CropLife Australia

April 2025

APVMA Strategic Plan 2025-30

1. Introduction

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers, formulators, registrants and suppliers of crop protection products (organic, synthetic and biologically based pesticides) and agricultural biotechnology innovations. CropLife's membership is made up of both large and small, patent holding and generic, Australian and International companies. Accordingly, CropLife only advocates for policy positions that deliver whole-of-industry and national benefit. However, our focus is specifically on the Australian agricultural sector and ensuring it remains internationally competitive through globally leading productivity and sustainability. Both of which are achieved through access to world-class innovation and products of the plant science sector.

The plant science industry contributes to the nation's agricultural productivity, environmental sustainability and food security through innovation in plant breeding and pesticides that protect crops against pests, weeds and disease. More than $31 billion of the value of Australia's agricultural production is directly attributable to the responsible use of crop protection products (CPPs), of which CropLife Australia's members represent over 70 per cent of the products in the Australian market. The plant science industry itself directly employs thousands of people across the country.[1] CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

CropLife welcomes the opportunity to provide comments to the Consultation Paper for the APVMA Draft Strategic Plan 2025–30.

[1] Deloitte Access Economics, 'Economic Contribution of Crop Protection Products in Australia', August 2023, https://www.croplife.org.au/resources/reports/economic-contribution-of-crop-protection-products-in-australia/.

APVMA Strategic Plan 2025–30

Our purpose

The draft strategy proposes to redefine the purpose of the APVMA as:

> "*The APVMA regulates agricultural and veterinary chemicals to protect the health and safety of people, animals and the environment, and to support Australia's primary industries, biosecurity and international trade*."

CropLife is concerned that the proposal does not appropriately reflect the statutory purposes of the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code). Section 1A of the Agvet Code, provides statutory guidance to the APVMA on how it should implement the regulatory framework. This outlines that the public policy objective of the Agvet Code is to support the wellbeing of the economy by operating as a well-functioning regulatory system that supports the viability and competitiveness of farmers through facilitating access to chemical products that can be safely used. It further provides that as part of facilitating this access, the first priority of the regulatory system is to protect the health and safety of humans, animals and the environment from any unsatisfactorily managed risks created by the use of chemical products. The APVMA is to achieve these outcomes through implementing best practice scientific risk assessment and management.

To this extent, CropLife supports the current drafting of the APVMA's purpose:[2]

> "*We regulate agricultural and veterinary chemicals to manage the risks of pests and diseases for the Australian community and to protect Australia's trade and the health and safety of people, animals, and the environment*."

This better recognises the purpose of the statutory scheme to support the agronomic and economic necessity of effectively managing pests and diseases, while maintaining the statutory priority of the APVMA to protect the health and safety of people, animals and the environment.

Our vision

The unamended **Our vision** statement, "*To be a global leader in agricultural and veterinary chemicals regulation for the benefit of Australia*", is supported.

[2] Australian Pesticides and Veterinary Medicines Authority, 'APVMA basics', https://www.apvma.gov.au/about/about-us/apvma-basics, accessed 9 April 2025.

Our strategic objectives

Being a trusted, transparent and fair regulator.

CropLife agrees that trust in the APVMA by the Australian public is critical to maintaining confidence in Australian agricultural and veterinary (agvet) chemicals. However, the objectives as listed pertain mostly to public perception. While this is indeed a vital component of the regulation of pesticides and veterinary medicines, confidence in the regulatory system by the innovators, developers, manufacturers, suppliers and users of crop protection products is equally so. Concerningly, the regulatory posture of the APVMA has changed to one that seeks to deny applications rather than delivering on the statutory requirements under Section 1A of the Agvet Code. This change in posture is most clearly seen in the change of the APVMA's key performance indicator for on-time performance for assessment of chemical products away from the 100 per cent compliance with legislated time limits. Importantly, this change was made without any engagement with stakeholders, which would have supported the APVMA Board to understand the importance of compliance with the statutory timeframes to achieving the public value proposed by the regulatory scheme.

External political factors, stemming from unfounded and sensationalised public accusations, resulted in the reputation and integrity of the APVMA being publicly tarnished and maligned. The operations and processes of the APVMA were subsequently derailed and repurposed. Unfortunately, throughout this disruption the Board failed to deliver on its chartered purpose to provide appropriate strategic guidance that established and entrenched a culture of accountability and professionalism. Consequently, this inaction left the dedicated and skilled scientists and staff of the APVMA unsupported towards meeting their statutory requirement at a time where such strategic direction was most needed.

