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Draft Report of the Independent Review of the Agvet Chemicals Regulatory System

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Independent Review Panel

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Foreword

This draft report provides stakeholders with the opportunity to review the Panel's proposed holistic reform package.

The draft report contains background, rationale and proposals that will form the basis of the Panel's final report to Government. The Panel considers that this reform package, if implemented in full, will deliver a modern, fit-for-purpose regulatory system for the foreseeable future. The Panel also considers that the reform package enhances human and animal safety whilst also providing increased access to safe and innovative pest and disease management options for users, including primary producers, veterinarians, environmental managers and other users of pesticides and veterinary medicines.

The package of newly designed reforms significantly changes the regulatory arrangements of the current system by embracing and leveraging modern practices and obligations, being increasingly adopted by other domestic regulatory systems and international jurisdictions. This is designed to bring the current regulatory system into the modern era where responsibility can be shared among different players within the system according to their expertise.

The Panel understands that great change can be daunting, especially for those directly impacted, and that often the easiest path is to maintain the status quo or select a few 'easy wins'. Having listened to stakeholder feedback, the Panel is of the strong view that these reforms are not only long overdue but essential for Australia's food chain supply safety, sustainability and competitiveness now and for the future.

I would like to extend a warm thank you to the many people, businesses, corporations and organisations that have freely and candidly contributed to this review and generously provided their time to meet with the Panel, provide submissions or in many cases, both. Your advice and insights have been invaluable, and you can be assured they have helped shape the policy reforms presented in this draft report.

The Panel looks forward to hearing further from stakeholders as we continue to progress this review.

Ken Matthews AO

Chair

Independent Review Panel

December 2020

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Origins of the review

First principles review

On 5 September 2019, Senator the Hon. Bridget McKenzie, the then Minister for Agriculture, announced a comprehensive first principles review of the regulatory framework for agricultural and veterinary (agvet) chemicals. The review was to examine the agvet chemicals regulatory framework's aims, structure, and operation, and make recommendations to ensure it is contemporary, is fit for purpose and reduces unnecessary red tape.

The review has been conducted by an independent panel with expertise in regulation, agricultural production, veterinary science, and public health (the Panel). Terms of reference for the review were released with the Minister's announcement (Annex 1). The Panel will deliver its final report to the Minister for Agriculture, Drought and Emergency Management no later than May 2021.

In undertaking the review, the Panel has:

- undertaken extensive consultation with a broad range of stakeholders from government, industry (manufacturing, importers and suppliers, chemicals users, veterinarians, and farm businesses), and non-government organisations
- assessed the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
- considered the vision for and objectives of Australian agvet chemicals regulation
- examined opportunities for reform across the whole of the regulatory system, including at the interfaces between agvet chemicals and other regulatory systems, while not recommending changes to regulatory systems outside the Terms of Reference for this review
- considered the current and future requirements of Australia's regulatory framework for agvet chemicals
- provided recommendations for reform of the regulatory framework to increase the value of Australian agriculture and allow Australia to remain competitive in global markets, while ensuring the safety of humans, animals, and ecosystems.

This first principles review is an opportunity to make fundamental changes throughout the regulatory system and boost timely access to innovative and safe pesticides and veterinary medicines. Balancing access to safe chemicals with the vital community objectives of health, safety, and environmental protection is vital for supporting sustainable agriculture – benefiting primary production, management of the environment, veterinary care (including animal health and welfare), trade, and the community.

In addition, the review provides an opportunity to deliver on the Australian Government's commitment to reduce unnecessary regulation to improve the processes for demonstrating compliance with agreed safety standards while retaining system integrity.

This draft report presents the Panel's view on the extent of reform required to truly modernise the regulatory system and as such it provides substantial recommendations for improvement to the current system (a full list of the recommendations is at Chapter 8). A first principles review by its very nature was always going to result in suggestions for significant change of a system nearly 30 years old.

Factors guiding the Panel's recommendations

The Panel is committed to delivering recommendations which provide meaningful improvements to bring the regulatory system into the modern era and ensure it is fit-for-purpose now and into the future. Key factors that have influenced and underpinned the Panel's approach to considering the regulatory framework from first principles include:

- The need to maintain and enhance health, safety, ~~and~~ environmental protection and animal welfare.
- The speed at which the world is changing – expectations of what constitutes a modern responsive regulatory system have been rapidly evolving and the science and technology associated with pesticides and veterinary medicines continue to advance.
- Upholding social licence and trust in the regulatory system – community perceptions of chemical use continue to become more demanding, as do our trading partners' attitudes and expectations of our treated commodities.
- Australia's small market share – the relatively small size of the Australian pesticide and veterinary medicine market mean that producers have access to only a fraction of the chemical uses available to their overseas competitors. Innovative thinking is necessary to find ways to counter this significant hurdle to competitiveness.
- Reducing unnecessary red tape – there are significant opportunities to streamline the framework and reduce red tape that should be embraced.
- Shared responsibility – co-regulation is being increasingly adopted in modern regulatory systems and provides for greater accountability on all parties within the system.

Commented [SPE1]: This will be developed further elsewhere, but the social licence and trust of the veterinary profession is, at least in part, founded on the knowledge and experience of veterinarians to select and use veterinary medicines that can be expected to be effective and safe. If medicines do not work as they are claimed to work, the veterinary profession would lose faith in the regulatory system. If such registered medicines with unproven effectiveness were used in the animals that veterinarians care for, then veterinarians would potentially be in breech of their Code of Professional Conduct, unless they explained to their clients that the registered medicines had not been registered as effective and received informed client consent to use these registered medicines.

Consultation process

Given the comprehensive nature of the review it was critical for the Panel to engage with as many stakeholders as possible. The Panel has consulted broadly and meaningfully to seek diverse feedback on ideas for reforms. The Panel initially convened and met with a special purpose Consultative Committee, comprising a broad range of stakeholders with diverse backgrounds. The consultation process involved meetings with 188 stakeholder groups, mostly via COVID-safe videoconference (see Annex 2). In addition, the Panel had early discussions with state and territory governments through the Harmonised Agvet Chemical Control of Use Task (HACCUT) network.

As the national regulator for the registration of pesticides and veterinary medicines in Australia the Panel recognises the Australian Pesticides and Veterinary Medicines Authority (APVMA) as an internationally respected regulator and a key player within the system. Given the importance of the APVMA's role, the Panel met with the CEO and senior officers multiple times, including face-to-face meetings in Canberra and Armidale (pre-COVID) which provided the opportunity for staff to contribute meaningful input to the Panel's deliberations.

The Panel were pleased that user groups, community groups and many chemical companies and other industries (e.g., chemical applicators) were very open and eager to consider change and offered valuable ideas for reform. However, of all the stakeholder feedback, the Panel was surprised that the key regulators, the APVMA and the states and territories, appeared most reluctant to genuinely consider or explore meaningful changes to the current system.

This report

The Panel is convinced that some far-reaching changes are necessary to deliver a responsive and adaptive future regulatory system. This draft report explores the Panel's thinking and explains its recommendations in depth. The Panel is interested in receiving stakeholder feedback on the recommendations in this draft report, prior to issuing its final report in May 2021.

As part of redesigning the scope of the future regulatory system the Panel has moved away from the current terminology of 'agricultural and veterinary chemicals' as this no longer reflects the current products or changes proposed. The new terminology adopted by the Panel is 'pesticides and veterinary medicines'. To avoid confusion in this report the Panel has chosen to refer to both the current and future system using this new terminology 'pesticides and veterinary medicines'.

It is important that stakeholders understand the likely indicative impacts on the regulatory costs of the system from the Panel's recommendations. The Panel considers this understanding will aid stakeholders in considering the reforms at both a conceptual and practical level.

Reducing regulatory costs has not been the key determinant of the Panel's recommendations. Rather, the Panel has been committed to ensuring the safety of humans, ~~animals,~~ ecosystems, and trade and the safety and welfare of animals ~~from~~ when ~~the use of~~ pesticides and veterinary medicines are used. However, in designing proposals to improve the regulatory system the Panel has identified numerous opportunities for both improved regulatory efficiency and more effective use of resources.

The Panel has conducted a preliminary exercise to estimate the impact on regulatory costs. Full implementation of all recommendations would represent over $160 million in reduced regulatory costs over 10 years. These estimates are very conservative and do not take into account the flow-on benefits to users, for example the benefits to farmers from increased access to a wider range of chemical uses, to name but one benefit. A summary of the estimated impacts on regulatory costs from the Panel's key reforms is included at Table 1.

The Panel acknowledges the costing estimates undertaken is not a regulation impact statement and therefore has not been subjected to the formal requirements of the Australian Government Office of Best Practice Regulation. The regulatory cost impacts of the Panel's recommendations are presented as a guide only to support stakeholder consideration. This reports only considers the direct changes in costs that industry (chemical manufacturers, suppliers, or fee for service users) would experience. The Panel did not include the value of any benefits that may accrue from reform. The Panel recognises that many of the recommendations would have significant direct and indirect benefits (separate to the changes in regulatory costs) to industry and the community, contributing to the improved outcomes from the reforms (i.e., exceeding the $160 million return over a decade).

Table 1 Key regulatory costs and savings that impact industry

Reform	Regulatory saving/cost (+/-) (10 years)	Benefit to Australia
Improved control of use (single national law)	$75 million	Nationally consistent approach to the use of pesticides and veterinary medicines. Reducing the administrative burden associated with multiple jurisdictions/systems and complexity in government interactions. Increasing mobility of the professional workforce by allowing cross-border activities under a seamless national licensing scheme.
Compliance and Enforcement resources to support a single national law	-$37 million	A nationally consistent approach to control-of-use providing transparency and predictability across the life cycle of the product.
Refocused scope of regulation – reduced scope of applications	$48 million	Providing faster access to products through reduced processing times. Targeting regulatory effort towards products that pose a measurable risk to the health and safety of humans, animals, plants or ecosystems, or prejudice to trade.
Improved access – improving access to international registered products	$55 million	Earlier access to high quality and safe internationally registered products, allowing Australian primary producers to compete with their international counterparts. Providing end users greater product choice and use, reducing commercial barries and improving resilience in supply chains.
Improving resilience in the supply chain	$40 million	Improved accessibility to active constituents and increase competition by encouraging new sources of active constituents. Providing flexibility of active constituent sources for manufacturers of pesticides and veterinary medicines, improving the resilience of chemical supply in the face of potential disruptions and competition.
International alignment of veterinary manufacturing standards (Pharmaceutical Inspection Co-operation Scheme – PIC/S)	-$16 million	Aligning Australian manufacturing standards with international manufacturing standards to facilitate more efficient and effective export.

Note: This table highlights the major costs and savings associated with the key elements of the Panel's proposed reform package but not all savings and costs that contribute to the overall amount of over $160 million (see Annex 4 for this detail).

Commented [SPE2]: More efficient and effective export may be a benefit to a small minority of companies with manufacturing licenses.

The Panel has relied on a range of assumptions, informed where possible from contemporary data. Regulatory cost impacts are presented both annually and as a 10-year projection, in line with the Panel's 30-year vision for the future regulatory system.

The regulatory costings exclude government funded activities as this represents no cost to industry. In general, the regulatory cost impacts sections of this report do not consider the potential to redirect resources within agencies where regulatory savings or increased efficiencies could be found, this has only been identified in a couple of measures.

Executive Summary

Pesticides and veterinary medicines (currently referred to as agricultural and veterinary (agvet) chemicals) play a fundamental role in weed, pest, and disease control. These are critical to agricultural productivity and competitiveness of Australian primary production, significantly contribute to environmental sustainability, and play a key role in animal health and welfare and via ownership of companion animals play a key role in human health and welfare. Effective pest and disease management in plants and animals (in production systems, our homes, and gardens, and through environmental management) improves Australia's social and economic wellbeing.

However, many pesticides and veterinary medicines are inherently hazardous, and the Panel recognises there can be detrimental effects of chemicals in general on human, animal, and environmental health worldwide. Consequently, the exposure of people, animals, plants, and the environment to these products requires robust, evidence-driven regulation, grounded in the principles of risk assessment, communication and management.

The Panel has conducted a comprehensive, first principles review of the current regulatory framework for pesticides and veterinary medicines in Australia. The Panel considers the key priority of the future regulatory system is protecting the health and safety of people, animals, plants, and ecosystems while also supporting pest and disease management in Australia through increased access to safe and effective pesticides and veterinary medicines.

The world has moved on since the inception of the National Registration Scheme in the early 1990s. The regulated industry (manufacturing, supply, and user industries) has changed significantly with greater professionalism and stewardship and a stronger commitment and capacity to meet and maintain international standards. The Panel considers that, over the decades, there has been an increasing commitment from Australian industries to manufacture and supply safe and suitable pesticides and veterinary medicines and to take more responsibility for the products they provide.

Looking to the future, the Panel can foresee industry exercising greater responsibility and accountability for managing the safe manufacture and use of these products in line with modern regulatory theory. This presents opportunities to further strengthen the system.

Community expectations have also changed and there is a greater awareness and understanding of the potential impact from the misuse of pesticides and veterinary medicines and a greater desire to know the provenance of food and how it has been treated. The general public expects, as it should, that people, animals, and the environment are suitably protected from harm from the use of these products.

By global standards, the Panel recognises that Australia is a relatively small market for pesticides and veterinary medicine products. A lack of access to safe and effective products and their uses places Australian primary producers at a competitive disadvantage in comparison to their overseas competitors. It also restricts access to the most advanced alternatives to current pesticide and veterinary medicine products, many of which can be less harmful to the environment or pose lower hazards to users or which provide better animal health and welfare outcomes.

One of the Panel's key reform proposals, **the licensing of the supply of internationally registered products into the Australian market** (see Chapter 5) will go a long way to addressing the small market size and associated lack of access to chemicals and their uses.

The Panel considers that the future regulatory system must be risk-based, with a strong emphasis on safety and effectiveness whilst being agile, innovative, and open to new approaches. All parties involved need to play their full part in strengthening the system as a whole. A modern attitude to regulating pesticides and veterinary medicines is required to deliver the expectations of all Australians into the future. Regulatory models have been evolving and the Panel is of the strong view that the future regulatory system needs to embrace these new approaches, including focusing on stewardship and co-regulation to ensure those best placed to manage risks take on that responsibility.

Improving access to safe and effective pesticide and veterinary medicine products and uses will be important to assist Australian primary producers to successfully compete with their international counterparts. This will also assist in achieving the Government's plan to support industry's target to achieve a $100 billion agriculture sector by 2030.

In order to create a nationally consistent and contemporary regulatory system for pesticides and veterinary medicines in Australia, and give effect to the first principles review, the Panel is recommending the following:

- A national regulatory identity to deliver **harmonised and consistent control-of-use** regulation (see Chapter 2):
  - Significant improvements to control-of-use regulation for pesticides and veterinary medicines is required in Australia. Throughout the review process, the Panel has heard, almost unanimously from stakeholders, that the biggest failing of the current regulatory system is the lack of national consistency in control-of-use functions.
  - The Panel recommends establishing a single national law, administered by the Commonwealth, that will see the Commonwealth take responsibility for both the supply and use of pesticide and veterinary medicine products.
  - A single national law will significantly improve protections for all Australians, by ensuring consistent and effective regulation of the full life cycle of pesticides and veterinary medicines.
  - It will improve clarity and responsibility, reduce inconsistencies, and mitigate duplications to deliver benefits to all users particularly primary producers, veterinarians and land managers.
- A **single, national centre** within the Department of Agriculture, Water and the Environment (the Department) to establish leadership, accountability and transparency (see Chapter 2):
  - The Panel identified that the current regulatory system as a whole lacks leadership, accountability, transparency, and a clear focal point. To address this, the Panel recommends establishing a Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner). The Commissioner will provide national policy leadership, accountability and guidance for Australia's pesticides and veterinary medicines (for production animal species as well as the vast number of non-production animal species) regulatory system.

  - As community concern about aspects of the use of pesticides and veterinary medicines increases, strong leadership and meaningful engagement is needed to maintain community and market confidence while continually adapting the system to address future needs.
  - The Commissioner will be required to report to parliament to demonstrate that the entire regulatory system is operating effectively, and problems are identified early. It is vital that there is oversight of the future regulatory system to strengthen accountability and transparency, increase public confidence, and maintain social licence.

Commented [SPE3]: The AVA recommends regular audits of the effectiveness and productivity of the office of the Commissioner.

- Increased protection for the **health and safety** of people, plants, animals, and the environment (see Chapter 3):
  - Modernisation of Australia's regulatory system is required to provide a comprehensive and contemporary surveillance system to allow increased awareness and understanding of ~~chemical~~ the use of pesticides and veterinary medicines and their~~its~~ impacts in Australia.
  - The Panel recommends a sophisticated surveillance system to collate and analyse a range of data. This should include adverse product quality and performance experience reports, and information gathered through residue monitoring programs for domestic produce and the environment.
  - The Panel recommends improvements to the speed and transparency of chemical reviews (currently known as chemical reconsideration) to ensure the continued protection of human, animal, plant, and ecosystems safety.
  - Safeguarding animal health and welfare is an objective of the future system, and as a result the Panel also recommends the incorporation of a humaneness score on labels of vertebrate pest control products to inform consumers of animal welfare implications of product selection and use.
- **Responsible and considered use** of pesticides and veterinary medicines (see Chapter 4):
  - All individuals and entities that interact with pesticides or veterinary medicines, from design to disposal, should deal with them in a considered and responsible manner to prevent harm to humans, animals, plants, or ecosystems.
  - To this end, the Panel recommends general product obligations are introduced to provide the basis for a preventative and performance-based regulatory system. All users will have an obligation, tailored to their specific situation, to ensure their dealings with pesticides and veterinary medicines are safe and effective and do not prejudice trade.
  - Well trained and competent users reduce the risks associated with chemical use. The Panel recommends greater use of high quality, nationally consistent, risk appropriate and competency-based training for a range of users, leveraging suitable industry accreditations where possible.
  - The Panel recommends that responsible and considered use, delivered through a nationally consistent control-of-use model, is supported by licensing of select activities directly associated with pesticides and veterinary medicines in Australia.
  - Further, to support safe and responsible use, the Panel recommends improvements to product labelling to accommodate future technology advancements whereby smart labelling will improve access to tailored information.

- The Panel recommends improvements to the manufacture and use of compounded ~~(bespoke)~~ veterinary products by increasing reliance on good compounding practice for ~~and~~ veterinary medicines (GCPvet)~~practice~~.
- Additionally, to reduce harm to the environment, the Panel encourages the continuation and expansion of product stewardship schemes.

- **Innovative approaches to improve access** to safe and effective products (see Chapter 5):
  - Access to a diversity of safe and effective pesticide and veterinary medicine products provides all Australians with flexibility to manage pests and diseases and use products that best suit their unique situation. Alternatives to existing products may offer lower impacts on human and animal health and ecosystems and may allow for improved resistance management or more innovative practices.
  - To improve access the Panel recommends an innovative licensing arrangement to provide an alternative regulatory pathway to products already registered by a comparable international regulator. This would allow a licensed entity to supply an internationally registered product in Australia without the need for registration in Australia. The entity must, however, address the risks associated with the use of the product and undertake measures to address any unique Australian circumstances. The Commissioner will be responsible for the licensing program and reviewing the measures proposed to manage risks.
  - The Panel considers this dual control approach (overseas registrations and local risk management plans) will allow concurrent launching of new products in overseas and Australian markets, providing Australians ~~producers~~ with equivalent access to their international counterparts.

- **Streamlining access** to safe and effective pesticide and veterinary medicine products (see Chapter 5):
  - The Panel recommends a number of additional measures to improve access, including regionally targeted controls rather than jurisdictional borders to consider chemical uses and, prioritisation of assessment by the APVMA for products that offer significant benefits to the Australian market. Separately, where risks can be adequately managed, the Panel recommends the APVMA consider the benefits of a pesticide or veterinary medicine if an application for product registration reaches the point of refusal.
  - To streamline processes and better target regulatory effort the Panel recommends refocusing the regulatory scope. The future regulatory system will provide for a 4-tiered approach to registration, based on risk, and a greater use of standards to effectively target assessment of resources on products of higher risk while supporting safety. This will ensure the level of regulatory intervention directed toward a product is commensurate with the risks needing to be managed.
  - The Panel recommends broader and more transparent exemptions powers apply to consolidate the existing permit scheme and current exemptions into a simpler, single modern exemption scheme.
  - To support biological based pest and disease management products, the Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

Commented [SPE4]: This must apply to production and non-production species. Having said that, the AVA is aware that for veterinary medicines there is already a process of overseas data recognition by the APVMA and products are already being reviewed and approved on the basis of overseas regulatory review.

- An **adaptable and resilient** regulatory system in the face of unexpected change (see Chapter 6):
  - Disruptions to markets occur globally and within Australia. While the pesticides and veterinary medicines regulatory system cannot, of itself, prevent disruptions, the Panel considers it important that the system does not create unnecessary barriers to supply continuity and improves resilience where possible.
  - In light of this, the Panel has examined opportunities for improving access to active constituents (the key substance within a pesticide or veterinary medicine which is primarily responsible for the product's effect). The Panel recommends replacing source specific approval of active constituents with a standards-based approach to remove unnecessary regulatory barriers, provide flexibility, and increase competition.
  - The Panel also recommends adoption of international standards, such as those for the manufacture of veterinary medicines. Such standards can reduce costs and increase opportunities for Australian manufacturers to access international markets.
  - Finally, the Panel sees opportunities to better support entry to the market, by pre-application third-party assessment, which would also expand the skills base in Australia for assessments beyond the APVMA. This will not only build resilience throughout the regulatory system due to a broader pool of skilled assessors, but also the supply chain.
- Improved transparency and equity by **modernising cost recovery** (see Chapter 7):
  - In the Panel's view, reforming cost recovery arrangements is a critical requirement if the total reform package of the first principles review is to be implemented successfully. The Panel considers the current cost recovery arrangements are not sustainable, with existing activities (e.g., control-of-use, chemical reviews, compliance, and enforcement) not adequately resourced.
  - The Panel has determined high-level, principles-based recommendations about how to fund various components of the system. The co-regulatory approach recommended by the Panel will substantially minimise costs to both the regulator and users. Nevertheless, there will be costs associated with control-of-use activities that will need to be resourced.

The Panel's recommendations aim to build and maintain a resilient, and effective pesticides and veterinary medicines regulatory system that is~~f~~ fit for the future. In making its recommendations, the Panel has considered how to optimise regulatory efficiency, and take best advantage of opportunities for streamlining the system. Overall, the Panel estimates its recommendations will provide a conservative saving of over $160 million across all pesticides and veterinary medicines industry sectors over 10 years, with these savings to be ongoing and likely to increase overtime as the proposals are fully embraced.

The Panel has heard of and identified significant problems in the current system. It considers the status quo is untenable. It is not a question of whether change is needed but when to change. In the Panel's opinion the report and its 139 specific recommendations (see Chapter 8) represent the best path forward. The Panel recognises the diversity of views within Australia on pesticides and veterinary medicines, but a national system that is adaptive, evidence-driven, engages all parties, and is safety focused, is a system that will maintain the trust of the Australian community and become an asset for Australians in the future.

1 Introduction

1.1 The role of pesticides and veterinary medicines in supporting agriculture and veterinary medicine ~~and~~ while protecting the environment

Pesticides and veterinary medicines play a fundamental role in Australia's social and economic wellbeing and are critical to agricultural productivity and competitiveness. They play a key role in animal health and welfare and significantly contribute to environmental sustainability through weed, pest, and disease control.

However, their contribution to Australia's safe, clean food supply chain is often misunderstood. Heightened consumer concerns and expectations about provenance and the traceability of food supply chains have increased demands for greater transparency about pesticides and veterinary medicines and their use. There has been an increasing diversity of views and debate about the use of pesticides and to a lesser degree, veterinary medicines in food production. The result has seen a sharp divide in parts of the community, with some recognising and valuing the benefits of these chemicals in contributing to safe and reliable food supply while others perceive that most pesticides are toxic, harmful, and damaging to humans, animals, and the environment.

While these perceptions need to be acknowledged respectfully, and evidence of harm investigated thoroughly and transparently, so too does the critical importance of pesticides and veterinary medicines. These products are a vital tool for everyday use across multiple industries that, when employed in the manner approved, enable users to:

- eradicate or control pests and diseases in domestic environments to ensure public health and safety
- manage the health and welfare of ~~our pets,~~ livestock, ~~and other~~ companion animals and the vast numbers of other animal species (including fauna) cared for my veterinarians
- safely control pests and diseases that may otherwise impact our food supply and damage agricultural, fishery and forestry production and our natural environment.

The Panel considers the benefits of having access to a broad range of pesticides and veterinary medicines are clear. They include, but are not limited to – improved quality and safety of produce and less food wastage due to pest damage; increased agricultural productivity; better animal health and welfare outcomes through prevention and treatment of disease and other ailments; reduced damage to the environment from feral animals; control of pest and animal diseases in the community, some of which could have significant human health implications; and protection of native flora and fauna through invasive pest and weed control.

> *"It is acknowledged that Agvet chemicals play a vital role in supporting sustainable agriculture with resulting benefits to primary production, veterinary care, management of the environment, and the broader community."* (Queensland Department of Agriculture and Fisheries 2020)

> *"Agvet chemicals are important not only to primary production, but also for other non-urban land management, particularly for the control of invasive pest species."* (National Farmers' Federation 2020)

Notwithstanding these benefits, there is no doubt there can be significant detrimental effects on humans, animals, and the health of ecosystems due to the improper use of pesticides and veterinary medicines. A modern and effective regulatory system must strike a balance between the recognised benefits of pesticides and veterinary medicines while protecting against their adverse impacts.

Community, consumers, and industry expectations about the use of pesticides and veterinary medicines have evolved over time. Globally, there is heightened awareness by all, including most producers, of chemical use and its possible impacts on the community, on the food we consume, and on the environment.

> *"The adverse effects of pesticides on the people who use them, workers, and communities – as well as the environment – is now recognised globally as an issue of significant concern. In 2015, the Fourth International Conference on Chemicals Management (ICCM4) formally recognised highly hazardous pesticides as an 'issue of concern'."* (National Toxics Network 2016)

Pesticides and veterinary medicines are part of a range of critical tools for effective management of Australia's natural environmental assets, particularly in controlling invasive weeds, feral animals and disease outbreaks in native flora and fauna. The management of weeds alone imposes an overall estimated average cost of more than $4.8 billion annually across Australia (McLeod 2018). This cost does not include estimates of non-market values associated with losses of biodiversity or environmental degradation as the result of weed infestation.

