



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

Consultation on the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

Agvet Chemicals Branch

Sustainable Agriculture, Fisheries and Forestry Division

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Submissions

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

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act)
- *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (the Levy Act).

The proposed changes deliver operational efficiencies for the APVMA, clarify ambiguities in the legislation and remove unnecessary and redundant provisions.

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 5pm on Wednesday 19 July 2017.

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 because 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.

You can return your submission in the following ways:

Submission:

Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency)
Bill 2017
Agvet Chemicals Branch
Department of Agriculture and Water Resources
GPO Box 858
Canberra ACT 2601

agvetreform@agriculture.gov.au

If submitted by email, a hard copy of your submission is not needed. The department endeavours to formally acknowledge receipt of submissions within three business days. We may not be able to consider submissions received after the closing date of 19 July 2017. However, suggestions for additional reform measures can be considered as part of the next phase of reform.

Privacy: Personal information collected by the department will only be used to enable you to be contacted about your submission and may be disclosed to specialists, other Commonwealth government agencies, a State and Territory government agencies or foreign government departments, provided the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*.

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

Collected personal information will be used and stored consistent 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*, content of submissions may be made public, unless you state you want all or part of your submission to be treated as confidential. A claim for confidentiality must be justified and provided as an attachment, marked 'Confidential'. 'Confidential' material will not be made public. The department reserves the right not to publish submissions.

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

If you are making a 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.

Next steps

After the consultation period has closed, the department will assess all submissions and consider what further amendments may be required to address the issues raised in submissions, while retaining protections for the health and safety of humans, animals and the environment.

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

Key dates for the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

To 19 July 2017 - Public consultation on the proposed legislative changes

August 2017 - Finalise amendments to the legislation

September 2017 - Introduction of the Bill to the Australian Parliament

Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017

Agvet chemicals are regulated under a cooperative national registration scheme involving the Australian Government, the states and territories.

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

- *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act)
- *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act)
- *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (the Levy 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 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 Levy Act contains measures that allow for levies to be assessed and collected on the sale of agvet chemical products registered for use in Australia.

The government is proposing legislative changes that would deliver operational efficiencies for the APVMA, clarify ambiguities in the legislation and remove unnecessary and redundant provisions. These proposed changes are included in the Exposure Draft of the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017.

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

Further legislative changes

The government is developing a second legislative package. This package will contain more measures to further streamline agvet chemical regulation in Australia.

Links to agvet chemical legislation

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

[Agricultural and Veterinary Chemicals Code Act 1994](#)

[Agricultural and Veterinary Chemical Products \(Collection of Levy\) Act 1994](#)

Summary of proposals

The government is proposing the following legislative changes. The department invites comment on these proposals.

The proposed legislative changes would:

- clarify confidential commercial information provisions to improve their operation and reduce uncertainty for the APVMA staff
- reduce the regulatory burden by simplifying reporting requirements for annual returns to align information requirements and timing with existing levy reporting; mandatory reporting will be restricted to providing total product quantities supplied for the previous year
- reduce administrative burden on the APVMA and industry by increasing the APVMA's flexibility to manage errors in an application at the preliminary assessment stage
- reduce regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Agvet Code
- amend the APVMA's timeframe for notifying FSANZ under the Agvet Code about whether a variation to the Maximum Residue Limit Standard is required, so that the timeframe provides for when fees are paid
- improve the operation of agvet legislation by enabling a person to apply to vary the particulars of a label approval that is suspended, to the extent that the variation relates to the matters relating to the grounds for suspension
- amend the definition of 'expiry date' in the Agvet Code to specify the date after which a product 'must not' be used and amend the date format for an expiry date
- add the potential for human exposure to antimicrobial resistant microorganisms as a specific safety consideration that the APVMA must have regard to for chemical products and active constituents
- provide a broader suite of sanctions by including civil penalty provisions in the Agvet Code and the Administration Act for providing false or misleading information
- make minor and technical amendments to the Administration Act and the Agvet Code, including to remove redundant provisions
- make related consequential, transitional and savings provisions arising from the proposed amendments, as needed.

The government proposes that these measures would 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'.

Context

The Australian Government is committed to further agricultural and veterinary (agvet) chemical regulation reform.

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 the chemicals farmers need to improve their commercial competitiveness, sustainability and farm gate returns.

The 2016–17 budget included \$17.1 million to streamline agvet chemical regulation under the *Agricultural Competitiveness White Paper*.

