

Chemical products contain active constituents that are primarily responsible for the biological or other effect of the product. Chemicals products also contain other, non-active constituents. These other constituents include substances that modify the effect of the active constituent or enable the active constituent to be manufactured or used as a product. This includes stabilisers, diluents, solvents and emulsifiers.

Currently, the concentration of each constituent in a chemical product must be the same as the concentration recorded in the register. It is an offence to supply a product that is formulated differently to the 'registered' formulation of the product (therefore, the concentration of the constituents in a product must match that in the register). This does not allow for the routine (safe) variations in constituent concentration arising in manufacturing.

The Agvet Code already provides for the regulations to prescribe variation in the kinds of constituents in a registered chemical product, as well as the concentration, composition and purity ranges for constituents in registered chemical products (section 83). Regulations 41 and 42 prescribe concentration ranges for active constituents in chemical products, including by reference to a hierarchy of standards, irrespective of whether such ranges are included in the register for a product. However, these ranges do not apply for all the offences or civil penalty provisions in Part 4 of the Agvet Code (for example, sections 75 and 78). This means that for these provisions, the product formulation must align exactly with the concentrations of constituents in the register, irrespective of any variation provided for by the regulations made for section 83.

### Current approach

Currently, the concentration of each constituent in a chemical product must be the same as the concentration recorded in the register. To allow for the routine (safe) variations in constituent concentration arising in manufacturing, the holder would have to ensure the register includes a concentration range for each constituent that reflects the variations that occur during manufacturing.

Any change in the concentration of a constituent of a product, including varying the concentration range for each constituent, would require the holder to make an application to the APVMA. The APVMA would then assess the application against the statutory criteria and, if satisfied, vary the relevant particulars for the formulation of the chemical product in the register by including a concentration range.

Amending the register to retrospectively apply a range of concentrations would be very cumbersome administratively for the APVMA and industry. The preparation of these applications and their assessment imposes regulatory cost that is disproportionate to the risk being managed.



## Proposed approach

The government proposes to amend the Agvet Code to provide for the regulations to prescribe standards for ranges of constituents in chemical products. These standards would apply for all offences and civil penalty provisions in the Agvet Code. This would allow for reasonable variations; for example, those that reflect manufacturing processes for chemical products. Holders would therefore not need to apply to the APVMA to amend the relevant particulars of their registration to ensure the register reflected an appropriate concentration range for constituents in chemical products.

The proposed measure would align with the current approach in section 83 of the Agvet Code, which already provides for the regulations to prescribe concentration ranges for constituents in chemical products. To further align with the approach in section 83, the proposed measure would also provide for regulations to prescribe the kinds of constituents (to provide for substitutions) and the composition and purity of constituents in chemical products.

It is not intended that this measure would allow for fundamental changes in a product's composition or purity. If the holder wished to vary the product's composition in such a way, this would continue to require a variation application to the APVMA.

The immediate focus of this measure is the concentration of constituents in chemical products and further detail on the proposed approach for the concentration of constituents is described below. However, the proposed measure would also be applicable to standards about the kinds of constituents, and the composition and purity of constituents, in chemical products. These matters would be subject to consultation when regulations and standards (legislative instruments) prescribing their detail was developed.

### *Agricultural chemical product constituent concentrations*

For agricultural chemical products, the government proposes that the Agvet Code could allow the regulations to continue to prescribe a hierarchy of standards that, in turn, would apply a 'default' concentration range for constituents of chemical products.

The government proposes that the current approach in regulations 41 and 42 be simplified and modernised so the concentration of constituents in a chemical product must comply with:

- the concentration range in the register, to allow holders of registration to arrange their own specific concentration ranges for constituents in their products if they considered the default concentration ranges (below) were not suitable
- if a concentration range is not specified in the register—an order made by the minister, to continue to allow the minister to make an order about the concentration range for constituents in chemical products
- if neither a concentration range is specified in the register and no order has been made by the minister—a standard made by the APVMA (which may refer to any international standards).

