18 FEBRUARY 2019

DISCUSSION PAPER

OPERATION OF THE AMENDMENTS IN THE AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT ACT 2013

CONSULTATION ON BEHALF OF THE DEPARTMENT OF AGRICULTURE AND WATER RESOURCES

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INVITATION FOR SUBMISSIONS

ACIL Allen Consulting (ACIL Allen) is seeking submissions on the operation of amendments to legislation made by the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (Amendment Act).

Section 4 of the Amendment Act specifies that the Minister must cause a review of the operation of the amendments made by the Amendment Act and a written report of the review to be laid before each House of the Parliament within 15 sitting days of that House after 1 July 2019:

> ***4 Review of operation of amendments***
>
> *(1) The Minister must cause a review to be conducted of:*
>
> *(a) the operation of the amendments made by this Act; and*
>
> *(b) any other related matter that the Minister specifies.*
>
> *(2) At least one of the persons conducting the review must be a person who is not otherwise appointed, employed or engaged by the Commonwealth.*
>
> *(3) The review must include a request for, and consideration of, submissions from members of the public.*
>
> *(4) The Minister must cause a written report of the review to be laid before each House of the Parliament within 15 sitting days of that House after 1 July 2019.*

The submissions will inform the review and will be used to develop the report to be tabled in Parliament.

1.1 Background

The National Registration Scheme regulates agricultural and veterinary (agvet) chemicals. The legislation that gives effect to the scheme includes the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act) and the *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 agvet chemical products. The provisions in the Code Act and the Schedule to it (the Agvet Code) allow the APVMA to evaluate, approve, register or review active constituents and chemical products (and their labels), and issue permits and 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).

The Amendment Act amended the Administration Act, Code Act, *Agricultural and Veterinary Chemicals Act 1994* (Agvet Act) and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Levy Act).

The term “agvet legislation” refers to these laws and to any regulations or legislative instruments made under them.

The Amendment Act aimed to simplify, re-organise and modernise the Agvet Code, and reform the approval, registration and reconsideration of agvet chemicals to improve the efficiency and effectiveness of the existing regulatory arrangements.

In general terms the purpose of the amendments in the Amendment Act included:

- enhancing the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, to which the APVMA must have regard, and legislative amendments to align regulatory effort with chemical risk
- ensuring the ongoing safety of agvet chemicals and improving the effectiveness and efficiency of then current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration scheme, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses
- improving the efficiency and effectiveness of assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations
- improving the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals
- improving consistency in data protection provisions and removing disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals
- addressing perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so
- providing greater certainty to the Australian public that agvet chemicals approved for use in Australia are safe by clarifying that the first priority of the regulatory system is the health and safety of human beings, animals and the environment.

1.2 Purpose of this discussion paper

This discussion paper describes the amendments made by the Amendment Act and invites submissions from interested parties on the operation of these amendments and other related matters. To assist stakeholders, this paper groups the amendments into six key themes and seeks comment on the operation of these amendments.

Complicating factors

The operation of some of the amendments made by the Amendment Act may be difficult to review due to the following factors:

- The provisions establishing the re-approval and re-registration scheme only operated for a short time until they were repealed by the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* (Removing Re-approval and Re-registration Act), therefore it is not possible to assess the operation of these provisions.
- Some measures have not been in effect long enough to allow a complete consideration of their operation. This is particularly relevant for some data protection measures and compliance and enforcement measures, which only apply in certain circumstances such as where certain information is provided or where non-compliance is detected. The operation of these types of amendments is difficult to assess until enough time has passed to allow the circumstances to manifest in a sufficient number of cases.
- Some measures, such as the levy collection arrangements, have never operated because the additional steps needed to bring them into effect were never implemented. It is therefore not possible to assess the operation of these amendments.

Operation versus implementation

This review is focused on the *operation* of the amendments in the Amendment Act, rather than the *implementation* of the amendments, which has already been comprehensively considered by the Australian National Audit Office in its 2017 report Pesticide and Veterinary Medicine Regulatory Reform, and the House of Representatives Standing Committee on Agriculture and Water Resources in its 2018 report, APVMA Regulatory Reforms.