In consultation with the APVMA, the Department of Agriculture and Water Resources is working on reforms with the farm industry, chemicals sector, environment and community groups and government agencies.

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.

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 then controls supply activities up to the point of retail sale. The control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The APVMA is established under section 6 of the Administration Act.

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) to constitute a single national Agvet Code applying throughout Australia.

The Administration Act, the Levy Act and the Code Act, including the Agvet Code, 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 licence the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products and ensure compliance with, and enforcement of, the Agvet Code, including suspending and cancelling registration of chemical products.

Our proposals for change

Proposal 1 - Clarifying confidential commercial information provisions

Clarify confidential commercial information provisions to reduce uncertainty for APVMA staff and allow for more efficient processing of applications.

Background

An applicant may apply to register a new 'generic' product on the basis that it shares characteristics with an existing product (a reference product). There are concerns that, in this situation, the APVMA may disclose confidential commercial information (CCI) by giving notices about decisions on the basis that the new product is the 'same', 'similar' or 'closely similar' to the reference product.

The proposed measures would improve administrative efficiency and provide certainty for the APVMA by clarifying provisions relating to the disclosure of CCI in certain notices. Such disclosure would be authorised only where this was necessary to perform functions or duties, or exercise powers, under the Agvet Code.

When assessing an application for a new generic product, the APVMA may consider the product's chemical similarity to a previously-registered 'reference product'. This is permitted under section 6C of the Agvet Code, which provides that the APVMA may use information, unless otherwise prohibited (for example it falls within the definition of "limits on use information"), from any source for the purposes of performing any functions or exercising any powers under the Agvet Code.

Subsection 162(1) of the Agvet Code prohibits certain persons, including APVMA employees, from disclosing information, indirectly or directly, to another person that the person knows to be CCI. This includes information about an active constituent for a proposed or existing chemical product, a chemical product, or a label for containers of a chemical product. CCI is defined at section 3 of the Agvet Code. The penalty for a breach of subsection 162(1) is imprisonment for two years. However, the prohibition generally does not apply to the extent a staff member is performing functions or duties, or exercising powers, under the Agvet Code (subsection 162(1A)).

Current approach

The Agvet Code requires the APVMA to issue notices of approval or refusal of an application (section 8F and 8G, respectively), and notices of proposed decisions to approve or refuse registration (section 8S—this includes proposed approval or registration with instructions or relevant particulars other than set out in the application). The APVMA must also issue similar notices for reconsiderations (subsection 34AB and 34AC).

Section 8X of the Agvet Code provides that engaging in duties or exercising powers such as those listed above does not authorise the disclosure of CCI when it would otherwise be prohibited by

section 162. This is despite subsection 162(1A) providing that this does not apply to the extent that an officer is engaging in their duties under the Agvet Code.

As a result, APVMA staff performing necessary function or duties, or exercising powers under the Agvet Code may be subject to prosecution under subsection 162(1). This is the same offence provision that applies to improper disclosure.

Proposed approach

The amendments would indicate clearly that APVMA staff will not be subject to prosecution under subsection 162(1) for issuing notices as part of their regular duties under sections 8F, 8S, 34AB and 34AC of the Agvet Code. However, the amendments would still prevent the disclosure of CCI except where necessary to perform functions or duties, or exercise powers under Agvet Code. The proposed amendments would remove uncertainty and reduce the handling time for applications, while retaining the original underlying intent of the legislation to ensure industry sensitive information is appropriately protected.

Exposure draft explanatory notes

In Part 1 of Schedule 1 of the Exposure Draft, items 3 and 5 would repeal paragraphs 8X(1)(a), (b), (f) and (g) to provide that issuing the following notices does not constitute disclosure of CCI:

- notices of approval, registration and variation (subsection 8F(2))
- notices of certain proposed decisions (subsection 8S(2))
- notice of proposed decision on reconsiderations (subsection 34AB(2))
- notice of decisions on reconsiderations (subsection 34AC(2)).

Items 1, 2, 4, 6, 7 would be consequential amendments to reflect the amendments made by items 3 and 5.

The government proposes that these amendments would commence three months after Royal Assent to the Bill to allow the APVMA to update relevant procedures and train staff.

Proposal 2 - Simplifying reporting requirements for annual returns

Reduce the regulatory burden by simplifying reporting requirements for annual returns to align information requirements and timing with existing levy reporting. Mandatory reporting will be restricted to total product quantities supplied for the previous year. This will provide the necessary information about registered chemicals in the marketplace to allow for appropriate levels of risk management.