This simplified approach would provide flexibility for those holders that wish to seek registration of bespoke concentration ranges, while allowing the technical detail of concentration ranges to be moved out of the regulations and into other legislative instruments (that is, an order made by the minister or standards made by the APVMA). This will enable these technical details to be updated more efficiently as standards develop. Orders made by the

minister and standards made by the APVMA are disallowable legislative instruments and thus subject to parliamentary scrutiny, and would continue to be made following appropriate consultation and regulatory impact analysis.

*Veterinary chemical product constituent concentrations*

The government proposes that the regulations could prescribe a different approach for veterinary chemical products to reflect that most of these are manufactured in compliance with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products or a standard that the APVMA has determined is equivalent to that code.

The government proposes that the concentration of constituents of veterinary chemical products meet the specifications set out in the documented quality assurance system for the manufacture of the chemical product. The government proposes that the approach for agricultural chemical products would only apply to those veterinary chemical products that do not need to be manufactured in compliance with the Australian Code of Good Manufacturing Practice for Veterinary Chemical Products or a standard that the APVMA has determined is equivalent to that code.

*Comment*

The government invites comment on this proposed measure, including:

- the need to provide for reasonable variations in a product's composition, for example to reflect manufacturing processes for chemical products, while preventing fundamental changes in a product's composition
- the need for flexibility so holders can vary from the default concentration ranges set out in an order made by the minister or standards made by the APVMA
- the proposed approaches for agricultural chemical products and veterinary chemical products (which would be provided for in the regulations and so subject to further consultation at the appropriate time).

**Exposure draft explanatory notes**

Part 9 of the exposure draft would deal with standards for the concentration range of constituents in chemical products. Part 9 would commence the day after royal assent.

Item 83 would insert new section 5AA into the Agvet Code. New section 5AA clarifies that a chemical product is a registered chemical product if it complies with the kinds of constituents, the concentration of constituents, the composition and the purity of constituents that would be specified in the regulations. Item 82 would be a consequential amendment to ensure that readers of the legislation can locate the new definition of a registered chemical product.

## **Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval (*suspension or cancellation of approval or registration for provision of false or misleading information*)**

Include more comprehensive grounds for suspending or cancelling approvals or registrations where false or misleading information is provided, including in a variation application or an application for label approval.

### **Background**

Section 38A of the Agvet Code provides for the APVMA to suspend or cancel an approval of an active constituent, or registration of a chemical product, if a holder provides false or misleading information in the application for that approval or registration. However, the provision does not apply for applications made for other reasons, nor for applications made by persons other than the registration or approval holder.

### **Current approach**

There is currently an anomaly in the Agvet Code whereby the APVMA is unable to suspend or cancel an approval or registration where false or misleading information is given:

- in connection with an application to vary an approval or registration
- in connection with an application to approve a label or vary the approval of a label.

In addition, the APVMA is unable to suspend or cancel an approval or registration where false or misleading information is given by a person other than the holder. For example:

- where a person other than the holder applies to vary a label approval or registration, and provides information to support that variation (subsection 27(2))
- where a person provides information on behalf of the holder in any application
- where a person provides information in response to notices under subsection 32(1) or sections 33 (chemical reviews) or 159 (additional information), or as required by sections 160A or 161 (relevant information).

This reduces the capacity of the regulator to respond where false or misleading information is given to the APVMA.

### **Proposed approach**

To improve the post-registration response capability of the APVMA, the government proposes to amend the existing provisions for suspending or cancelling an approval or registration where false or misleading information is given in connection with an application.

The proposal would reduce the complexity of these provisions and provide a discretionary mechanism for the APVMA to suspend or cancel an approval or registration for providing false or misleading information:

- in connection with an application to vary an approval or registration

- in connection with an application to approve a label or vary the approval of a label.

The government further proposes to improve the scope of the current power to allow the APVMA to suspend or cancel an approval or registration where false or misleading information is given by any person (not only the holder) in connection with an application for approval or registration or variation of an approval or registration.