Stakeholders should therefore limit their comments to the operation of the amendments since they commenced on 1 July 2014.

Notifiable and prescribed variations

In addition to the amendments made by the Amendment Act, we also invite you to comment on the extent to which notifiable and prescribed variations (as amended by the Removing Re-approval and Re-registration Act) have or have not been successful and whether or not stakeholders see scope for expanding the concept to other types of applications.

1.3 How to have your say

The deadline for receipt of all submissions is **5:00 pm on Friday 29 March 2019.**

ACIL Allen will consider all relevant material provided in submissions. While there is no set format for a submission, please make sure you include your name and title, your organisation's name (if applicable) and your contact details.

We would appreciate your assistance by identifying the relevant section of this document when making a comment on that specific section. Please note that the discussion points in this document are a guide only. They do not all need to be addressed, and stakeholders are welcome to raise other matters relating to the operation of the amendments.

Submissions can be emailed to agvetreview@acilallen.com.au.

Questions about the review or the submission process can be directed to Teresa McMichael at the email address above, or on (02) 6103 8216.

1.4 Publishing of submissions

Unless requested otherwise, submissions will be published on ACIL Allen's website. All personal contact details will be removed before publication.

Please advise if you would like some or all of your submission to be kept confidential and indicate your reasons for withholding the information.

We reserve the right not to publish submissions or to redact parts of submissions, for example, if they contain defamatory comments.

Privacy: We will only use the personal information collected 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 the Department of Agriculture and Water Resources (the Department). Confidential submissions will not be disclosed to the Department.

We will use and store all personal information in accordance with the National Privacy Principles as outlined in ACIL Allen's privacy policy available on our website.

1 DISCUSSION THEMES

Theme 1: Application assessment efficiency and effectiveness

The Amendment Act included measures aimed at improving assessment efficiency and effectiveness.

Amendments were included to address concerns about the time taken by the APVMA to complete applications. The (then) timeframes for applications did not take into account the total time that had elapsed for considering an application. The timeframes for applications operated on a 'stop the clock' model, whereby the timeframe paused if the APVMA sought additional information from the applicant. This model did not provide for certainty and predictability in assessment timeframes for either the applicants or the APVMA.

In addition, applicants could lodge an incomplete application, and provide data for the APVMA's consideration at any time during the assessment process. These arrangements unnecessarily delayed the finalisation of assessments for applications, as whenever the applicant provided new information, the APVMA would need to reassess the application based on that information.

Before the Amendment Act commenced, the APVMA conducted preliminary assessments of applications, which included an assessment of the adequacy of the technical information provided. This meant that the APVMA had to consider the technical information twice – once at preliminary assessment stage and again at the assessment stage of the application.

The Amendment Act (and regulations amendments) introduced:

- timeframes for assessments based on total elapsed time, including the time taken to provide more information (elapsed time model)
- amendments requiring the APVMA to refuse inferior or deficient applications so that it was only required to assess applications that were complete and of the required standard at the time of lodgement (refusal of applications)
- amendments that specified the information the APVMA must take into account for an application, to prevent the practice of some applicants submitting incomplete applications, and 'drip-feeding' information to the APVMA as it became available, thereby lengthening assessment timeframes and consuming more regulatory resources than warranted
- the "shut the gate provisions", being the provisions above, used in combination with the operation of section 159 notices[1], which are mirrored for reconsiderations (discussed in Theme 2)
- amendments to preliminary assessment so that it dealt only with administrative matters concerning applications and did not include a technical assessment (preliminary assessment)
- amendments to ensure that there was no undue impediment to the APVMA's use of overseas data and assessments conducted by comparable regulatory agencies, while recognising differences in national approaches (overseas data and assessments)
- amendments that enabled the APVMA to require electronic communication between it and applicants to improve efficiency in providing applications and information (electronic communication)
- guidelines for the APVMA to make, publish, and have regard to, as part of an overarching risk-based compendium that would be developed, maintained and published by the APVMA (guidelines)
- pre-application assistance so prospective applicants could obtain information on making a quality application.