This failure led to the APVMA developing the Australian Public Service inertia-laden culture, resulting in a regulator more inclined to implement risk avoidance that restricts innovation, than deliver best practice scientific risk management. In doing so, it has denied Australian farmers access to safe and effective agricultural chemicals that have been approved for use elsewhere by science-based regulatory systems implemented elsewhere in the world.

Such outcomes impacting culture and purpose are not congruent with "*...being a trusted, transparent and fair regulator*" and must be corrected immediately.

Measure 1

Measure 1, *The proportion of stakeholders surveyed who agree that the APVMA has been a trusted, transparent and fair regulator over the past 12 months*, is supported, however, due to the open self-selection of the Stakeholder Survey, appropriate measures should be taken to ensure this measure is not hijacked by ideological interest groups.

The CSIRO report, *Australian Egg Industry Community Research: 2018 Report* and the separately published Appendix illustrates these risks. The report relied upon data from two identical surveys that used different collection methodologies, with one using a representative sample of the Australian community and another utilising an online self-selection methodology. Stratifying the data by collection methodology showed a clear difference between results of the open survey and those of the representative sample.

Care must be taken in the collection and interpretation of these results to ensure the APVMA remains focussed on the task of facilitating predictable and timely access to agricultural chemicals.

Measure 2

This recognition is somewhat borne out in ***Measure 2****: The proportion of all applications finalised within legislative timeframes*. A predictable and efficient regulator, relying on the best available science, is imperative to ensure that Australian farmers and environmental land manages have timely access to the innovations of the plant science industry in a manner not impeded by unscientific claims. This is supported by the consultation draft, which affirms that ***compliance with legislative timeframes*** *is a key measure* of the APVMA's success in delivering on its statutory purpose.

Current delays and unpredictability, coupled with the ever-looming threat of substantially increased regulatory costs, have already begun to dissuade registrants from seeking registration of new, innovative products and uses in Australia. This includes the cancellation of some projects.

For over two years, since September 2022, the on-time registration of new products has been deprioritised. Currently, more than one in five new registrations are being significantly delayed. Simultaneously, the APVMA has utilised its Operating Plan to reduce the targets of adherence to these legislated timeframes to 90 per cent, aggregated across technical and non-technical assessments. As a result, the abysmal performance of the regulator on Major Pesticides, being those that require technical assessment, is diluted by the generally on-time assessment of non-technical assessments. Such non-technical, administrative applications generally deliver no innovations or improved access to crucial crop protection products to the farming sector.

Throughout this period, the APVMA has failed to fully utilise the suite of tools made available to them through enabling legislation, such as the use of competent external scientific reviewers, computer and software enabled decision making, and the acceptance of internationally approved data.

The cost of these assessment delays cannot be overstated. Australian farmers are once again paying the price for a prolonged, stark and entrenched inefficiency culture within the APVMA. Historically, delays of lesser magnitude and duration than those experienced in this current state have cost the farming sector hundreds of millions of dollars. The loss of capacity resulting from the relocation of the APVMA to Armidale in 2016 initiated a series of delays that impacted the performance of the regulator across the breadth of its remit. Upon detailed analysis in 2019, the Grains Industry reported as much as $500 million in direct losses to productivity resulted from delayed access to new, novel chemistries which were available to their overseas competitors.[3]

These calculated losses were attributable to a small handful of products that were only delayed for a season. In the last two years, CropLife members alone have now seen delays in over 50 new, innovative products and uses, with nearly as many potential projects cancelled. However, this most recent series of delays has been centred on one specific aspect of assessment; efficacy. Assessors have suddenly increased demand for data to support efficacy assessments, far in excess of historical norm and frequently exceeding the APVMA's own guidance on data to support label claims. Efficacy assessments in crop protection, which carry the least regulatory risk for the APVMA, have nearly overnight become the most difficult and costly hurdle for registrants. This change has happened despite there being no change to the regulation or to guidance material. Nonetheless, it has resulted in the current level of unnecessary bureaucratic decisions being made by officers of the APVMA.

In effect, the APVMA have throttled the flow of innovative, safe and novel chemistries developed and introduced by overregulation not related to the genuine safety of agvet chemical products. These delays are not from unanticipated legislative changes or Ministerial direction, but rather are of the APVMA's own making by exceeding even the strictest interpretation of their own guidance.

