Australian Government
Department of Agriculture and Water Resources

DEPUTY SECRETARY

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Dr Jane Thomson
Committee Secretary
Senate Rural and Regional Affairs and Transport Legislation Committee
Department of the Senate
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Dear Dr Thomson

The Australian Government Department of Agriculture and Water Resources welcomes the opportunity to provide the attached submission on the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 to the Senate Rural and Regional Affairs and Transport Legislation Committee.

Yours sincerely

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Senate Rural and Regional Affairs and Transport Legislation Committee Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

Submission by the Department of Agriculture and Water Resources

On 29 November 2018, the Senate Standing Committee for the Selection of Bills referred the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (the Bill) to the Rural and Regional Affairs and Transport Legislation Committee (the Committee) for inquiry and report by 11 February 2018.

This submission provides further information about the Bill and the context in which it would operate.

The 2015 Agricultural Competitiveness White Paper

In the 2015 Agricultural Competitiveness White Paper (the White Paper), the government committed to reducing red tape across the economy, including streamlining the approval of agricultural and veterinary (agvet) chemicals to reduce industry and user costs. The White Paper included a commitment to provide more timely access to productivity-enhancing chemicals, while ensuring the continuation of appropriate safeguards (page 8, 2015 Agricultural Competitiveness White Paper).

The White Paper noted that Australian agvet chemical regulation imposes a large regulatory burden, which is often disproportionate to the risks these products pose. It noted that this regulatory burden impedes Australian farmers' ability to improve their competitiveness and manage agvet chemical resistance. While acknowledging past agvet chemical reform efforts, the White Paper outlined further areas for improvement. This included limiting pre-market assessments of low- and medium-risk products and recognising assessments from accredited third party suppliers (pages 37–38, 2015 Agricultural Competitiveness White Paper).

The Bill supports the White Paper commitments to streamline agvet chemical regulation.

Australia's Agvet Chemical National Registration Scheme

Agvet chemicals are regulated through a cooperative National Registration Scheme (NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for the assessment and registration of agvet chemicals, as well as the control of supply activities up to and including the point of supply (for example, from importing an agvet chemical to manufacture, through to retail sale). The control of agvet chemical use after supply is the responsibility of individual states and territories.

The NRS is implemented, in part, through the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act). The Code Act contains, as a schedule, the Agricultural and Veterinary Chemicals Code (the Agvet Code). The Agvet Code operates in each state and territory (including Norfolk Island) to constitute a single national Agvet Code applying throughout Australia.

The *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act) establishes the APVMA as an independent statutory authority and contains provisions controlling the import and export of chemicals, enforcement and inspectors.

Consultation on the Bill

The department released an exposure draft of the Bill for public consultation between July and August 2018. State and territory governments and Commonwealth agencies were also consulted at this time. Stakeholder feedback gathered during the consultation was used to inform amendments to the Bill before it was presented to parliament. More details about stakeholder views are included in the commentary on each specific measure below. Stakeholder submissions made during the public consultation period are available via the department's website.

Compatibility with Human Rights

The Parliamentary Joint Committee on Human Rights, in its human rights scrutiny report 12 of 2018 (published on 27 November 2018), found that the Bill does not raise human rights concerns.

Overview of the Bill

The Bill seeks to improve the effectiveness and efficiency of the national system for regulating agvet chemical products. To do this, the Bill will amend the Administration Act, the Code Act and the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act).

The Bill will also repeal the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*, which is spent.

