



Submission

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

The VMDA is a peak body representing the largest group of registrants and manufacturers of animal health products, as well as other key industry participants. We have as our key platform the support and development of local industry, including manufacturing and export.

The VMDA supports the objects of the Agvet Code, including those that require the APVMA to take into account best practice scientific principles and the health and safety of human beings, animals and the environment, in the regulatory process.

We note also that the Agvet Code recognises that the furthering of trade and commerce between Australia and places outside of Australia, the viability and competitiveness of primary industry, and a viable domestic industry for manufacturing chemical products, are essential for the well-being of the economy.

The Agvet Code further states that this requires a system for regulating chemical products and their constituents that is cost effective, efficient, predictable, adaptive and responsive, and that the implementation of the Code is to be in a manner that balances regulatory effort and any burden imposed on holders of approvals, registrations and the domestic industry.

The VMDA urges the Government, APVMA and others providing input to the regulatory process to take particular note of all of the objects of the Agvet Code, and the need for a clear, predictable, cooperative and non-adversarial approach to agvet chemical regulation.

We hereby present our submission for consideration.

J D Adams
Executive Director

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Executive Summary:

The VMDA broadly supports the concept of improving the Operational Efficiency of the APVMA, in particular where this improvement is related to providing further clarity and certainty of timelines and outcomes for applicants.

We welcome the adoption of an approach to the handling of confidential commercial information (CCI) that allows the APVMA staff to carry out their duties with confidence, however we continue to protest the failure of the APVMA to take account of and operate under, the direction of the Federal Court of Australia in the matter of ABBEY LABORATORIES PTY LTD and AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY, heard on February 1st, 2016 with judgment handed down on June 10, 2016. While the proposed legislative change appears to assuage the concerns of some APVMA staff, this could have been achieved without legislative change by means of a clear and concise direction from senior APVMA management, based upon the judgment of Rares J as above. A different approach would have avoided the consequent costs to industry which amount to many millions of dollars, with ongoing costs to the farming community as yet unable even to be calculated.

The VMDA supports proposals 1, 2, 4, 5, 6, and 10.

The VMDA partially supports proposal 3 but disagrees with one aspect (see submission below).

The VMDA does not support proposals 7, 8, and 9.

While the VMDA commends the overall aims of the proposed legislative amendments in terms of improving operational efficiency, we urge the Government to take into account the comments and suggestions of industry as to the apparently unforeseen consequences of some of the proposals and the associated construction of the legislative proposals.



Proposal 1: Clarifying confidential commercial information provisions:

The VMDA supports this proposal while noting our comments as above regarding the Federal Court Case. It is incumbent upon this (and any other) regulator to ensure that they take appropriate steps to consult with industry on major issues such as CCI, and to take steps to ensure that such momentous decisions are carefully considered especially in the face of such overwhelming evidence to the contrary as was the case with the CCI issue.

Proposal 2: Simplifying reporting requirements for annual returns:

The VMDA supports this proposal. We have for many years pointed out the inaccuracies of the reporting of active constituent quantities because of the inability to gain access to details of the quantities of raw materials imported, as well as to gain access to the same figures for exports. We accept that there is a need to provide some degree of information, and support this proposal as a practical means of providing the information without imposing on industry a complex and unwieldy system that is, in the end, inaccurate.

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

The VMDA broadly supports the proposal to enable the correction of minor errors or omissions within a reasonable time. However we do not support the added element of 'refusal' if the APVMA is 'not satisfied that the defects in the application can reasonably be rectified;'

It is quite possible that an APVMA assessor would 'believe' incorrectly that a particular defect could not 'reasonably be rectified' when in fact it could be. The APVMA cannot know what resources or information the applicant has on hand or has access to that may rectify any defect regardless of how 'major' it may appear to the APVMA assessor at Preliminary Assessment.

The VMDA suggest that these provisions be deleted from the proposed legislative changes OR that the following wording be substituted:

'The APVMA may refuse the application if it is not satisfied after consultation with the applicant that the application can reasonably be rectified.'



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

The VMDA supports this proposal.

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

The VMDA supports this proposal.

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

The VMDA supports this proposal.

Proposal 7: Amend the definition of 'expiry date'.

The VMDA does not support this proposal.

Changing the date format to “date” rather than “month and year” reduces clarity in the legislation and seems to imply that a full date (dd-mm-yyyy) would be required to be printed. This would be problematic for very small containers where there is insufficient room for a full date. Current label artwork is designed around the required space to fit month and year only, and any changes to the space requirements for expiry date would have an impact on many labels. It would take time for new labels to be designed, printed and phased in, whereas the proposal is for the amendment to commence with immediate effect.

A change from ‘month and year’ to absolute date would also potentially:

- a) Confuse consumers who would believe that the product is absolutely ineffective as
- b) Reduce the shelf life of a product by up to a month if for instance the date of labelling/release were to be the 1st of any given month rather than the product being ‘effective’ for the whole of the month.

Additionally, the change in definition of expiry date from “should not” to “must not” may present legal issues for veterinarians, who currently will allow a product to be used “at” expiry, sometimes by increasing the dose in an educated manner. This is potentially in conflict with the veterinarian’s ‘right to prescribe’.

Scientifically, given that the APVMA has recently asserted that it ‘may require’ shelf life data to extend for 3 months beyond the proposed period, therefore reducing ‘statutory’ shelf life for products that have already completed their stability testing, there is no justification for applying a specific date for expiry.



Proposal 8: Add antimicrobial resistance as a specific safety consideration.

The VMDA does not support this proposal in its current form.

We recognise that measures should be implemented to reduce and prevent the spread of antimicrobial resistance, however the question of 'the potential for human exposure to antimicrobial resistant microorganisms resulting, directly or indirectly, from the use of the constituent' is a complex issue. While we support the concept, inclusion in the legislation as a specific safety consideration to which APVMA must have regard is premature. Given the current pressures within APVMA, it is unlikely that they will be sufficiently resourced to consider how to best implement the proposal, and develop appropriate guidance material for applicants, within the proposed 6 month timeframe. Further, the VMDA would like to see a formal period of consultation with industry via expert scientific opinion from both sides and internationally before adoption of such a measure.

A better approach may be for APVMA to develop a specific strategy on antimicrobials, similar to EMA CVMP's 2016-2020 strategy. This would permit greater flexibility to assess and address the areas of concern, and allow more time to develop and implement considered measures over a longer period.

Proposal 9: Including civil penalty provisions for false or misleading information.

The VMDA does not support this proposal.

These criteria are already covered by Competition and Consumer Act 2010 Schedule 2, Section 18. Additional provisions in the AgVet Code may lead to additional complication and confusion, and potentially result in different outcomes under the two Acts.

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

The VMDA supports this proposal.

End.