The financial impact of competitive weed infestations for primary producers is multifaceted as they affect yield and production management systems across all seasons and sectors and sometimes also affect crop price. In addition, changes in weed types and their characteristics, such as herbicide resistance, require the ongoing adaptation of weed management strategies. In 2016, it was estimated that weeds were costing Australian grain growers $146 per hectare in expenditure and losses (Llewellyn et al. 2016).

Feral and pest animals can also cause significant damage to crops and seriously affect Australia's livestock industries by preying on stock, transferring disease and competing for pasture. A conservative estimate places the economic impact of pest animals in Australia, particularly in agricultural systems, at between $720 million and $1 billion annually, in production losses and public and private management costs (Invasive Plants and Animals Committee 2016).

Biosecurity controls at Australia's borders minimise the risk of exotic pests and diseases entering Australia. An ABARES analysis found that without Australia's current biosecurity system, annual average broadacre individual farm profits would be an estimated $12,000 to $17,500 lower due to the higher risk of foot and mouth disease, Mexican feather grass and Karnal bunt outbreaks combined (Hafi et al. 2015). This may represent approximately 10% of a broadacre farm profit, as in 2019/2020 the average farm cash income for broadacre farms in Australia was $153,000 per farm (Martin & Topp 2020).

A range of risk mitigation strategies have been developed and are now in place to prevent pests and diseases of biosecurity concern from entering and establishing in Australia. Among those strategies is the offshore treatment of goods, animals, and animal products with pesticides and veterinary medicines to prevent the introduction of unwanted pests and diseases. Pesticides and veterinary medicines also play a key role in managing pest and disease incursions in Australia both at, and post, the Australian border such as through fumigation, insecticide treatments and vaccinations.

The Panel was informed during its stakeholder consultations that pesticides are also an important tool, albeit used sparingly, for the forestry industry particularly early in the planting cycle.

> *"… Pesticide use in plantation forestry is largely constrained to herbicide and insecticide application in the first two years following planting whilst the trees are established. Unlike agriculture, chemicals are rarely used in forestry thereafter as they are applied once or twice to an area every 10 to 30 years rather than annually, unless required in insect break-out situations, for example, that only then may be similar to that for agricultural insect break-outs."* (Forest Pest Management Research Consortium 2020)

Pesticides and veterinary medicines are vital for Australia's agricultural exports (valued at $54 billion in 2018). International trading partners have restrictions on the presence of certain chemical residues in agricultural imports and improper use of pesticides and veterinary medicines used in agricultural systems can jeopardise Australia's international trade and market access.

Overall, pesticides and veterinary medicines play a critical role in human and animal safety and welfare, environmental and ecosystems management, and Australia's agricultural production. A future pesticides and veterinary medicines regulatory system must meet the community's expectations of protecting the environment and human and animal health and welfare, while enabling our primary producers to remain internationally competitive.

In this report, the Panel has sought to develop a regulatory system for Australia's future that delivers both safety and access to ~~chemicals~~pesticides and veterinary medicines. The system needs to support innovation and grow our national capacity to manage the use of ~~chemicals~~ these products responsibly. It needs to respond to the requirements of ~~chemical~~ pesticide and veterinary medicine users while at the same time building public confidence and supporting the social licence to continue to use ~~chemicals~~pesticides and veterinary chemicals. Our future regulatory system should nurture Australia's reputation as one of the global leaders in food safety, animal health and welfare, and environmental stewardship.

1.2 Drivers for change and the need for improvement

The regulatory controls for pesticides and veterinary medicines in Australia have not changed significantly since the inception of the National Registration Scheme for Agricultural and Veterinary Chemicals in the 1990s. While the establishment of a single national system for the registration of agricultural and veterinary medicines was a significant improvement over the previously separate systems in each state and territory, regulatory arrangements have not kept

pace with changes in consumer, and community expectations, technology, business structures, and the needs of agricultural and veterinary stakeholders.

Primary producers are increasingly adopting scientific and technological developments to maximise their productivity, corporate accountability, product stewardship, and to maintain their social licence. There is less reliance today on unskilled farm labour inputs, and a correspondingly greater reliance on the advice and services of skilled professionals including agronomists and contract sprayers.

Australia's domestic chemical manufacturing industry has developed to specialise in market niches, with Australia also reaping the benefits of advanced research, and large-scale offshore manufacturing available through globalised supply chains.

Speedy and inexpensive access to information provides the community with unprecedented opportunities to seek knowledge about what is in their food, how and where their food and fibre is produced, or where there may be human health, animal welfare or environmental issues. As a result, chemical suppliers and users face increasing pressure to be accountable for how pesticides and veterinary medicines are produced, distributed, used, and disposed of.

Over the decades since the introduction of the National Registration Scheme, at least 24 reviews into pesticides and veterinary medicines regulation have been conducted (see Annex 3) and approximately 22 substantive amendments have been made to primary legislation plus numerous smaller changes and regulation amendments. However, these incremental and issue-by-issue changes have not generally addressed the fundamental recurring concerns about the current system, and many of the changes proposed did not progress to completion. Nor was there the opportunity to review the legislative system from first principles. The Panel welcomes the opportunity its Terms of Reference (see Annex 1) provide for such a fundamental first principles review.

Throughout the consultation process, the Panel has heard consistent messages from stakeholders particularly regarding: the lack of national consistency of control-of-use regulation; the absence of residue surveillance systems and monitoring data; and delays and difficulties in gaining access to new products and new uses and application technologies for products.

> *"Access to chemicals is critical for aerial application and clients. The current system intentionally discriminates against aerial application and makes it significantly harder for a registrant to attain an on label aerial approval."* (Aerial Applicators Association of Australia 2020)

Stakeholders also highlighted the importance of ensuring the future regulatory system is responsive to the changing chemical landscape, including support for innovative product and delivery technologies and being responsive to steadily more demanding community expectations both domestically and in international markets.

The Panel considers the following matters are key drivers for changing and improving the regulatory system over the decades ahead:

- changing attitudes to chemical use
- changing attitudes to animal welfare

- increased awareness of how chemicals are used
- demands for nationally consistent control-of-use arrangements
- demands for better access to products and uses available overseas
- trade and market access pressures
- transparency and accountability of decisions
- new technologies and evolving practices
- reducing regulatory duplication
- implications of climate change.
- increasing role of companion animal ownership and the multitude of unmet needs for veterinary medicines
- the emerging and expanding role of the veterinary profession in caring for wildlife and other species in the context of One Health and its focus on zoonotic diseases

Changing attitudes to chemical use

Increasing interest in chemical use and its potential impacts on the community is focusing attention on the quality and integrity of global regulatory systems, including Australia. Social media, and other mechanisms for rapid communication provide means to publicly highlight any real or perceived lapses in safe practice or shortcomings in government regulatory oversight.

For example, there has been an increased focus on glyphosate because of well publicised allegations made in numerous litigation cases about its impact on human health. This litigation has heightened community concerns over its safety in many countries around the world. These concerns have been increasing, despite all comparable regulators (USA, Europe, Canada, and New Zealand) as well as international bodies such as the United Nations' Food and Agriculture Organization and the World Health Organization publicly advising at this time that glyphosate is safe to use when specific label instructions for use are followed.

The Panel considers the continuing intensification of community concern about, and scrutiny of, pesticides and veterinary medicines use to be the greatest long-term challenge to the regulatory system. It is vital that the concerns be heeded, and the scrutiny be responded to positively. The growing community attention should be capitalised on to help drive better performance of both pesticides and veterinary medicines users and regulators. **In the Panel's view, the necessary social licence to continue to use pesticides and veterinary medicines in Australia will ultimately be dependent on demonstrating that usage is responsible and safe, and that community concerns are being heard and taken into account in the operation of the regulatory system.**

Commented [SPE5]: For veterinary medicines trust and social licence are tied to use of effective medicines.

Public perceptions and attitudes concerning the human health and environmental impacts of chemicals are also driving a significant interest in farming systems and land management practices involving minimal or highly selective use of pesticides. Examples are organic farming systems and regenerative farming practices. The challenge for the regulatory system will be to ensure that such different farming systems can co-exist and compete on their merits, and that regulatory arrangements serve all farming systems equally well. In its work, the Panel has

adopted the principle that the future regulatory arrangements need to be 'future-neutral' or 'farming system agnostic'.

> *"… given the relatively small size of the organic sector, compared to conventional chemical-based agriculture, we are not suggesting that conventional practices be abandoned for organic, but that organic agricultural practices provide solutions that can be incorporated and encouraged in Australia's agvet chemical system."* (NASAA Organic 2020)

Even for conventional farming systems, there is increased pressure on primary producers to demonstrate through their on-farm quality assurance systems that they are managing their chemical use responsibly. Over the decades to come, community and consumer pressures will increase for more transparent chemical usage data and better surveillance of residues in domestic food supply systems. Similarly, community demands are likely to intensify for better quality and more transparent data about residues present in the natural and built environment.

> *"Consumers want to know how a food was produced, what went into that food and the story behind the product."* (AgriFutures Australia 2020)

In short, the Panel is convinced that users of chemicals and chemical companies should not be complacent about their social licence to continue to use and supply pesticides and veterinary medicines. A regulatory system that listens and responds objectively to community concerns and maintains community trust in the use of these chemicals, is essential.

Changing attitudes to animal welfare

Social attitudes to the use of veterinary medicines in part mirror those seen for pesticides, as there are increasingly demanding expectations regarding the welfare of production animals used for products people use or consume (RSPCA 2020). Both domestically and internationally, consumers are increasingly seeking assurance that production animals are only treated with medicines necessary to protect their health and to ensure their welfare. However, this is complicated by issues such as the development of antimicrobial resistance and the use of antibiotic growth promotors in animals, particularly those used in food production.

> *"We agree that animal welfare and food safety are both significant social concerns important for the future."* (CSIRO 2020)

> *"Not only should products be safe and appropriate, they should work as intended to fulfil the social licence for chemical and vaccine use."* (Invetus Pty Ltd 2020)

The Panel recognises that community demands for high standards of animal welfare have been intensifying in recent years. The Panel sees these demands as likely to further increase in the decades to come, and likely to go beyond production, companion, and native animals only to also include concern over the treatment of vertebrate pest species. Such expectations by the community, particularly the urban community, will add to pressures on social licence as it relates to the responsible use of veterinary medicines. For that reason, the Panel has sought to design the future regulatory system to build public confidence that animal welfare is properly considered in regulatory decisions and usage practices.

Commented [SPE6]: The AVA believes that the use of antibiotics as growth promoters (not an act of veterinary medicine as this was a use pattern implemented by particular parties when antibiotics were not prescription medicines) is no longer a major issue in Australia now that almost all uses of antibiotics have been assigned to Schedule 4, Prescription Animal Remedy.

Increased awareness of how chemicals are used

Intrinsically linked to the social attitudes towards pesticides and veterinary medicines is the growing expectation among consumers and in export markets that any use of chemicals can be traced and accounted for. Currently, to satisfy consumer expectations, the major Australian grocery retailers implement their own standards and monitoring controls over the produce they sell domestically. For international markets, the National Residue Survey has for many years monitored Australian products for export. These systems, alongside increasingly more sensitive residue testing as the result of improved detection methods and instrumentation, will continue to increase the pressures on users to be aware of, and responsible in, their use of chemicals.

Multiple stakeholders highlighted this as an ever-increasing issue, with AgriFutures Australia and the Public Health Association Australia emphasising the importance of this awareness both for the community as well as the regulator.

> *"Providing information about what chemicals were used, how much and any other factors that may mitigate or reduce chemical usage is important to the end user."* (AgriFutures Australia 2020)

> *"It is important for regulators to be aware of the volumes of chemicals in use so that trends are understood by all stakeholders, including environmental and health authorities."* (Public Health Association Australia 2020)

As the Panel looks forward, it sees growing pressures from Australian consumers to make more testing data publicly available.

> *"… consumer awareness and concern of residues as well as industry focus on sustainability targets and monitoring is driving increased interest in chemical monitoring."* (Cotton Australia 2020)

More comprehensive traceability arrangements will need to be correspondingly improved so prompt and effective response measures can be implemented. Questionable or ad hoc monitoring, traceability, and response measures would jeopardise the social licence on which chemical users critically depend. There are new technologies emerging such as blockchain that are likely to play a significant role in the future in providing authoritative traceability and provenance information to consumers.

> *"Many food industries including new and emerging products are now looking to QR codes linked to blockchain technology to monitor and demonstrate both provenance and authenticity."* (AgriFutures Australia 2020)

Demands for nationally consistent control-of-use arrangements

Since the introduction of the National Registration Scheme in 1995, the states and territories have been responsible for controlling the use of nationally registered chemicals (control-of-use).

A fundamental requirement for an effective regulatory system is compliance with risk management directions prescribing how a chemical should be used. The current inconsistencies and steadily declining allocation of resources in control-of-use regulation across the states and territories weakens the overall system and continues to frustrate manufacturers, users, some state governments, and the community at large.

> *"Without harmonisation, inefficiencies and confusion of regulations that currently apply will remain, leading to the potential for non-compliance by industry users. This could lead to consequences such as loss of vital chemistry or diminished reputation in both domestic and international markets."* (GrainGrowers 2020)

This is evident in the lack of harmonisation for monitoring of chemical residues in domestic produce, veterinary prescribing rights, remotely piloted aircraft systems and pest control businesses, and off-label use. Almost all stakeholders remarked that to date, attempts by the states and territories to harmonise control-of-use have been exceedingly slow and have achieved only minor advances in some non-contentious areas.

> *"… the lack of consistent national control of use regulation, training requirements and licensing…and even drift management policy reform have all been identified as problematic and some attempts at reform have been attempted. But nothing meaningful has changed for the chemical users – if anything, it has deteriorated."* (Aerial Application Association of Australia 2020*)*

> *"States and the Commonwealth need to agree on the policy principles for control of use and this is challenging to achieve as evidenced by the longstanding reviews and consultation attempts."* (AUSVEG 2020)

In the Panel's view, such a widely recognised failure of the regulatory system, where intergovernmental efforts to correct the problem consistently stall, is discrediting the system overall. The Panel was concerned that the government officials responsible for progressing the harmonisation agenda projected no real sense of the urgency or the pressing need for their work to be accelerated.

> *"The panel does not fully recognise that progress has been made in harmonizing control of use regulations in national agvet chemical reform, albeit slowly."* (Western Australian Government 2020)

Multiyear timeframes to address issues were not considered unreasonable by jurisdictions. Decisions to not even commence work on the most contentious and necessary reforms were seen as pragmatic or 'politically realistic'. As the Panel looks forward, it sees the conspicuous need for reform of control-of-use arrangements to be another crucial driver for change to the system. The status quo is clearly failing.

Fully functioning control-of-use arrangements are critical factors in a truly effective national regulatory regime. Effective and trusted control-of-use arrangements also underpin the community's consent for continued access to pesticides and veterinary medicines, and, without demonstrable and effective reforms, the failings in this area will continue to jeopardise social licence for primary producers and other users of pesticides and veterinary medicines.

Demands for better access to products and uses available overseas

By global standards, Australia is a small market for pesticides and veterinary medicine products. In comparison to other countries, many stakeholders stated that Australia has far less access to pesticide products, and even lesser access to registered uses. Stakeholders also expressed concern about the lack of access to certain veterinary medicines including ~~modern~~ many

biologicals such as vaccines. Lack of access to minor use products in minor species can also adversely impact productivity, health, and welfare outcomes.

A lack of access to new products and existing product uses (available overseas) places Australian primary producers at a competitive disadvantage in comparison to their overseas counterparts. In the consultations and submissions to the Panel, this disadvantage was identified as a serious concern to Australian producer groups.

The disadvantage derives from the size of the Australian pesticide and veterinary medicine market. Global chemical firms must judge whether seeking registration for a chemical or its use in Australia is cost effective. To date, their judgements have often been that registration in Australia is simply not an economically viable proposition.

Lack of access also disadvantages Australians in other ways. It restricts access to alternatives to current products which may be more innovative, safer, or less harmful to the environment. New products can slow the emergence of chemical resistance which is currently compounded by the comparatively narrow range of available products. New products can provide alternatives, enabling access to markets with otherwise increasingly prohibitive Maximum Residue Limits (MRL) for older chemistries.

> *"Access to safe, effective, innovative technologies – such as agvet chemicals – underpins agricultural productivity, sustainability and competitiveness, and is a priority for the farm sector. Indeed, access to world leading technologies will be critical to achieve the sector's ambition of $100 billion in farm gate output by 2030."*
> (National Farmers' Federation 2020)

Looking ahead, the Panel considers that access to a broader and more extensive range of safe, effective, products and product uses, equivalent to those available to international counterparts, to be a vital goal for regulatory reform. Safety, however, must not be compromised. Unique Australian circumstances must continue to be considered, and public confidence must be retained. However, the Panel is convinced that competitive pressures and opportunities to achieve safety, environmental and other benefits will drive change in the regulatory system towards much improved access to chemicals and uses for Australians. While the Panel supports greater access, it is not proposing that all products available overseas should be available in Australia.

Commented [SPE7]: Apart from impaired access to biological products because of restrictive import requirements there are very few examples of pharmaceutical products available outside Australia that are not also available in Australia. For the multitude of non-production animal species unavailability is more a matter of small market size and low economic return rather than due to a regulatory barrier.

Trade and market access pressures

Overseas markets present ever changing and challenging standards for acceptable chemical use. MRLs frequently change in response to science-based risk assessments, or sometimes, shifting consumer, community, and political concerns. Residue analysis technology continues to improve identification and detection sensitivity, which intensifies the challenge.

Key markets, particularly the European Union, are influential in directing global trends towards reducing or removing MRLs (with many countries following their lead) and guiding discussions at international forums. While Australia can and does seek to influence overseas MRLs, Australian exporters must generally accept and comply with MRL decisions made elsewhere.

Stakeholders advised the Panel that ever-changing residue requirements are an increasing concern that require Australian exporters to adapt or change their destination markets. This pressure will likely intensify in future.

> *"While the current regulatory system has provided a rigorous and science-based screening of chemicals, it also represents a barrier to the timely introduction of new chemistry to replace chemistry that are no longer options for use either due to withdrawal of registrations or because our trade partners have not established MRLs."* (Citrus Australia 2020)

The Panel is mindful of this emerging matter and its recommendations reiterate the importance to Australia's primary producers of having access to an equivalent suitable range of pesticides and veterinary medicines as in overseas markets if it is to remain competitive (particularly in light of pandemics like COVID-19).

The economic stakes are high if Australian exporters breach an MRL in an overseas market. Market access could be lost across entire sectors and not just individual businesses. The Panel considers MRLs to be a continuing driver of change in pesticide and veterinary usage patterns and in regulatory practice in the years ahead.

Commented [SPE8]: The AVA supports this statement and recommends that commensurate with the importance of this issue there should be support for establishing appropriate WHPs for off-label use of veterinary medicines in production species to ensure compliance with MRLs. A significant driver for off label use is inappropriate label dose regimens for antimicrobial substances. Many labels are unchanged in decades. During the period of label stasis improved understanding of dosage regimens has become available. In addition, the susceptibility of pathogens is under continuous change and almost always in the direction of reduced susceptibility – requiring modification of label dose rates. WHP adjustment is necessary, but no standardised or harmonised approach exists. There is an important opportunity to redress this unmet need.

Transparency and accountability of decisions

Trust in science should not be taken for granted or assumed. To maintain trust and confidence in the regulatory system, clear and open decision making is required. Increasingly, there will be pressure for the rationale, reasoning, and evidence base for decisions to be made public. Regular, proactive engagement and input from the regulated industry, users and the community is needed to demonstrate transparency and build public confidence about how both policy and regulatory decisions are reached. This sentiment was strongly shared by all stakeholders; CropLife Australia observed that its members:

> *"… see an important role for governments and regulators to engage more proactively with the community regarding the regulatory process, to improve trust in the system."* (CropLife Australia 2020)

The Panel expects that pressures from the community for more transparency will increase in the years ahead. This will drive change in both pesticide and veterinary medicine usage and regulatory practice. If successfully delivered, improved transparency can only strengthen trust and confidence for all connected with the regulatory system.

New technologies and evolving practices

The entire life cycle of practices related to a pesticide or veterinary medicine product's development, including design, manufacture, on farm application, and disposal continues to change. Advances in application technology and product delivery are already producing innovative solutions in response to changing expectations and requirements. Examples include spray application by drone, new nozzle designs, autonomous farm vehicles, various techniques for precision application of pesticides, automation of spray record keeping, and new techniques for veterinary medicine targeting.

Similarly, practices for the use of chemicals in land management off-farm, including uses in conservation areas, are evolving. New techniques for the management of weeds and feral

animals on public lands are becoming available to develop more active management in response to concerns.

The future regulatory system needs to be flexible and agile in design to adjust to such evolving practices. The benefits of innovation need to be captured, not deterred, by the regulatory system. In designing its reform recommendations, the Panel has therefore sought to make the future system adaptable as well as 'future neutral' as far as possible without compromising health and safety.

> *"The regulatory system must be flexible to adapt to changes in technology – both chemistry and application, including drone technology. The current system is lagging well behind advancements in technology."* (Sports Turf Australia NSW Incorporated 2020)

> *"There is a need for the system to be able to review, access and consider changes in technology that does not fall under the traditional definitions of agvet chemicals. Such as the use of smart labelling, autonomous application devices (i.e. drones) and the use camera detection to target reduced treatment areas but with different chemicals or higher rates than would be allowed on a broad cast system. Such changes in technology are happening at a much faster rate than the current system can respond to."* (Grains Research and Development Corporation 2020)

> *"While the trends touch on smart labelling, it should be noted that agriculture aspires towards increased automation and future technology trends such as artificial intelligence (AI), augmented vision, and integration of decision making should be considered."* (Cotton Australia 2020)

Additionally, increased demand for the treatment of companion animals and other non-production animal species is expected to lead to a significant growth in veterinary medicine products and uses, including the need for compounded products.

> *"Companion animals will expand in number and type … This will drive more demand for additional veterinary medicines for their care and welfare."* (Australian New Zealand College of Veterinary Science 2020)

> *"… there is a well-established and clear trend for greater growth of companion animal veterinary medicines in terms of innovation and sales."* (Australian Veterinary Association 2020)

Reducing regulatory duplication

The current coverage of pesticides and veterinary medicines in the Australian regulatory system is broad. There are various substances and compounds that are regulated across multiple frameworks due to their label claims or intended use. This leaves scope for duplication and cumbersome overlap with other regulatory systems. Examples include the possible crossover with multiple regulatory bodies such as the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutics Goods Administration (TGA), the Australian Competition and Consumer Commission (ACCC), the Office of the Gene Technology Regulatory (OGTR), the Australian Industrial Chemicals Introduction Scheme (AICIS) and Safe Work Australia, plus a range of individual and sometimes delegated State and Territory regulatory bodies.

This complex array of Commonwealth/jurisdictional relationships together with arrangements and requirements associated with jurisdictions' sovereign rights increases regulatory burden, has the potential to deter companies from introducing newer and safer chemistries, as well as causing confusion and lack of clarity to industry about its obligations.

> *"Co-ordination between regulators to avoid duplication is a separate issue to efficiency or simplicity of agvet chemical regulation considered on its own and deserves to be considered as a principle guiding the design of the regulatory system."* (Bioproperties Pty Ltd 2020)

The Panel notes that most governments across Australia have an agenda to deliver better regulation including reducing duplication and overlap. Meanwhile, the theoretical literature about deregulation has become more sophisticated and new models of good regulatory practice are becoming available (Gunningham, N, Sinclair, D 2017). Examples include regulatory arrangements that rely more formally on industry quality assurance and good stewardship practices, and arrangements that build-in continuous regulatory reform, rather than only responding to specific short-term issues.

A number of stakeholders were keen for the Panel to make recommendations to change what they perceive as either duplication or inefficient interaction between differing regulatory systems such as those previously mentioned. The Panel considers that its remit did not extend to being in a position to make broad sweeping changes to other regulatory systems that interact with the pesticides and veterinary medicines system but has made suggestions for improvement where they are sensible. More broadly, the Panel sees reducing regulatory duplication and overlap where possible as a significant contribution to the current better regulation agenda. The Panel expects that in the years ahead, pressures for further regulatory improvement will (and should) be an enduring driver of change.

Implications of climate change

Climate change presents significant challenges for pest and disease management in the future. Australia will likely face increasingly volatile weather events and higher temperatures, and accordingly the viability, distribution and occurrence of diseases, pests and weeds will change. Pests and diseases are likely to extend into new habitats which could pose problems for farmers, human and animal health and environmental land managers and threaten biosecurity.

The impact of pesticides and veterinary medicines on the environment, such as how a product degrades and dissipates, is strongly influenced by temperature and it is likely climate change will alter this process (Bloomfield et al 2006). Climate change may also impact product efficacy. As a result, there may be a need for changes to label instructions for use to ensure continued product safety.

> *"Global warming, climate disruption and other ecological changes are going to have a huge impact on agriculture. These include warming and climate disruption, water availability, salination, changes in pests and weeds, as well as friendly plant symbionts and natural pest controllers. The regulatory system needs to factor in how these affect the need for and potential unintended consequences of chemical use within the environmental and human health protection frames."* (Public Health Association Australia 2020)

Climate change is likely to impact agricultural production differently across Australia's extensive geographical expanse depending on region, and farmers may need to adapt practices to respond to these impacts. Agricultural pests such as weeds are likely to be affected as weed biology and management are influenced by a range of climate factors including temperature, rainfall and frost which are predicted to become more variable with climate change (Scott et al. 2014).

> *"It is expected that as summer rainfall increases, combined with elevated summer temperatures, summer weeds will become more widespread and difficult to control. Many tropical and subtropical weeds are expected to move south."* (Hayman et al. 2012)

The Panel's proposed reform to remove the artificial barrier to access to uses imposed by state and territory borders, replacing them with a regionally based approach (see Chapter 5) is one element of increasing the flexibility of the future regulatory system to deal with changing environmental conditions.

The Panel's reforms, informed by these diverse drivers for change, touch all aspects of the pesticides and veterinary medicines regulatory system, from improving animal welfare, to improved access to pesticides and veterinary medicines, and governance and funding arrangements.

1.3 Vision for the new system

The current regulatory system, as a whole, lacks focus or a clear identity, vision, and leadership. This makes it difficult for producers, manufacturers, users, consumers, and the broader public to understand and engage with it, and for all players in the system to operate in a coherent and coordinated way.