The Bill includes measures to:

- enable the use of new, simpler regulatory processes for chemicals of low regulatory concern (to simplify the approval of active constituents and labels, and the registration of certain products through prescribed approvals and registrations)
- provide the APVMA and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application
- provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products—particularly those uses (minor uses) with insufficient commercial return for chemical companies to otherwise add these uses to the product label (these are periods when the APVMA is prevented from using data that was provided to support the registration of a reference product, to register a second 'generic' product without the data holder's approval)
- support computerised decision-making by the APVMA
- provide for a legislative instrument to be made by the APVMA in the future, to prescribe a scheme that would formalise existing arrangements for applicants and the APVMA to use accredited third party assessment services
- optimise risk communication about chemical products by improving the transparency of voluntary recalls
- harmonise the need to inform the APVMA of new information (where it relates to the safety, efficacy, trade and labelling criteria) so that the same obligations apply to all holders and applicants
- provide a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process
- provide the APVMA with more proportionate options (suspension or cancellation of an approval or registration) for dealing with false or misleading information

- clarify what information must be included on a label (address an inconsistency in label particulars)
- allow the holder of a suspended product to address the reason for the suspension
- fix anomalies in the regulation-making powers for the safety, efficacy, trade and labelling criteria
- simplify the APVMA's corporate reporting requirements
- make minor and machinery changes including removal of unnecessary and redundant provisions.

More detailed information about these measures is provided below.

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

The Agvet Code provides for streamlined variations to *existing* approvals of active constituents and labels and registrations of chemical products, through 'notifiable' and 'prescribed' variations (Divisions 2A of Part 2 of the Agvet Code). These processes, which were introduced by the Amendment Act in 2013, provide for variations with reduced information requirements and lighter-touch 'assessments' (for example, there will be no requirement for a preliminary assessment), where the risks associated with a variation warrant such an approach. This reduces the time and effort for industry to seek, and for the APVMA to manage, these particular variations.

However, there is no equivalent 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 new approvals and registrations in the Agvet Code. It also means there is an inconsistency in how the Agvet Code deals with new and existing approvals and registrations.

Similar to the approach currently used for prescribed variations, the measure would provide for prescribed approvals and registrations to simplify the approval of certain active constituents and labels, and the registration of certain products (to be set out in regulations or other instruments made by the APVMA).

This measure implements the government's 2015 White Paper commitment to reduce pre-market assessment for lower regulatory risk products and instead focus on higher risk products. The proposed amendments will introduce a system change to enable the use of new, simpler regulation processes for these approvals and registrations where minimal or no assessment of technical information occurs. These changes would better align regulatory effort with risk and therefore improve access to safe and effective chemical products by reducing some of the red tape and reducing some of the costs associated with approval and registration. However, safeguards will remain in place to ensure that only safe and effective products continue to be available.

Stakeholder views

Stakeholders generally supported this measure to provide for simplified approvals and registration of products of low regulatory concern. Although it did not oppose the measure, one stakeholder was concerned that the measure could simplify market access pathways for generic products.

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

Prior to the 2013 Amendment Act, applicants could provide information to the APVMA while an assessment was underway. This resulted in the APVMA having to manage 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, introduced in the Amendment Act, now prevent the APVMA from considering new information provided by an applicant after an application has been made. An exception is 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 APVMA's efficiency.

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

Stakeholder views

Most stakeholders supported this measure as a way to reduce red tape and provide a practical means of allowing the APVMA to receive information.

The department opened public consultation on 12 December 2018 for proposed regulation amendments, which includes consultation on the information that could be provided through the mechanism proposed in the Bill.

Part 3 – Limits on use of information

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 competitors' 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.

The Agvet Code limits the use of information for a period of time to prevent the innovators' information being used to support applications by competitors for 'similar' products. The Agvet Code provides similar protections for information provided to support a chemical reconsideration (protected information), which also allows innovators to seek compensation from the generic competitors for use of the innovators' information.

Some chemical uses that are available overseas are not registered in Australia because they are not expected to produce sufficient economic return to offset the cost of approval or registration (including data generation), despite farmers (and other users) needing these chemical uses. The proposed measure would provide extensions to limitation and protection periods, to incentivise product registration holders to register priority uses of chemical products (including 'minor uses'). This is 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. Encouraging more priority uses to be added to product labels is also anticipated to reduce the regulatory burden on product users who may otherwise seek 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 measure would result in more uses being available 'on label'; however it would also mean that market entry of generic products would be delayed.