[3] GPA response to the consultation on operation of the amendments in the agricultural and veterinary chemicals legislation amendment act 2013 – March 2019

To assist the APVMA to return to the statutory intent of the regulatory scheme, the implementation of Performance Measure 2 must be accompanied by a reinstatement of the performance indicator to 100 per cent of assessments completed on time in the corporate plan. Returning this measure as the key indicator of the regulator's performance will provide the APVMA Board and Management with a clear metric on whether the agency is effectively identifying and seizing the strategic opportunities available to it to create and deliver maximum public value.[4] It would create the imperative to examine what management initiatives are available that would deliver on-time regulatory assessment in a manner that does not detract from the necessity of also delivering against the APVMA's other regulatory functions. Options already available to the APVMA include the enhanced use of regulatory technologies, such as computer aided decision making and an improved integration of independent experts into the APVMA's assessment pipeline as external scientific reviewers. Likewise, the APVMA should be actively looking to the opportunities that could be created by utilising new scientific methods to support the delivery of consistent, accurate and transparent regulatory assessments in reduced timeframes.

The experience of other regulators, such as Food Standards Australia and New Zealand (FSANZ) and the Office of the Gene Technology Regulator (OGTR), which target and routinely deliver against a target of 100 per cent on-time assessment performance, demonstrates the opportunity for the APVMA to enhance its delivery of public value.

Measure 3

CropLife has serious concerns with **Measure 3:** *The number of Proposed Regulatory Decisions and Final Regulatory Decisions for chemical reconsiderations that are released within the reporting period*. This measure is not commensurate with a risk-based chemical review program and does not allow the measurement to capture the responsive nature of Proposed and Final Regulatory Decisions. As such, it cannot be supported. A more appropriate measure would focus on the achievement of risk-based outcomes. For example:

- The number of decisions that are released in accordance with the timeframe specified in the workplan; or
- In cases where the APVMA are made aware of information that compromises satisfaction in the statutory criteria, the speed of action taken to take corrective action.

[4] John Braithwaite, 'Responsive Excellence', a paper prepared for the Penn Program on Regulation's Best-in-Class Regulator Initiative (June, 2015). Available at https://www.researchgate.net/publication/304570291_Responsive_Excellence

Measure 4

Measure 4: is generally supported, however, we suggest that the measure be slightly reworded, for clarity, to "*the proportion of serious adverse experience reports assessed by the APVMA within 20 business day* ***of being received***".

Support a contemporary regulatory system

CropLife is supportive of the objectives within this pillar, with the caveat that the Department of Agriculture, Fisheries and Forestry (DAFF) is the responsible agency for the development of policy on behalf of the Australian Government. Support for science and rules-based trade are imperative for the economic sustainability of Australian Agriculture. The participation of and contributions by Australian experts in international fora are critical to achieving these outcomes. Three of the 20 Experts on Pesticide Residues (2020-2024) at the UNFAO Joint Meeting on Pesticide Residues are Australian, demonstrating Australian commitment to science-based trade. CropLife is supportive of this active participation in discussions at both domestic and international fora.

Measure 5

Measure 5*: The number of compliance activities, recalls and/or other regulatory actions the APVMA undertakes, including those with State and Territory partners*, is not a risk outcomes-based metric. As such this measure is not supported. Consistent with this submissions feedback on other measures, this should be captured as an assessment of responsiveness. We suggest that it be rephrased to *the number of compliance activities, recalls and/or other regulatory actions the APVMA undertaken, including those with State and Territory partners that require action, and a percentage of how many of these were resolved*. A register of these requests could then be implemented to support this measure.

CropLife action and advocacy over the past decade has resulted in the APVMA being vested with new and effective compliance and enforcement capabilities. The flow of illicit and counterfeit chemicals, both realised and potential, can now be addressed by APVMA compliance action. Further action by CropLife resulted in the *Agricultural and Veterinary Chemicals Code (Conditions of Approval or Registration)* Order 2021, when CropLife made the Regulator and AgVet Policy Branch of the Department of Agriculture, Fisheries and Forestry aware of a potential threat to the integrity of the regulatory system in Australia. However, despite several instances of the regulator being made aware of unlawful manufacture and supply of chemicals, no action has been taken.

The publicly available register suggested above would capture such instances and force the APVMA to be transparent and accountable in the adjudication of misdeeds that threaten to undermine the integrity of the regulatory system.

Measure 6

CropLife supports **Measure 6**

Measure 7

Measure 7. *The cumulative amount of time saved in application assessments by using international assessments* could be bolstered to include an analysis of time savings not just by using international assessments, but identification and elimination of regulatory overlap between Australian regulators as well.