The Panel considers that a unified regulatory system is critical to its future efficiency and effectiveness. This depends, at its foundation, on a unifying vision and clear objectives.

Stakeholder feedback highlighted the need for the Panel to be clearer about its goal of protecting health and safety than that presented in the Panel's initial Issues Paper.

> *"Growcom is concerned that the proposed vision statement places chemical access and timeliness before health and safety. … Whilst timeliness of access to chemicals is important to industry, the protection of human, animal and environmental health must trump timeliness of access. An industry's desire to use a particular pesticide will ultimately not benefit them if it is found to be too toxic to use safely, or it cannot be used in a way that does not meet acceptable residues in produce."* (Growcom 2020)

> *"The vision statement should include other users and have health priorities listed first as the overarching requirement."* (Public Health Association of Australia 2020)

> *"It is WA Government's view timely access should always remain a secondary consideration to the health and safety of people, animals, and the environment."* (WA Government 2020)

The Panel considers that the vision should focus on 2 key outcomes – protection and access, rather than trying to capture a multitude of concepts which are best articulated as objectives or principles governing a future regulatory system. These 2 outcomes encompass: protecting

people, animals, plants, and Australia's ecosystems; and enabling equivalent access for Australians to suitable and safe chemical and biological tools as their overseas competitors. The purpose is to enhance agricultural production and environmental land management while assuring human, animal and environmental health and wellbeing.

The Panel therefore proposes that the 'vision statement' for the new pesticides and veterinary medicines regulatory system should be:

> *A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to safe and effective products and uses.*

The Panel considers that this vision provides clarity on why we have a regulatory system for pesticides and veterinary medicines – because people want to be able to use these chemicals but in order to do so it must first be confirmed that these products do not have significant and unacceptable adverse impacts on the health of humans, animals and ecosystems.

1. Recommendation

The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system.

"**A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while ~~improving~~ allowing access to safe and effective products and uses."**

Objectives

This vision should be supported by clear objectives which underpin and elaborate on the vision and emphasise what the system should deliver. These need to be simple and easy to understand and provide clear guidance for decision-makers and stakeholders.

In its Issues Paper, the Panel proposed that the objectives comprise a primary purpose statement affirming the need to protect the health and safety of people, animals, plants and the environment, supported by a hierarchy of tiered supplementary objectives. Many stakeholders did not support the hierarchical presentation of the secondary objectives. The Panel accepts this view and understands that the supplementary objectives should be given equal weighting.

> *"It is suggested that all three objectives are on an equal level rather than prioritising them. Poor animal welfare outcomes can impact on trade, so placing animal welfare third does not reflect the potential inter-relationships between these objectives."*
> (RSPCA 2020)

> *"The NFF generally supports the proposed system objectives, noting that the concept of a hierarchy (ranking one objective over another) is somewhat fraught. Our preference would be for a set of objectives that are not labelled as a hierarchy …"*
> (National Farmers' Federation 2020)

> *"However, the NSW Government recommends that each of the three supplementary objectives should be regarded as equally important. Primary production, trade, and animal welfare are closely interlinked, and all require equal consideration during the*

agricultural and veterinary chemical regulatory process."
(New South Wales Government 2020)

Thus, in the Panel's view, the vision for Australia's future pesticides and veterinary medicines regulatory system should be underpinned by 4 equally weighted objectives that would:

- ~~safeguard~~ enhance animal health and welfare
- support primary industries
- protect Australia's trade
- contribute to biosecurity preparedness.

Some stakeholders suggested other matters should be included in the objectives, including alignment with international standards, and support for domestic manufacturing. However, the Panel considers that, while obviously significant, these concepts are best acknowledged and incorporated into guidance for implementation of the future system.

Animal health and welfare has always been an important concern for farmers, veterinarians, and the public, and is almost certain to increase in importance in the years ahead. As the Panel identified in its vision, protecting animal health and welfare into the future should be a key focus of the future regulatory system.

Supporting primary industries through improved and increased access to safe and effective products and their uses is important for realising the Panel's vision. The objective as proposed, recognises that pesticides and veterinary medicines are necessary for the viability and competitiveness of Australia's food production, veterinary/animal husbandry, and environmental management sectors.

The Panel recognises that as the bulk of Australia's primary production is exported (ABARES 2020) and, as participants in a highly trade-competitive sector, Australia's primary producers value the APVMA's **consideration of trade impacts** (such as residues) for a chemical when it is assessing an application. Given Australia's strong reliance on export trade to maintain and grow its economic viability and strong stakeholder support for the need to include market access as an objective, the Panel considers that a trusted and nationally consistent regulatory system is essential to the protection of Australia's trade interests.

Finally, the objectives recognise the vital and ongoing need to remain vigilant for **biosecurity preparedness**. While COVID-19 is a human health pandemic, it has highlighted the potential fragility of Australia's food production and supply systems. It is critical, therefore, that there is a trusted regulatory system that is adaptable and can contribute to Australia's national response to crises. Pesticides and veterinary medicines will often be vital in such responses.

2. Recommendation

The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives:

- **~~safeguard~~ enhance animal health and welfare**
- **support primary industries**

Commented [SPE9]: There does not seem to be any reason why the objectives should be equally weighted. They are all important and each needs to be considered, but the significance or need for 'equally weighted' is not clear. Important objectives not included but which should be considered include objectives that would:
Ensure Judicious use
Provide environmental protection

- **protect Australia's trade**
- **contribute to biosecurity preparedness.**

1.4 Principles underpinning the new regulatory system

Australia's primary producers, veterinarians, and other users rely on timely access to safe and effective pesticides and veterinary medicines.

A modern regulatory system must ensure that the risks associated with the manufacture, handling, use and disposal of pesticides and veterinary medicines – including more benign alternatives such as many biological compounds – are adequately managed. This core function of the regulatory system is vital to improving and protecting the health and safety of people, animals, plants, and ecosystems, and to manage risks to trade while continually maintaining community confidence. However, poorly designed regulation – for example, regulation that is ineffective, unenforceable, or inefficient in meeting its objectives – can also damage businesses and expose users and the community to unnecessary risks.

This includes regulation that is not adaptive, that is overly bureaucratic, that does not demonstrate accountability, does not integrate with other regulatory systems, or does not adequately identify, manage, and respond to risks. Indeed, poorly designed regulation can stifle innovation, deter investment, increase costs, constrain the chemical tools needed to maximise productivity and protect animal health and welfare and support economic activity. It is important, therefore, that the regulatory system should be tailored to the real level of risk that a chemical poses and should not be unnecessarily burdensome.

The vision and objectives describe the regulatory system's high-level goals and the core outcomes it needs to achieve. The Panel also proposes a range of principles to guide how the vision and objectives will be met in practice. These principles will support the performance of the system as science-based, efficient, and adaptive. Other principles focus on increasing shared responsibility and engagement with industry, users, and the community, to increase accountability and transparency.

Many submissions received by the Panel through the consultation process supported the proposed principles in the Issues Paper; for example, CropLife Australia, National Farmers' Federation, National Association for Sustainable Agriculture Australia (NASAA) Organic, Public Health Association of Australia, RSPCA, NSW Farmers Association, Horticulture Innovation Australia, Grain Growers, Grains Research and Development Corporation, and Cotton Australia.

> *"The principles that the system should be based on sound science and be evidence- and risk-based in its decision making, and that decisions of the national regulator should continue to be independent from government are particularly important and underpin confidence in the regulatory system."* (National Farmers' Federation 2020)

> *"Hort Innovation agrees that the Australian regulatory system should follow a science-based, weight of evidence approach that could be expressed in terms of a guiding principle to ensure decision making is sound and defensible."* (Horticulture Innovation Australia 2020)

> *"Grain Growers supports the principles proposed to guide design and reforms to the future agvet chemicals regulatory system, particularly that the system should be*

based on sound science, be evidenced and risk-based in its decision making." (Grain Growers 2020)

The Panel proposes that the following principles should govern the design and implementation of the new regulatory system to enable it to deliver against its primary purpose of protecting the safety and welfare of humans, animals, plants, and ecosystems:

The regulatory system should be based on **risk**, not on hazard alone.

Commented [SPE10]: Risk and hazard are terms of fundamental importance but with definitions that are not widely appreciated. Both terms should be added to and defined in the glossary.

- The risks posed by exposure to a chemical product are a function of both its inherent hazards and the likelihood and extent of exposure (e.g., to people, animals, plants, ecosystems, or traded commodities) to each of those hazards.
- Where the risks of dealing with a chemical product – including during manufacture, transport, storage, use (e.g., for mixers, applicators and bystanders) and disposal of products – can be safely and reasonably managed, then the product can be approved on that basis. If the risks are manageable, even a hazardous product can be approved. Approval based on manageable risk, not solely based on intrinsic hazard, will ensure that users and the community have access to the broadest possible suite of safe chemicals to manage pests and diseases and safeguard animal welfare.
- However, where a risk cannot reasonably be managed, then the product should ~~be prevented~~not be approved.

Processes and decisions should be **objective**, **independent** and **science based**.

- Regulatory decisions should be independently made based on contemporary science and objective risk assessments to the extent possible.
- As in any subject area of government, policy decisions are ultimately the prerogative of the democratically elected government of the day. However, in the day-to-day operations of the system, all decision-makers should exercise their policy and regulatory functions based on sound scientific evidence and objective risk assessments within their legal obligations.

Regulatory decisions should be **transparent**, and decision-makers should be **responsive** to all stakeholders, including the community, users, and the regulated industry.

- While maintaining decision-making independence, the future regulatory system should incorporate a formal, transparent, and accessible consultative framework that provides visibility, and the opportunity for input from a diverse range of stakeholders and interested parties that contribute to the pesticides and veterinary medicines regulatory system.
- Communication should be timely and effective, while reporting should be meaningful, regular, clear, informative, and objective.

Risk management measures should be **reviewed** as new information becomes available.

- The system should deliver timely and efficient reviews of pesticide and veterinary medicine products, with clear triggers, fixed timeframes for completion, opportunities for public engagement, and transparent reporting.

- The need to update risk management decisions should be informed by new knowledge, data, and information received from surveillance and monitoring of chemical residues in the environment, produce monitoring, and through analysis of data.

The system should be **efficient and outcomes-focused** by making use of streamlined and fit-for-purpose regulation.

- The regulatory system should apply the minimum necessary level of regulation required to address the risks associated with dealings with pesticides and veterinary medicines throughout their life cycle.
- Its focus should be on achieving the necessary policy outcomes (the safety and ultimately the health of humans, animals, plants, and ecosystems) rather than overly prescribing how the outcomes are to be achieved. This will avoid unnecessary regulatory burden, minimise costs to both the regulator and the regulated community and encourage innovation in achieving contemporary safety standards for all consumers, domestically and in global markets.

The system should achieve a single nationally **consistent** model with **shared responsibility** for controlling the manufacture, import, export, supply, use, and disposal for regulated products.

- Regional differences should only be required where necessary to manage specific risks or accommodate different regional practices. This approach will remove any arbitrary and unnecessary state and territory-based differences in access to uses.
- The system should be cooperative and acknowledge that safe dealings with pesticides and veterinary medicines is a shared responsibility between government and industry with respect to handling or otherwise dealing with these substances, from design to disposal.
- Regulatory responsibility within the future system should be shared with those best positioned to manage the risks to the safety and welfare of humans, animals, ecosystems, and trade. This will provide greater assurance that risks are actively managed throughout the supply chain and contribute to high safety standards and community confidence. Relevant parties include governments, registration holders, suppliers, and users.
- Where possible, the system should adopt a co-regulatory approach that capitalises on suitable processes such as those required by customers through their supply chain quality assurance schemes or record keeping requirements under work health and safety laws.

The system should be **adaptive** to new technologies, practices, and knowledge.

- Through stakeholder consultation and horizon scanning activities, the regulatory system should adapt to accommodate new technologies and practices.
- The regulatory system should encourage innovation and reward success, and not unnecessarily impede industry from developing and commercialising new technologies. The system must, however, continue to ensure that these developments are applied in a safe and appropriate manner.

The regulatory system should support a **resilient** supply chain.

- The regulatory system should facilitate supply chain resilience and not impede competition or manufacturing within the chemicals industry where possible.

3. Recommendation

The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:

- **The regulatory system should be based on risk, not on hazard alone.**
- **Processes and decisions should be objective, independent and science based.**
- **Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.**
- **Risk management measures should be reviewed as new information becomes available.**
- **The system should be efficient and outcomes focused by making use of streamlined and fit-for-purpose regulation.**
- **The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products.**
- **The system should be adaptive to new technologies, practices, and knowledge.**
- **The regulatory system should support a resilient supply chain.**

1.5 Intelligent regulation – flexible and adaptive deregulation

In its terms of reference, the Panel was asked to have regard for the Government's agenda to reduce red tape wherever possible. In approaching this task, the Panel has sought to implement a contemporary vision of intelligent regulation which strengthens the regulatory system and enables improved relationships and aligned effort between the regulator and industry.

The Panel's recommendations aim to build, and maintain a resilient, and effective pesticides and veterinary medicines regulatory system for now and into the future. In making its recommendations, the Panel has considered how to optimise regulatory efficiency, and take best advantage of opportunities for streamlining the system.

A traditional concept of regulation typically involves 2 parties: the government (the regulator); and industry (the regulated). This form of regulation is often referred to as 'command and control regulation' or 'direct regulation'. 'Command' refers to targets and standards set by the government authority and 'control' signifies sanctions for non-compliance. Direct regulation involves prescriptive standards imposed by the regulator through legislation. The regulated industry is told what to do, how to do it, and when to do it.

Such direct regulation can be strict and inflexible and provides industry with little scope or incentive to do more or better than the minimum required. It perpetuates a one-way relationship between the regulator and the regulated and discourages innovation by industry and the acceptance of shared responsibility. To avoid this outcome, the Panel has sought to build a more respectful, creative, and contemporary relationship between the regulator and the

regulated industry without compromising human safety, animal welfare or the environment. Wherever possible:

- Regulation based on the outcomes to be achieved (especially safety) is preferred to detailed specification of the process to be followed.
- Regulation that formally acknowledges industry's best practice through its own quality assurance and safety-related standards will be utilised.
- Clear channels have been put in place to enable industry to propose improvements to regulatory arrangements to maintain dynamism in the regulatory system and to reduce the need for once-a-decade regulatory overhauls as has been the case over decades past.

Nevertheless, the Panel considers that it will continue to be necessary to use direct regulation in certain parts of Australia's regulatory system and this form of regulation will clearly have an ongoing role in the future.

Direct regulation involves attempting to deal in detail with many scenarios. This can lead to complex legislation and can create legal 'loopholes' which, when discovered, tend to be addressed through the introduction of more legislation which compounds the complexity. The application of prescriptive requirements is appropriate in specific circumstances but not where it leads to duplication between regulatory systems which have separate requirements on the same regulated entity for different regulatory purposes. In the case of pesticides and veterinary medicines labelling, for instance, the regulator dictates the standards and information to be used including the many circumstances of use. Product labelling has become overly prescriptive with unnecessary overlap, containing content required under multiple regulatory systems including pesticides and veterinary medicines, work health and safety, poisons scheduling and dangerous goods. The Panel's recommendations for labelling (see Chapter 4) removes several prescriptive requirements and makes best use of the existing requirements across other regulatory systems, thus avoiding duplication. It also provides a vehicle for current technological developments, such as smart labelling, whilst being flexible in providing for future technological advances.

The Panel considers that the conventional view of deregulation which centres on reduced or better regulation does not give effect to the full range of possibilities available. The Panel has taken a broader, and richer, approach to the concept of deregulation in developing its recommendations for the future pesticides and veterinary medicines regulatory system. The Panel's 30-year vision for the regulatory system eschews the traditional, process driven approach to regulation and instead drives towards a contemporary regulatory system that embodies the ideas of modern regulatory theory and practices, including principles-based, performance-based, responsive, and co-regulatory approaches. It embraces flexible, imaginative, and innovative forms of regulation, which is matched to the level of risks present to humans, animals, and ecosystems. In doing so it empowers governments, businesses and third parties to deliver regulatory outcomes where they are best suited to do so.

An example of this is the Panel's recommendation for a co-regulatory approach delivered by means of general product obligations. General product obligations (GPOs) (see Chapter 4) define the outcomes required of participants in the system. At the same time, GPOs will allow the future regulatory system to leverage industry's own quality assurance and stewardship programs to demonstrate compliance with the safe use of pesticides and veterinary medicines. These obligations give credit for the intimate knowledge of pesticide and veterinary medicine

operations by industry and utilises investments and processes already in place (for example, codes of practice, WHS plans, spray diaries and animal treatment records), rather than imposing additional processes and costs to meet the regulator's mandated requirements.

These arrangements will also incentivise innovation by providing flexibility for different businesses to manage risks in a manner tailored to their individual circumstances. Moreover, as circumstances change in any given business, the risk management measures adopted by the business will evolve with those changes. This was not always possible under traditional prescriptive regulation. Good industry quality assurance schemes will speedily disseminate new ideas to other industry participants, so accelerating the adoption of best practice throughout the sector.

Through these co-regulatory efforts, the Panel has endeavoured to build a 'culture' of shared responsibility between government and industry to meet regulatory requirements. This is important as the system as a whole will be stronger if all players are committed to and accountable for the responsible production and use of pesticides and veterinary medicines. It is the Panel's strong view that ensuring safety should not be the responsibility of the regulator alone.

This greater reliance on industry best practice will also require a cultural change for regulators in terms of compliance roles. Where industry is in a position to ensure and monitor compliance with the outcomes required, then this should be supported, with regulators undertaking random system surveillance activities to confirm that the necessary standards are being achieved.

Significant changes to regulatory practice such as those now proposed by the Panel will need to be carefully communicated to the public. The intention of the Panel's deregulatory reforms is to achieve equivalent or better standards of safety and responsible use than currently, resulting in more efficient and effective deployment of regulator and industry resources. Importantly, the risk of regulatory 'capture' by industry is significantly reduced when outcomes-based regulation and co-regulation are adopted to replace input or activity-based regulation.

Aligning regulatory effort with risk

From the outset, the Panel adopted the principle that the level of regulatory intervention should match the level of risk being managed. For example, the Panel's proposal to refocus the scope of products subject to regulation (see Chapter 5) excludes product classes or uses that are expected to have low hazard or low exposure, such as seaweed extract biostimulants, or which would be more appropriately regulated under other systems, such as whole plants or animals that are genetically modified and would be better regulated solely by the Office of the Gene Technology Regulator. This proposal also creates pathways for exemption from registration for low regulatory concern products where established standards are met, for example pool and spa chemicals for domestic use. Such tailoring of regulatory approaches, depending on the risk profile of the product, enables better deployment of valuable regulatory resources and therefore better safety outcomes for the community.

Avoiding duplication of regulatory effort

Regulatory systems often involve multiple parties with overlapping responsibilities – between agencies, levels of government and even between government, industry, and product users. Certain responsibilities may also be duplicated between Australian and overseas regulatory

agencies. The Panel is seeking, wherever possible, to eliminate the unnecessary regulatory effort arising from duplicated processes.

The Panel's proposal to achieve nationally consistent control-of-use (see Chapter 2) is driven by the many benefits of a single, harmonised approach, including the elimination of the duplication of regulatory effort between jurisdictions. It will reduce regulatory costs and provide greater efficiency for primary producers, industry, and the community.

The future regulatory system will also have improved access to internationally registered pesticides and veterinary medicines (see Chapter 5) which seeks to leverage, rather than duplicate, regulatory effort – in this case, the effort by equivalent international regulatory systems. This principles-based regulation will enable importers and manufacturers to avoid time delays and costs ordinarily associated with duplicative assessment and registration of individual products, provided international standards are sufficient to meet Australian requirements.

Identifying and responding effectively to changes

The efficiency of many of the Panel's proposals will also depend on whether the regulatory system can quickly adapt to changing circumstances and unexpected events. The Panel considers that the legislative framework for the future system should therefore include an emphasis, where relevant, on delegating regulations to instruments. This would allow the regulatory system to be more responsive, as legislative instruments (excluding regulation) can be made more quickly than primary legislation or regulations and are less administratively burdensome. The importance of such system resilience has been thrown into high relief by the pandemic experience of 2020.

2 Establishing a truly national regulatory system

Throughout the review, the Panel has heard, almost unanimously from stakeholders, that the biggest failing of the current regulatory system is the lack of national consistency in control-of-use functions – currently, the responsibility of the states and territories. Tied to this is also a lack of national leadership for the system as a whole that provides for a clear point of accountability, broad engagement, and direction.

To that end, the Panel believes there are 3 significant reforms necessary to build a truly national and responsive regulatory system:

- nationally consistent control-of-use
- national leadership through the creation of the Commissioner of Pesticides and Veterinary Medicines Stewardship
- meaningful and constructive engagement with the broader community and industry.

2.1 Achieving nationally consistent control-of-use

Thirty years ago, each state and territory were separately responsible for registering pesticides and veterinary medicines. Through an Intergovernmental Agreement between the Commonwealth and the states and territories, the National Registration Scheme was then established to ensure that all products were subject to common criteria in terms of safety for humans and non-target species and the environment; efficacy; managing risks to Australia's international trade; and labelling. The scheme provided for a single national authority under Commonwealth legislation (now the APVMA) to regulate supply-side activities. As a result, supply-side controls on these substances are consistent across Australia. This has had significant deregulatory benefits resulting in harmonised risk management approaches through one Commonwealth regulator taking the place of 7 state and territory supply-side regulators. Stakeholders continue to strongly support the national harmonisation of supply side regulation.

Thus, the APVMA is the national independent regulator that assesses and registers pesticides and veterinary medicines and other non-related chemicals (pool and spa and anti-fouling paints) for supply within Australia. These activities include: authorising import, issuing export certificates and manufacturer licensing; assessing the risks that products and active constituents pose to the safety of humans, animals, plants, the environment and to trade; considering a product's efficacy; approving label instructions to ensure risks are appropriately managed; approving permits for activities with unregistered products or for uses of products contrary to label instructions; chemical reviews; and, undertaking certain compliance and monitoring functions, including managing adverse experience reporting and recalls of these substances.

The control-of-use of pesticides and veterinary medicines *after registration* is regulated by each state and territory. Control-of-use activities include ensuring labelling instructions on chemicals are followed to the extent required in that jurisdiction; licensing of commercial spray applicators (including aerial applicators); regulating the handling and use of restricted chemical products; investigating breaches in the use of pesticides and veterinary medicines; ensuring that these

substances are disposed of properly; dealing with contaminated produce and compliance and monitoring activities (for instance, audit, inspection, veterinary compounding rights).

The regulatory approach to controlling use of nationally registered products, differs, sometimes markedly between each state and territory. This inconsistent national approach:

- makes it more complex for the APVMA to put in place effective risk management measures, as the controls on the use of products vary among the states and territories
- allows products to be used a certain way in one jurisdiction, but not others
  - for example, Victorian growers have greater latitude to diverge from label instructions than producers in other states and territories – growers outside Victoria require APVMA-issued permits to do this, which adds costs, delays access and may encourage unauthorised off-label use – and there are also differences in approach to veterinary prescribing rights and the scope to treat multiple animals simultaneously
- adds complexity and increases compliance costs for business – particularly those that operate across jurisdictions (including, for example, primary producers, professional ground and aerial spray applicators, agronomists, veterinarians, chemical companies, and those that export produce)
- increases costs and complexity of training provided by assessors, and risk of non-compliance of users between jurisdictions due to differing training and licensing requirements across borders (for example, for aerial application of pesticides by drones)
- increases the risks to trade and to Australia's national reputation as a safe user of pesticide and veterinary medicine products, and makes our control arrangements difficult to explain internationally to overseas regulators and customers
- impedes the identification of emerging safety, health, or environmental concerns through a lack of co-ordinated communication about whole-of-system trends
- increases transaction costs for developing and implementing regulations, diverting resources away from compliance and enforcement activities
  - compliance and enforcement efforts have reduced significantly over time in some states and territories which increases system failure risks
- contributes to consumer and community confusion resulting in a lack of confidence in the system.

The need for a single national approach to regulate the control-of-use of pesticides and veterinary medicines has been recognised for many years. As far back as 2008, the Productivity Commission's review into chemicals and plastics regulation concluded that integration of control-of-use into a single national regime would improve both the effectiveness and efficiency of the national registration system for agvet chemicals (Productivity Commission 2008).

Through the Panel's consultation process, stakeholders communicated a strikingly strong and consistent message about their dissatisfaction with the current inconsistent approach to regulating control-of-use across borders. There was extensive support for control-of-use regulation of pesticides and veterinary medicines to be consistently applied through a single

national regulator. The need to deal with the current problems with the system was the most consistent message received from all stakeholders in the consultation process.

> *"Inconsistencies can be a source of frustration, confusion, uncertainty and administrative burden for end users – including those who operate in multiple states and territories – and create duplication and inefficiencies in the system. The current arrangements can also lead to inconsistent regulatory interpretation and advice from regulators."* (National Farmers' Federation 2020)

> *"Much has been written and said about the issue of control of use for agvet chemicals over many years. As noted, it is a major weakness in the current regulatory framework … Nationally consistent control of use needs to be a priority."* (Chemistry Australia 2020)

> *"As noted in the discussion paper, previous attempts to harmonise off-label use of chemicals across jurisdictions have not been successful. This is an ongoing frustration for producers who rely on access to these chemicals. NSW farmers does not want to see a situation where lack of clarity about off-label use leads to serious harm and erodes community confidence in our ability to safely use chemicals."* (NSW Farmers Association 2020)

> *"We believe this option (expanded applied law model) will deliver the best chance of consistency in control of use and the greatest likelihood of success. It would also give consumers the most comfort that a uniform, consistent position would apply nationwide."* (GeneEthics 2020)

> *"One national law that applies to pesticides in all jurisdiction is required. This will remove state 'control-of-use' issues, that currently frustrate farmers. It also provides increased consumer confidence in the produce purchased. But a 'national control of use' legislation needs to be adopted by all states and territories. This has been difficult to achieve for the past 15+ years."* (Agrifutures 2020)

> *"Whilst all the options suggested by the panel risk some level of inconsistency or failure, this approach (the expanded applied law model) has previously been successfully implemented on the supply side of the regulatory system, and therefore there may be more likelihood of success."* (Australian Meat Industry Association 2020).