The requirements for extending these periods will include technical detail and priority uses would be subject to change over time. For this reason, the measure proposes that regulations would specify the high level criteria for extending limitation and protection periods with the technical details to be included in an instrument made by the APVMA.

Stakeholder views

Stakeholders, including user groups and farm industry bodies, generally supported the incentives proposed in this measure for agricultural chemical products as it would result in more chemical uses being available 'on label'.

Some stakeholders were concerned the measure may restrict access to generic chemical products. These aspects will be considered (and further consulted on) when the regulations are developed to support the limits on use of information measure.

Part 4 – Computerised decision-making

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, the proposed amendments address this deficiency by allowing computerised decision-making.

Computerised decision-making can, where applied properly and with appropriate safeguards, improve the APVMA's administrative efficiency. For example, 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 Industry Chemicals Bill 2017 would also provide for the Executive Director of the Australian Industrial Chemicals Introduction Scheme to use computer programs to make decisions.

The measure would provide for the APVMA to use computerised decision-making to support it as part of its processes and align the Agvet Code with other Commonwealth legislation. Where the APVMA considers it appropriate, this power would help the APVMA become more efficient and could be used for activities such as preliminary assessments. Preliminary assessments involve an administrative check to ensure all elements of an application have been provided by an applicant.

Stakeholder views

There was unanimous stakeholder support for this measure. A change was made to the policy following consultation, to ensure that the opportunity for internal review would be preserved where the APVMA substitutes a decision for a decision made by a computer.

Part 5 – Accreditation of assessors

This measure supports the government's 2015 White Paper commitment to recognise assessments from accredited third party suppliers and the findings of the APVMA's independent review into operations, which was released in late 2017.

The APVMA currently 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.

In addition, the APVMA is working with industry to conduct a pilot project in which third party external assessors are engaged directly by applicants (from a list of APVMA-approved applicants) to conduct pre-application assessment of efficacy and target animal and crop safety. The APVMA has indicated that this pre-application approach to assessments may be expanded in the future to assessments other than efficacy and target animal and crop safety. The use of external assessors in this way has the potential to:

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

The measure in the Bill would amend the Agvet Code to provide for a legislative instrument to be made by the APVMA, setting out an accreditation scheme for assessors. This would provide a mechanism to further formalise the existing arrangements by providing a transparent legislative basis for the assessment scheme, with a view to possible expansion (particularly in relation to assessors engaged by industry). It 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 provide additional transparency, help ensure quality and consistency, and safeguard the integrity of the third party assessment process. It should be noted that while the measure would improve the efficiency of assessments, the APVMA will continue to be the decision maker for active constituent and label approvals, and chemical product registrations.

The measure would provide for the APVMA to develop the detail of the accreditation scheme through a legislative instrument. This mechanism is proposed due to the technical nature of an accreditation scheme, the expertise required to establish and oversee it, and the flexibility required to tailor a scheme that evolves over time. This would provide a suitable legislative basis for the scheme, be disallowable in parliament and subject to parliamentary oversight through the Senate Standing Committee on Regulations and Ordinances. It would also ensure the scheme can be sufficiently responsive to the needs of the APVMA, regulated entities and the broader Australian community.

The scheme would need to provide for charges for functions the APVMA would perform, consistent with cost-recovery principles and as currently provided for in the Agvet Code. 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. 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 would reflect the costs of the effort required to deliver a specific good or service (for example, if the APVMA were to take a 'lighter-touch' assessment approach to applications already assessed by an accredited service provider, the fee would be lower than for a full APVMA assessment).

The Senate Scrutiny of Bills Committee considered the Bill on 14 November 2018. The committee identified two issues, both of which relate to this measure. The first matter, for which the committee sought a response from the Minister for Agriculture and Water Resources, was that for significant matters, such as a scheme to accredit persons to perform functions in relation to the Agvet Code, should be included in primary legislation unless a sound justification for the use of delegated legislation is provided (noting that contraventions of the requirements under the scheme may be subject to penalties prescribed in the regulations). The second matter related to the Scrutiny Committee's general principle and view that any member of the public should be able to freely and readily access the terms of the law. This may not occur where relevant information, such as standards or industry databases, is not publicly available or is available only if a fee is paid.