Recognising that persons (other than the holder) can provide information to the APVMA, the government also proposes to improve the current power to allow the APVMA to suspend or cancel an approval or registration where false or misleading information is given by any person in response to notices under subsection 32(1), sections 33 (chemical reviews) or 159 (additional information), or as required by sections 160A or 161 (relevant information).

There is the potential for persons other than holders to provide false or misleading information to the APVMA and for this information to impact on holders of approval or registration. The government considers that the potential for this 'mischief' is low and can be managed through existing arrangements in the Agvet Code. Specifically, section 34P requires the APVMA to notify a holder if it intends to suspend or cancel an approval or registration because of the provision of false or misleading information. This is in addition to a notice that the APVMA might consider issuing under section 159 where it requires information from a holder to decide whether to suspend or cancel an approval or registration.

These notices provide the opportunity for the holder to address any issues with the relevant information and ensures that there are safeguards to mitigate the potential for any 'mischief' from other persons providing false or misleading information.

In addition, section 146 of the Agvet Code includes offences for providing false or misleading information, and so there are other sanctions available to deal with persons that provide false or misleading information, including where persons provide such information with a view to creating 'mischief' for existing holders of approval or registration.

Any suspension or cancellation would only be in respect of the approval or registration to which the false or misleading information was provided, and not to any other approval or registration that may be held by the same holder.

This measure would strengthen the APVMA's post-registration compliance ability. It may also reduce the need for the APVMA to divert technical resources to assess whether previously given false or misleading information was of relevance for the safety, efficacy, trade or labelling criteria.

The government invites comment on this proposed measure, particularly on its application to persons generally, rather than to holders only.

### **Exposure draft explanatory notes**

Part 10 of the exposure draft deals with amending the provisions for suspending or cancelling an approval or registration where false or misleading information is given to the APVMA, including in connection with an application. Part 10 would commence the day after royal assent. However, to avoid retrospective application, item 86 provides that the amended requirements would only apply to information given on or after Part 10 commences.

Item 85 would repeal the existing section 38A and replace it with a new section 38A. New section 38A authorises the APVMA to suspend or cancel an approval or registration if false or misleading information is given by any person in connection with an application for approval or registration, or an application to vary an approval or registration. New section 38A also authorises the APVMA to suspend or cancel an approval or registration if false or misleading information is given by any person in response to notices under subsection 32(1) or sections 33 (chemical reviews) or 159 (additional information), or as required by sections 160A or 161 (relevant information).

Item 84 would be a consequential amendment to the explanation section for suspensions and cancellations (section 34N) to reflect that the new section 38A would apply to persons and not only to holders.

## **Proposal 11 – Addressing an inconsistency in label particulars (*supply of registered chemical products with unapproved label*)**

Address an inconsistency in the Agvet Code by clarifying what information must be included on a label.

### **Background**

Section 81 of the Agvet Code incorrectly requires all ‘relevant particulars’ to be contained on a label when only a subset of these relevant particulars should be on a label.

### **Current approach**

The current section 81 of the Agvet Code requires ‘relevant particulars’ to be contained on a label. However, the only ‘relevant particulars’ that should be required on a label are the ‘instructions’ for use and the ‘particulars to be contained on the label’ as prescribed in regulation 18D of the Code Regulations.

It is not appropriate that all relevant particulars appear on a label. For example, the name of the nominated agent and the holder of approval—as opposed to the marketer of the product—are unnecessary. This inconsistency needs to be addressed as there is a serious criminal offence and a civil penalty provision for not including all ‘relevant particulars’ on a label.

### **Proposed approach**

To address these inconsistencies, the government proposes to amend section 81 of the Agvet Code to require a product to only be supplied if the label includes the information that is required to be included on a label.

The government invites comment on this proposed measure.

### **Exposure draft explanatory notes**

Part 11 of the exposure draft deals with amending section 81 to require a product to only be supplied if the label includes the information that is required to be included on a label. Part 11 would commence the day after royal assent. However, to avoid retrospective application, item 93 provides that the amended requirements would only apply to supplies occurring after Part 11 commences.