There have been previous efforts to reduce inconsistencies among the states and territories, albeit by painstaking negotiation. In 2009, the Council of Australian Governments (COAG) launched an effort to harmonise control-of-use among the states and territories through a committee consisting of all signatories to the National Registration Scheme. While ultimately the responsibility of state and territory governments, this work is being facilitated at Commonwealth level by the Department of Agriculture, Water and the Environment, through the Harmonised Agvet Chemicals Control of Use Task Group (HACCUT) and its predecessors.

The process for seeking harmonisation has relied on 'consensus through negotiation'; however, this has achieved very limited success to date. In the 11 or so years of negotiations, only 4

(minor) measures have been endorsed, and full implementation of these is not expected until 2022:

- authorisation for use of pesticides and veterinary medicines at lower rates, frequencies or concentrations than stated on the label, or to treat a different pest in a commodity stated on the label
- arrangements for licensing fee-for-service users (excluding operators on their own land)
- training and competency assessments for users of certain highly hazardous chemical products
- record keeping requirements for agricultural chemical use.

The last 3 of these measures have been agreed as a minimum standard with the ability for jurisdictions to add additional requirements for their respective state or territory – again, diluting the effect of harmonisation.

Other more substantial issues relating to harmonisation, such as wider off-label use of chemicals, veterinary prescribing rights and the national coordination of domestic produce monitoring, remain unresolved.

Stakeholders expressed frustration and dissatisfaction with the lack of progress towards harmonising control-of-use regulation.

> *"Efforts to achieve nationally harmonised control of use regulation across all jurisdictions have been underway for many years, and have met with limited success … As the panel has noted in the issues paper, benefits from nationally harmonised use arrangements would accrue to the full spectrum of system participants, including registrants, regulators, exporters and end users."* (National Farmers' Federation 2020)

> *"Lack of harmonisation of control of use has been a problem for many years. HRA supports the principle of consistency of control of use across states and territories – there should be one adequately resourced national regulatory system to ensure consistency, a national approach to compliance and public justification of any jurisdictional differences."* (Harness Racing Australia 2020)

However, not all state and territory governments agreed with the stakeholder feedback on control-of-use.

> *"… the WA Government believes proposals put forward are premature given ongoing efforts by all jurisdictions to achieve harmonisation of agvet chemical regulations in line with the intergovernmental agreement signed by the Council of Australian Governments in 2013."* (Western Australia Government 2020)

> *"DAF believes that the current Agvet chemicals regulatory system works reasonably effectively, and the fundamental principles are sound."* (Queensland Department of Agriculture and Fisheries 2020)

Boundaries to the national law

State and territory legislation cover a range of areas including environmental protection, work health and safety, and public health. For example, in NSW, most control-of-use legislation for pesticides is the responsibility of the environment portfolio and in many jurisdictions, pest controller arrangements reside with the health portfolio. Should a national law approach for control-of-use be adopted, it will be important to clearly define the boundaries between a national control-of-use law and other state regulations, such as dangerous goods, biosecurity, the scheduling of medicines and poisons by State Departments of Health, and the registration of veterinarians.

The Panel is also aware that some jurisdictions include other farm chemical activities within the same legislation that manages control-of-use. These include matters relating to fertilisers, stock food and contaminated land. The Panel will make no recommendations in relation to these matters, which should remain under the control of states and territories.

What change is recommended?

The Panel, with overwhelming support from stakeholders, considers there should be one coherent national system for regulating control-of-use of pesticides and veterinary medicines.

However, the Panel recognises that the Commonwealth has no direct constitutional powers to regulate dealings with pesticides and veterinary medicines – including supply-side matters.

The current supply-side regulation of pesticides and veterinary medicines is based entirely on an applied law scheme whereby the states and the Northern Territory apply the Commonwealth law as a law of their own jurisdictions. The Panel supports the use of a Commonwealth-hosted law to regulate both supply side and control-of-use activities. It proposes that the Commonwealth work in cooperation with the states and territories to pursue a single regulatory scheme for pesticides and veterinary medicines. This should rely on the broadest extent of the Commonwealth's constitutional reach.

The Panel considers that the Commonwealth is likely to have constitutional authority to regulate the use of pesticides and veterinary medicines by corporations and other entities, including individuals and non-corporate entities who sell treated produce or goods to a corporation. The Panel further considers that the Commonwealth is also likely to be able to regulate where interstate and international trade is involved. The Panel also considers that Australia's participation in several international treaties may trigger the external affairs power, including those covering biological diversity and human health.

The Panel concludes that the most effective way to achieve this would be to work cooperatively with state and territory governments at the legislative and executive level to arrange voluntary referral of state powers to the Commonwealth under section 51(xxxvii) of the Constitution and use of the territories power (section 122 of the Constitution). However, the Panel appreciates that this may not be achievable in practical terms within a reasonable timeframe.

While the Panel is of the view that referral of powers is the preferred and most effective approach, if agreement cannot be reached, the Panel proposes that the Australian Government work with states and territories to implement a national applied law approach to control-of-use regulation. Again, this would be hosted by the Commonwealth and operate to the full extent of the Commonwealth's constitutional reach. The success of this approach for the current supply

side of the regulatory system suggests that this would be a viable means to deliver a coherent national control-of-use system.

The Panel does not support the alternative, where the states and territories could regulate independently in the gaps. This would be inefficient and lead to a fragmented regulatory approach, exacerbating many of the problems of the current system. A precedent already exists in the current national maritime safety legislation, with the Commonwealth-hosted law operating to the extent of the Commonwealth's constitutional reach and most jurisdictions applying the Commonwealth–hosted national law to operate 'in the gaps' through their own legislation.

Establishing a single comprehensive suite of legislation spanning the life cycle of pesticides and veterinary medicines from manufacture and supply, through use, to disposal, would deliver a simplified and consistent approach to regulatory arrangements. This would: reduce confusion and misunderstanding (with their associated risks of regulatory breaches); strengthen the current weakest links in the assurance and compliance chain; provide a level playing field for producers across Australia; reduce costs, especially for trans-border operations; strengthen risk management systems; simplify training requirements; facilitate greater recognition of national industry quality assurance (QA) schemes; and build public confidence to sustain the social licence to use pesticides and veterinary medicines.

It will also provide certainty, reduce regulatory costs, and provide greater efficiency for primary producers, industry, and the community. The Panel concurs with the New South Wales Government's statement through its submission that any control-of-use reforms should not reduce current protections provided by state and territory legislation.

> *"The NSW Government expects that any changes to control of use legislation would not reduce the protections provided by the Pesticides Act 1999 (NSW) or the Stock Medicines Act 1989 (NSW)."* (New South Wales Government 2020)

The Panel considers it an overdue reform, proposed as long ago as 2008 by the Productivity Commission, still widely supported by stakeholders today, and a critical initiative if a truly effective national regulatory scheme is to be achieved for the long term future.

Cost of reform

The Panel has considered the analysis in the 'Decision regulation impact statement on a National scheme for assessment and control-of-use of agricultural and veterinary chemicals' (Harding 2013) which considered the financial implications of a harmonised approach to control-of-use. While there has been some progress and achievements made in this space, many of the benefits envisaged are yet to be realised. The Panel estimates a single national approach will save approximately $75 million, after applying inflation, over a 10-year period (equating to $7.5 million a year corrected for inflation). These savings will be especially focused on the chemical user industries, such as farm businesses and commercial spray operators.

The Panel also estimates the government resources necessary to undertake the national control-of-use functions by the Commonwealth would be approximately $37 million over 10 years. The 2013 Regulatory Impact Statement (RIS) estimated state and territory resources to be in the vicinity of $39 million over 10 years (corrected for inflation). The Panel considers these

functions should be cost recovered (see Chapter 7), achieving a net saving to industry from a single national law of approximately $36 million.

The Panel's estimates do not account for the anticipated benefits to farmers, licence holders and business operators of working under a single national law; only the impact on regulatory costs (in this case a reduction) has been considered.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

4. Recommendation

The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.

Intergovernmental agreement (IGA)

The National Registration Scheme and the roles and responsibilities of the Commonwealth and the state and territory governments under the scheme are currently supported by an intergovernmental agreement (IGA) between the jurisdictions. The Panel has been tasked with reviewing the current IGA as part of its independent review of the regulatory system.

Although IGAs are not legally binding, they can be an important tool to transparently and explicitly set out the principles, procedures, roles, and responsibilities that apply to Commonwealth, state, and territory signatories. The Panel recognises, however, that attempts to harmonise control-of-use through the existing IGA have been largely unsuccessful.

The precise form of an IGA, including whether there would be a need for one, will depend upon the form of implementation to be pursued. An IGA may be particularly relevant if it is necessary to:

- facilitate consultation and cooperation between the Commonwealth and the states and territories
- achieve a strategic priority by pursuing and monitoring issues of national significance which require sustained and collaborative shared Commonwealth effort.

There is an option for there to be no IGA, as is the case for therapeutic goods regulation. An IGA may not be necessary, for example, if it is contemplated that the states and territories would not be expected to have any responsibility (legislative, regulatory or administrative) in relation to the regulation of pesticides and veterinary medicine products, such as:

- implementation of legislation for regulator and regulatory requirements
- implementation of a national policy framework for the assessment, registration and control-of-use of pesticides and veterinary medicines
- formalisation of consultation arrangements between parties
- agreement on how to deal with users and produce residues (including matters such as licensing, monitoring, risk management and similar agreed dealings).

If, for some reason, a national law approach cannot be achieved (e.g., due to broader issues in Commonwealth-state relations), the Panel recognises that continuing an IGA may be the only option available to pursue national consistency. However, given the lack of success of the current IGA-based process, the Panel considers this to be the option of last resort and unlikely to lead to any significant or meaningful change. Without a serious commitment to change, the Panel considers that the overall future pesticides and veterinary medicines regulatory system objectives described in Chapter 1 are unlikely to be achieved.

Given the uncertainties about the ongoing applicability of such an agreement (based on the Panel's reform proposal), the Panel does not believe that a review of the IGA can be meaningfully done at this time. Rather, the Panel recommends that the need, scope, role, and form of a new IGA (if necessary) are considered as part of this review's implementation, drawing on lessons learnt from the current IGA.

For example, the Panel is aware that consensus has been difficult to achieve when seeking to harmonise control-of-use arrangements under the current IGA. While included in the current IGA, allocation of adequate resourcing has also been problematic, with a substantive absence of public reporting of progress, and accountability by all signatories.

Therefore, in addition to outlining policy goals, division of responsibilities and inter-governmental consultation arrangements, the Panel recommends that if an IGA is needed it should:

- provide that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) of jurisdictions will prevail
  - a jurisdiction choosing not to fully implement the agreed common national approach should publicly provide reasons for any departure within a specified timeframe, which will provide transparency, accountability, and encourage cooperation
- mandate minimum resourcing levels for regulating control-of-use (perhaps as a proportion of jurisdictional domestic production value)
  - the allocation of resources to regulating pesticides and veterinary medicines appears to have declined over the years to the point where, in many cases, they are at risk of falling below the critical mass required to effectively undertake their control-of-use statutory functions and obligations
  - the Panel considers that providing clarity and specified resources for regulating pesticides and veterinary medicine use will significantly contribute to community confidence in the regulatory process
- require regular input by each jurisdiction for the purpose of public accountability and reporting against agreed performance indicators
  - this should relate to the entire regulatory system, and be supported by clear targets or goals
  - the Panel has concluded that lack of such performance reporting in the existing IGA has inhibited the identification of emerging cross-jurisdictional issues and failed to provide sufficient transparency and scrutiny to incentivise performance improvements by jurisdictions

- public reporting of performance by state, territory and Commonwealth Governments would be led by the Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner) (see Section 2.2) in the Commissioner's biennial reports on progress in reform and overall performance of the regulatory system as a whole.

5. Recommendation

The Panel recommends that the need for, and the scope, role and form of, a new IGA are considered as part of this review's implementation. The Panel recommends that the existing IGA be extended until this time, recognising that there are some matters, such as those relating to funding, that are unlikely to be resolved in the interim period.

6. Recommendation

The Panel recommends that should there be a need for an IGA in future, it should reflect the lessons learnt from the shortcomings of the current IGA including that it:

- **provides that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail**
- **requires any jurisdiction that departs from the IGA approach to provide a public reason for such departure**
- **mandates minimum resource levels for regulating control-of-use, to effectively meet assurance and compliance obligations (perhaps as a proportion of each jurisdiction's domestic production value)**
- **requires regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals**
- **requires regular publication (or input to the Commissioner's reporting) of performance against these indicators and targets or goals.**

2.2 Providing national leadership across the whole of the regulatory system

The most important recommendation by the Panel to improve Australia's pesticides and veterinary medicines regulatory system is the single national law for regulating the life cycle of pesticides and veterinary medicines recommended by the Panel in Section 2.1.

When examining the shortcomings of the current regulatory system, especially pertaining to control-of-use and the need for a single national law, a fundamental issue clearly identified by the Panel was the lack of centralised leadership of the system as a whole. The current regulatory scheme has had no identifiable leader, and as a result, no clear identity and critically, no clear accountability for its operation across the full life cycle of products regulated by the system.

The proposed single national law for regulating the life cycle of pesticides and veterinary medicines will contribute to providing certainty and greater efficiency for primary producers, the chemicals industry, veterinarians, and the community, establishing a vital foundation for the next 30-years. Without strong national leadership and a unified approach, the full benefits will not be realised.

Currently, responsibility for the many elements that make up the regulatory system is fragmented and decentralised among many parties. Any reforms, particularly in the control-of-use elements of the system can only be reached through consensus, or not at all. As a result, accountability is unclear, leadership is diffused and obscure, and change is slow. The Panel's firmly held view is that the continued absence of national leadership risks not only the success of the reforms it is proposing, but over time could undermine the integrity of the regulatory system for pesticides and veterinary medicines in Australia. As community concern about aspects of the use of pesticides and veterinary medicines increases, strong leadership is needed to maintain community and market confidence while continually adapting the system to changing future needs.

Clear, national leadership will ensure that the coherent framework established and recommended by the Panel can be presented internationally, acting as an asset for our export efforts.

It is apparent from several submissions, that there is a perception that the APVMA embodies the entirety of the regulatory system. This derives in part from the shorthand used to describe the APVMA as the 'national regulator of agvet chemicals', when in fact the APVMA should more correctly be described as the 'national product registration regulator'. Regulation of the control-of-use of agvet chemicals is currently the responsibility of the jurisdictions.

The Panel recognises the APVMA's expertise in product risk assessment and the role it plays as a national product registration regulator, but it is not a policy agency. Nor is it appropriate for an independent statutory regulator such as the APVMA to hold a role in setting the government's regulatory policy – rather its role is implementation of that policy. This view was also raised by some stakeholders.

> *"GrainGrowers also believe that it is not, nor should it become, within the APVMA's remit to set and drive a broader policy agenda. The APVMA's role is in implementation, and as such should lead the delivery of policy outcomes in the agvet chemicals space once key decisions are determined by the DAWE."* (GrainGrowers 2020)

The APVMA is a technical, science-based agency. It lacks the policy expertise to propose policy changes or to negotiate these among governments. It is responsible for part of, but not all of, the regulatory chain. It cannot speak publicly for the whole of the regulatory system, as might be required in the event of a regulatory lapse affecting public confidence. The system as a whole currently lacks such leadership.

The reality of multiple players and many legislative and policy drivers across Australia means our system appears complex to many stakeholders. Domestic users, consumers and community and other groups are often unclear about how the system works and who is responsible. For example, stakeholders reported confusion about which is the relevant agency responsible for dealing with adverse event reporting related to the use of pesticides and veterinary medicines.

The range and diversity of agencies directly involved in the regulation of pesticides and veterinary medicines currently has meant ultimate responsibility for action is dispersed through the bureaucratic collective. This has meant valuable reforms have been too long in development,

delivered inefficiently or ineffectively, subject to competing policy drivers and resource demands, or have had limited practical effect to users or the community.

The current approach has failed to consider the regulatory scheme as a system comprising many interdependent parts, with reforms commonly targeted to address supply or control-of-use in isolation. Given the multiple agencies involved, with no one entity that will (or is able to) take full responsibility for issues pertaining to the whole regulatory system, there is often confusion about who is accountable and responsible for dealing with problems or matters raised by stakeholders. Through public submissions to the review, there was strong support for introducing more accountability into the regulatory system.

> *"A critical contributor to this failure (of Agvet chemicals reviews) has been the lack of strong government oversight of and accountability for the individual agencies that constitute the national Agvet system. How to construct this accountability and drive for reform – in addition to establishing the reform needed – should be a central focus for the review team in its recommendations."* (Aerial Application Association of Australia 2020)

> *"NASAA Organic policy suggestions: transparency and accountability – to ensure a cooperative model of regulation and improve social licence."* (NASAA Organic 2020)

The Panel heard stakeholders' clear concerns that, without changes to system governance, the vision and recommendations of this Panel would be left behind like those of previous reviews. Over the decades at least 24 reviews into agricultural and veterinary chemicals regulation have been conducted (see Annex 3) and around 22 substantive amendments to primary legislation plus numerous smaller changes and regulations amendments.

Without addressing the lack of leadership and accountability within the regulatory system and providing a clear point of responsibility to actively drive implementation of the proposed new system and measure its performance, a single national law will not deliver the full benefit Australians should expect from the reform process.

There is broad recognition of the importance of the APVMA's role in the current regulatory system. Many submissions commended to the Panel the APVMA's expertise and rigour in science-based risk assessment.

> *"EnHealth considers the APVMA as the central body of science expertise for all agvet chemicals in the Australian system, is a strength of the current system. EnHealth considers that the coverage of the existing system, enables a consistent and efficient approach to the regulation of agvet chemicals."* (EnHealth 2020)

> *"While there are clearly many limitations to how the regulator can operate under the AgVet Act, GPA would like to commend the APVMA and its staff. The APVMA have supported the Australian grains industry with effective and timely communication on key chemical access issues including permits and the ongoing product registration needs of the industry."* (Grains Producers Australia 2020)

> *"(The RSPCA supports the) scientific rigour and technical proficiency of the APVMA, leading it to be a world class regulator."* (RSPCA 2020)

> *"APVMA is recognised globally for the quality and integrity of its science and risk-based regulatory decisions. It is an important asset to Australian farmers, the environment and consumers."* (Syngenta Australia 2020)

The Panel recognises, and agrees with, the strong support from stakeholders for maintaining the APVMA as a structurally separate, independent national regulatory agency that is founded on a strong scientific evidence base to make day-to-day decisions for registering pesticides and veterinary medicines. However, the Panel considers that there are also some regulatory areas that the APVMA does not appear to have the appropriate risk appetite to deliver. This conclusion is based on stakeholder feedback and the Panel's own engagement with the APVMA which demonstrated the agency's lack of willingness to meaningfully entertain the possibility of innovation or reform, as well as a reluctance to make greater use of the lower regulatory effort tools already available in legislation. Specific examples are outlined within this report.

It is government's role to set policy and develop and enact laws. At the Australian Government level these roles are undertaken by the Department. The Panel considers this separation has served Australia well by giving the APVMA independence from some of the policy debates and allowing it to focus on objective, scientific assessment of risk. However, in the absence of a clear point of leadership in the regulatory system there is a tendency for the community and industry to call on the APVMA when seeking both scientific and policy answers and advocacy for the regulatory system itself. A dedicated system leader is needed to engage in the full policy conversation and protect the independence and scientific focus of the APVMA.

The jurisdictions' control-of-use regulators show that where much of the regulatory role is centred on compliance and enforcement activities, which are a combination of both black letter law and judgement on how to best reinforce and encourage good behaviour, it is beneficial to have policy and regulatory functions located together. There is a strong educational component to control-of-use compliance that fits well within a government department. The Panel considers that where regulatory activities require these types of judgements that may go beyond a science-based consideration, it is a sound basic principle that the activity rest with a Department that through the Minister and Government is fully publicly accountable. In addition, there are a number of reforms related to control-of-use that the Panel is proposing that do not naturally fit with the technical role of the APVMA, such as general product obligations (Chapter 4) and co-regulation using industry quality assurance schemes. The Panel considers it could compromise the well-established and recognised reputation of the APVMA as an independent science-based registration authority if it were placed in the position of regulating control-of-use activities.

The Panel recognises that there is also a more pragmatic argument based on cost efficiency and national coverage for having the Department undertake control-of-use compliance and enforcement functions as it can leverage and build upon existing compliance systems and 'on the ground' resources used for other national regulatory arrangements (such as biosecurity systems, managing imports and export certification).

Advocacy

Another issue identified through stakeholder consultation is the benefit of having an 'advocate' to support industry (users and manufacturers), governments and the community to engage with the regulatory system. Currently, within the pesticides and veterinary medicines regulatory system, there is no central liaison point where relevant issues across the whole system can be

considered and actioned, or from where they can be delegated to the appropriate agency or regulator. The Panel heard repeatedly of 'buck passing' between agencies which left stakeholders confused as to who could assist with their issue or inquiry.

Furthermore, the regulatory system is in need of leadership to take carriage of formal consultative mechanisms that bring together and facilitate communication between governments (regulators and policymakers), chemical suppliers, users and community groups – enabling responsive, meaningful and productive engagement between these groups. Like other central roles undertaken by the Department, such as the Threatened Species Commissioner, the Panel views the creation of a principal position that addresses stakeholder concerns and speaks publicly on behalf of the entire regulatory system to ensure clear, consistent and accountable communication, as essential to the success of these reforms.

What change is recommended?

The Panel proposes the creation of a statutory office holder within the Department – to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner). In combination with the single national law, the Panel considers the Commissioner is critical to the success of the proposed reforms. For the first time, policy responsibility for the whole of the regulatory system would lie with a single entity.

This central point of responsibility for the future regulatory system will offer national policy leadership for the entire pesticides and veterinary medicines regulatory system, and act as a key liaison point for stakeholders and governments through formal consultation mechanisms. The Commissioner will take responsibility for the direction and core functions of the regulatory system including legislation, design, and program implementation, and will focus on continuing system improvement by establishing whole-of-system performance measures, by regularly and openly engaging with stakeholders, by publicly reporting on reform progress, and by driving change. The Commissioner will also be responsible for delivering a system-wide surveillance program drawing on data from a range of sources (see Chapter 3).

The Panel emphasises that the Commissioner will not be just another 'layer of bureaucracy'. Rather, when established in conjunction with the single national law, there will be a reduction in the number of regulators and policy makers in the current system (the APVMA, the Department, state and territory control-of-use regulators and policy makers), to just 2 (the APVMA and the Commissioner). The Commissioner will have regulatory responsibility for licensing (including national licensing schemes; other than manufacturer licensing) and most aspects of the use of pesticides and veterinary medicines (as discussed previously); that is, the Commissioner's regulatory focus will be on activities (the use of pesticides and veterinary medicines) while the APVMA's will be on regulating things (the products themselves).

Commented [SPE11]: Why not "while the focus of APVMA will be on regulating the products themselves."

The position will be accountable to the Australian Parliament through the responsible Commonwealth Minister for pesticides and veterinary medicines. The Panel considers that together with the CEO of the APVMA, the Commissioner will fill the current leadership gap for the regulatory system as a whole. To be clear, the Panel sees the Commissioner and the CEO of the APVMA having a collaborative and co-operative relationship, that would maintain the APVMA, as the national registration authority. The functions and powers of both the APVMA and Commissioner will be (and in the case of the APVMA, already are) set out in legislation and will be clearly separate.

The model for this position has similarities with other centralised government Commissioner positions such as the Inspector-General of Live Animal Exports and the Inspector-General for Biosecurity, which review their respective systems through independent audit and evaluation.

However, the Commissioner will have a broader role than those positions and subsume current functions from the Department. These functions include assessing progress and outcomes in the system's operations, providing policy advice to the responsible Minister, undertaking legislation development, policy design and implementation. The Commissioner would also participate in national level strategic policy discussions, including for example, those related to chemicals of security concern. Importantly, these functions will now capture, directly, the entirety of the regulatory system.

The Commissioner will advise Government and the community on the performance of the regulatory system, based on regular public reporting framed against a set of whole-of-system performance measures (discussed in Section 2.5). With the benefit of advice from the APVMA and other relevant agencies, the Commissioner will also take leading roles in domestic and international policy discussions, complementing and cooperating with the APVMA's leading roles in technical and scientific fora, such as the Codex. The Panel expects that it is these dual leadership roles, reflecting the separate areas of expertise between the Commissioner and APVMA, that will act as the primary source of information and knowledge sharing.

7. Recommendation

The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

8. Recommendation

The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.

9. Recommendation

The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.

As the Commissioner would have both policy and legislative authority (responsibility for proposing changes to legislation), the holder of the position would be empowered to respond when areas of regulatory inefficiencies or deficiencies are identified. These may include issues drawn to attention through the Stakeholder Forum (see Section 2.4), or as good regulatory practice progresses. Either could require the design and preparation of new legislation for Ministerial or parliamentary consideration. For example, the Commissioner could propose the refinement of control-of-use licence types or conditions, or the recognition of industry QA standards and schemes. The Commissioner would keep the single national law as a contemporary document.

The Commissioner would become the 'public presence' that is lacking in the current system as a whole, and the key liaison point for stakeholders on matters relating to the entire pesticides and veterinary medicines regulatory system.

The Commissioner would manage 2 key engagement groups:

- The primary group would be a 2-way stakeholder engagement and consultation review forum (Stakeholder Forum).
- The second group would be an implementation and operational forum of jurisdictions and regulators including consumer and fair trading and work health and safety regulators (or their representatives) (Operational Forum).

The Commissioner would also have the authority to convene Expert Advisory Panels. The panels would consist of experts in the fields of public health, regulatory theory and implementation, and others as appropriate to consider contemporary issues of public concern and provide independent advice on those matters. The panels would have the option to conduct inquiries to guide their advice.

Commented [SPE12]: The availability, prescribing and use of veterinary medicines, especially in the vast number of non-production animal species, is a very specialised area and fully justifies the establishment of a Standing Expert Advisory Panel on Veterinary Medicines.

The Panel's recommendations on greater industry and community engagement through these bodies can be found in Section 2.4.

10. Recommendation

The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.

The Commissioner would also undertake the following administrative and corporate responsibilities:

- administer grants programs, e.g., the existing assistance grants program for minor uses
- refer matters to relevant operational areas (such as compliance and enforcement, or in response to triggers for review of chemical products within government) for further action.

An important function of the Commissioner would be to maintain momentum in reform and to drive continuous improvement in the regulatory system. This function is a conspicuous deficiency in the current arrangements. The Commissioner would build on the future regulatory system's principles (Chapter 1) of accountability and transparency by establishing and reporting against performance indicators that will measure efficiency, compliance, and safety. In its first year, the Commissioner will prepare a public report on the progress of reform implementation. Thereafter, the Commissioner will report on the state of the system biennially. The APVMA will continue to report separately on its performance annually.