The Minister responded to the Scrutiny Committee on 27 November 2018. The Minister stated that providing the APVMA, via legislative instrument, with the power to mandate requirements of the accredited assessor scheme, provides the APVMA with the flexibility it needs to tailor the scheme according to its needs, allows it the ability to readily amend as the relevant science evolves and the flexibility to quickly respond to matters where the integrity of Australia's agvet regulatory framework may be compromised. It also reflects the discretion that APVMA has in reaching satisfaction that a chemical product or active constituent meets the statutory safety, efficacy and trade criteria and that a label for chemical products meets the labelling criteria. However, high level guidance about the requirements of the proposed accreditation scheme has

also been included in the draft Bill in proposed subsection 6G(2). This largely reflects the approach of the *Marine Safety (Domestic Commercial Vessel) National Law Act 2012* (section 160).

The committee noted the Minister's response, and while not seeking a further response, maintained its position that the amendments it suggested should be considered.

Stakeholder views

Most stakeholders generally supported an accreditation scheme for assessors.

The department addressed stakeholder concerns relating to offences by not pursuing a proposed aggravated offence while retaining the ability to prescribe a strict liability offence, albeit with a lower penalty than proposed during consultation (this would be prescribed in the regulations rather than the primary legislation, which allowed the Bill to be simplified). Any decision about penalties, fees or other aspects of the scheme, would be subject to consultation when the legislative instrument setting out the scheme is developed in the future.

Part 6 – Voluntary recalls

This measure will amend the Agvet Code to require persons to inform the APVMA when they are undertaking certain voluntary recalls and compel the APVMA to publish such recalls. This person need not be the holder of an approval or registration, as there are a number of different points in the supply chain of a chemical product where a voluntary recall may occur.

Part 6 of the Agvet Code provides for the APVMA to issue recall notices for chemical products (compulsory recalls). 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. Part 6 of the Agvet Code also clarifies that this power is in addition to those powers conferred on the Australian Competition and Consumer Commission under the *Competition and Consumer Act 2010.*

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 if it:

- contradicts any information entered in the Record of approved active constituents, the Register of registered chemical products 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.

The APVMA receives some notifications from industry about voluntary recalls and may, at its discretion, publish this information on its website. However, the Agvet Code does not currently specify notification and publication requirements if an agvet chemical product is being voluntarily recalled. As a result, it is left to the person recalling the product to determine how the recall is conducted and how stakeholders are notified.

The measures in the Bill will ensure that the APVMA must be informed if certain voluntary recalls are being conducted, where these relate to the matters set out in sections 5A to 5D of the Agvet Code (i.e. the safety, efficacy, trade and labelling criteria) or where the chemical product is not a registered product (i.e. where a product no longer meets the chemical product requirements in the register). The APVMA will then be required to publish such recalls. This will improve transparency and ensure a baseline of information is available to all stakeholders.

Stakeholder views

Stakeholders supported this measure.

After consultation the measure was updated to provide for a two day period for recallers to provide a voluntary recall notice to the APVMA, which aligns with the Australian Consumer Law.

Part 7 – Notification of new information

This measure amends the Agvet Code to ensure that obligations to provide relevant information to the APVMA apply to holders of label approvals, and applicants for both label approvals and variations to approvals or registrations. These obligations currently exist in relation to holders of active constituent approvals and product registrations under sections 160A and 161 of the Agvet Code.

Currently, information is 'relevant information' if it shows the active constituent or product may not meet the statutory criteria or if it contradicts information in the application or information the APVMA has recorded in the Record or the Register.

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.

The proposed measure would ensure the regulator is aware of the latest information that is available and provide safeguards to protect public, animal and plant health and the environment from potential damage where new information about an agvet chemical comes to light. This addresses a gap in the current requirements in sections 160A and 161 (to provide relevant information) as they do not apply to an applicant for approval of a label for containers for a chemical product nor to applicants seeking to vary an approval or registration.