Items 87, 88, 89 and 90 would replace the current reference to ‘relevant particulars’ in section 81 with ‘minimum information’. Item 92 would specify what ‘minimum information’ means for the purposes of section 81. The effect of these amendments would be to specify the minimum information that must be included on a label (i.e. distinguishing number, instructions and particulars that are to be contained on a label).

Item 91 replaces subsection 81(3) to provide for the APVMA to continue to determine that products with labels containing earlier information (the previously required minimum information on a label) can continue to be supplied.

## **Proposal 12 – Improving dealings with suspended approvals and registrations (*variation of approval or registration during suspension*)**

Introduce practical measures to deal with suspended approvals and registrations, to address the reason for a suspension and to allow holders to request a suspension.

### **Background**

The Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill ([Operational Efficiency Bill](#)), which is before parliament at the time of writing, would amend the Agvet Code to allow a person to apply to vary the relevant particulars and conditions for a label approval that is suspended.

During consultation on these amendments, the Queensland Department of Agriculture and Fisheries noted that similar restrictions existed for chemical product registrations. At the time, the department was unable to remove these chemical product restrictions without delaying the Operational Efficiency Bill.

In addition, the Agvet Code provides that a holder can only request cancellation of their registration or approval and cannot request suspension of registration or approval (see section 42 of the Agvet Code).

### **Current approach**

Currently, there is an administrative barrier to varying a suspended chemical product registration to deal with the problem that led to the registration suspension. This prevents the holder of registration from dealing with the problem that led to the suspension and putting the chemical product back on the market.

In addition, because a holder can only request cancellation of their registration and not suspension, a holder is placed in the difficult position of having to cancel their registration to deal with administrative matters (for example, arranging a new nominated agent in Australia). The holder would then have to re-apply for registration at a later time. This is an unnecessarily restrictive and costly means of dealing with administrative matters.

### **Proposed approach**

Similar to the approach taken for suspended label approvals in the Operational Efficiency Bill, the government proposes to amend the Agvet Code to allow a person to apply to vary the relevant particulars and conditions for a product registration that is suspended. The variation application is only to relate to the matters relevant to the suspension. This will allow the holder of registration to deal with the suspension problem and put their chemical product (as varied) back on the market.

A person may already apply to vary the relevant particulars and conditions for an active constituent that is suspended. This is because of subsection 47(1) of the Agvet Code, which provides an active constituent approval is in force while suspended. Active constituent approvals can therefore be varied, as required.

The government also proposes to provide that a holder can request suspension of an approval or registration, in addition to requesting cancellation. This will enable a holder to have their approval or registration suspended while they deal with any issues with their registration or approval.

The government invites comment on this proposed measure.

### **Exposure draft explanatory notes**

The amendments in the exposure draft are based on the Agvet Code as if the [Operational Efficiency Bill](#) had already commenced.

Part 12 of the exposure draft deals with improving how the APVMA can handle suspended approval or registrations. Part 12 would commence the day after royal assent but item 103 provides extra flexibility in that Part 12 could apply to suspensions that were in effect before commencement.

Items 95 and 96 would provide for a holder to request that the APVMA suspend an approval or registration (as an alternative to requesting cancellation of approval or registration) and that the APVMA must suspend an approval or registration if the APVMA is satisfied that there are no valid reasons why it should not agree to the request. Item 94 would be a consequential amendment to the heading of section 42 to reflect that it would now deal with requests for suspension of an approval or registration by a holder. Items 101 and 102 would be consequential amendments to section 45A to reflect that holders may now request suspension of approval or registration.

Items 97, 98, 99 and 100 would amend section 43 to allow a person to apply to vary the relevant particulars and conditions for a product registration that is suspended.



## **Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria (*safety, efficacy, trade and labelling criteria*)**

Address anomalies in the Agvet Code in relation to prescribing matters for the labelling criteria, and for overseas trials and experiments (including international assessments and data) for the safety, efficacy, trade and labelling criteria.