The Commissioner will also establish and maintain a list of nationally consistent training and competency standards for operators who apply chemicals in a commercial setting (be it agricultural or domestic) (see Chapter 4).

11. Recommendation

The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.

12. Recommendation

The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.

Cost of reform

In the initial years following implementation, the Panel expects most of the Commissioner's resources will be met through existing appropriation for pesticide and veterinary medicine functions undertaken by the Department.

The Panel recognises that as the future system matures to a steady state, the resource requirements of the Commissioner will grow commensurate with the functions. As the new aspects of the future system become operational, the resources for many of these will be cost recovered (such as licensing arrangements see Chapter 4) or be supported through appropriation for example consultation mechanisms(see Section 2.4) expanded system surveillance (see Chapter 3),domestic produce monitoring (see Chapter 3) and environmental monitoring (see Chapter 3).

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

2.3 Governance of the APVMA

Good governance is fundamental to the success of any regulatory agency. Without this, the agency may not achieve its objectives; meet its legal obligations; build and maintain the confidence of both the public and the regulated community; be flexible, responsive, accountable, and efficient; and drive continual improvement. This is true at both a systemic as well as organisational level.

The APVMA is, and will remain under the new scheme, a corporate Commonwealth entity (CCE) subject to the *Public Governance, Performance and Accountability Act 2013* (PGPA Act) and the chief executive officer (CEO) of the APVMA is currently the APVMA's accountable authority under this Act (although the minister may give written directions to the APVMA concerning its functions or powers).

Despite the APVMA's complex regulatory obligations – and the critical impact of its decisions on human health, animal welfare, ecosystems, trade, and agricultural production – all responsibility for its strategic leadership, governance, financial management, staff management, and day-to-day operations currently resides with the APVMA's CEO. This creates a potential vulnerability, as the inward-facing management, leadership and governance demands on the CEO's time, compete with the outward-facing obligations associated with regulatory functions.

The fundamental role boards play in good governance of corporate Commonwealth entities is apparent from the fact that the APVMA is one of only a few such entities without a board to support corporate compliance and management accountability (approximately 90% of these entities have a board). Tellingly, all other Commonwealth regulatory entities with direct responsibility for protecting human life or health – such as Food Standards Australia New Zealand, the Australian Maritime Safety Authority, and the Civil Aviation Safety Authority – have boards.

The Panel therefore considers that there are substantial benefits – both to the authority's governance and to its regulatory performance – to be realised from re-introducing a board to enhance the CEO's capacity and accountability in governance matters.

In addition, the Panel sees the board as an important new instrument to drive the reform agenda and ensure past criticisms of slow or no progress in procedural improvements are avoided in future. The Panel will be recommending a range of far-reaching reforms to the regulatory system as a whole. Many of those reforms have an impact on the APVMA's approach to regulatory decision-making. The APVMA's responsiveness to the new arrangements will therefore be critical to the success of the reforms as a package. An important role for the APVMA board will be to initiate and maintain reform momentum and ensure the Authority takes full advantage of the opportunities provided by the new arrangements. This role should be reinforced by the Minister in commissioning guidance to the new board.

Some stakeholders thought that a board would be a valuable addition:

> *"A strength of the APVMA is its capacity to operate independently from Government. However, its performance may be improved with the addition of a board of directors".* (AgriFutures Australia 2020)

> *"The governance structure that is most desirable consults with stakeholders, seeks guidance from within and beyond when addressing complex issues, appreciates the separate but related importance of science based risk assessment and socially and environmentally responsible risk management, retains scientific vigour, is consistent in decision making while being flexible. Option 2, statutory authority with board, may most closely reflect these features".* (Australian Veterinary Association 2020)

> *"… we would support Option 2 (governance board) as our first preference, with Option 1 as a second preference".* (NSW Farmers Association 2020)

However, other stakeholders – particularly those in the chemicals industry – have expressed reservations about the introduction of a board. These largely related to the board's running costs (recognising that the costs of the board would be recovered from industry), representation, and a perception that it would have limited benefit.

> *"CropLife and our members do not, in principle, oppose governance structures like a board of directors. It is essential, however, that appropriate analysis and genuine industry and farmer consultation be conducted regarding the development of a governance arrangement that could add genuine value to the APVMA, rather than just adding an additional layer of costly administration and management. If a Board were to be introduced, the direct and associated costs should be fully funded by the Federal Government as an appropriate contribution to the effective operations of the Regulator."* (CropLife Australia 2020)

> *"… the Board should be funded by government and not be part of the cost recovery from industry. We are not opposed to a board in principle but can't see the benefit versus the cost".* (Syngenta Australia 2020)

> *"The VMDA does not support a 'skills based' governance board such as that proposed in the legislation before the Parliament. We believe that this arrangement will not*

> *lead to an improvement in the rigour and transparency of the regulation process."* (Veterinary Manufacturers and Distributors Association 2020)

The Panel supports the board model proposed in the Government's *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* (the APVMA Board Bill), and agrees that the board should be responsible for appointing and terminating the CEO. This will ensure that the APVMA CEO is not only supported but that their performance is closely monitored. This will help to ensure that the organisation's governance and regulatory performance will be less variable and that the organisation's dominant culture will be one of continuous improvement rather than a static business-as-usual approach.

The Panel considers that board members should be appointed on the basis of their qualifications, skills and experience. The APVMA Board Bill requires that appointed board members must possess appropriate qualifications, skills or experience in one or more of financial management, law, environmental toxicity, risk assessment, risk management, public sector governance, science (including agricultural science and veterinary science), public health or occupational health and safety. The Panel considers that these skills are broadly appropriate. However, it suggests that environmental science be explicitly added to the list of appropriate skills (alongside agricultural and veterinary science) to help ensure that environmental interests in pesticides are available to the board.

The Panel agrees that a 5-member board – including the chair and APVMA CEO – will provide an appropriate diversity of skills and experiences for the organisation while keeping costs constrained. The inclusion of the CEO as an *ex officio* board member will provide the board with the necessary operational insight, strengthen 2-way communication between the board and CEO, and ensure the CEO understands and can influence and implement the board's policies. The costs of operating the board would be incorporated into the APVMA's operating costs and hence its charging structure.

Recognising the critical importance of independent science-based decision making, the Panel considers that the board should not be involved in day-to-day management and operational activities of the regulator, nor should it impact or influence the scientific integrity of regulatory risk assessment. This is consistent with stakeholder views:

> *"… we note the importance of ensuring that a board does not exercise undue control over the operations of the regulator, safeguarding evidence-based decision making from board intervention."* (NSW Farmers Association 2020)

> *"The most important elements are that the agency responsible for agvet chemical regulation should be independent, accountable, science-based and free of any political influence."* (Chemistry Australia 2020)

13. Recommendation

The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.

2.4 Meaningful engagement with industry and the community

Through the Panel's consultations, a common theme that emerged was that many stakeholders wanted more formal engagement and consultation arrangements on matters relating to the regulatory system and felt that their voices were neither heard nor considered in decision-making, particularly by the APVMA and the Department. Many stakeholders were unclear about the channels available through which to provide input or their views. Some were aware of and acknowledged current as well as previous efforts by the APVMA to consult on specific APVMA processes or decisions, but most could not see easy mechanisms to comment on system-wide issues beyond the APVMA.

In the Panel's view this is further evidence of the lack of a focus of leadership for the system as a whole. The APVMA is an important part of the system, but as a technical regulator with defined responsibilities, cannot be expected to provide a channel for dialogue regarding those elements of the system outside its own remit.

The Panel's discussions with stakeholders highlighted that in the consultations on regulatory matters to date, many groups felt under-represented at best, and excluded at worst, the latter being the predominant view expressed by community group stakeholders in relation to APVMA decisions and policy development undertaken by the Department.

> *"… open and transparent reporting should also be built into the system so it is much more than just the domain of privileged insiders who can unilaterally make decisions that affect us all. Scant information is publicly available about the Registration Liaison Committee, its original intent, membership, past operations or decisions. The effective participation of independent experts and the interested public in redesigning and implementing new regulatory regimes is essential."* (GeneEthics 2020)

> *"To rebuild public confidence in the regulator and government integrity and to combat the perception that government and regulators are 'in the pockets' of industry interests, a new approach to governance of the regulatory system is needed. Including community interests on boards and other regulatory panels means the broader community interests can be seen to be included from the very beginning of the process."* (Public Health Association Australia 2020)

The social licence that permits chemical pest and disease management in the production of Australian food and fibre commodities, and in treating companion animals, should never be taken for granted. Ultimately, it is the consumers of produce, and owners of animals, who choose to accept that the use of pesticides and veterinary medicines is safe to human and animal health and wellbeing as well as appropriate and responsible. The Panel recognises how fragile this social licence can be. The community is seeking assurances that adverse impacts on ecosystems arising from the use of pesticides are minimised and that treated produce is being adequately monitored to ensure the safety of their food as well as the supply chain. Transparent consultation arrangements can make an important contribution to such public assurance.

> *"Consumers want to know that the produce they buy is fresh, healthy and clean. A small but growing segment of consumers want to know the provenance of their food,*

> *and that it was produced sustainably. The latter group may be interested in the regulatory process."* (Citrus Australia 2020)

The community is also seeking assurances that animal welfare is not being compromised because of a lack of appropriate veterinary medicines to prevent and treat diseases and ailments in production and companion animals. Key factors where social licence has been revoked or threatened in other fields include a lack of transparency and poor communication and failure to effectively engage with the broader community, particularly in urban areas. Examples include live animal exports, greyhound racing, and feral animal control programs in conservation areas.

The Panel is not satisfied that there has previously been adequate consultation on reforms to the regulatory system to date; there is an absence of an effective dialogue between regulators, industry, and the community. Historically, engagement with the system's regulators, policy makers and the broader community has usually occurred on an 'as needed' basis. The Department, in developing reforms to the regulatory system, has not effectively engaged with stakeholders beyond key industry groups, nor with the broader community. For example, policy advisors and implementers, including the Commonwealth and other jurisdictions seek public engagement and consultation on relevant reports or legislative amendments. Stakeholders are routinely encouraged to either provide written feedback or contact relevant departmental officers for further discussions.

The Panel particularly heard from environmental and community NGOs that they felt that the Department and the APVMA have never seriously considered their views or concerns and this has made them reluctant to continue to engage as they see no benefit in doing so. They were frustrated at the amount of effort and time they had repeatedly expended previously to put their views to government with no acknowledgement of the issues they raised.

Too often past reforms have been seen as overly process-focused and only targeted towards making improvements for the regulated community or user industries. The benefits that accrue to the community and Australia more broadly have not been effectively conveyed and community concerns have not been seen to be adequately considered.

> *"Comprehensive public participation (not consultation) in every aspect of its creation, deployment, and ongoing operation will be key to overall success."* (GeneEthics 2020)

The Panel considers that a well-informed community and industry will produce positive social and economic benefits for human safety, agricultural production, the environment, animal welfare and trade. The Panel understands that the diversity of views on the role and place of pesticides and veterinary medicines means it is unlikely that a consensus will ever be established. However, the Panel is convinced that it is only through productive dialogue across the spectrum of stakeholders that social licence can be sustained. There needs to be an effective mechanism for all groups that have a key stake in the regulatory system to be heard and their views considered.

The Panel heard repeatedly the need for better communication between regulators, industry, the community, and policy makers.

> *"… the regulator and the department should play greater roles in educating and reassuring the community regarding the regulator's purpose and processes."* (National Farmers' Federation 2020)

> *"We strongly support communication, consultation and transparency*." (Pesticide Action Group of Western Australia 2020)

Similarly, CropLife Australia considered that the regulator should engage further with local councils.

> *"CropLife recommends the Regulator engages proactively and effectively with local councils to educate them regarding the APVMA's regulatory activities and scientific assessment processes. This is not part of the APVMA's draft Framework. Local councils are often the first point of contact for residents regarding concerns they may have with the safe use of pesticides in their community."* (CropLife Australia 2020)

The Panel notes that it is not the role of the APVMA, as the independent science-based regulator, to advocate for either chemical products or the regulatory system more broadly, but accepts stakeholders' desire for more engagement by the government in public discourse.

In addition to sustaining the social licence regarding the use of pesticides and veterinary medicines, the Panel considers that strong consultation arrangements are vital to build the sense of shared responsibility among stakeholders that needs to be a foundation for the future regulatory system. The Panel is recommending a range of measures to better inform community, industry, and other stakeholders on the operation of the regulatory system and policy reform and national risk management arrangements. Consultation machinery will therefore be an important means to mobilise the active engagement of non-government parties in the shared responsibility of the safe use of pesticides and veterinary medicines.

There was strong support for the establishment of a formal consultative forum in Australia. Submissions from the Australian Groundsprayers Association, Horticulture Innovation Australia, Pesticide Action Group WA, RSPCA, Australian Grape and Wine, Syngenta, Australian New Zealand College of Veterinary Science(ANZCVS), the National Farmers' Federation (NFF), Public Health Association Australia and GrainGrowers all supported a formal consultation mechanism.

> *"The NFF support's the panel's view that there would be value in establishing a formal consultative mechanism that brings together and facilitates communication between governments (regulators and policymakers), the agvet chemical industry, users and community groups."* (National Farmers' Federation 2020)

> *"The AGA strongly supports the establishment of a formal consultative forum."* (Australian Groundsprayers Association 2020 and SprayPASS 2020)

> *"Australian Grape and Wine is supportive of the introduction of a formal mechanism for consultation between governments and industry stakeholders to ensure regulatory systems are accessible and responsive to the needs of users and to assist in informing policy."* (Australian Grape and Wine 2020)

> *"There needs to be an ongoing formal consultative forum with representation from all key stakeholders, including the broader community, such as established by AICIS.*

How the community is engaged as a stakeholder is important." (Public Health Association Australia 2020)

What change is recommended?

The Stakeholder Forum

The Stakeholder Forum would establish a channel for dialogue between stakeholders to provide input to the development of policies across the whole regulatory system relating to pesticide and veterinary medicines.

The Stakeholder Forum is to be the primary means of government engagement with stakeholders, and stakeholders communicating back to government. The Stakeholder Forum would promote effective ways for all participants in the regulatory system to contribute to ensuring the responsible use of pesticides and veterinary medicines. It would also monitor reform progress.

The Stakeholder Forum would have broad based membership reflecting the range of interests in pesticide and veterinary medicine product use and impacts. The Panel expects representation would include farming, environmental, animal welfare, consumer and health groups, chemical companies, veterinarians, chemical applicators, trade unions, education, and training organisations and relevant government agencies. The Panel acknowledges the United Kingdom (UK) Pesticide Forum as the basis for this Stakeholder Forum. The Stakeholder Forum would provide recommendations to the Commissioner.

To ensure the independence of the Stakeholder Forum, an independent chair should be appointed by the Minister for a 3-year term with an option for renewal for a second term. Secretariat support would be provided through the Commissioner.

In addition, the Panel proposes that:

- the chair of the Stakeholder Forum meets with the Commissioner, the CEO of the APVMA and the Minister at least twice a year and independently of the Stakeholder Forum meetings
- the Stakeholder Forum will be actively involved in the development of, and then review and comment on, the health risk indicators and system performance measures developed by the Commissioner (see Section 2.5)
- the Stakeholder Forum will review and provide comment on proposed annual monitoring and surveillance plans (see Chapter 3)
- the Stakeholder Forum will monitor progress of the reforms decided by the government following the Panel's report
- the Stakeholder Forum may recommend topics to the Commissioner for consideration by an Expert Advisory Panel
- the Stakeholder Forum will prepare annually, a list of prioritised issues and submit these to the Commissioner. The Commissioner must provide a response to each issue on the list within 6 months of receipt. Both the list and the response from the Commissioner will be published in the Stakeholder Forum's annual report. The report is to be publicly available and provided to the Commissioner, the CEO of the APVMA and the Minister

- the Stakeholder Forum will meet biannually (at a minimum) during the implementation and first 2 years of operation of the reformed regulatory system. The effectiveness of the Stakeholder Forum will be reviewed by members after the first 2 years of operation.

The Operational Forum

The Operational Forum to be established by the Commissioner provides a mechanism for Government and government entities to discuss issues relating to the operation of the regulatory system.

The Operational Forum provides a vehicle for regular comprehensive discussions between governments and regulators on the operation and implementation of policies, legislation and operational practices for pesticides and veterinary medicines. The Operational Forum will identify points of conflict, opportunities, and areas for improvement between regulatory arrangements relating to pesticides and veterinary medicines and develop and address operational approaches to resolve conflicts.

Membership will include state and territory governments and regulators, including regulators involved with operational matters in the regulatory system. The Panel anticipates members would be drawn from agencies and departments with operational or policy responsibility for the environment, work health and safety, biosecurity, fair trading and consumer protections, health, poison scheduling, agriculture, and the APVMA. This forum can also provide advice to relevant Ministers on legislative reforms that are needed to action policies and operational practices related to the regulation of pesticides and veterinary medicines.

The Expert Advisory Panel

The Panel considers that Commissioner should have the power to convene an Expert Advisory Panels to provide input into any significant issues relating to the functioning of the regulatory system as a whole. The Commissioner would require a response from the Expert Advisory Panels within a specified time.

The Expert Advisory Panels would consist of independent experts, with relevant expertise to the topic of enquiry. Similar to the formal arrangements that exist for hearings conducted by the APVMA, the Expert Advisory Panels will, as needed, be able to undertake inquiries (such as calling for submissions or formal presentations) to support their consideration of a topic and subsequent advice.

The Panel does not expect the Commissioner would convene Expert Advisory Panels frequently. It is also not the Panel's intention for the Expert Advisory Panels to become a 'standing' entity. The Expert Advisory Panels will be convened for the purposes of seeking evidence on critical issues to assist the Commissioner in the performance of their duties, functions, and powers. This could include the significance of matters identified through surveillance programs, a specific area of regulation, (such as compliance and enforcement where new theories are established) or advances in application technology (such as autonomous vehicles).

The Panel is cognisant that the expert advisory panel could be perceived to undermine the independent scientific reputation of the APVMA and re-prosecute regulatory decisions with a view to obtaining a different outcome. The Panel is strongly of the view that it would not be appropriate for the expert advisory panel to undertake inquiries that relate to APVMA regulatory decisions, rather it would focus on broader policy issues.

Commented [SPE13]: In view of the specialised nature of the medicine of non-production animal species the AVA sees considerable need for and merit in a Standing Expert Advisory Panel on Veterinary Medicines (SEAPVM). Many decisions made for pesticides may have unintended consequences for the species under the care of veterinarians (for example, wildlife and aquatic animal species). Unintended consequences can be difficult or impossible to reverse and their early recognition and avoidance is far preferable. The SEAPVM could reduce the likelihood of such adverse events and as well as ensure other implications of decision making were more thoroughly and completely discussed.

14. Recommendation

The Panel proposes the establishment of 2 formal and one ad hoc consultation mechanisms by the Commissioner to consider, and offer advice to Ministers and the Commissioner as appropriate on, the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are:

- **a Stakeholder Forum**
- **an Operational Forum**
- **an Expert Advisory Panel (as needed).**

15. Recommendation

The Panel recommends the Stakeholder and Operational forums have terms of reference consistent with those set out in Annex 10 and Annex 11.

Cost of reform

The Panel estimates that $325,000 per annum ($3.25 million over 10 years) is needed to establish and maintain the improved communication and consultation mechanisms. This will include the costs of the Stakeholder Forum (and the independent chair), and accessible funding for the Expert Advisory Panel. The Panel views each of these mechanisms as a public good function (in terms of policy development and advice to government), and these costs should be met through government appropriation.

The Panel considers the Operational Forum a function of government with associated costs absorbed into appropriated activities. The Panel does not anticipate any regulatory cost impacts from this reform to any sector of industry.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

2.5 Introducing whole-of-system performance measures

Performance measures are a critical part of any regulatory system. They provide information on activities, demonstrate accountability and transparency of the system, and provide insight into the efficiency and effectiveness of regulatory actions. There are currently no effective system-wide performance measures for the pesticides and veterinary medicines regulatory system. As a result, there is no way to measure the performance of the system as a whole or its major individual parts.

To the extent that performance measures exist, they relate mostly to the operational performance of the APVMA. Moreover, where performance measures do exist, they are frequently in the form of input or output measures, not outcome measures. Contemporary best practice performance measurement arrangements focus on the latter.

Stakeholders agree that the pesticides and veterinary medicines regulatory system should be more transparent and that regulators should provide public information on their activities.

> *"(Stakeholders would like to see) information about the processes themselves, the governance arrangements, what chemicals are being and have been assessed, the*

> *assessment outcomes, what breaches to the regulations and what action has been taken by the regulator and government."* (Public Health Association Australia 2020)
>
> *"Ongoing publication of relevant issues and responses will help to support the public position of the regulator as a responsible entity and perhaps prevent unexpected issues from becoming 'overblown'."* (Veterinary Manufacturers and Distributors Association 2020)

Performance measures are needed across the whole system so that government can provide assurance to stakeholders, the community, and trading partners that the system is transparent, robust, and accountable and is delivering the outcomes required of it, efficiently and effectively.

What change is recommended?

The Panel recommends the establishment of a comprehensive set of performance measures. It further recommends that leading the performance assessment and reporting system should be the key public-facing role for the proposed Commissioner.

The pesticides and veterinary medicines regulatory system, plus the performance measures themselves will be determined and administered by the Commissioner. The set of performance measures will include indicators to track progress against the reform agenda set by government decisions following the Panel's current review. In this way, progress on reforms will be actively driven. This has not always been the case in the past.

Although reporting against the whole system's performance measures will be the responsibility of the Commissioner, some reporting responsibilities will continue to sit with the APVMA, who whilst reporting on them separately, would also have them incorporated into the Commissioners overall system report.

The performance measures, while established to report on specific parts of the supply chain, should also, in combination, provide an overall view of the system's performance in its entirety. Performance measures should align with the vision of the regulatory system and deliver against its objectives, as described in Chapter 1 but also include measures for health, environmental outcomes, industry, and community sentiment, and regulator performance. Wherever possible, performance measures will be designed to be outcome, rather than output, based.

The Panel recommends that performance measures include those that monitor the health status of people, animals, and the environment. Health risk indicators are of particular importance and can establish trends in the use of pesticides or veterinary medicines. An example of the use of health measures by a jurisdiction is the European Union. Each year, member states are obliged to calculate health risk indicators, identify trends in the use of certain active substances, identify priority items that require attention and communicate the results of evaluations to the European Union Commission.

The Panel recommends that industry measures should encompass the entire life cycle of pesticides and veterinary medicines, across the supply chain, from development of new chemistries through to supply, use and product disposal. Measures would also include Australia's involvement in international forums, trade statistics, and capability and capacity building.

The Panel also recommends that community measures be developed to assess how the community views and interacts with pesticides and veterinary medicines and the regulatory system and its responsiveness in addressing these concerns. Measures may be qualitative or quantitative and provide a broad overview of sentiment at a given point in time.

The Panel recommends that regulator performance measures should relate to obligations or requirements of the regulator to measure and report on statutory functions and outcomes, including compliance and enforcement, cost recovery and national capacity building (e.g. number of accredited assessors) and consumer education . This should include the activities of both the APVMA and the Commissioner.

In the first 2 years from the commencement of the role, the Commissioner will work to define and implement performance measures, which should be developed in consultation with the Stakeholder and Operational Forums (see Section 2.4). Existing performance measures should be reviewed and consolidated or revised as part of the development of whole-of-system performance measures. Measures should be nationally consistent and be contextualised so as not to be misinterpreted or create perverse incentives by 'meeting the target but missing the point'.

Box 1 Illustration: adverse experience reporting in a future regulatory scheme

An increase in total numbers of adverse experiences is reported over a 2-year period. The Commissioner recognises the issue deserves further investigation and commissions research to analyse the contributing factors. After further enquiry, it emerges that initiatives instigated by the Commissioner to promote the program to users, manufacturers and the community in the preceding year have been highly effective, and that the increase in reporting may in part, be due to increased awareness of the system and of user obligations. A contributing factor identified was increased use of unregistered companion animal products purchased over the internet. Armed with this information, the Commissioner developed an information campaign to address this issue.

Commented [SPE14]: The AVA definitely supports adverse experience reporting [in fact the AVA had a fully functioning and effective adverse event programme operating many years before the national regulator commenced its programme in the mid 1990s] believes that a properly functioning pharmacovigilance system could identify this issue earlier and respond more readily.

Performance reporting must capture the entire regulatory system, including pre-and post-market activities. The Panel recommends a biennial public reporting system (led by the Commissioner) as a reasonable approach to capture key changes over time and to strike a balance between the need for transparency and accountability with associated costs and resources for data collection, analysis and reporting.

The Panel sees the biennial reports by the Commissioner as a major contributor to continuous improvement of the whole regulatory system. These regular reports will provide the impetus for agreed reforms and better outcomes. The unfortunate history of lapsed reform initiatives of the past will be avoided.

For that part of the overall system occupied by the APVMA, statutory timeframes currently prescribe the maximum timeframes within which the APVMA must complete an assessment. Statutory timeframes provide a transparent indicator of expectations and are used by industry and government to monitor the APVMA's output performance; however, there are no legal consequences if the regulator fails to meet the timeframes. The statutory timeframe varies depending on the complexity of the application and can be extended in certain circumstances. On occasion, assessments can be unreasonably complex or require specialist external knowledge that is difficult to source. In these cases, it is better for the regulator to delay its assessment than

reach a decision simply to meet timeframes. For these reasons, reporting performance against statutory timeframes is a coarse measure and a poor indicator of overall performance; however, it is one of the few tools currently available to assess performance.

While statutory timeframes alone are a less than ideal indicator of the APVMA's overall performance, these input or lag measures will continue to be an important part of a broader range of system performance measures in the future.

Performance against timeframes should be publicly reported to increase accountability. Compliance with statutory timeframes should be reported quarterly but should also include an indication of the number of days from target (for both applications completed early and late) in order to encourage efficiencies and gain a more comprehensive picture of the timeliness of decisions.

The Panel recommends that existing statutory timeframes be retained and expanded to include a range of other decisions, including for example, licensing decisions (made by the Commissioner, and the APVMA), reconsiderations, and responses to recommendations made by the Stakeholder Forum in the future regulatory system to improve transparency and accountability.