[1] Under section 159 of the Agvet Code, the APVMA can require an applicant to do specified things, such as clarify aspects of an application, or provide specified information, such as reports or samples. The APVMA may issue a section 159 notice where an application is deficient and they are unable to assess the application against the statutory requirements.

BOX 2.1 DISCUSSION THEME 1: ASSESSMENT EFFICIENCY AND EFFECTIVENESS

Stakeholders may wish to comment on the following:

1) The effectiveness of the 'elapsed time' model versus the 'stop the clock' model, and whether the elapsed time model can be made more flexible through broadening the scope of 'time-shift' applications.
2) Whether the amendments have assisted stakeholders with the application process.
3) Whether there should be more flexibility in the time period used to rectify defects in applications.
4) Whether the preliminary assessment step should be retained.
5) The value and effect of the APVMA's use of international assessments and data for assessing applications.
6) Any other issues (caused by the amendments) relating to the efficiency and effectiveness of assessments.

Theme 2: Reconsiderations (chemical review)

The Amendment Act introduced measures to improve the transparency and predictability of reconsiderations of an active constituent, label approval, or product registration in response to concerns about the time taken by the APVMA to complete reconsiderations (chemical reviews). In addition, persons could provide data for the reconsideration at any time. These arrangements unnecessarily delayed the APVMA's finalisation of reconsiderations.

The Amendment Act also introduced the following changes:

— a requirement for the development and publication of a work plan for the reconsideration to provide transparency and predictability
— allowing for the legislation to prescribe time limits for requests for information, reports, samples and trial and experiments data, to provide predictability
— focusing reconsiderations on specific matters to do with an approval or registration, and concluding reconsiderations after those matters have been addressed, with any additional concerns identified in the course of reconsideration to be dealt with as the subject of a new reconsideration with a different work plan
— specifying the information the APVMA must take into account for a reconsideration, to address incentives for affected stakeholders to frustrate the reconsideration process by continually providing reconsideration information and thereby delaying final APVMA action.
— timeframes for reconsiderations to provide for a more predictable completion of the reconsideration.

BOX 2.2 DISCUSSION THEME 2: RECONSIDERATIONS

Stakeholders may wish to comment on the following:

7) Whether the amendments, including the published work plans and timeframes, have improved the transparency and predictability of reconsiderations.

Theme 3: Compliance and enforcement

The Amendment Act improved the ability of the APVMA to enforce compliance with its regulatory decisions by providing it with a graduated range of compliance and enforcement powers.

The amendments aimed to improve the APVMA's ability to administer its regulatory decisions efficiently and effectively by tailoring sanctions to the severity of the non-compliance. The measures are similar to those available to other Commonwealth regulators and they modernised the APVMA's investigation and enforcement provisions, consistent with contemporary standards.

The largest schedule of amendments in the Amendment Act encompasses compliance and enforcement measures. Some of the most significant amendments included:

- aligning the monitoring and investigation powers in the Agvet Code and the Administration Act, with regulatory powers in the later *Regulatory Powers (Standard Provisions) Act 2014*, including applying the powers in the Administration Act for the Levy Act (so that the Levy Act did not need to mirror the monitoring, investigative and enforcement powers in the Administration Act)
- introducing civil penalty provisions (and the ability for civil penalty orders), the ability to issue infringement notices, substantiation notices, enforceable undertakings, enforceable directions, warnings and notices to attend, give information or produce documents or things
- introducing a power to apply statutory conditions to registrations and approvals so the regulations could prescribe conditions, including an offence for contravening conditions of a permit
- improving suspension and cancellation powers to include where there is imminent risk to persons of death, serious injury or illness, or where false or misleading information is provided, as well as providing for a procedural fairness mechanism where the APVMA is proposing to suspend or cancel an approval, registration or licence
- providing for costs of investigations to be offset in particular situations to avoid drains on the APVMA resources
- increasing the penalty for some offences to align with contemporary standards
- introduction of the term 'holder' to replace the expression 'interested person'
- introduction of a procedural fairness mechanism if the APVMA proposes to suspend or cancel a permit
- updating the fit and proper person tests for permits and manufacturing licences so they reflected the Australian Government's Spent Conviction Scheme (which provides that only convictions or penalty orders in the previous ten years need to be declared)

There is scope in the future to simplify the Agvet Code further, with a greater use of conditions of registration to regulate the labelling of chemical products, and less reliance on specific labelling offences. For example, the current labelling of a restricted chemical product could become a condition of registration, and non-compliance dealt with as a contravention of a condition of registration rather than a separate offence. This would simplify the Agvet Code and may assist compliance with labelling requirements by co-locating the labelling requirements in one place as conditions of registration.

