Comments by Aglign Ag Pty Ltd in collaboration with Dairy Australia on the ACIL Allen review

https://acilallen.com.au/agvetreview - Review of Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.

ACIL Allen discussion paper.
https://acilallen.com.au/uploads/files/page/29/ACILAllenAgVetdiscussionpaper130219-1550449536.docx

Aglign Ag was engaged by Dairy Australia to provide suggestions on some key points for consideration on the paper released by ACIL Allen on AgVet Legislation. Comments are presented in **red**.

ACIL Allen call for discussion on 6 discussion themes. They preface reviews with the following:

From the ACIL Allen paper - 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*The provisions establishing the re-approval and re-registration scheme only operated for a short time until they were repealed by the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014 (Removing Re-approval and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.

AGLIGN AG/DAIRY AUSTRALIA feedback:

Theme 1 – Applicant assessment efficiency and effectiveness.

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.

Comment - If the submission quality is of sufficient standard, there should be no reason to "stop" the clock. Encouraging quality submissions results in improved turnaround and more effective approvals

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.

A discretionary "higher" management decision process may be useful for particular applications. It should be irregular used and applied when common sense is necessary for the best outcome

4) Whether the preliminary assessment step should be retained.

DA is not involved in submission for registering actives, but has been involved in submitting for minor use permits. Preliminary Assessments are a means for APVMA to refuse an application via s159 notices which provide the only means of addressing amendments. Dairy Australia's ise of permits in the Ag space is relatively small and selected for their likelihood to succeed. Future permits may be more "uncertain" and a more flexible approach allowing discussion between evaluator and applicant may better serve industry.

5) The value and practical effects of the APVMA's use of international assessments and data for assessing applications.

APVMA has shown helpful responsiveness and willingness to review and include overseas data for DA. Future recognition of the value of good overseas data to reduce local needs is encouraged. Regarded as positive

6) Any other issues (caused by the amendments) relating to the efficiency and effectiveness of assessments

Theme 2 - Chemical Review

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

No particular comment from DA "ag" involvement where permit applications have been limited to date, but other industries such as Horticulture find pre-plans helpful in developing industry responses and effects. This may impact Dairy more in the future for permits where use patterns are more extensive such as in animal processes.

Theme 3 – Compliance and Enforcement

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 the 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 the consistency of data protection provisions

12) Whether the amendments have improved data protection and made the associated provisions easier to understand.

Provisions relating to data protection were removed in the case of minor uses because they were complex and not used and proved of little <u>practical</u> use to registrants. They were not used because they were complex – it is a circular argument to sustain. The lack of effective incentive or reward for registrants to undertake label extensions in minor crops <u>is an important reason why it is sometimes difficult to get registrant support for permits</u> (held for later future submissions or data not developed because no exclusive value can be harnessed by the company in a generic market place. <u>A MEANINGFUL WAY OF IMPLEMENTATION SHOULD BE PURSUED</u>.

13) Whether stakeholders have experienced benefits from using data contained in withdrawn and refused applications, or permit applications, for a subsequent product registration.

See point 12 as well. Registrants can be reticent about providing supporting data towards permits when no data protection exists for their proprietary data into Australia's generic pesticide market. There is also a concern that providing data for permits negates data protection that would be applied if the data was held for later product label submission

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.

A form of commercial arbitration may be a useful in certain circumstances, however, commercial advantage would be a pressing inhibitor of potential market sharing and access in Australia where generic access to many pesticides cancels commercial advantage.

15) Whether 'protected information' and 'information with limits on its use' should be consolidated.

Theme 5 – Legislation Improvements

16) Whether the simplification and re-organisation of provisions has helped them to better understand the legislation.
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

18) The value and practical effects 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?