16. Recommendation

The Panel recommends that the Commissioner establish a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The biennial reports would review progress in implementing the reforms decided by the Government in light of the Panel's current report. Reporting should commence 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Performance measures, as a minimum, should address:

- **health impact**
  - **establishing formal human, animal, and environmental health risk indicators**
  - **number and nature of adverse experience reports and pharmacovigilance findings, and time taken to respond to adverse experience reports and any consequential actions.**
- **industry impact**
  - **supply, use and disposal of pesticides and veterinary medicines.**
- **community impact**
  - **social attitudes**
  - **community outreach and engagement.**
- **regulator performance**
  - **number and type of regulatory decisions by the APVMA and Commissioner**

  - **number and type of audits and compliance activities, including information and education campaigns.**
- **responsiveness to community concerns raised.**

17. Recommendation

The Panel recommends that the Commissioner establish health risk indicators for Australia, similar to those used in the European Union, and publish outcomes in its reporting of performance measures.

18. Recommendation

The Panel recommends the retention of statutory timeframes for the APVMA to complete its pre-market assessments as a vital input measure to the regulatory system and recommends that statutory timeframes should be expanded to a range of other decisions, such as licensing and responsiveness to the Stakeholder Forum, in the future regulatory system to improve transparency and accountability.

3 Protecting the health and safety of people, animals, and the environment

The Panel considers that protecting the health and safety of people, animals, and the environment is an essential purpose of a safe and effective pesticides and veterinary medicines regulatory system. While the current regulatory system has a range of measures in place to protect health and safety, especially in relation to the scientific assessment process for registering products, the Panel has, in addition to its other reforms, targeted 3 key areas for transformation: surveillance and monitoring; chemical reviews; and a new humaneness indicator for vertebrate pesticides. The measures proposed here will ensure that the system continues to meet community and industry expectations, build public confidence, and sustain social licence, and improve protections for people, animals, and ecosystems.

Better surveillance and monitoring will enhance safety through the implementation of 5 elements: system surveillance and data mining and analysis; domestic produce monitoring; environmental monitoring; identifying product related concerns; and transparency through public reporting of system surveillance. These elements will work together to ensure that pesticide and veterinary medicine use is effectively monitored and that any areas of concern are detected as early as possible to limit potential harm and enable a proportionate response.

Chemical reviews can offer critical insight into the health and functioning of the regulatory system as a whole and should be used to address issues arising as a result of new science and information on possible adverse chemical impacts. The transparency and speed of chemical reviews needs to be improved to protect human and animal health, animal and crop safety and trade. A contemporary, more expeditious review process will ensure that the risks of dealing with pesticides and veterinary medicines are identified and managed as information becomes available.

Good animal welfare and the humane treatment of animals are essential for maintaining the social licence for livestock production, including for the domestic and international trade in animals and animal products. There are expectations that safe and effective veterinary medicines should be available to treat diseases and conditions of production and companion animals. The community also places high importance on good animal welfare in the management of vertebrate pest animals. Providing consumers with the choice to use more humane treatments for the eradication of vertebrate pests should be part of any contemporary fit-for-purpose pesticides and veterinary medicines regulatory system.

3.1 System surveillance and data mining and analysis

Vital to any effective regulatory system is the ability to objectively monitor performance and to ensure any areas of regulatory concern are identified for investigation and response. The social licence to continue to use pesticides and veterinary medicines depends on robust data to instil public confidence in such arrangements.

There is a vast literature available that describes the detrimental effects of chemicals in general on human and environmental health worldwide. For example, the Panel received from the National Toxics Network an array of references to overseas studies demonstrating the impacts of pesticides on human health. Many of these chemicals have similar exposure pathways in Australia and could be expected to have comparable potential detrimental human health outcomes. Additionally, there are numerous studies on the presence and potential detrimental effects of these chemicals on the health of the Australian environment, to complement the extensive studies found in the international literature.

The Panel recognises the importance of this research. It also recognises that such findings, if taken in isolation, could underpin public disquiet about the use of chemicals, and could impact public confidence in the future pesticides and veterinary medicines regulatory system.

Likewise, there is a wealth of information, both publicly available or collected by industry, that could be better utilised to establish a more sophisticated system surveillance model and inform risk management measures as well as policy discussions and reform proposals.

Annual pesticides and veterinary medicines sales data is currently reported by chemical companies to the APVMA. This sales data appears to be used sporadically by researchers and policy makers to provide an indication of the use of these chemicals in Australia. However, the use of sales data to indicate the volume of chemical use in Australia is somewhat misleading as it does not account for price fluctuations or stockpiling. The Panel supports the current proposal before Parliament which requires total product quantity supplied to be reported on an annual basis, in addition to the current requirement for sales data.

> *"Reporting of the use of veterinary medicines has many benefits, however, registrants can only report sales data and quantities of active constituent used in manufacture of veterinary medicines, not how the product was ultimately used. A system of clinical record review and audit to determine actual use that was anonymised and non-threatening could provide valuable ongoing real time information."* (Australian Veterinary Association 2020).

Separately, jurisdictional control-of-use legislation currently requires that users record their pesticide and veterinary medicine use. These record keeping requirements can be highly detailed but are currently disconnected from any wider outcome. Many industry quality assurance (QA) schemes require chemical use to be recorded (e.g. myBMP for the cotton industry). Within a sophisticated surveillance system, the Panel considers commercial and professional (i.e., not home garden or domestic) pesticide and veterinary medicine use should continue to be recorded but could be better utilised.

A 2017 report, commissioned by the Department of Agriculture and Water Resources identified that industry quality assurance schemes such as Freshcare, Graincare and the National Feedlot Accreditation Scheme, could play a greater role in managing the risks associated with pesticide and veterinary medicine use (GHD 2017). Industry systems and QA programs are existing sources of information that capture chemical use on farm through longstanding record keeping requirements (e.g., spray diaries). It is the Panel's strong view that these schemes could also be utilised to support surveillance of the regulatory system.

The APVMA and the states and territories all currently conduct limited post-market compliance efforts to consider how effectively pesticides and veterinary medicines risks are being managed. This includes enforcing operator training requirements, certain (limited) produce monitoring to identify if pesticides are being used according to label instructions and investigations of non-compliance or adverse experience reports for veterinary medicines and pesticides (in terms of both use and supply). There is also ad hoc research into environmental impacts of chemicals undertaken by universities and research organisations.

However, these information sources are disparate. Many of the data sets are passive and not utilised to the extent they could be. A well-devised and comprehensive regulatory system should effectively coordinate, collate, and analyse the various sources of post-market information. Data and intelligence collected post-market would allow regulators to determine the actual level of risk posed by pesticides and veterinary medicines, confirm whether the current controls are effective, and improve the ability of regulators to target their efforts to detect and respond to non-compliance.

> *"This could provide accurate information of pesticide uses in crops, areas treated, resistance potentials and the likely impact on trade. This information can be valuable to Australian agriculture but it may be outside the scope of the regulator."* (AgriFutures Australia 2020)

A diverse range of stakeholders expressed support for greater use of intelligence from credible data sources to inform regulatory decisions.

> *"Obviously, the more comprehensive the data available to any authority, the better and more beneficial will be the determinations made by that authority."* (Public Health Association of Australia 2020)

> *"The regulatory system should actively explore innovation and data mining to support improvement and efficiencies and support management."* (Cotton Australia 2020)

> *"The Panel's view that the regulatory system should capitalise on the vast amount of expertise and data being generated from farm businesses, universities and the private sector is supported."* (CropLife Australia 2020)

> *"A state repository of chemicals applied could increase user accountability and the collected information would enable the government agency to more effectively monitor and audit use. Publicly available, anonymised, collective data would enable interested citizens and advocacy groups to track overall use, have a say, and contribute their own data, to enrich the system."* (GeneEthics 2020)

Collecting such data over a prolonged period would allow robust and useful datasets to be established and maintained. 'Big data' offers significant opportunities in the future, providing an increased understanding of on-the-ground activities and allowing long-term strategies and management plans to be more accurately developed. The current absence of this data in Australia compromises research efforts.

> *"A lack of centralised and detailed records of product sales, use, non-compliances and environmental and product residues makes it difficult to prioritise research and*

> *conduct research in ways useful for product manufacturers, regulators, public good and end users".* (CSIRO 2020)

While the case for better utilisation of data is therefore strong, multiple stakeholders including Australian Grape and Wine, CropLife Australia , Australian Groundsprayers Association, Grain Trade Australia and the National Working Party on Grain Protection, and Grain Growers argued that any utilisation of data requires careful consideration of issues around intellectual property, confidentiality and privacy protection. The Panel agrees with these sentiments and notes that governments have strong processes in place to ensure confidentiality, privacy and intellectual property which would be incorporated into any data surveillance system.

Some stakeholders also questioned the way in which a grower's data might be utilised, expressing a view that users may be reluctant to participate if their own data may be used for compliance activities or there were added costs on users to provide data.

> *"It is difficult to see how the supply of such information to a regulator could assist in assessing aggregate risks from residues … It also presupposes a grower's capacity to be able to engage with whatever data collection system might be established."* (Horticulture Innovation 2020)

> *"Citrus Australia is unsure how the regulatory authority would use data about chemical use sought from chemical users. Growers will not readily cooperate with a program of mandatory reporting if they believe that their own data will be used to prosecute them."* (Citrus Australia 2020)

> *"The NFF appreciates that there may be benefits associated with regulators and governments improving their data holdings to improve the management of agvet chemicals, however we have serious reservations about imposing new data reporting requirements on registrants or chemical users without first fully assessing the purpose and benefits of any such requirements, as well as the risks and costs."* (National Farmers' Federation 2020)

These challenges notwithstanding, the Panel consider it is imperative that comprehensive data sets be collected, analysed and reported on to demonstrate how the system is working, and acted upon where there are either non-compliance matters, or safety concerns. Data on the use of chemicals is critical to underpinning and demonstrating the integrity of the regulatory system. Provided that costs are minimised, users should have no concern in delivering such data to the regulator to demonstrate their responsible use. This data collection will help to build and maintain a robust, effective regulatory system that is both adaptive and responsive.

What change is recommended?

The Panel believes it is critical to establish effective, system-wide surveillance arrangements for pesticides and veterinary medicines. These arrangements would collect, collate and utilise multiple inputs to identify areas of concern, inform users and the community clearly and transparently, and provide a foundation for regulatory action or compliance.

Further, the Panel considers that the lack of comprehensive surveillance and monitoring arrangements undermines the legitimacy of the current Australian regulatory system as it provides little evidence to demonstrate how the system is working to protect consumers, animal

health and the environment. The Panel considers this absence of data about system performance will become increasingly unacceptable to both industry and the community in the years ahead. Conversely, the availability of convincing data on safe performance would provide strong support for the social licence to continue to use pesticides and veterinary medicines in Australia.

The Panel recommends that the Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner) (see Section 2.2) be assigned responsibility to build a cost-effective nation-wide surveillance system fit for the needs of a 30-year future. The system should collate information from multiple data sources which may include annual pesticides and veterinary medicines sales data, industry quality assurance programs (e.g., FreshTest), users' records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions. In addition, residue detections from monitoring of domestic produce (see Section 3.2), environmental monitoring data (see Section 3.3), adverse experience reports (see Section 3.4), would all aid in building a comprehensive surveillance system.

The Panel recommends the Commissioner should develop arrangements to curate all such sources of information to enhance the data's accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes.

Cost of reform

The Panel estimates the government resources necessary to maintain and operate an effective system surveillance model would be approximately $600,000 per annum ($6 million over 10 years). The Panel views these functions as a public good function (in terms of policy development and system monitoring) and these costs should be met through government appropriation.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

19. Recommendation

The Panel recommends that the Commissioner be assigned responsibility to build a surveillance system fit for the needs of a 30-year future. The system should:

- **Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions.**
- **Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.**

20. Recommendation

The Panel recommends that the Commissioner develop arrangements to curate all such sources of information to enhance data accessibility and usefulness for research, policy

formulation, public transparency, international reporting obligations, and system response purposes.

21. Recommendation

The Panel recommends the Commissioner consider how to best utilise and capitalise on current record keeping requirements for use of pesticides and veterinary medicines in Australia.

3.2 Domestic produce monitoring

While Australia has a nationally consistent, albeit largely export focused pesticide and veterinary medicine residue monitoring system undertaken by the National Residue Survey, there is no comparable system for monitoring broad domestic produce.

The National Residues Survey monitors major agricultural export commodities such as meat, grains and some horticultural commodities but only a limited number of domestic animal products (meat, eggs, honey), pome fruit (apple and pear) and grains.

The states and territories are responsible for monitoring chemical residues as per control-of-use, however, there is a lack of consistent methodology applied across jurisdictions and currently only 3 states (Queensland, Victoria, and Western Australia) undertake routine monitoring. Some jurisdictions rely on industry quality assurance schemes to monitor residues, but as these schemes are not formally recognised and incorporated within the regulatory system they do not necessarily lead to, or result in, compliance and enforcement activity by the jurisdictions. These industry schemes include Freshcare which provides assurance to supermarkets through an annual residues test and FreshTest which conducts tests at major vegetable markets (such as Brisbane, Sydney, Melbourne, Darwin, and Adelaide).

Although chemical residues in food do not necessarily equate to a human health risk (the MRL is set well below the level that could pose health and safety risks to consumers), the increasing community concern about the safety of pesticides and veterinary medicines is bringing greater attention to the presence of chemical residues in food.

Since the 1970s, Food Standards Australia New Zealand (FSANZ) has sampled a broad range of Australian foods for pesticides and veterinary medicines residues under the Australian Total Diet Study (ATDS) (FSANZ 2019). ATDS surveys are generally undertaken every 2 years with results released every 4 to 5 years. These surveys have repeatedly demonstrated high levels of compliance with food safety standards. While relevant state or territory regulators are notified of noncompliance with maximum residue limits (MRLs), the Panel considers that the ATDS does not provide sufficient breadth, granularity, or regularity in monitoring and traceability to support adequate monitoring of control-of-use regulation.

With the costs of testing falling, and the sensitivity of tests increasing, it is inevitable that data on domestic residues will become publicly available in the years ahead. Depending on its source, the quality and integrity of such data may be uncertain but the risks to social licence and confidence in Australia's pesticide management arrangements in export markets may be in jeopardy. Consumer and export customer alarm could escalate quickly, perhaps unnecessarily. The Panel therefore considers it important that a credible national domestic monitoring system be initiated to preserve confidence in Australia's regulatory system.

Many comparable international regulators, such as those in the US, Canada and the European Union have comprehensive government-led chemical residue monitoring programs in place and release annual reports summarising the findings of these programs. A government-led national domestic produce monitoring system would align Australia with international best practice standards.

Stakeholders generally agreed on the need for a national domestic produce monitoring system and repeatedly raised the importance of monitoring and tracking pesticide and veterinary medicine use in Australia.

> *"The need for domestic products to be monitored and reported is long overdue."* (AgriFutures Australia 2020)

> *"We agree with the need for a regular monitoring system. It is essential that the risk to human health is foremost in deciding how priority chemicals for monitoring are selected if this approach is chosen."* (Cancer Council 2020)

However, the Panel recognises that there are many complexities associated with establishing and implementing a national produce monitoring framework.

> *"We maintain our position that this is unwarranted given that as previously stated, residues and residue status reporting is already conducted by many throughout the supply chain as part of food safety and trading standards, as well as QA."* (Grain Growers 2020)

The Panel has heard, and agrees, that clearly communicating residue monitoring results and their implications, will be extremely important and there may be a need to target relevant information to the user and consumers both domestically and internationally. There were some mixed views from stakeholders on the benefits of publicly reporting residues data, some arguing that it would cause concern in the community whist others argued that it would build public confidence.

> *"Testing per se or increased residue testing will have little benefit or impact on increasing the public's confidence in the regulatory system. Rather, unless there are clear messages around what is detected and the meaning of in many cases "expected residues that will be found", the opposite will occur and the somewhat "breadth of residues found" would possibly lead the community to a lack of faith in the regulatory system."* (Grain Trade Australian and the National Working Party on Grain Protection 2020)

In responding to whether data on residues in domestic produce should be publicly available the Public Health Association of Australia stated that it was essential to ensure that agricultural products are safe and that monitoring usage by producers was an important part of building public confidence in the system.

What change is recommended?

The Panel recommends the establishment of a comprehensive but cost-effective, Government-led national domestic produce monitoring system.

The Panel recognises that there has been work underway for many years between the Commonwealth and states and territories to develop a national domestic produce monitoring system modelled on the current National Residue Survey. Regrettably, and similar to the work on harmonised control-of-use, progress has been slow. Nevertheless, the Panel considers the work undertaken to date is likely to provide the most effective basis for the further development of a nationally consistent domestic monitoring and traceback system.

The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.

The national produce monitoring program would operate using existing methodologies from the National Residue Survey. The Commissioner could design the final aspects of the program, including the multi-year sampling priorities, in consultation with the National Residues Survey, primary producers and the community and state and territory governments (through the Stakeholder Forum and Operational Forum see Chapter 2). To avoid an open-ended cost, there will need to be careful risk-based targeting of effort. The early years of the program would be carefully staged in development and the program expended over time.

The results of the monitoring program will be a key input to the system surveillance (see Section 3.1) and the APVMA, providing a much needed feedback mechanism to demonstrate that good agricultural practices are being followed in Australian primary production as well as providing data to support regulatory action in case of residue violations.

Cost of reform

While the Panel acknowledges the costs of participating in a produce monitoring program cannot be attributed to a single user, they are directly attributable to the entire sector of primary producers who use pesticides on their produce. These producers would benefit directly from a robust means of confirming the high quality of their produce.

That said, the Panel considers the strong public good aspect of such a program provides justification for this to be government funded. The Panel further considers that the program should be targeted based on risk and developed in a graduated manner. The costs of the program will depend on the number of commodities monitored per year. Roughly, 30 commodities would cost around $5m per annum.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

22. Recommendation

The Panel recommends a Government-led national domestic produce monitoring program be established.

23. Recommendation

The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.

24. Recommendation

The Panel recommends the Commissioner finalise the design of the domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residues Survey, primary producers, manufacturers, state and territory governments, and the community.

3.3 Environmental monitoring

Pesticides are used in the environment and therefore it is to be expected that there will be some level of pesticides detected at any given time in the ecosystems in which they are used. This in itself should not necessarily be cause for concern, however, should there be a build-up or high levels of pesticides detected in specific ecosystems, such as waterways or soils, this may necessitate remedial action to reduce the possibility of adverse environmental impacts. Given the widespread use of pesticides in the environment the Panel was surprised to discover a lack of monitoring for residues across Australia's waterways and that essentially no soil testing is undertaken.

On 18 July 2019 the Prime Minister made a commitment to a national focus on soil. This included the development of the National Soil Strategy which highlights the importance of effective soil management for improving agricultural production and profitability, as well as the protection of natural resources. Following an extensive consultation process, the Department is currently exploring opportunities to commence implementation of the strategy, including scoping the development of a national soil monitoring program. If this program was to include soil residue monitoring, it would put Australia at the forefront of environmental pesticides monitoring globally.

There is currently no national monitoring program for the presence of pesticides in waterways and soils in regions with concentrated chemical use. Various agencies such as the New South Wales Environmental Protection Agency, the Great Barrier Reef Marine Park Authority and some university researchers do conduct more targeted monitoring but there is limited consistency (either in terms of analyses or requirements) among them. Most of the water monitoring undertaken by jurisdictions is currently limited to drinking water.

> *"Monitoring of agricultural chemicals in waterways is ... currently conducted predominantly by government agencies and water authorities, there is no requirement for users of agvet chemicals to contribute to any form of monitoring. There should be a requirement for agricultural users of these chemicals to ensure that their practices do not cause adverse environmental impacts."* (Northern Territory Department of Environment and Natural Resources 2020)

Consistent with the many responses the Panel received for implementing a national produce monitoring system, numerous stakeholders were supportive of a national environmental water monitoring program. Community disquiet about the use of chemicals stems in part from perceptions, not necessarily supportable by comprehensive data, that the Australian environment is being negatively affected by chemicals. As was the case for domestic monitoring of residues in food, the introduction of credible environmental monitoring should assist with the maintenance of social licence to continue to use pesticides and veterinary medicines.

However, stakeholders highlighted the potentially significant costs associated with this activity and suggested that the monitoring program should be targeted to risk in order to minimise cost and to focus on areas of greatest need.

> *"The cost of environmental monitoring is significant and to minimise costs there would have to be prioritising based on risk. Priority should be given to environments that are deemed at risk from drift, run-off and or because of the vulnerability of species."* (Citrus Australia 2020)

> *"Recent research on agricultural chemical hazards (Navarro et al 2020 currently under peer review) highlights potential hotspots but prioritisation should consider current environmental assets and the restorative potential of environments. In addition, analysis of data collected … could be used to help identify and prioritise areas for testing."* (CSIRO 2020)

Separate from environmental testing of waterways, drinking water quality is tested by the states and territories for pesticides, with results publicly available in some jurisdictions. Current guidelines recommend that pesticides are monitored annually and if there is a pesticide detected above acceptable levels, testing frequency is increased to monthly until there is a return to acceptable levels. This testing ensures the safety of Australian drinking water; however, it does not assess non-potable water standards nor monitor water safety and its impact on Australia's ecosystems.

Currently, there are 2 distinctly different methods to derive water quality guideline values in Australia. The APVMA assessment of environmental risk uses the assessment factor method (also called the safety factor method), whereas the National Water Quality Management Strategy (NWQMS) uses the species sensitivity distribution method to obtain threshold values for potable drinking water. Unlike MRLs established for treated produce or animal feed, neither the APVMA environmental residue level nor the drinking water quality guidelines levels are enforceable residue limits. This discrepancy was raised by multiple stakeholders.

> *"The approach that the APVMA uses to determine the acceptable water quality does not match the approach used in setting ecosystem protection guidelines … Therefore agricultural producers that use [pesticides] could be reasonably expected to produce water quality associated with their use of products in accordance with the approved instructions that is not acceptable to state environment departments."* (Growcom 2020)

> *"Most disturbingly there is no routine monitoring for these widely used hazardous poisons in air, soil, vegetation and surface water. No Australian Standards for acceptable levels in the environment or the human body are readily available."* (Pesticide Action Group Western Australia 2020)

What change is recommended?

The Panel recommends that both water and waterway sediment samples be analysed as a means of monitoring for the levels of pesticides in the environment. In addition, there would be benefit in soil testing in targeted areas to determine how chemical residues may be impacting soil fertility and soil health. As part of the National Soil Strategy, the Panel recommends including soil pesticide residues in a national soil monitoring program. The testing programs should be

scalable and targeted based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.

The Environmental Monitoring Program should be developed using pre-existing government guidelines (for water) and as part of the National Soil Strategy (for soil) in consultation with the community and industry and both government and non-government experts through the Stakeholder Forum (see Chapter 2). The NWQMS provides guidance for developing water monitoring programs including how to develop tests and determine baseline levels of contaminants.

The Environmental Monitoring Program may consider collecting samples at various locations throughout the 13 major water catchments (for water) and key agricultural zones (for soils) across Australia (BOM 2012). These collection locations should be determined by the Commissioner based on risk, regulatory need, and recommendations through consultation with the Stakeholder Forum (see Chapter 2). The collection and testing of samples should be conducted on a seasonal basis to take account of differing cropping and weather patterns.

The collection of monitoring data for environmental impacts should be undertaken as part of the responsibilities of the Commissioner. Information collected during monitoring activities will then be directed by the Commissioner to the relevant agency for action. The Commissioner should also explore possible links with existing QA systems and the possibility for co-regulatory approaches.

Environmental monitoring results will provide a valuable data source for system surveillance. It will also guide prioritisation of residue monitoring in produce, as unacceptable residues detected in a waterway may indicate poor agricultural practices upstream from the site of water testing and unacceptable residues in soil could provide similar indications about poor agricultural practice or overuse of chemicals.

The Panel acknowledges that the current situation of 2 separate non-enforceable water quality 'standards' is a challenge for implementing the Panel's recommendation(s) related to water monitoring. In the longer term, the Panel recommends that the alignment of the 2 standards be resolved. In the short to medium term, the dilemma can only be managed by continuing to assess potable drinking water under the Australian Drinking Water Guidelines and non-potable water under APVMA standards. The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.

The Panel recommends the Commissioner explores with the relevant areas of Government the possibility of extending mandatory reporting to the relevant compliance authority in all jurisdictions where information is identified relating to residue exceedances or suspected contamination of drinking water.

Cost of reform

The Panel considers the costs associated with establishing and operating a national environmental pesticides and veterinary medicines residues scheme, in terms of water, soil and sediment, represents a public good and should be funded through appropriation. There would therefore be no impact on industry regulatory costs.

Consistent with the Panel's recommendation to incorporate pesticide and veterinary medicine residue monitoring in soil into the proposed monitoring program under the National Soil Strategy, the costs for this aspect would be addressed in the strategy.

The Panel estimates the costs for water and sediment monitoring, while higher in the initial years, would on average cost $819,000 per annum, and cover multiple sites across Australia's drainage divisions.

The costs of ongoing soil monitoring including sample collection and analysis should be funded under the National Soil Strategy.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

25. Recommendation

The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.

26. Recommendation

The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.

Commented [SPE15]: Suggest reversing the order of these recommendations – putting consultation first!

27. Recommendation

The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.

28. Recommendation

The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.

29. Recommendation

The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.

3.4 Identifying product related concerns

Currently, holders of active constituent approvals, registrations and permits must provide the APVMA with any information they become aware of, after approval or registration, that indicates the safety, trade or efficacy criteria used for the approval may no longer be met, or that contradicts information held by the APVMA for the active constituent or product. The Panel is

also aware that reports are routinely made to the state and territory control-of-use regulators in relation to a product's use and the undesirable effects that may have resulted from that use.

The Panel recognises that distinguishing between an issue related to the product (at a manufacture or formulation level) and the products use according to the label (or not in accordance with the label but allowed in a specific jurisdiction) can be difficult. The Panel is not aware of any effective means to date where these disparate information sources are bought together, to view the issue in terms of the full life-cycle of the product.

Adverse Experience Reports (AERs) provide a valuable source of information to identify product related concerns allowing regulators to act promptly. Reports come from the full spectrum of stakeholders that interact with pesticides and veterinary medicines, including veterinarians, farmers, and the public. Over the past 3 years, the APVMA alone has processed more than 20,530 adverse experience reports. These include duplicate reports of the same incident, reports unrelated to the registered product and non-serious reports.