There is also future scope to include more measures in the disallowable legislative instruments made by the APVMA. For example, conditions of registration could be set out in an APVMA legislative instrument instead of in regulation. Another option could be to authorise the APVMA to set out a licensing scheme for the manufacture of chemical products, thereby allowing the existing Good Manufacturing Practice licensing scheme to be in a legislative instrument the APVMA would make, instead of the prescriptive requirements in the Agvet Code or the Agricultural and Veterinary Chemicals Code Regulations 1995.

While the examples given in the latter two paragraphs were not changes made by the Amendment Act, stakeholders may wish to comment on whether these matters should be considered in any future changes to agvet legislation.

BOX 2.3 DISCUSSION THEME 3: COMPLIANCE AND ENFORCEMENT

Stakeholders may wish to comment on the following:

8) Whether the amendments have improved compliance and enforcement.
9) Whether, as a legislative priority, agvet legislation should be aligned with the *Regulatory Powers (Standard Provisions) Act 2014*.
10) Whether the Agvet Code should be simplified through greater use of conditions of registration to regulate labelling of chemical products and less reliance on specific labelling offences.
11) Whether more measures should be included in disallowable legislative instruments made by the APVMA.

Theme 4: Improve consistency in data protection provisions

The Amendment Act improved consistency in data protection provisions and removed disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals.

The Agvet Code provides for two kinds of 'periods' during which information provided to the APVMA can be protected from unauthorised use. These are known as 'limitation periods' and 'data protection periods'.

'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 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 as soon as they become aware of it. If the APVMA relies on this information in making a decision, it receives a 'limitation period'. 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 APVMA to use the information).

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

Such limitations on the use of information are sometimes called 'data protection', and the period during which the information cannot be used is often called a 'data protection period'.

Data protection is a common feature of agvet regulation in countries with regulatory systems comparable to Australia's. Since investment in regulatory data can require significant resources, and given that the time taken to collect such data and have it assessed by the regulator also diminishes its value, the protection of data encourages innovation in agvet chemicals.

Where data protection applies, the APVMA is prevented from using data generated or owned by a person or company when determining (including assessing) an application from another person or company. This restriction on the use of data is for a specific period and protects the data owner's investment from competitors gaining an unfair commercial advantage over those who have been involved in the generation of that data.

Prior to their amendment, the data protection provisions were complex and did not provide meaningful access to data protection for information provided to a reconsideration. By enhancing these provisions, the Amendment Act removed disincentives to invest in innovative product development and improve the productivity of Australia's agri-food industries.

The Amendment Act included amendments to improve the mechanism by which data owners could obtain compensation for information submitted in relation to a reconsideration. These amendments aligned the data protection for new products and reconsiderations. Other amendments included:

- consolidating data protection provisions into a more contemporary format without changing their effect
- extending data protection eligibility to efficacy data, and data relating to the use of products on non-food-producing animals (for example, companion animals), therefore removing disincentives to generating and providing data for these situations
- maintaining data protection eligibility where data is provided as part of an application and that application is withdrawn or refused, and where data is provided as part of a permit application and those data are provided in relation to a future application
- partially addressing 'spring-boarding' by preventing the APVMA from using protected information when assessing and making a decision on the second application
- removing provisions relating to data protection extensions for minor uses because they had never been used in the nearly ten years they had been included in the Agvet Code.

An option for future consideration may be to consolidate 'protected information' and 'information with limits on its use' so that the information used for applications and reconsiderations is considered equitably and consistently throughout the Code. This would essentially treat 'protected information' like information currently provided under section 161 of the Agvet Code but with eight years instead of the three to five years protection given to section 161 information. Stakeholders may wish to comment on whether this consolidation should be considered in any future changes to agvet legislation.