Current Approach

There are two distinct but related activities within agvet legislation that provide for measuring and reporting the scale of Australia's agvet chemical trade. These are:

- Financial/Value measure – The Levy Act states that the interested person in relation to a registered chemical product (routinely the holder of registration) must report the value of product disposed of (supplied) in the previous financial year. The interested person must submit the report to the APVMA by November each year.
- Quantity/Volume measure – Section 69E of the Administration Act requires any person who imports, manufactures or exports an active constituent (either as a commodity for, or as part of, an agvet chemical product) must report annually the quantity of active constituent involved.

The department understands that companies typically collate information on the quantities of product supplied when reporting on their annual levy obligation. However, the department also understands industry finds the degree of reporting for annual returns unnecessarily complex under the current arrangements, and in some cases duplicative.

Proposed approach

The government proposes to simplify the annual reporting of active constituent quantity to align information requirements and timeframes with existing levy reporting. This measure will reduce the mandatory reporting requirements for industry. It will also reduce the time the APVMA requires to collect these data and prepare annual reports about active constituents, while still ensuring sufficient information about active constituents is available for policy development.

Focusing reporting to product quantity provides the necessary information and is much less complex and burdensome for industry than reporting on active constituents (both as 'isolated' substances and when incorporated into chemical products). The proposal is to reduce the number of individual reporting items for products and actives from six (import, manufacture and export for both active constituents and chemical products) to one (the leviable disposal).

Under this proposal, the following measures would apply from 1 July 2018:

- only the holders of product registrations or the holders of permits for the supply of unregistered chemical products would be required to report product quantity supplied
- the reporting obligation would relate to the product directly supplied either by the holder or by an order from the holder to a third party
- holders would report only on total product quantities supplied for the previous year

- holders would also be required to continue to keep quantity records for six years, which also aligns with the Levy Act record keeping requirements
- reporting would occur concurrently with holders' annual levy reporting to the APVMA, with the reporting window opening on 1 July of each year and the holder submitting reports no later than 30 November of the same year
- the APVMA would report the collated returns (these reports would provide the amounts of active constituents—collated across products—and will not include information about products or companies) to the department no later than 30 June of the following year from a reporting period
- the information would be collected under the Levy Act, rather than the Administration Act (as is currently the case).

Exposure draft explanatory notes

In Part 2 of Schedule 1 of the Exposure Draft, item 10 inserts new section 35 into the Levy Act. This new section requires interested persons to give the APVMA a return setting out the total quantity of the chemical product covered by leviable disposals during a financial year. Section 35 also requires the APVMA to provide statements to the department about the total quantities of active constituents covered by those returns. Item 9 inserts a definition of active constituent so that this expression in section 35 has the same meaning as in the Agvet Code.

Item 11 inserts section 37 to require interested persons to keep records about leviable disposals.

Item 12 provides that the requirements in new sections 35 and 37 apply from the 2018–19 financial years and later financial years.

Items 13 to 15 repeal section 69E of the Administration Act and make consequential amendments to the Administration Act to reflect this repeal.

Item 16 would provide that despite the repeal of section 69E and amendments to section 69EA of the Administration Act, the obligations of these sections remain in force immediately before the commencement of this item and continue to apply on and after that commencement in relation to the keeping and retaining of records in respect of relevant transactions.

Proposal 3 - Increase the APVMA's flexibility to manage minor errors in applications at preliminary assessment

Reduce administrative burden on the APVMA and industry by increasing the APVMA's flexibility to manage errors in an application at the preliminary assessment stage.

Background

Under the current arrangements the APVMA must reject an application if it does not meet the application requirements, including because of minor errors. Under these circumstances, the applicant is forced to make a new application, which is burdensome for industry and time consuming for APVMA staff.

Sections 11 and 28 of the Agvet Code provide for the APVMA to undertake a preliminary assessment of an application for approval or registration or an application for variation of the relevant particulars or conditions of an approval or registration. These sections require the APVMA to refuse an application following preliminary assessment, unless the APVMA assesses the application as meeting statutory requirements.

Section 110A of the Agvet Code also provides for preliminary assessment of applications for a permit. Section 110A enables the APVMA to be more flexible in managing the preliminary assessments of permit applications than it is able to for work done under sections 11 and 28.