Building foresight capability

CropLife supports these objectives as written, particularly the commitment from the Regulator to harness and engage the expertise contained within the regulated industries. Clear and effective communication with industry will enable the APVMA to understand and enable rapid response to emerging trends potentially impacting on agvet chemical regulation.

Measure 8

As such, **Measure 8** is supported with the same caveat as Measure 1; care must be taken in the interpretation of these results to ensure the APVMA remains focussed on the task of facilitating predictable and timely access to agricultural chemicals.

Measure 9

Measure 9, *The proportion of externally validated evaluations of the APVMA's scientific capability that pass quality and performance criteria*, is strongly supported. Independent, impartial and external validation is an important aspect of regulatory self-evaluation.

Measure 10

Measure 10 is supported, as an entirely appropriate measure supporting the objectives of building foresight capacity.

Striving for operational excellence

Recognition that the APVMA plays a critical role in ensuring Australians have access to safe and effective agricultural chemicals is the cornerstone of operational excellence and reflects adherence to the principles put forward in the Agvet Code. Facilitating access to the innovations of the plant science industry helps ensure the future economic viability and competitiveness of primary industry, which relies on access to agricultural chemicals.

Measure 11

Measure 11: *The APVMA Regulatory Achievement score is at or above the target* is not supported. We do not support the use of aggregate or composite measures such as the proposed Regulatory Achievement Score. While we acknowledge the intent to create a high-level proxy for overall performance, the aggregation of distinct metrics into a single score can obscure important variation between individual assessment areas. This approach risks masking underperformance in critical sections and unfairly diminishing the recognition of areas where the APVMA is performing well.

In particular, the current weighting system allows poor results in one component (e.g. timeframe performance) to disproportionately impact the overall score, even when other components (e.g. quality audits or timely regulatory activities) are meeting or exceeding expectations. This can distort both internal accountability and external perceptions of performance

Measures 1, 2, and 3 can be reported and assessed independently. This allows for clearer, more transparent insight into how the APVMA is tracking against each of its key regulatory functions, supports more targeted performance management and avoids the pitfalls of oversimplification inherent in composite metrics.

If a summary measure is required for high-level reporting purposes, it should be clearly positioned as supplementary and not a substitute for detailed reporting against each discrete measure.

Measure 12

Measure 12 is supported.

Attracting, developing and retaining talented people

CropLife supports the strategic objective of ensuring the APVMA has an eco-system of talented people and expertise available to it as part of delivering an efficient and effective regulatory system. In particular, the recognition of the important role external scientific reviewers (ESRs) play in providing capability to the APVMA as it seeks to deliver the statutory objectives of the agvet chemical regulatory scheme is commendable. The development and design of measures that support management approaches to the use of ESRs is an important step toward harnessing the capacity of the full regulatory eco-system towards this objective.

As part of this effort, CropLife also encourages the APVMA to implement the recommendations of the *Independent Review of Assessment Performance* delivered by the Reason Group in December 2017 that enhance the efficient and effective use of ESRs.

Measure 13

Measure 13 is supported

Measure 14

Measure 14 is supported. Each of the sub-measures ((a), b), and c)) should be reported separately.

In addition, sub-measure b) should also be expanded further to include a measure of the timeliness of external assessments to accompany the indicator of quality. This could be achieved by adopting the proposal included below:

b) *the proportion of draft technical reports from ESRs that are accepted by the APVMA without significant rework, and received within the contracted timeframe*

As such, in addition to effective cost analysis, analysis of efficiency improvements can be better communicated to industry, users and registrants.

As above, if a summary measure is required for high-level reporting purposes, it should be clearly positioned as supplementary and not a substitute for detailed reporting against each discrete measure

2. Conclusion

CropLife welcomes the opportunity to work with the APVMA in the development and execution of this expanded Strategic Plan. As we noted in response to the October 2022 *Draft Australian Pesticides and Veterinary Medicines Authority (APVMA) Strategy* the APVMA should include communication, support and explanation of regulatory processes and decisions as part of their role. Part of being a trusted regulator is proactively responding to community concerns and demonstrating the rigour of the system. This is particularly relevant as anti-science activists continue to hijack public attention with misleading, misrepresented, or outright false assertions about the activities and rigour of the APVMA.

CropLife is pleased that the APVMA has committed to developing this strategic plan, with the overarching intent of ensuring Australians continue to have access to safe and effective agvet chemicals.