The majority of AERs received by the APVMA relate to animal health concerns arising from the use of veterinary medicines, forming the basis of a nascent pharmacovigilance system. During the Panel's consultation with veterinary medicine stakeholders, they emphasised the importance of pharmacovigilance systems which utilise adverse experience reports to collate, monitor, respond to and identify trends.

> *"Post-registration, pharmacovigilance plays a key role as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem."* (Animal Medicines Australia 2020)

Multiple international regulators, including the European Medicines Agency and Health Canada's Veterinary Drugs Directorate and the United States Food and Drug Administration, maintain formal pharmacovigilance systems for veterinary medicines, bringing together data from a variety of sources (including AER) to identify the effects of veterinary medicine products after use and to identify unintended events. In Australia, there is no formal pharmacovigilance program for veterinary medicines although the Panel is confident there is significant support amongst the veterinary sector for the establishment of such as a scheme.

The Australian Veterinary Association and Ceva Animal Health, in their meetings with the Panel, expressed a strong desire for a pharmacovigilance scheme to be adopted in Australia and for improvements to the AER process to encourage greater reporting.

The existing adverse experience reporting program, as discussed previously, is largely utilised for animal health concerns, and does not correlate or integrate well with state and territory AER. The Panel acknowledges that reporting on veterinary medicines is well advanced compared to pesticides, which is at best lacking. The Panel does not accept the argument, put by some, that the absence of reports for pesticides is evidence of the absence of adverse experiences. Indeed, stakeholders expressed their concern to the Panel, regarding the oversight of current adverse experience reporting for pesticides:

> *"Where a breach is related to product failure due to manufacture or packaging, and APVMA are involved, the process to address non-compliance via lodging an online*

> *adverse experience report is very slow, and at the coal face we rarely see APVMA directly involved in non-compliance."* (Citrus Australia 2020)
>
> *"At present, there is no consistency in managing and reporting adverse chemical residues being detected, nor used incorrectly."* (Grain Trade Australia and the National Working Party on Grain Protection 2020)

The Panel sees the underutilised potential of a coherent consistent approach to handling AERs, both in terms of responding to issues in product quality or use, but more importantly as an effective measure of the regulatory system's performance and responsiveness. Analysing AER information and converting this data into knowledge would provide the Commissioner (having overall responsibility for the system) with invaluable intelligence.

What change is recommended?

The Panel recommends that adverse experience reporting be consolidated, improved and better utilised. The new arrangements would incorporate a pharmacovigilance scheme as part of a single national scheme.

The Panel recommends that both the structure and reporting process required when reporting adverse experiences should be detailed in legislation for both pesticides and veterinary medicines.

The Panel considers it vital that adverse experiences or uncommon events for the whole life cycle of the product continue to be notified and assessed. Importantly the Panel expects that the assessed reports should form part of the intelligence available to the Commissioner to inform their assessment of the entire system.

Under the new single national law for control-of-use, AERs that would have been provided to a state or territory government would be provided to the Commissioner. The Panel considers that it would be most efficient for AERs to only be reported to a single regulator. As AERs relate to concerns from product use, the Commissioner as the control-of-use regulator should have primary responsibility for AERs. The Panel is also very aware of the importance of AERs to the APVMA's compliance activities and the need for it to have continued access to AERs. The Commissioner and the APVMA will therefore need to closely collaborate on AERs, perhaps through information sharing or dual system access.

Holders of active constituent approvals, registrations or exemptions would be required to submit an adverse experience report to the Commissioner. This occurs when they become aware of an unintended safety effect, lack of efficacy, quality or contamination concern (either product related or in terms of unintended exposure to humans, animals or the environment), or other adverse events associated with the use of a pesticide or veterinary medicine product. Likewise, a licence holder for dealings with internationally registered products (see Chapter 5) or one having a general licence (see Chapter 4) should be obligated to submit adverse experience reports.

The Panel sees those users who obtain a licence in relation to the use of the product, should have the formal responsibility to report adverse experiences they encounter. Licence holders will have firsthand information in relation to adverse outcomes, related to the use of the licensed product, including where all label instructions are followed. It is these circumstances in

particular the Panel considers to be of high worth to the Commissioner, as they may indicate that the existing risk mitigation strategies warrant revision. In this way the Panel is supporting a responsive and adaptive regulatory system, by empowering the Commissioner with a set of comprehensive information sources.

Any individuals, for example farmers, companion animal owners, gardeners, veterinarians or members of the public, should be able to voluntarily submit a report concerning the registration or use of a pesticide or veterinary medicine product to the Commissioner when they become aware of product-related concerns. This aligns closely with the obligations of all users to consider dealings with pesticides or veterinary medicine products in a responsible manner (see Chapter 4). The Panel considers there is value in all users reporting adverse experiences, as the earlier a risk is identified, the earlier the concerns can be addressed.

The Commissioner would be responsible for developing and implementing a more streamlined process for reporting and collating the adverse experience system and for establishing whole-of-system 'pharmacovigilance', incorporating an equivalent pharmacovigilance system for veterinary medicines as established internationally. This would enable the Commissioner or the APVMA to undertake further investigation or compliance action if it was related to supply concerns (APVMA) or control-of-use (Commissioner). This would ensure regulatory action is undertaken as soon as an issue is identified and contributes to the continued safety, quality and effectiveness of pesticides and veterinary medicines.

The Panel envisions a future where adverse experiences are reported and publicly available in near real time after validation. As technology progresses and smart labelling (see Chapter 4) becomes more integrated in farming practices, the Panel considers there is an opportunity to explore user friendly applications that allow real time (or close to) reporting and recording of adverse experiences. For instance, guidance could be taken from the Emergency Services Agency incident map which is updated in near real time (ACT Emergency Services Agency 2020).

Cost of reform

The Panel's recommendation to provide structure and a streamlined process to submit adverse experience reports formalises existing practices in most cases. The Panel does not expect any regulatory cost impacts to most product users or suppliers or licence holders. The increased obligation for some licence holders to report adverse experiences is not expected to have significant regulatory costs.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

30. Recommendation

The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.

31. Recommendation

The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.

32. Recommendation

The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.

Commented [SPE16]: The veterinary profession could contribute enormously to the review of AERs and the development of risk management plans. An AER Advisory Panel of appropriately experienced veterinarians could add significant value to the process.

33. Recommendation

The Panel recommends sound information sharing practices be established between the APVMA and the Commissioner to allow APVMA access and the opportunity to respond to those matters relating to the registration and exemption of products, or the supply of those products.

34. Recommendation

The Panel recommends the Commissioner establish an interface that provides users and the public with contemporary details of validated adverse experience reports. The Panel also recommends the interface support the streamlining of submission of adverse experience reports.

3.5 Transparency and public reporting of system surveillance

The areas of data collection outlined in the preceding sections that contribute to system surveillance need to be communicated to the public to underpin transparency and achieve ongoing confidence in the regulatory system.

Publication of this data would also strengthen assurances to our international trading partners as well as Australia's domestic community that Australian produce is of the highest safety and quality and grown in accordance with good agricultural practices. Furthermore, it will provide a means for improving food safety and 'lifting the bar' where necessary, on residues across all produce.

Data gathered through system surveillance would support evidence-based advice to ministers and better inform future arrangements to improve the regulatory system. It will also identify information gaps to inform scientific research and build national capacity with experts in the field of pesticides and veterinary medicines, allowing researchers to better target research problems to be addressed. Moreover, the Panel considers this data could be better utilised to identify trends. For instance, repeat reports of a herbicide not effectively killing a weed in a region may lead to a targeted investigation of resistance patterns.

What change is recommended?

The Panel recommends that the results of residue monitoring of domestic produce and the environment and adverse experience reports should be publicly available, providing the community with assurance that pesticides and veterinary medicines are being used responsibly

and safely, or in cases of exceedances, that proportionate responsive action is being taken. The objective is to sustain social licence to continue to use pesticides and veterinary medicines.

Residue results should be collated by the Commissioner and presented annually in an informative and educational manner. Consistent with the successful public reporting approach undertaken by the National Residue Survey, data should be de-identified when released to the public and privacy matters dealt with in a manner consistent with Government standards. The approach taken by the European Food Safety Authority to present results of its pesticide residues in food survey is an excellent example of communicating data in an interactive manner (European Food Safety Authority 2017).

The Commissioner would be responsible for analysing the multiple data inputs (including produce and environmental residue monitoring, adverse experience reports, chemical company quantity and sales reporting and literature searches). The Panel recommends that the use patterns and trends collated by the Commissioner be published in its biennial report to parliament. For example, the UK Pesticides Forum provides an annual report that publishes trends in the UK from indicator data providing transparency and increasing community awareness, understanding and confidence about the benefits and risks associated with pesticide and veterinary medicine use (Health and Safety Executive 2019).

The Panel understands many stakeholders have concerns about the potential for increased reporting requirements to the regulator and how this information will be utilised. However, the Panel considers most data gathered through system surveillance such as data captured through industry systems and QA programs could be utilised for intelligence gathering and to better target and inform compliance actions. More importantly, the Panel considers that this data would demonstrate the effectiveness (or not) of regulatory controls.

35. Recommendation

The Panel recommends that trends identified through system surveillance data be reported publicly in the Commissioner's biennial report.

36. Recommendation

The Panel recommends that the residue monitoring results of domestic produce and environmental water and adverse experience reports should be publicly available, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken.

Commented [SPE17]: The reports of the NRS should be available in a timely manner, for example, within 3 months of the end of each year of data collection.

37. Recommendation

The Panel recommends that the results of these programs should be collated and published in an informative and educational manner. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

3.6 Improving the speed and transparency of chemical reviews

New scientific information continues to emerge about established active constituents or products and their impacts on human health, animal health and ecosystems. This can make it

necessary, from time to time to re-evaluate and review whether a registered chemical is still fit for purpose and safe to use. As a result of these reviews, new risk mitigation measures may be implemented to manage the risks of dealings with these chemicals. This can include removing a use on a particular crop or animal or withdrawing a substance from the market altogether. Regular and transparent reviews can increase public confidence and maintain social licence for the use of pesticides and veterinary medicines in a future regulatory system.

Reviews of established chemistries can, therefore, be vital to ensuring that the risks associated with dealing with pesticides and veterinary medicines remain well understood and rigorously managed.

> *"It is vital for Australia's threatened wildlife that we have a rigorous review process."* (Australian Environmental Pest Managers Association 2020)

> *"A more rapid review would instil greater confidence in the regulator that a decision to review, and thus continue approval or modify/withdraw a chemical in a more timely manner and its use would be seen as a positive by the general public."* (Grain Trade Australia and National Working Party for Grain Protection 2020)

The APVMA is solely responsible for undertaking chemical reviews (formerly called chemical reconsiderations) in Australia. Many chemical reviews have taken more than a decade to complete and many chemicals remain under review after more than 15 years. While the APVMA may make 'interim' decisions to manage the potential risks associated with the chemical ahead of a final review outcome, the seemingly open-ended duration of these reviews undermines public confidence in the rigour of the regulatory system. There have been mixed views from stakeholders about the timeliness of reviews; some suggesting that reviews should be completed in a timelier fashion whilst others argue that the length of time enables thorough stakeholder engagement.

> *"…there should also be a degree of structure to ensure that reviews are completed within a specific timeframe addressing the particular risk identified."* (Accord 2020)

> *"Chemical reviews should be conducted in a robust, efficient and timely manner. This is particularly relevant for chemicals which pose risk in terms of development of resistance and also for chemicals which pose high welfare risks where more humane alternatives are developed."* (RSPCA 2020)

> *"Current timeframes for the chemical review process are long, presumably to allow for a thorough review. Shorter timeframes would potentially result in less thorough review and more sudden cancellation of registration or reduction in MRLs."* (Citrus Australia 2020)

Chemical reviews are currently initiated solely at the APVMA's discretion, generally following consultation with relevant Commonwealth, state, and territory agencies. The APVMA normally does this when there is a mounting body of evidence (including from overseas markets) that the risks associated with a chemical are greater than or different from those previously assessed. This evidence may come to the regulator's attention from its internal information monitoring processes (such as literature scans and interactions with overseas regulators) as well as through a public nomination process that it currently operates.

The lack of clear review triggers means that the process for initiating a review may be somewhat subjective and lacking in transparency. In addition, the APVMA may consider whether to review a chemical or to decide whether a full review is needed, but it does not formally produce a statement of reasons to explain why it has reached this conclusion. This can further add to public scepticism about the rigour and transparency of the review process and does not build public confidence in the review itself or the associated processes.

In contrast, the 're-registration' schemes for pesticide products of Europe, Canada and the USA require all pesticide products to be reviewed according to a rolling timetable (veterinary medicine products are also subject to review in these markets but not on a rolling basis). This means that the risks associated with handling each chemical are periodically re assessed; however, it comes at a very high cost. The Panel understands these international chemical review schemes are running considerably behind schedule in each of the markets that conduct reviews on a rolling basis.

Stakeholders had mixed views about adopting a rolling review schedule in Australia.

> *"… the adoption of calendar-driven reviews by other international regulators has tied up important regulatory resources and led to lengthy delays, and reduced the ability of regulators to respond to emerging issues."* (National Farmers' Federation 2020)

> *"A specified time frame for review should be retained as a safety backup, even if formally deferred if no information requiring full review is found."* (Public Health Association of Australia 2020)

It may be partially as a result of these overseas rolling review decisions that certain chemicals (and chemical uses) that are available in Australia have been withdrawn in comparable markets; for instance chlorpyrifos and paraquat, and historically endosulfan, fenthion and mercury-based fungicides.

However, the Panel has heard anecdotal reports that chemical reviews in overseas markets may lead to chemicals being withdrawn – and thus to loss of chemical access for users – for reasons other than unacceptable risk. It has been suggested, for example, that chemistries may be withdrawn because the costs of generating the information needed to 'defend' a chemical through a review process may not justify the investment. This may be, in part, because market competition – which 'fragments' market share and reduces profit margins – limits the financial returns on older chemistries. Incentives, such as data protection on information used to support decisions to retain chemicals or their uses, can be important therefore to ensure that access to safe chemicals is not lost unnecessarily. Relevantly, chemicals can also be banned in overseas markets on the basis of political decisions made despite scientific evidence that the chemical does not pose unacceptable risks; the Panel does not support political intervention in what should always be a scientific and evidence-based process.

Finally, there is no process by which interested parties, other than those with 'standing' in relation to administrative appeals or judicial review processes, may engage with the APVMA in relation to a chemical review decision. This means that there is little opportunity for appeal against a decision or finding other than by registration holders.

Previous reforms have aimed to address the transparency of chemical review decisions and predictability of timeframes. In practice, however, these have had very limited success.

What change is recommended?

The Panel recognises the need to improve both the transparency and speed of the chemical review process. Chemical reviews must be science-based and designed to increase public confidence and maintain social licence related to the use of pesticides and veterinary medicines. The Panel recommends that in future, reviews are initiated through one of 3 mechanisms: as the result of a legislated trigger (such as a relevant international decision); at the discretion of the APVMA; or on referral from the Commissioner.

Legislative trigger

The APVMA would be required to commence a review into substances on the basis of a well-defined trigger and that would include public disclosure of the review commencing. The Panel considers this trigger could include:

- a comparable international regulator (for example, from Canada, the European Union, New Zealand, the United Kingdom, Japan or the USA) cancelling a use of a chemical product for science-based reasons where:
  - the international decision relates to use on a commodity (including food producing livestock) that is commercially produced in Australia and the chemical is used on that commodity in Australia
  - the use is in domestic households, companion animals or other non-agricultural uses
  - there were identified risks to human, animal, or environmental health and safety.

The Panel recognises the potential for the trigger to occur repeatedly within a short period of time. The Panel proposes to address this by providing that the APVMA would not be required to commence a subsequent review of a substance on the same grounds (i.e., relevant international decision) within 3 years of the completion of the first review. For clarity, this would not apply where the grounds for the subsequent international decision differed from those of the first review trigger.

Where an international decision would trigger a chemical review, but notwithstanding that trigger, the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA must publish a statement of reasons for why it will not commence a review. The statement would include all information the APVMA relied on to form its position. The APVMA may not rely on information that would be confidential (except in terms of privacy).

APVMA initiated reviews

As is currently the case, the APVMA will continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.

Referral from the Commissioner

The Commissioner would have responsibility of referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.

Enhanced and focused process for review

The future process for chemical reviews would focus more heavily on the holder of a registration demonstrating to the APVMA their product's safety, trade status, effectiveness, or compliance with other statutory criteria in relation to the specific issue(s) identified. To the extent that access through exemptions are relevant to the scope of the review the holder of the exemption would be included in the process.

The model adopts the established administrative practice of 'show cause'. When seeking information from the registrant, the APVMA would also publish a notice seeking evidence-based submissions from the public on the matter.

Similar to the process used by the Therapeutic Goods Administration, the Panel recommends that the future regulatory system should rely on the general powers to seek information, including the results of laboratory tests and field trials where relevant. The APVMA would be able to take administrative or other action as necessary, up to and including suspension, cancellation, or amendment of the registration or exemption (as commensurate to the risks). This approach would allow the APVMA to reconsider the risks associated with a product (or group of products) without the need for a separate, detailed legislative review pathway.

The APVMA would publish a notice of its proposed decision, providing the registration holder and public with the opportunity to comment. If additional information was received from the public that affected the APVMA's decision, the holder would be given an additional opportunity to respond to the APVMA.

Each of these steps would have a defined and fixed timeframe. A holder of a registration may request from the APVMA an extension to the response period to undertake laboratory experiments or field trials. If the APVMA is satisfied that the trial will aid its decision, it may grant a time-limited extension period. The Panel considers this supports scientific rigour in the APVMA's decision.

Multiple holders of registration with similar products being reviewed for the same matter may seek to establish a formal collaboration to offset the costs of generating the necessary information. Holders may be provided with a limited timeframe extension to arrange this collaboration.

A failure to respond, or to provide adequate argument against the proposed action, would result in the APVMA suspending or cancelling the product's registration, or removing a specific use from the product.

The APVMA would retain the ability to proactively manage risks before the conclusion of a review process, such as one that causes it to believe there is an imminent risk to human or animal safety.

The Panel considers that the APVMA's decisions on reviews would, in most instances, conclude within a maximum of 3 to 4 years of commencement. Progress on review decisions should be reported in the APVMA's annual report.

The current requirement to publish a statement of reasons outlining the APVMA's final decision would be retained.

Timeliness of chemical reviews

Legislative changes that took effect in 2014 required a work plan outlining the stages of review, consultations and expected timeframes. The Panel recommends that retaining these plans and defined timelines for completing chemical reviews will support timely completion of reviews. The APVMA's performance against these timeframes would be published as part of the APVMA's quarterly timeframe performance reporting and would also be included in the system performance measures.

Taken together, these planning and reporting measures should improve the timeliness of chemical reviews and will be critical to maintaining the social licence of the system and public confidence in the APVMA, the review process and chemicals approved for use.

Data protection

Any new information provided in support of the review process would continue to be protected (see Chapter 5). The Government would not mediate or arbitrate information sharing arrangements between interested parties, as is currently required but rarely used.

Consideration of products introduced through the licensing model

Products registered by a comparable overseas regulator and introduced to Australia through the licensing model (see Chapter 5) would be subject to a similar level of scrutiny as products registered by the APVMA. This would operate through a different mechanism to reviews but would be subject to similar and independent oversight of risks. The Commissioner would be responsible for setting robust licence conditions and conducting regular audits of licensees. The Commissioner would be able to vary, suspend or cancel the licence which allows access to the Australian market where licence conditions are not met. For instance, licence conditions may stipulate that the Commissioner is informed when the overseas regulator identifies an issue with a product brought to Australia under licence. The Commissioner may then act, including varying, suspending, or even cancelling a licence if the risk mitigation plan is inadequate or where false or misleading information was provided.

Cost of reform

While the Panel is not directly recommending the number of the reviews undertaken by the APVMA is increased, the formal triggers the Panel has recommended will likely lead to an increased number of reviews being undertaken. The cost for industry to generate data and 'show cause' why an action should not be undertaken on their product is not expected to increase. The Panel expects that in many cases, industry already holds much of the data from responding to similar concerns from overseas regulators and, for some registration holders at least, holders of similar registered products would seek formal collaboration to offset costs of generating necessary information.

With the additional workload for the APVMA's chemical review staff, the Panel estimates a moderate increase of resources would be required (in the order of $400,000 per annum). While the Panel has considered each reform's impact individually, it anticipates there would be opportunities to 'offset' resources across reforms. Other Panel recommendations, such as to reduce the scope of regulation (see Chapter 5) and to improve resilience in the supply chain (see Chapter 6), are likely to decrease the APVMA's resource requirements for those functions providing an offset opportunity.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

38. Recommendation

The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.

39. Recommendation

The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.

40. Recommendation

The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.

41. Recommendation

The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.

42. Recommendation

The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.

43. Recommendation

The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.

3.7 Including a humaneness assessment for vertebrate pest control products

Good animal welfare, including ensuring animals are treated humanely in food production, is an increasingly important consideration for domestic and export trade in animals and animal products. Similarly, the impacts of vertebrate pest control products (VPCPs) on the suffering of pest species is increasingly attracting community interest.

In its submission to the review, the RSPCA stated:

> *"… there is increasing community concern and expectations regarding the treatment of all animals including vertebrate pest species. In the past, little scrutiny has been given to the animal welfare impacts of vertebrate pest control methods."*
> (RSPCA 2020)

These growing community concerns on animal welfare over the impacts of VPCPs is likely to impact on their usage in the future.

The current situation

Given the growing concerns over animal welfare, including the humane treatment of pest animals, the Panel considers that the future pesticides and veterinary medicines regulatory system should have greater regard to animal welfare considerations for treating pests. Whilst acknowledging that animal welfare is a state and territory responsibility, the registration of pesticides (chemicals that kill pest animals) is the responsibility of the Commonwealth and therefore animal welfare impacts should be considered in the regulatory system.

There are currently no simple, transparent mechanisms in place that encourage those that deal with VPCPs – such as users (including licensed pest controllers), suppliers and manufacturers or importers – to consider the humaneness of a product and compare it to that of alternative products. Any information that is currently available is not easily accessed by consumers. If there are products that provide more humane ways of killing pest animals, it seems reasonable that users should have the information necessary to make informed choices among alternative products.

Humane vertebrate pest control may be defined as:

> *"… the development and selection of feasible control programs and techniques that avoid or minimise pain, suffering and distress to target and non-target animals."* (Humane Vertebrate Pest Control Working Group 2004)

During consultation, some stakeholders raised the potential to apply a humaneness assessment in the registration process for VPCPs. They felt that introducing a humaneness assessment would provide those who deal with VPCPs with an evidence base to allow them to select the most humane method of control for the pest management task at hand.

The RSPCA's submission to the review noted the importance of a humaneness assessment.

> *"… this model is internationally recognised and provides a practical way of assessing humaneness that can be applied to any pest control method, thus allowing comparisons of animal welfare impacts of different methods."* (RSPCA 2020)

What change is recommended?

The Panel considers there is an opportunity to advance animal welfare objectives, at minimal cost, and without sacrificing users' decision-making prerogatives. The Panel proposes that the humaneness of pest animal control methods be assessed and displayed on the product label so that users can make an informed decision regarding humaneness of a VPCP. This level of transparency established by this approach will provide users with greater capability to make informed decisions which in turn will shape decisions made by product developers. This approach has little regulatory impact as the regulator will not be required to assess any additional data; additional data requirements can be collected during existing trials and there are no additional obligations for users.

The Panel considers that the humaneness assessment methods suggested in the Australian Animal Welfare Strategy (AAWS) model provides a sound basis for the future system. The AAWS

was an initiative led by the then Australian Government Department of Agriculture, Fisheries and Forestry, in conjunction with the states and territories and key stakeholders, including the APVMA. The model was developed by the NSW Department of Primary Industries (NSW DPI) Vertebrate Pest Research Unit (VPRU).

The model takes account of the level and duration of suffering caused by the killing technique (Sharp and Saunders 2011) and has regard to the 5 'domains of humaneness', which are used to evaluate the level of suffering that an animal experiences:

1) water deprivation, food deprivation, malnutrition
2) environmental challenge
3) disease, injury, functional impairment
4) behavioural or interactive restriction
5) anxiety, fear, pain, distress.

The vertebrate pest control products humaneness assessment model

The key objective of the proposal is to provide users and others who deal with VPCPs – whether for agricultural, commercial, home or garden use – with objective information about the relative humaneness of those products. This will allow them to make informed decisions about these products' manufacture, marketing, sale, and use.

The model will only apply to VPCPs and is designed for pest control methods that specifically cause the death of vertebrate pest animals. It is not intended for use in veterinary medicines that treat illness, disease, or conditions.

The proposal establishes a score reflecting how humane a VPCP is, noting that a product designed to kill a vertebrate animal will also have some potential to cause distress and suffering. It would be a requirement of VPCP registration that this score is displayed on the label. While the AAWS model comprises 2 components – a number representing the intensity of suffering and a letter reflecting the duration of that suffering. The Panel proposes a modified, easy-to-understand scoring system communicated using a single number from 1 (being the most humane) to 8 (least humane). The 1 to 8 scoring system is based on the model developed by the NSW DPI.

The data required to perform this assessment can be collected through existing data requirements, minimising the need for additional animal testing.

Guidance on the data requirements and methodologies to undertake this assessment could rely on the work of the NSW DPI's VPRU, which routinely updates its model as new information becomes available. Moreover, the VPRU, a world leader in this field of research, is willing and able to undertake these assessments.

Established VPCPs (i.e., those already registered) would also require a humaneness score. Some of the necessary assessment work has already been completed by the NSW DPI's VPRU. In many cases, it will be possible to assign a score through the extrapolation of existing data. This removes the need for additional and unnecessary animal trials and avoids additional costs on industry.

However, it is possible that the humaneness score of a product may change over time. For example, a new product with new mode of action may initially cause rapid mortality and be considered relatively humane on that basis. Over time, resistance in the target pest may decrease its susceptibility to its effects, such that mortality is significantly delayed. In this case, suffering would be prolonged, and the product may therefore be less humane than when originally introduced to the market. New trials and analyses may be required when registrants or licence holders become aware of evidence (e.g., field data or research reports) of significant resistance to their VPCP.

Considerations for implementing a humaneness model

The Panel understands that no comparable international regulator requires relative humaneness information be placed on a label. Doing so would place the Australian pesticides and veterinary medicines regulatory system in a world-leading position.