### **Background**

Section 5A of the Agvet Code sets out matters the APVMA must have regard to for the purposes of being satisfied whether an active constituent or chemical product meets the safety criteria. Subparagraphs 5A(2)(a)(vii) and 5A(3)(a)(vii) provide for the regulations to prescribe matters to which the APVMA must have regard.

Section 5B sets out matters the APVMA must have regard to for the purposes of being satisfied whether a chemical product meets the efficacy criteria. Paragraph 5B(2)(d) provides for the regulations to prescribe matters to which the APVMA must have regard.

Section 5C sets out matters the APVMA must have regard to for the purposes of being satisfied whether a chemical product meets the trade criteria. Paragraph 5C(2)(c) provides for the regulations to prescribe matters to which the APVMA must have regard.

However, under section 5D of the Agvet Code, there is no power for the regulations to prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria.

In addition, section 160 of the Agvet Code provides the APVMA with the discretion to consider overseas trials and experiments, including international assessments and information. This discretion creates an anomaly as it means the regulations made under sections 5A to 5C may not be able to prescribe that the APVMA must have regard to overseas trials and experiments.

### **Current approach**

The Agvet Code provides that regulations can prescribe matters the APVMA must have regard to for the purposes of being satisfied about the safety, efficacy and trade criteria. Regulations 8AA and 8AB, for example, prescribe matters the APVMA must have regard to in relation to the safety criteria. However, an anomaly in the Agvet Code means that regulations cannot prescribe matters the APVMA must have regard to in relation to the labelling criteria.

A further anomaly means that the regulations may not be able to prescribe that the APVMA must have regard to the matters in section 160 of the Agvet Code, relating to overseas trials and experiments (which may include international assessments and data) when determining if:

- an active constituent meets the safety criteria
- a chemical product meets the safety criteria, efficacy criteria and trade criteria
- a label meets the labelling criteria (if the Agvet Code was amended to allow regulations to prescribe matters the APVMA must have regard to for the labelling criteria).

## **Proposed approach**

The government proposes to correct the anomalies in the statutory criteria by amending the Agvet Code to provide that:

- regulations, if made in the future, may prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria, similar to the current regulation making powers in sections 5A to 5C of the Agvet Code
- regulations, if made in the future, could prescribe that the APVMA must have regard to the matters in section 160 of the Agvet Code (overseas trials and experiments, which could include international standards, assessments and data).

The APVMA advises it is already maximising the use of international standards, assessments and data in its assessments and there is no need, at this time, to introduce a legislative requirement to do so. However, a minor amendment to the Agvet Code would, if considered necessary in the future, allow the regulations to prescribe that the APVMA must have regard to this information when registering chemical products and approving active constituents and labels.

If a supporting regulation was made in the future that prescribed that the APVMA must have regard to international standards, assessments and data, the APVMA would retain discretion over how it used this material and its decision-making role in registrations and approvals would be preserved. The potential benefit of such a regulation, if the government ever considered it necessary, would be to support the APVMA's current approach to using international assessments and data, and to provide greater predictability for stakeholders about the APVMA's ongoing use of international data and assessments.

The government invites comment on this proposed measure.

## **Exposure draft explanatory notes**

Part 13 of the exposure draft would deal with addressing some anomalies with making regulations in respect of the statutory criteria. Part 13 would commence the day after royal assent. However, to avoid retrospective application, item 106 would provide that the amendment of section 5D applies in relation to deciding whether a label for containers for a chemical product meets the labelling criteria on or after commencement of Part 13

Item 104 would amend section 5D of the Agvet Code to allow the regulations to prescribe matters the APVMA must have regard to for the purposes of being satisfied that a label meets the labelling criteria, similar to the current regulation making powers in sections 5A to 5C of the Agvet Code.

Item 105 would insert a new section 5E into the Agvet Code to allow regulations in the future to prescribe that the APVMA must have regard to the matters in section 160 of the Agvet Code.

## Proposal 14 – Simplifying APVMA corporate reporting requirements (*annual operational plans*)

Simplify the APVMA's corporate reporting requirements by removing the need for the APVMA to develop and seek approval of an annual operational plan in addition to the corporate plan required annually under the *Public Governance, Performance and Accountability Act 2013*.