Stakeholder views

Stakeholders generally supported this measure, which ensures that holders of a label approval and applicants for variation applications must provide new information to the APVMA, where this new information relates to the safety, trade, efficacy or labelling criteria. This is the same obligation that currently applies for holders of product registrations and active constituent approvals, and applicants for registration and approval.

Part 8 – Definition of registered chemical product

Chemical products contain active constituents that are primarily responsible for the biological or other effect of the product. Chemical 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.

Section 83 of the Agvet Code already provides for the regulations to prescribe, among other things, concentration ranges for constituents in chemical products (both active and non-active constituents). This, for example, allows for the routine variations in constituent concentration arising in manufacturing to be prescribed. However, offences and civil penalty provisions in Part 4 of the Agvet Code operate such that a product cannot be supplied if it is formulated

differently to the 'registered' formulation (therefore, the concentration of the constituents in a product must match that in the register for chemical products). Consequently, there is an anomaly in the Agvet Code in that, for the offences and civil penalty provisions in Part 4, the chemical product formulation must align exactly with the concentrations of constituents in the register, irrespective of any variation in constituent concentration that is provided for by the regulations made for section 83.

This inconsistency places an unreasonable burden on the APVMA and industry because the only means to address this would be through holders making applications to the APVMA to include more detail about a product's composition in the register. The regulatory effort associated with this task is inconsistent with the risks, particularly given that some provisions of the Agvet Code already provide for these reasonable variations in a product's composition.

The measure proposed will address these inconsistencies by amending the Agvet Code to provide, through the definition of registered chemical product, for prescribed standards for the concentration range of constituents, the kinds of constituents, and the composition and purity of constituents in chemical products to apply for all offences and civil penalty provisions in the Agvet Code.

It is not intended that the amendments would allow for fundamental changes in a product's composition, which would continue to require a variation application to the APVMA. 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.

Stakeholder views

Stakeholders generally supported this measure to allow minor variations in the constituents of a product, such as normally occur in the manufacturing process.

Part 9 – Suspension or cancellation of approval or registration for provision of false or misleading information

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, as per section 27(2) of the Agvet Code (for example, the holder may be a nominated agent for an overseas company that provides data to the APVMA).

To improve the post-registration response capability of the APVMA, this measure seeks 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 more proportionately respond, i.e. suspend or cancel an approval or registration, for providing false or misleading information in these situations.

Stakeholder views

Stakeholders supported this measure. Some were concerned the measure may affect access to chemical products and one stakeholder suggested its scope be limited to holders of registration and approval. This is a discretionary power the APVMA would exercise. In doing so, the APVMA would be required to issue notices of proposed suspension or cancellation and provide an opportunity to comment on these notices, before suspension or cancellation occurred.

Part 10 – Supply of registered chemical products with unapproved label

Section 81 of the Agvet Code requires all 'relevant particulars' to be contained on a label when only a subset of these relevant particulars should be on a label. This is inconsistent with other

labelling requirements of the Agvet Code and it is not appropriate that all relevant particulars should appear on a label. For example, the name of the nominated agent and the holder of approval—as opposed to that of the marketer of the product—are unnecessary.

Section 81 contains a serious criminal offence and a civil penalty provision for not including all 'relevant particulars' on a label. It is appropriate that the inconsistency be addressed.

To do so, the measure 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.

Stakeholder views

Stakeholders supported this measure.

Part 11 – Variation of approval or registration during suspension

This measure amends the Agvet Code to introduce practical mechanisms to deal with suspended registrations and to address the reason for a suspension. It will also allow holders to request a suspension of an approval or registration.

These proposed amendments will allow a holder to apply to vary the relevant particulars and conditions for a product registration that is suspended, provided the application relates to the reasons for the suspension. This will ensure that the issues with a product that led to its suspension can be appropriately rectified prior to revocation of the suspension.