BOX 2.4 DISCUSSION THEME 4: DATA PROTECTION

Stakeholders may wish to comment on the following:

12) Whether the amendments have improved data protection and made the associated provisions easier to understand.
13) Whether stakeholders have experienced benefits from using data contained in withdrawn and refused applications, or permit applications, for a subsequent product registration.
14) Whether Part 3 of the Agvet Code should be omitted to allow stakeholders to rely on commercial arbitration legislation for persons to negotiate access to both protected information and information with limits on its use.
15) Whether 'protected information' and 'information with limits on its use' should be consolidated.

Theme 5: Legislation improvements

The Amendment Act simplified, re-organised and modernised the Agvet Code to reduce uncertainty and complexity in the legislation. The Act also removed redundant provisions and amended out of date provisions in all Commonwealth agvet legislation.

The Office of Parliamentary Counsel made extensive technical revisions to the Agvet Code, amending provisions around applications, reconsiderations, suspensions and cancellations, notices and data protection. These revisions brought the Agvet Code up to contemporary standards for legislative drafting.

The revisions included:

— the insertion of explanation sections
— consolidation of existing 'legislative tests' for approval and registration, variation, reconsideration and elsewhere into four new tests (the 'meets the efficacy criteria', 'meets the labelling criteria', 'meets the safety criteria' and 'meets the trade criteria' tests) under subsection 3(1)
— a single set of general provisions relating to all applications except those for licences
— consolidating notice provisions
— simplification of provisions around 'interested persons', 'approved persons' and listed registration to address some inconsistencies in the Agvet Code.

BOX 2.5 DISCUSSION THEME 5: LEGISLATIVE DRAFTING

Stakeholders may wish to comment on the following:

16) Whether the simplification and re-organisation of provisions has helped make the legislation easier to understand.
17) Whether the redrafting of existing 'legislative tests' into the four 'meets the X criteria' tests in subsection 3(1) of the Agvet Code has assisted them to comply with safety, trade, efficacy and labelling criteria.

Theme 6: Variations to relevant particulars and conditions

The Agvet Code currently provides for the variation of relevant particulars and conditions of an approval or registration (Division 3 of Part 2 of the Agvet Code – sections 27 to 29B). The Agvet Code also provides that some variations to relevant particulars of approval or registration may be made by 'notification' (Division 2AA of Part 2 of the Agvet Code – sections 26AA to 26AD) or as a 'prescribed variation' (Division 2A of Part 2 of the Agvet Code – sections 26A to 26D). These notifiable variations and prescribed variations only allow some relevant particulars to be varied and do not authorise conditions to be varied as notifiable variations and prescribed variations.

Notifiable variations were introduced in the Removing Re-approval and Re-registration Act. Prescribed variations were first introduced in the *Agricultural and Veterinary Chemicals Code Amendment Act 2010* but the Amendment Act also included them to further the policy developed in the Code Amendment Act.

The Amendment Act also included:

— the new option for regulation to prescribe 'prescribed variations' as an alternative to the previously specified APVMA legislative instrument

— the requirement that a prescribed variation take effect within a period prescribed in the regulations (currently one month).

It is noted that notifiable variations and prescribed variations can contain incorrect information. Stakeholders may wish to comment on what mechanisms could be introduced to help the APVMA deal with this situation in a cost-effective manner. For example, an option may be for the APVMA to apply a specific fee in these circumstances instead of rejecting the variation.

BOX 2.6 DISCUSSION THEME 6: NOTIFIABLE AND PRESCRIBED VARIATIONS

Stakeholders may wish to comment on the following:

18) The value of having multiple processes for varying relevant particulars.
19) The effectiveness of existing processes for varying conditions, and whether there should be a streamlined means of varying conditions (recognising the technical assessment that can be required).
20) Whether agvet legislation could be simplified by dealing with variations to approval and registration as new approvals and registrations.
21) What mechanisms would stakeholders support for dealing cost-effectively with incorrect information in notifiable variations and prescribed variations?

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ABOUT ACIL ALLEN CONSULTING

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