### Background

The Administration Act (Part 6) currently includes requirements for the APVMA to prepare an annual operational plan. This is in addition to a corporate plan required under section 35 of the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

The annual operational plan sets out the actions the APVMA intends to take to comply with the objectives in the corporate plan in the coming year. It includes any performance indicators that the Chief Executive Officer considers appropriate and any information prescribed by regulations. The plan requires annual ministerial approval.

The corporate plan must include the following matters (see section 16E of the Public Governance, Performance and Accountability Rule 2014):

- 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
- a summary of the risk oversight and management systems in place for each year of the plan.

The corporate plan is prepared annually (and covers four years) and is presented to both the Minister for Agriculture and Water Resources and the Minister for Finance. The APVMA must report annually on its performance against the corporate plan.

### Proposed approach

The government proposes to remove the requirement for the APVMA to prepare an annual operational plan as it essentially duplicates reporting required by the PGPA Act. This amendment would mean that the APVMA would continue to be required to comply with annual corporate reporting requirements under the PGPA Act, but would no longer be required to separately develop and seek approval of an annual operational plan.

### Exposure draft explanatory notes

Part 14 of the exposure draft would remove the requirement for the APVMA to prepare an annual operational plan. Part 14 would commence on 1 January 2020.

Item 108 would omit sections 55, 56 and 57 of the Administration Act and remove the requirement for the APVMA to develop an annual operational plan.

Items 107, 109, 110 and 111 would be consequential amendments to the heading to Part 6 of the Administration Act and section 61 (annual report requirements) of the Administration Act to reflect the removal of the annual operational plan.

Item 112 is an application and savings provision. Subitem 112(1) provides that the amendments apply to calendar years beginning on 1 January 2020. Subitem 112(2) provides that despite the repeal of sections 55 and 57, these sections continue to apply to an annual operational plan for the 12 months beginning on 1 July 2019. Subitem 112(3) provides that despite the amendments to section 61, section 61 continues to apply to an annual report for the 12 months beginning on 1 July 2019. Subitem 112(4) provides that any regulations made for subparagraph 61(b)(ii) of the Administration Act continue in force as if they were made for amended paragraph 61(b).

## **Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation (*other amendments*)**

Align the review measures in agvet chemical legislation.
--

### **Background**

Under subsection 4(4) of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act), the minister is required to provide a report to parliament on the amendments made by that Act within 15 sitting days after 1 July 2019. Separately, the minister must also ensure, at least every 10 years, that a review is made of the agvet chemical regulatory framework under section 72 of the Administration Act.

It is inefficient to conduct two parallel reviews when the issues in section 4 of the Amendment Act would be better aligned with the review required by section 72 of the Administration Act.

### **Proposed approach**

The government proposes to align the timing of the review required under section 4 of the Amendment Act and that of the review that is required under section 72 of the Administration Act. This would consolidate the timing of the two reviews and could avoid the need for separate and potentially confusing (and overlapping) reviews of agvet legislation.

The government invites comment on this proposed measure.

### **Exposure draft explanatory notes**

Items 117 and 150 of Part 15 of the exposure draft deal with aligning the timing of the review of the Amendment Act with the review provided for in section 72 of the Administration Act.

It also provides that the review, and tabling of the review report, in section 72 of the Administration Act may be tabled earlier than the current ten year timeframe. Part 15 would commence the day after royal assent.

## Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (*other amendments*)

Make minor and technical amendments to the Administration Act and the Agvet Code, including removing redundant and unnecessary provisions.

### Background

#### *Redundant provisions*

When the NRS for Agricultural and Veterinary Chemicals commenced in 1995, some transitional provisions were included in the Agvet Code to deal with certain matters that were underway before the NRS commenced. These include:

- reconsiderations of existing clearances for registration (section 180)
- pending proceedings before the AAT (section 183)
- existing notices requiring further information and samples (section 184).