Current approach

The APVMA has limited flexibility to manage applicant errors during preliminary assessments of applications for registration and approval under section 10 and variation applications under section 27. For example, an application may be missing information that was stated as being contained in the package; a third party provider may not have submitted information within the required timeframe, or an applicant may have simply attached the wrong piece of information.

The current inflexible requirements impose an unnecessary administrative burden on the applicant and the APVMA.

Proposed approach

The government proposes to provide the APVMA with more flexibility to manage applicant errors during preliminary assessments of applications for registration and approval under section 10 and variation applications under section 27. These would mirror the measures available to applications for permits under section 110A of the Agvet Code.

These new processes would enable a consistent approach to be adopted by the APVMA and make processes more consistent for applicants, who often make numerous types of applications; that is, for a chemical product registration, active constituent approval and permit applications. This change is not intended to allow applicants an ability to rectify a major defect but rather to allow them to submit missing items from their application, where that information was inadvertently left out. Reflecting this, a short timeframe for such a rectification is provided (a month). The preliminary assessment timeframe would be paused for this period.

Exposure draft explanatory notes

In Part 3 of Schedule 1 of the Exposure Draft, items 17 and 18 insert new subsections to provide for the APVMA to deal with defects in applications that can reasonably be rectified. The government proposes that these amendments would commence 12 months after Royal Assent to the Bill to allow the APVMA to update relevant procedures and train staff.

Proposal 4 - APVMA amendment of the relevant particulars or conditions in a variation application

Reduce regulatory burden by enabling the APVMA to grant part of a variation application under section 27 of the Agvet Code.

Background

For an application to vary the relevant particulars or conditions of an approval or registration, the APVMA cannot amend the relevant particulars or conditions of an approval or registration from those set out in the application. As a result, where applicants apply for multiple or particular variations in an application, the APVMA must reject the application unless it is satisfied that all proposed variations meet the statutory criteria.

The Agvet Code currently enables the APVMA to approve or register an active constituent, chemical product or label with instructions or relevant particulars other than those set out in the application (see paragraph 8S(1)(b)).

In addition, subsection 28(4) provides for the APVMA to alter an application with the written consent of the applicant or the holder and section 29A provides for the APVMA to vary relevant particulars or conditions of an approval or registration with the written consent of the holder. These provisions require the specific consent of the applicant (in the case of an application) and the holder.

However, the Agvet Code does not provide equivalent flexibility for the APVMA to alter applications to vary relevant particulars or conditions of registration or approval under section 27 of the Agvet Code.

Current approach

In practical terms the APVMA currently works with applicants for registration of chemical products to agree on a set of label instructions and use patterns that can be supported based on its satisfaction of the safety, efficacy, trade and labelling criteria. These instructions and use patterns may be a subset of those in the initial application for registration or approval. For example the application may be for wheat, barley and rice but the APVMA may only be satisfied that the data and information support the use on wheat and barley.

For an application for registration of a chemical product and approval of a label, the APVMA would work with the applicant and use paragraph 8S(1)(b) to formalise its satisfaction for wheat and barley uses and effectively refuse the use for rice in determining the application.

If the application in question is an application to vary the relevant particulars or conditions of a registered chemical product to provide for the same three uses then the APVMA would have to refuse the whole variation application. This is because the Agvet Code does not currently provide for it to work with applicants to vary instructions or relevant particulars other than those set out in the application.

Proposed approach

The government proposes to enable the APVMA to effectively grant part of a variation application by allowing it to vary any of the relevant particulars or conditions of a registration or approval in this variation application. The legislative changes would mirror the flexibility the APVMA has for determining applications to register a chemical product or approve a label.

Exposure draft explanatory notes

In Part 4 of Schedule 1 of the Exposure Draft, item 22 provides for the APVMA to amend relevant particulars and conditions for an approval or registration other than as set out in a variation application made under subsection 27(1). Items 20 and 21 provide for the APVMA to notify an applicant where it proposes to vary relevant particulars or conditions other than as set out in the variation application. Item 23 provides for internal and external review of a decision to vary relevant particulars or conditions other than as set out in the variation application.

The government proposes that these amendments would commence three months after Royal Assent to the Bill to allow the APVMA to update relevant procedures and train staff.

Proposal 5 - Timeframe for notifying Food Standards Australia New Zealand (FSANZ) about variations to the Maximum Residue Limit Standard

Amend the APVMA's timeframe for notifying FSANZ about whether a variation to the Maximum Residue Limit Standard is required so that this provides for when fees are paid.

