Australian Government
Australian Pesticides and Veterinary Medicines Authority

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Regulatory Reforms Team
Therapeutic Goods Administration
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Submission on the TGA's options for the future regulation of 'low risk' products

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide comments on the Therapeutic Goods Administration (TGA) consultation paper.

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemical products proposed for supply and use in Australia to ensure that the health and safety of people, animals, crops and the environment are protected. The APVMA approves active constituents and registers agricultural and veterinary chemical products in consideration of statutory criteria relating to safety, efficacy and impacts on international trade. These criteria are set out in the Agricultural and Veterinary Chemicals Code 1994 (the Agvet Code).

The APVMA's legislative framework provides for the consistency, efficiency and transparency of agvet chemical approvals, registrations and reconsiderations, and helps us to align our regulatory effort with risk. Section 1A of the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* sets out the purpose and framework for regulatory decision making for agvet chemicals.

This section highlights the importance of maintaining a balance between our regulatory effort, the regulatory burden imposed on those affected, and the risk associated with chemical use. In administering the code, we aim to ensure regulatory compliance in keeping with what is reasonably necessary to manage risks to the health and safety of human beings, animals and the environment.

The legislative framework provides us with certain discretions—such as the extent to which we need to take into account particular matters in determining whether the efficacy and trade criteria have been met. By allowing us these discretions, constrained within appropriate limits by the Agvet Code Regulations, the framework makes us better able to match our regulatory effort with risk.

The APVMA is currently investigating and implementing lower regulatory approaches for all applications for active constituent approvals, product registrations and variations. A selection of these approaches are summarised below.

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International assessments

In March 2017, the APVMA published *Guidance for the use of international data, standards and assessments*. This guidance articulates the policy by which the APVMA will consider international assessments when assessing applications. The policy is available at apvma.gov.au/node/14186.

This policy and its implementation delivers against the Australian Government priority to improve access to chemicals by Australian farmers and other users and supports the principle of aligning regulatory effort and risk.

The key features of the policy are:

- Definitions of acceptable international assessments, including their potential scope and a list of organisations whose assessment reports the APVMA will accept,
- A clear statement that the active constituent or product which is the subject of the international assessment must be identical to the active constituent or product intended for approval or registration, respectively, in Australia,
- Listed criteria that the international assessment must fulfil to be acceptable to APVMA,
- Requirements covering the submission of multiple assessments and underlying data or studies,
- Confirmation of how the APVMA will use the data provided, including a clear statement that the APVMA does not simply adopt the conclusions of an international assessment—each international assessment must be fit-for-purpose and supported by studies that fulfil our regulatory (data) requirements, and
- Guidelines for the submission of an international assessment.

The APVMA has also provided guidance to staff on how to implement the policy. Industry are being encouraged to discuss any international assessments with the APVMA prior to submission to ensure the best use can be made of this data and information.

Crop groupings

The APVMA is working with the Department of Agriculture and Water Resources on a project to improve access to chemical products for use on minor crops by streamlining registration requirements.

An official Australian crop groups list, and the individual crops which form these groups, has been finalised and published. The next phase is to review and update data guidelines to identify representative crops from each group which can be used to generate acceptable data for safety, efficacy and trade criteria.

Fully modular assessment system

The APVMA is defining the conceptual framework, business requirements and legislative changes required to support a fully modular assessment system for applications. This will enable tailoring of assessments and regulatory treatment to individual applications. The modular system will be flexible and better able to make use of international or third party assessments and crop groupings. A proposal is under discussion with the Department of Agriculture and Water Resources for possible inclusion in reforms to agvet chemical regulation.

Fast-track registration

In July 2016, the APVMA piloted a fast-track registration pathway for companies wanting to repack their own products. The pilot used IT enhancements and internal process revisions to reduce the time taken to process these lower risk applications. This initiative was directly responsible for identifying the business change to allow upfront payment of the full application fee, saving time for applicants and the APVMA.

The APVMA has continued the fast-track registration pathway for applications that meet the same criteria set for the pilot. We are reviewing the lessons learnt from the pilot to identify business processes and legislative changes that could improve the current process before we widen the scope of the types of applications that can use the fast-track pathway.

Further information about the fast-track registration process is available at apvma.gov.au/node/20276.

Listed standards

Listed standards define the conditions under which the APVMA is satisfied in relation to a particular group of products. Products that meet the requirements of the standard could achieve registration through the fast-track registration system. The APVMA is developing guidance material for industry wanting to develop such standards.

Consultation with dairy sanitiser and anti-fouling paint industry members is ongoing to determine how this approach may be useful for those products. The APVMA will then explore this approach with other industry sectors where appropriate.

Further information about listed chemical products is available at apvma.gov.au/node/173.

Notifiable variations

In September 2016, the APVMA added five new items to the list of notifiable variations which allow companies to make minor changes to active constituents, products and labels through a simpler and faster process of notification. The APVMA will continue to look for other application types that may be suitable to be a notifiable variation.

Further information about notifiable variations is available at apvma.gov.au/node/12846.

Thank you for the opportunity to provide comments on the consultation paper. I look forward to continuing to share information with the TGA about aligning regulatory effort and risk.

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Yours sincerely

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Chief Executive Officer