When the National Registration Authority for Agricultural and Veterinary Chemicals (now APVMA) was created under the Administration Act in 1993, some transitional provisions were included to deal with certain matters. These included:

- money transferred to the APVMA from the Commonwealth where that money was paid to the Commonwealth for a function now done by the APVMA (section 78)
- proceedings for debts, liabilities and obligations that were pending in a court before commencement of the Administration Act on 15 June 1993 (section 79)
- delegations made by the Australian Agricultural and Veterinary Chemicals Council to a person of all or any of its powers or functions under the Agricultural and Veterinary Chemicals Act 1988 (section 80).

#### *Classes of products*

The Agvet Code and Code Regulations are inconsistent in their approach to dealing with ‘classes’ of matters. Some provisions refer to kinds of products and classes of products (reserved chemical products and listed chemical products), whereas other provisions do not (restricted chemical product, prohibited chemical product). This is confusing and creates uncertainty when developing legislative instruments under the Agvet Code.

Both subsection 33(3A) of the *Acts Interpretation Act 1901* (Cth) and subsection 13(3) of the *Legislation Act 2003* (Cth) apply for the Agvet Code and Code Regulations and clearly state that all references to particular matters (e.g. active a constituent or a chemical product) are intended to include classes of particular matters.

#### *Ceased approvals and registrations*

The Agvet Code provides for possession or custody of active constituents and products with the intention of supply for a period after approval or registration has ceased (paragraphs 74(1)(d), 75(1)(c), 76(1)(c) and 78(1)(c)). These provisions have never been used by the APVMA.

### *Reconsiderations (internal reviews)*

Under section 166 of the Agvet Code, a person can request the APVMA to reconsider a decision it has made under that code. These are known as ‘internal reviews’. However, the APVMA cannot internally review a decision on its own initiative. This restricts the ability of the APVMA to respond where errors are made and places the onus on other persons to request the APVMA to internally review a decision. This problem also exists where the APVMA makes a decision on an application for an export certificate under section 69D of the Administration Act.

### **Proposed approach**

There are no reconsiderations (chemical reviews), pending AAT proceedings or notices for further information or samples left from before the NRS commenced. The transitional provisions in sections 180, 183 and 184 of the Agvet Code have served their purpose and the government proposes they be repealed.

In addition, there is no need to retain the transitional provisions in sections 78, 79 and 80 of the Administration Act and the government proposes that they be repealed.

The government also proposes to modernise the Agvet Code (and Code Regulations) to remove specific references to classes and include a general provision to expressly make clear that references to kinds of substances, chemical products, constituents or labels includes classes of substances, chemical products, constituents or labels. This approach is already provided for in the Acts Interpretation Act and Legislation Act.

The government proposes to remove the provisions set out below as they are unnecessary. These provisions have not been used by the APVMA since the commencement of the Agvet Code. In addition, sections 45B and 47D already provide that a permit is automatically provided for an active constituent or product whose approval or registration ceases. Permits under these sections are only in place for a period of up to one year, while the provisions proposed to be deleted could provide for a longer period. Despite this, the custody and possession with the intention of supply or the supply may already be dealt with efficiently and effectively under a permit (either on application or on the APVMA’s initiative). For these reasons, and to remove unnecessary provisions from the Agvet Code, the government proposes to remove the following provisions:

- paragraph 74(1)(d) and subsections 74(2) and (4)
- paragraph 75(1)(c) and subsections 75(2) and (4)
- paragraph 76(1)(c) and subsections 76(2) and (4)
- paragraph 78(1)(c) and subsections 78(2) and (4)
- paragraph 167(1)(i).

The government proposes to provide the APVMA with more flexibility to conduct internal reviews by amending the Agvet Code to provide for the APVMA to, on its own initiative, internally review a decision it has made under the Agvet Code. The government similarly proposes to provide for the APVMA to, on its own initiative, review a decision it has made under section 69D of the Administration Act in relation to export certificates.