Background

This proposal would improve the operation of agvet chemical legislation by harmonising the timing of APVMA's notifications to FSANZ, with the timing for payment of fees.

Section 8E of the Agvet Code requires the APVMA to notify FSANZ when a variation to the Maximum Residue Limit Standard is likely for an approval, registration, variation or permit. Subparagraph 8E(2)(c)(i) of the Agvet Code specifies a 28 day timeframe for this notification.

Current approach

The 28 day timeframe causes difficulties as it is imposed from the date 'after the APVMA completes a preliminary assessment of the application'. However, an applicant is only required to pay part of the fee when the application is lodged and the applicant has 28 days to pay the balance of fees for the application (section 164 and subregulation 70(7)).

Therefore, the timeframe to notify FSANZ frequently expires before any assessment can be made about whether a variation to the Maximum Residue Limit Standard is required.

Unless the applicant pays the balance of their fees before they are obliged to do so, there is insufficient time to make an assessment as to whether a variation to the standard is required and to notify FSANZ.

Proposed approach

The government proposes to provide that the notice be given to FSANZ before the approval is given, registration is made, variation is made or permit is issued. This approach will allow the APVMA and FSANZ to agree (administratively) on appropriate timeframes, which will allow the APVMA to assess whether a variation to the Maximum Residue Limit Standard is likely to be required, but still allow FSANZ time to consider the notification.

Exposure draft explanatory notes

In Part 5 of Schedule 1 of the Exposure Draft, item 25 would substitute a new paragraph 8E(2)(c) that removes the 28 day timeframe and provides the notice must be given to FSANZ before the approval, registration, variation or permit is given, made or issued. The government proposes that these amendments would commence the day after Royal Assent to the Bill as minimal changes to relevant procedures would be necessary to implement this change.

Proposal 6 - Enable a person to apply to vary the particulars of a label approval that is suspended

Improve the operation of agvet legislation by enabling a person to apply to vary the particulars of a label approval that is suspended, to the extent that the variation relates to the matters relating to the grounds for suspension.

Background

The APVMA may suspend an approval for a label for containers for a chemical product (Division 5 of Part 2 of the Agvet Code). Subsection 43(2) provides that an approval for a label for containers for a chemical product is not in force when it is suspended. Division 3 of Part 2 of the Code sets out how variations to label approvals take place.

Current approach

The APVMA is unable to vary a label approval where the approval is suspended under the current provisions. This means the APVMA cannot amend a label to address the problem that required the label approval to be suspended without first revoking the suspension. This creates an administrative block to addressing suspended chemical products where a variation to the label is sufficient to revoke the suspension.

Proposed approach

The government proposes to provide that a person may apply to vary the particulars of a label approval that is suspended, to the extent that the variation relates to the reasons for the suspension.

Exposure draft explanatory notes

In Part 6 of Schedule 1 of the Exposure Draft, item 28 would insert two subsections at the end of section 43 of the Agvet Code. The new subsection 43(4) would provide that a suspension under subsection 41(2) does not prevent the variation of relevant particulars occurring while a label approval is suspended. The new subsection 43(5) would provide that these variations must be in relation to the reasons for the suspension of the approval.

Item 27 would be a consequential amendment to provide for certain actions to be taken while a label approval is suspended. Item 29 amends subsection 45A(2) so it correctly refers to the notice in paragraph 45A(1)(a). Item 30 amends paragraph 45A(2)(b) so that the notice of suspension or cancellation for a label approval contains the same matters as a notice of suspension or cancellation of an active constituent approval or chemical product registration. The government proposes that these amendments would commence 12 months after Royal Assent to the Bill to allow the APVMA to update relevant procedures and train staff.

Proposal 7 - Amend the definition of 'expiry date'

Amend the definition of 'expiry date' in the Agvet Code to specify the date after which a product 'must not' be used and amend the date format for an expiry date.

Background and current approach

The definition of 'expiry date' in section 3 of the Agvet Code currently refers to when the contents 'should not' be used. There are serious offences in the Agvet Code for making claims inconsistent with the expiry date (section 85).

Proposed approach

The government proposes the definition provide that the expiry date is the time after which the contents must not be used. This change is primarily linked to ensuring the expiry date reflects the timeframe in which the product remains safe, efficacious and that its use does not cause unmanageable risks. The government also proposes to change the date format, with 'date' rather than 'month and year' being specified.