Currently, under Part 2 of the Agvet Code, the APVMA may suspend an approval or registration. Subsection 43(2) of the Agvet Code provides that an approval or registration is taken, for the purposes of the Agvet Code (other than sections 74 and 75), not to be in force during any period in which it is suspended. Part 2 of the Agvet Code also sets out matters in relation to varying relevant particulars and conditions of approvals and registrations. However, the APVMA cannot currently amend a product registration to address the problem that led to the requirement to suspend the product registration without first revoking the suspension.

The proposed amendments will remedy this unintended administrative barrier to the appropriate rectification of issues with suspended product registrations, which prevents the holder of a registration from dealing with the suspension problem.

In addition, as the Agvet Code provides that a holder can only request cancellation of their registration or approval, not suspension (section 42 of the Agvet Code), a holder may be placed in a difficult position of having to cancel their registration to deal with administrative matters. An example of a potential administrative matter is where an overseas holder needs to arrange a new nominated agent in Australia. The holder then has to re-apply for registration at a later time. This requirement is an unnecessary restriction and may be costly to holders in these situations.

The proposed measure will enable a holder to have their approval or registration suspended while they deal with any issues with their registration or approval, which is aimed at reducing the administrative and cost burden.

Stakeholder views

Stakeholders supported this measure.

Part 12 – Safety, efficacy, trade and labelling criteria

The proposed measure will amend the Agvet Code to address anomalies in relation to prescribing matters for the labelling criteria (section 5D of the Agvet Code) and for overseas trials and experiments (including international assessments and data) in relation to the safety, efficacy, trade and labelling criteria (section 160 of the Agvet Code).

Section 5A of the Agvet Code sets outs 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 such matters.

Similarly, sections 5B and 5C set out matters the APVMA must have regard to for the purposes of being satisfied whether a chemical product meets the efficacy criteria or the trade criteria, respectively. Paragraphs 5B(2)(d) and 5C(2)(c) provide for the regulations to prescribe such matters.

Section 5D of the Agvet Code sets out matters that the APVMA must have regard to for the purpose of being satisfied that the label for containers for a chemical product meet the labelling criteria. However, section 5D does not provide for the regulations to prescribe matters the APVMA must have regard to for the purposes of the section. This is inconsistent with the regulation-making powers for the other statutory criteria in sections 5A–5C (safety, efficacy and trade 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, should such a regulation be considered desirable in the future. This is because the discretion in primary legislation means the regulations cannot modify this discretion.

The measure 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
- 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) for the purposes of sections 5A to 5D of the Agvet Code.

The APVMA advises it is already maximising the use of international standards, assessments and data in its assessments. Our conversations with stakeholders support this assessment.

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.

Stakeholder views

Stakeholders supported the policy intent behind this measure, although there were varying views in relation to its necessity given recent operational improvements by the APVMA in this regard.

Part 13 – Annual operational plans

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 (these include things such as a list of the standards made under the Code Act, the number of reconsiderations to commence under the Agvet Code and the number of applications made and not determined in each item under Part 2 of Schedule 6). 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.

The measure 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.

Stakeholder views

Stakeholders generally supported this measure.

Part 14 – Other amendments

Align the 2014 legislation review with the overarching review of agvet chemical legislation

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. The measure 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 avoid the need for separate and potentially confusing (and overlapping) reviews of agvet legislation.

Redundant provisions

The measure will seek to remove redundant provisions to help simplify and streamline the legislation. These provisions include transitional provisions that assisted in the establishment of the APVMA.

Classes of products

The proposed measure also seeks 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.

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.

The proposed measure will 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 measure 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.

Stakeholder views

Most stakeholders supported the proposal to align the two reviews.

Stakeholders generally supported the other measures.

Schedule 2 – Parts 1 and 2 – Other Amendments

The Agriculture and Water Resources Legislation Amendment Bill 2016 (the Omnibus Bill) included certain amendments to agvet chemical legislation. The relevant measures are:

- amendments which would require the notice provided by the 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.

The measures are now proposed to be pursued in the Streamlining Regulation Bill.

Stakeholder views

Stakeholders generally supported these measures.