The government also proposes to amend the Administration Act to clarify some measures and remove redundant provisions. Specifically:

- amendments to paragraph 7(1A)(a) to replace 'sale' with 'supply' as supply more correctly describes the functions of the APVMA
- amendments to section 8A to remove reference to granting an application as the Agvet Code no longer provides for the APVMA to 'grant an application'
- amendments to section 69D (which deals with export certificates) to clarify that the fees for export certificates are to be paid to the Commonwealth, like all other fees the APVMA collects.

The government invites comment on these proposals.

### **Exposure draft explanatory notes**

Part 15 of the exposure draft would make a number of minor or machinery changes to the Agvet Code and the Administration Act. Part 15 would commence the day after royal assent.

Items 113 and 114 would be minor amendments to the Administration Act to align section 7 with the role of the APVMA and section 8A with the approach used for applications in the Agvet Code.

Item 115 would amend section 69D of the Administration Act (about export certificates) to clarify that the fee for export certificates is to be paid to the Commonwealth. Item 116 would also amend section 69D of the Administration Act to provide that the APVMA may, on its own initiative, reconsider a decision to refuse to give an export certificate. Item 119 provides that the amendments made by item 116 only apply to decisions made after commencement, to avoid retrospective application of the amendments.

Item 118 would repeal sections 78, 79 and 80 of the Administration Act as these transitional provisions (from commencement of the Administration Act in 1993) are no longer necessary.

Item 120 would insert a new section 6F into the Agvet Code to expressly make it clear that references to kinds of substances, chemical products, constituents or labels includes classes of substances, chemical products, constituents or labels, consistent with the approach provided for in the Acts Interpretation Act and the Legislation Act.

Items 121 to 144 and 147 would remove unnecessary provisions for determinations that the APVMA could make about approvals and registrations that had ceased under sections 74, 75, 76 and 78.

Items 145 and 146 would provide for the APVMA to, on its own initiative, reconsider a decision under the Agvet Code or regulations. However, to avoid retrospective application, item 149 would provide that these amendments only apply to decisions made after commencement.

Item 148 would repeal transitional provisions in the Agvet Code that are no longer necessary (sections 180, 183 and 184).



## **Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (*other amendments*)**

Incorporate agvet chemical-related measures currently in the Agriculture and Water Resources Legislation Amendment Bill 2016, into the Streamlining Regulation Bill.

### **Background**

The Agriculture and Water Resources Legislation Amendment Bill 2016 (the Omnibus Bill) included certain amendments to agvet chemical legislation. The government now proposes to pursue these measures in the Streamlining Regulation Bill. The relevant measures are:

- amendments which would require the notice provided by APVMA to Food Standards Australia New Zealand (FSANZ) under section 8E of the Agvet Code, to set out the names or proposed names of the active constituents concerned, which would reflect the information required to be recorded in the Maximum Residue Limit Standard (Standard 1.4.2 of the Australia New Zealand Food Standards Code)
- amendments to paragraph 117A(1)(a) of the Agvet Code so that it refers to where the APVMA proposes 'to suspend or cancel a permit' rather than an 'approval or registration' ('approval or registration' is an error)
- repealing references to the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*, as all the transitional provisions for this Act are no longer required.

### **Current approach**

Unnecessarily detailed information currently needs to be provided by the APVMA to FSANZ. In addition, the error in paragraph 117A(1)(a) detracts from the efficient administration of the Agvet Code.

### **Proposed approach**

The government proposes to include these measures in the Streamlining Regulation Bill and invites comment on these proposed measures.

### **Exposure draft explanatory notes**

Schedule 2 of the exposure draft deals with measures that were in the Omnibus Bill. These measures would commence the day after royal assent. These measures would:

- require the notice provided by APVMA to FSANZ under section 8E of the Agvet Code to set out the names, or proposed names, of the active constituents concerned (Part 1, item 1, noting that this amendment only applies to notices given after commencement—see item 3)
- amend paragraph 117A(1)(a) so it refers to where the APVMA proposes 'to suspend or cancel a permit' (Part 1, item 2)
- repeal references to the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Part 2, item 4).