Exposure draft explanatory notes

In Part 7 of Schedule 1 of the Exposure Draft, item 32 provides that the expiry date is the date after which the contents must not be used. These amendments clarify what the expiry date is for a product and the format the expiry date must take. The government proposes that these amendments would commence the day after Royal Assent to the Bill as minimal changes to relevant procedures would be necessary to implement this change.

Proposal 8 - Add antimicrobial resistance as a specific safety consideration

Add the potential for human exposure to antimicrobial resistant microorganisms as a specific safety consideration that the APVMA must have regard to for chemical products and active constituents.

Background

Section 5A of the Agvet Code specifies the requirements for how a chemical product or active constituent meets the safety criteria.

Current approach

Section 5A of the Agvet Code does not specifically require the APVMA to have regard to antimicrobial resistance as part of this assessment, however the section does allow the APVMA to have regard to such other matters as it thinks relevant.

Proposed approach

As the potential for human exposure to antimicrobial resistant microorganisms is a growing global concern, the government proposes to include the potential for this exposure as an explicit requirement the APVMA must have regard to when determining whether it is satisfied that a chemical product (subsection 5A(3)) or an active constituent (subsection 5A(2)) meets the safety criteria.

Exposure draft explanatory notes

In Part 8 of Schedule 1 of the Exposure Draft, items 34 and 35 insert the additional criterion of the potential for human exposure to antimicrobial resistant microorganisms. The government proposes that these amendments would commence six months after Royal Assent to the Bill to allow the APVMA to update relevant procedures and train staff.

Proposal 9 - Including civil penalty provisions for false or misleading information

Provide a broader suite of sanctions by including civil penalty provisions in the Agvet Code and the Administration Act for providing false or misleading information.

Background

Section 146 of the Agvet Code and section 69ER of the Administration Act contain criminal offences relating to false or misleading information or documents.

The offence in subsection 146(1) of the Agvet Code deals with information and documents about matters referred to in sections 5A (safety criteria), 5B (trade criteria), 5C (efficacy criteria), 5D (labelling criteria) or subsection 123(1) (manufacturing licence applications). The offence in subsection 146(2) deals with information and documents about other matters.

The offence in subsection 69ER(1) of the Administration Act deals with information and documents about matters referred to in section 69B. The offence in subsection 69ER(2) deals with information and documents about other matters.

Current approach

Unlike other provisions in the Agvet Code and the Administration Act, the provisions relating to providing false or misleading information do not provide for civil penalties. This reduces the sanctions that are available for responding when false or misleading information is provided.

Proposed approach

The government proposes to provide for a broader suite of sanctions to be available if false or misleading information is provided. Specifically, the government proposes to include civil penalty provisions in both the Agvet Code and the Administration Act in relation to providing false or misleading information, similar to those in the Biosecurity Act 2015 (see sections 532 and 533).

Exposure draft explanatory notes

In Part 9 of Schedule 1 of the Exposure Draft, items 36 and 38 include civil penalty provisions for providing false or misleading information in the Administration Act and the Agvet Code. Item 37 is a minor technical amendment. The government proposes that these amendments would commence three months after Royal Assent to provide sufficient notice of their introduction.

Proposal 10 - Minor technical amendments to the Administration Act and Agvet Code

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

Background

Part 7B of the Administration Act gave effect to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) before the commencement of Division 4A in 2005. Part 7B became redundant in November 2016 as there are no applications remaining to which these provisions apply.

Proposed approach

The government proposes the Administration Act be amended to remove redundant Part 7B and the other technical amendments are made to the Agvet Code to clarify some provisions.

Exposure draft explanatory notes

In Part 10 of Schedule 1 of the Exposure Draft, item 40 repeals redundant Part 7B of the Administration Act (sections 69EV to 69ZB). Item 41 is a savings provision for any active constituent approval that would have been prohibited by section 69EY (in Part 7B). It provides the approval is not invalid and the APVMA must cancel the approval if that approval was prohibited by section 69EY.

Item 42 is a minor technical amendment to subparagraph 8A(a)(v) of the Agvet Code. Items 43 and 44 replace 'relevant file' with the more correct reference to 'relevant APVMA file' in the Agvet Code.

The government proposes that these amendments would commence the day after Royal Assent as minimal changes to relevant procedures would be necessary to implement these changes.