A provision to include a humaneness assessment could help maintain social licence in relation to vertebrate pest control. For example, industry codes of practice could incorporate consideration of humaneness, to demonstrate a commitment to humane vertebrate pest management.

In addition, it is likely that the scoring system will influence market decisions about the use of pest control products. Over time, this is likely to lead to improved humaneness outcomes and may incentivise investment in more humane technologies.

Adopting humaneness pest control techniques should alleviate public concerns regarding the control of invasive animals. This will contribute to the protection of non-target species, and result in reduced harm to livestock and the loss of crops, and decreased impact to Australian wildlife habitats.

Importantly, the AAWS model has application beyond chemical control methods. Using the model will allow pest controllers to compare the use of chemical controls to other control techniques, such as physical controls like trapping and shooting, although these techniques are not covered in the current review.

Cost of reform

Incorporating a humaneness score on labels is expected to cost industry approximately $2,230 per relevant product (or classes of product). This is a one-off cost to cover a humaneness assessment by NSW DPI VPRU and amendments to physical labels. Based on 10 new products (or classes of products) per year, the total cost to industry over 10 years is estimated to be approximately $230,000.

Product labels already in the marketplace will be required to pay for and undergo assessment by the VPRU. However, over-stickers can be applied to display the humaneness score and no label change will be required until such time as the holder intends to make other label variations, or their 5 yearly review of label content (see Chapter 4).

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

44. Recommendation

The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.

4 Ensuring responsible use

Currently, the regulation of pesticides and veterinary medicines rests with either the Commonwealth (the regulator of product registration) or state and territory governments (the regulators of use). The regulated industry (manufacturing, supply, and user industries) has changed significantly since the inception of the National Registration Scheme in the early 1990's with greater professionalism and a stronger commitment and capacity to meet and maintain international standards. At the same time, the community's high expectations of effective regulation and safe use of pesticides and veterinary medicines from both government and industry have been made increasingly clear.

The Panel heard during the consultation process, that there is a strong commitment from Australian industries to manufacture and supply safe and suitable pesticides and veterinary medicines which will maintain community confidence. Given these objectives are shared between government and industry, and given the improved capacity of industry to deliver quality and safety, the Panel considers the system as a whole can be strengthened by placing greater responsibility and accountability with industry for managing the ~~safe~~ high quality manufacture and safe and effective use of these products. There are multiple beneficiaries along the supply chain that can take responsibility for the production and use of products that are safe and effective when used properly. It is the Panel's view that accountability should not be the sole responsibility of the regulator; as all parties in the supply chain who benefit from their participation in the regulatory system have a responsibility to ensure that their products are safe when used appropriately, however, prior evidence of efficacy and effectiveness is considered essential for veterinary medicines.

A similar approach has been successfully implemented by other safety regulatory systems (such as work health and safety and consumer products) in which co-regulatory arrangements have been expanded to co-opt a range of non-government participants and give them formal and shared responsibility for safety. The parties best suited to deliver specific aspects of safety have been allocated those responsibilities. These arrangements ensured that general safety within the system was not compromised or reduced in any form, and indeed, the aggregate effect was reinforcement of safety via a system-wide and collective effort. Utilising non-government individuals and organisations in this way has allowed government regulators to concentrate their efforts on high risk areas of the regulatory system, improving overall outcomes.

The Panel considers that equally effective arrangements can be built into the pesticides and veterinary medicines system, by introducing a range of 'general product obligations' (see Section 4.1) to apply to dealings with these products across their life cycle (from design to disposal). The Panel is convinced there will be significant benefits for the regulator, users and industry, and better safety outcomes for the whole community. Shifting the focus to regulating activities, rather than only the product in terms of its use (noting that the supply of products is regulated), is similar to the approach used in work health and safety legislation.

The Panel also proposes a single common national licensing system (see Section 4.2). Currently licensing and other use arrangements (such as ground spraying, aerial application, and permits for handling restricted chemical products), differ significantly across state and territory boundaries resulting in inter-state operations being expensive, time consuming and confusing. A

harmonised common licensing arrangement would facilitate mutual recognition and greater mobility across borders, reduce risk of error, and remove administrative burden.

Common licensing arrangements will rely on contemporary training and competency standards to improve the safe and effective use of pesticides. Training and education in this sphere are inconsistent and confusing across Australia. In line with common licensing arrangements, the Panel proposes establishing nationally consistent training packages and competency standards utilising existing industry programs (such as Spraysafe) and accredited training through the vocational and tertiary sector (see Section 4.3). This will result in much greater consistency and improved training and competency standards for industry and users throughout Australia.

While training and licensing for the safe use of pesticides and veterinary medicines would be expected to be a key focus for the regulatory system, activities such as compounding veterinary products are not currently subject to the same regulatory system's safety and quality standards and controls as veterinary medicines within the system. Products compounded by a veterinarian, or by a pharmacist as prescribed by a veterinarian, do not fall within the existing legal definition of a veterinary chemical product, and therefore are not captured by the APVMA's manufacturing licensing requirements. The Panel recommends that products compounded to fill a veterinarian prescription or instruction should be brought within the scope of the future regulatory system (but remain exempt from registration) by formalising the rules relating to veterinary prescription of compounded products (see Section 4.4).

The product label is the primary and most effective means of conveying the necessary information on safe and effective use of pesticides and veterinary medicines to users. The current labelling of pesticides and veterinary medicines is complex and inflexible with different labelling codes and information for differing legislative requirements. The Panel recommends streamlining assessment, by focusing the APVMA's regulatory effort to those label elements that are not covered by other legislative schemes, making use of existing requirements under the poisons standard, work, health and safety, and dangerous goods laws. Labels have become lengthy and detailed, so critical information is sometimes difficult to find. In addition, updating information on labels takes place over time, sometimes resulting in differing labels in the supply chain for the same product. The Panel recommends the regulatory system adopt advances in 'smart labelling' technology where information can be supplied via electronic means (see Section 4.5). This will allow targeted data to be provided in real-time including updated information in different languages for users from culturally and linguistically diverse communities.

Within the disposal/recycling phase of the pesticides and veterinary medicines product life cycle, Australian industries have stewardship programs to manage the end of life impacts of these products. Major industry programs for pesticides and veterinary medicines manufacturers include drumMuster and ChemClear. The Panel considers these programs to be excellent examples of successful voluntary stewardship programs and would encourage further participation by industry players. The Panel recommends that industries should ensure their quality assurance schemes include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations and as part of licensing conditions (see Section 4.6).

4.1 Introducing general product obligations

Acknowledging shared responsibility and promoting preventative action

Many chemicals are inherently hazardous. That is, they have the potential to cause harm to humans, animals, plants, or ecosystems if not managed appropriately. Recognising this, the Panel considers that individuals and entities that interact with pesticides or veterinary medicines, from design to disposal, have a responsibility to deal with chemicals in a considered and conscientious manner to prevent such harm.

Currently, applicants for pesticide and veterinary medicine registrations and approvals have a responsibility to satisfy the APVMA that products are safe, effective, and will not prejudice trade. After registration or approval, holders have an ongoing responsibility to supply products whose characteristics are consistent with the details assessed and recorded by the APVMA, and to advise the APVMA about any new information that shows that the constituent or product may not continue to meet the statutory criteria.

Chemical users also have responsibilities. These currently centre on dealing with pesticide or veterinary medicines according to the label directions. However, an exclusive focus on compliance with a label risks encouraging a 'set and forget' mindset. Users may consider that compliance with the label is a sufficient contribution to responsible use, even when tailored, local management of the specific risks of each user would achieve better risk management outcomes.

Currently, the APVMA dedicates significant resources to pre-market assessment and management of chemical risk, and less to post-market compliance. Many stakeholders told the Panel that the APVMA generally applies this pre-market focus consistently, with an apparent lack of regard to the level of risks posed by the product (thus low risk products are assessed to the same degree as high risk products). This reflects, to some degree, the current design of the regulatory system where compliance with label directions is a function delegated to the states and territories.

The Panel considers that through more sophisticated regulatory arrangements, industry can be empowered to be more actively responsible for safe products, safe handling, and safe user practices, and can deliver solutions that are more responsive, creative, and efficient in delivering some of the outcomes required from regulation.

The Panel's objective is to move beyond a traditional mindset that the regulator is the single entity with responsibility for safety outcomes ('if it's registered it's safe' and 'just follow the label') to a more sophisticated mindset of shared responsibility ('how can I operate safely, in my circumstances, consistent with the label').

Placing a duty to actively manage safety and other risks associated with pesticides and veterinary medicines, on all those that deal with them, would encourage a mindset of taking initiative and care throughout a product's life cycle. To support this concept, a single national approach to the control-of-use of pesticides and veterinary medicines is necessary (see Chapter 2). As noted previously, this shared responsibility approach has been successfully applied through work health and safety (WHS) provisions in Australia. The 2018 review of the model WHS laws considered that the duty of care framework is working well (Boland 2018). Similarly, the Australian Fisheries Management Authority recognises the importance of shared

responsibility and encourages voluntary compliance as a tool in conjunction with other measures to effectively deter illegal fishing practices (Australian Fisheries Management Authority 2017).

The Panel considers that broadening ownership for responsible interactions with pesticides and veterinary medicines to minimise risks to human health, animals, plants, and ecosystems would strengthen the whole regulatory system. This approach would provide for modern, efficient, and flexible regulation. Moving beyond a 'one size fits all' approach will increase the opportunities for modern outcomes-based regulation and reduce costs without sacrificing effectiveness and safety outcomes.

Many stakeholders supported a co-regulatory approach, to capitalise on and formalise current, good practice industry-led systems for active risk management. Too often, such schemes exist alongside regulatory requirements but are not recognised nor acknowledged and do not count as accredited means of delivering on those requirements.

> *"Shared responsibility is an important mechanism for achieving regulatory efficiencies, and there are opportunities for expanding this approach."* (National Farmers' Federation 2020)

> *"Australian Grape & Wine accept that industry (including both chemical industries and users) have a shared responsibility in the management of agvet chemical use and as such we will continue to promote the importance of compliance as well as uptake of any quality assurance schemes for good agricultural practice such as our Sustainable Winegrowing Australia program. This program provides for opportunities to guide industry toward best practice and has the potential to be strengthened over time so as to promote improved compliance in agvet chemical use."* (Australian Grape and Wine 2020)

Some stakeholders raised concerns about the differing capabilities across the agricultural industry and the potential for this to increase regulatory burden in some sectors.

> *"It is also important to recognise that the agricultural industries differ in their ability to risk manage for the same Agvet chemical products. The major animal industries have reasonably sophisticated quality assurance and auditing practices. By contrast, systems for smaller animal industries and horticultural producers are often not as well developed."* (Queensland Department of Agriculture and Fisheries 2020)

> *"… the introduction of a duty of care on the chemical industry and chemical users, would need to determine what efficiencies and additional human health and environmental safeguards would be derived and what overlap there would be with current consumer laws."* (Grains Research and Development Corporation 2020)

Introducing general product obligations, and harnessing industry's own quality assurance and standards programs, would move the regulatory system from a passive to an active approach to provide a modern, sophisticated system that engages all players to manage risks preventively. This approach consolidates and formalises existing chemical risk management measures and does not present an additional regulatory burden as users of pesticides and veterinary medicines for production animals already undertake these obligations (e.g., spray diary or

animal treatment records) throughout the product life cycle to meet customers and other regulatory system obligations.

The Panel considers this approach would incentivise innovation by providing flexibility for different businesses to manage risks in a manner tailored to their individual circumstances.

Relying more heavily on industry's QA and good stewardship schemes would also have incidental benefits to continuously improve the schemes themselves. It would build incentives on the program managers to ensure high standards (to ensure accreditation) while also enhancing the value proposition for producers to join the programs.

What change is recommended?

Concurrent with the recommendations for achieving nationally consistent control-of-use provisions, the Panel considers a range of general product obligations should apply for dealings with pesticides and veterinary medicines across the life cycle of a product from design to disposal. These dealings would include, but are not limited to, the design, import, manufacture, transport, supply, use, and disposal of pesticides and veterinary medicines. This will create a better balance between regulating activities and not just products, like the approach used successfully in work health and safety legislation.

These obligations should improve confidence in post-registration risk management, providing a performance-based approach for regulating products and their uses while encouraging co-regulation. Examples of these general product obligations are provided at Annex 7.

The key features of general product obligations are:

- **life cycle** – the obligations would apply throughout the life cycle of pesticides or veterinary medicines, recognising everyone along the supply and use chain has a responsibility for safe dealings
- **performance-based** – the obligations would set a simple and clear outcome, i.e., responsible and safe use
- **preventative** – the obligations would be based on what is reasonably practicable for the obligation holder
- **tailored** – the obligations would be commensurate with the activity the individual obligation holder undertakes and would be tailored to their local circumstances
- **integrated and consistent** – the obligations would be nationally integrated and consistent with existing obligations for other regulatory systems, such as the WHS obligations (e.g., requiring suppliers and resellers to ensure containers of chemicals are correctly labelled).

The obligations would be consistent with management practices that most businesses already have in place, which would lead to no additional regulatory burden over and above that required to meet these obligations. For example, many workplaces have plans for managing chemical use, WHS risks, and on-farm biosecurity. In many cases, the practices for complying with the general product obligations could incorporate such arrangements already in place for complying with these obligations. As noted previously, this could also include practices that obligation holders already implement through established industry QA schemes and stewardship programs.

The Panel envisions these general product obligations would enhance the existing regulatory functions such as product registration. As an example, general product obligations could require registration holders to reasonably ensure, on an ongoing basis, that chemical use will not result in harm to humans, animals, plants, and ecosystems; will not prejudice trade; and continues to be effective. This would make the initial government assessment of the safety and trade risks during registration less 'point-in-time' and provide more continuing assurance of product safety over the years of product supply.

Importantly, the Panel considers general product obligations should be limited to what is reasonably practicable for the obligation holder to achieve, allowing the obligation holder to develop and implement their own risk management approach. A user's obligations may need tailoring to allow for safe harbours (exemption from the obligations) where certain persons using a product will comply with the general product obligations if they also comply with the authorised supply and use of that product. For example, safe harbours may include primary producers using a registered pesticide in accordance with the label instructions on their own property, or pet owners treating their own companion animals with registered veterinary medicines, or consumer products used in household situations and thus exemptions from the obligations (safe harbours) would apply (see Annex 7).

General product obligations would build a culture of compliance by allowing industry and all users to demonstrate ongoing responsibility. Providing relevant information, such as records of use, to the Commissioner, or making this information available to the Commissioner on demand, would facilitate compliance monitoring and auditing. To minimise the burden of providing this information, existing data collection and reporting processes for the purposes of meeting requirements of quality assurance schemes or government should be accepted to the greatest extent possible. This would allow for real-world implementation at a practical level.

Cost of reform

The Panel expects general product obligations to build on existing processes already in place to acknowledge and formalise responsibilities through the life cycle of a product. The Panel does not anticipate that formalising these obligations will have material financial impact on industry.as a whole.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

45. Recommendation

The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.

46. Recommendation

The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.

47. Recommendation

The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).

4.2 Introducing seamless national licensing for the regulatory system

In regulatory terms, registration schemes are generally used to regulate 'things', for example, pesticide and veterinary medicine products, cars and boats. Registrations allow a regulator, for example, to specify minimum standards that must be met in relation to the registered thing and track who owns or is responsible for that 'thing'.

Licences, on the other hand, are used to regulate 'activities' such as applying chemicals, operating a vehicle, or conducting a trade. Licensing allows regulators to ensure that the licensed entity has the appropriate qualifications and competencies and is of an appropriate character to conduct the licensed activities.

In the pesticides and veterinary medicines regulatory system, licensing may apply to both supply side activities (e.g., good manufacturing practice (GMP) licensing for veterinary medicines) and control-of-use (e.g., pesticide applicator licensing). Although there are some issues with supply side licensing that warrant reform (e.g., harmonising GMP licensing with international best practice; see Chapter 6), these activities are already regulated under a single national scheme and so harmonisation is largely achieved.

However, as with other areas of control-of-use regulation, licensing arrangements for activities such as ground spraying, aerial application, and permits for handling restricted chemical products, differ markedly among the states and territories. Each jurisdiction operates its own licensing scheme(s). These differ, among other things, in relation to the necessary qualifications, competencies, rules and offence provisions. For example, in NSW, occupational pesticide users (with some exceptions) are required to have appropriate accreditation and licensing for fee-for-service weed spraying. In Queensland, depending on area and equipment, individuals who operate ground equipment for herbicide distribution are required to hold a commercial operator's licence. NSW requires 2 competencies for a ground applicator licence, but Queensland requires a third competency. In Queensland, the business organisation or individual contractor also needs an additional licence (ground distribution contractor or aerial distribution contractor), but this is not required in NSW. Adding to this complexity is the fact that mutual recognition arrangements are only in place between some states, and do not always allow operators licensed in one jurisdiction to operate in any other.

The Panel also heard from stakeholders of issues with recognition of registration of veterinarians in some jurisdictions. National Recognition of Veterinary Registration (NRVR) is in place in New South Wales, Victoria, South Australia, Tasmania, ACT and Queensland. Each of these jurisdictions recognises the registration of a veterinarian in any other state or territory of

Australia with 'deemed registration'. Under NRVR veterinarians register in the state or territory in which they reside. Registration fees will be payable only in one state for states participating in NRVR. In practical terms a veterinarian with full registration who resides in NSW, e.g., will be deemed as registered should they wish to work in the ACT, Queensland, South Australia, Tasmania, Victoria. While the recognition of veterinary registrations in jurisdictions is out of the remit of this review, the Panel considers that the Western Australian and Northern Territory Governments should be encouraged to participate in the National Recognition of Veterinary Registration scheme.

For chemical users who operate across multiple states and territories, the different requirements set by each jurisdiction make operating across state and territory boundaries onerous, expensive, time consuming and restrictive – both for primary producers and especially for commercial applicators. This is unfortunate because the farming operations they serve frequently straddle jurisdictional borders. Examples are cotton across the NSW and Queensland borders and grain cropping across South Australia, Victoria, and NSW.

In a 2015 report on mutual recognition in Australia (across the economy; not just pesticides and veterinary medicines regulation), the Productivity Commission supported the concept of 'automatic mutual (occupational licensing) recognition' as a flexible, low-cost way of facilitating trade and labour mobility while minimising the regulatory burden (Productivity Commission 2015). However, it recognised that there were challenges implementing this, especially in occupations where health and safety considerations are material, and qualifications vary significantly between jurisdictions. It is also acknowledged that previous attempts to improve consistency of occupational licensing, for example the National Occupational Licensing Scheme, have failed. However, these challenges will be able to be managed through implementing the Panel's recommendations for a single national law.

For example, the APVMA's national risk assessment role, and nationally consistent WHS laws for chemicals, provide for safety and use instructions, and risk management requirements that apply nationally. Variation of qualifications among jurisdictions will be ameliorated by the Panel's recommendation for a nationally consistent approach to education, training, and competency; see Chapter 4.

Despite this, protracted efforts by the Harmonised Agvet Chemical Control of Use Taskforce (HACCUT) to align these arrangements; or at least provide for mutual recognition of licences among jurisdictions; have been unsuccessful. This reflects the fact that mutual recognition of licences for pesticide applicators – let alone harmonisation of licensing schemes – would require a serious commitment to reform by all states and territories as the administrative arrangements (both legislative and practical) in each jurisdiction vary widely.

Throughout the stakeholder consultation phase, the Panel repeatedly heard of the shortcomings and failures of the regulatory system due specifically to a lack of national consistency – be it for control-of-use, (see Chapter 2), training or accreditation (see Section 4.3) or a cohesive and coordinated residue surveillance and monitoring program (see Chapter 3). A similar message was received about applicator licensing.

> *"… a nationally consistent approach would be extremely welcome and would lead to significant practical improvements – especially for those businesses that operate*

> *across States/Territory borders, which in aerial application is almost all of them."* (Aerial Applicators Association of Australia 2020)
>
> *"The current situation of state-based regulation (especially control of use) has produced many anomalies which pose significant difficulties for spray application businesses and farmers operating across state borders."* (Australian Groundsprayers Association and SprayPASS 2020)

In the Panel's view a simpler, more efficient licensing system is needed.

What change is recommended?

The Panel has recommended the implementation of a single national control-of-use law and a Commissioner (in addition to the national registration regulator) to provide one seamless national system for regulating the use of pesticides and veterinary medicines (see single national law in Chapter 2). This should incorporate a single national licensing system.

All states and territories (except the ACT) signed the intergovernmental agreement on automatic mutual recognition of occupational registrations in mid-December 2020, to provide for automatic mutual recognition of occupational licences commencing from 1 July 2021. Despite this significant step forward, the Panel considers that a single national licensing scheme is preferrable as the intergovernmental agreement still allows a jurisdiction to 'opt out' of automatically recognising a licence type.

The Panel considers a single national licensing system would provide a better option than the current fragmented arrangements. It would be a once and for all 'fix' to a longstanding and widely recognised flaw in national regulatory arrangements and would be consistent with the Panel's ambition to recommend a regulatory system fit for a 30-year future. Developing a common licensing framework for the majority of pesticide and veterinary medicine activities will consolidate and simplify many layers of state and territory legislation, providing for simpler implementation. The common basic framework for all licensing schemes will improve public and stakeholder understanding of the system and removing duplicative state- and territory-based systems should reduce costs to industry.

A seamless national licensing scheme would facilitate increased mobility of the professional workforce by allowing them to easily conduct activities across state and territory borders. Common licensing arrangements that rely on consistent, up-to-date training and competency standards (see Section 4.3) would facilitate improvements in the safe and effective handling and use of pesticides. A single national licensing system would also remove the administrative burden associated with developing and maintaining mutual recognition systems (where they exist).

> *"Contractors especially must be nationally licensed, and ideally all agricultural chemical applicators should be licensed. Licensing needs to incorporate appropriate training, pesticide best management practices, and adherence to application equipment standards."* (Australian Groundsprayers Association and SprayPASS 2020)

However, licensing schemes are not unique to control-of-use regulation. For example, the APVMA currently regulates good manufacturing practice for some veterinary medicines under a

national licensing scheme and there is scope to regulate other supply side-activities more efficiently via licences.

Another example relates to, an activity with multiple steps that may require separately seeking import consents, registrations, and permits or exemptions. Using an unregistered product or unapproved active constituent under a minor use or research permit may also require an import consent for each substance (issued for short periods with restrictions on multiple shipments). There is therefore scope for a single national licensing system to combine linked regulatory actions (such as import and use) into a single licence, thus simplifying and reducing regulatory interactions. A national licensing scheme, developed within the national licensing framework, could replace the current 'one-off' regulatory arrangement of using an 'assigned notification number' mechanism for regulating the supply of hormonal growth promotants. In addition, a national licensing scheme could manage activities (conducted by analytical laboratories) in Australia for pesticides containing chemicals listed under the Stockholm Convention (as ratified by Australia), to reduce the number of exemption transactions currently associated with these substances.

Given the variety of potential licensing arrangements, the Panel recommends, more broadly, that a single national legislative framework be developed to accommodate all licences, throughout the product life cycle. The single national licensing framework would enable specific, targeted licensing schemes to be created to regulate specific activities irrespective of whether they relate to supply or use activities. This will provide for a consistent, efficient approach to licensing and the underlying regulatory outcomes needed; for example, ensuring that licensing is consistent with and supports the product stewardship and shared responsibility approaches across the entire product life cycle. The new single national law would describe the mechanisms for licensing e.g., applying for and issuing licences, imposing licence conditions, and licence suspension and cancellation. The law would also enable licensing schemes to be created and define standard conditions that apply to all licences, e.g., to provide any required records of activities to the regulator on request. This is similar to licensing requirements in the *Export Control Act 2020*.

48. Recommendation

The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.

Regulation of pesticide and veterinary medicine activities would occur through licensing, and product regulation would continue to occur through registration (as is currently the case). The Commissioner would issue most licences, with certain exceptions, such as for good manufacturing practice licences which would continue to be administered by the APVMA (under the same legislation as the other licensing arrangements). The Panel considers this approach aligns with the Commissioner's responsibility for control-of-use – as most licensable activities, such as those for aerial applicators, and ground sprayers relate to control-of-use activities.

Proposed national licensing schemes would include mandatory licence conditions, where necessary, to manage risks associated with the licensed activity. In the Panel's view, a critical part of the reform is that these conditions should allow for recognition of suitably rigorous industry schemes. Well developed, high quality and increasingly mature industry QA, education, training, standards, product stewardship, and similar schemes should be recognised more formally as an underpinning requirement for licensing requirements. They may not always, by themselves, be sufficient to meet all licensing requirements but should often be able to provide a sound basis for many of the requirements for a licence.

The long-sought recognition of industry QA schemes by a licensing authority would have the ancillary benefit of strengthening the appeal of such schemes to farmers and other chemical users. This could provide incentives for improved adoption, raise standards, and strengthen risk management across the whole system. Recognising industry-based schemes is consistent with other Panel recommendations including in relation to education, training, and competency (see Section 4.3) and General Product Obligations (see Section 4.1).

> *"There are a number of key changes proposed in this detailed submission, however, the following recommendations provide a clear focus on priorities: … Establish a national system for application pilot licencing requiring a single licence based on AAAA's Spraysafe accreditation."* (Aerial Application Association of Australia Ltd 2020)

49. Recommendation

The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.

Existing national 'licensing' schemes (e.g., good manufacturing practice and hormonal growth promotant supply) would transition to the new legislative framework with minimal, if any, noticeable impacts on existing participants. This would happen on, or soon after commencement of the new legislation.

Certain licensing schemes would continue under state and territory laws where this is the most efficient means of regulating activities. For example, it would be more efficient for existing licensing schemes for activities with poisons and the registration of veterinarians to remain under state and territory laws.

Other existing state and territory licensing schemes (e.g., aerial application of pesticides) would be consolidated into the new national framework, with appropriate transitional measures to ensure minimum impact on existing licence holders. Any new licensing scheme developed to regulate other activities with pesticides and veterinary medicines would operate on a national basis from their commencement.

Some stakeholders have sought additional flexibility in using products. This is because the APVMA risk assessment of a product's use is based on the 'worst case' scenario for re-entry intervals (REI), withholding periods (WHP), export slaughter intervals (ESI) and spray buffer zones (BZ) etc. While this assessment is appropriate for most users, some users have sought additional flexibility in their businesses, arguing that – in their specific circumstances – the worst case scenario does not apply, or that risks can be safely managed by local measures.

The Panel considers it appropriate to utilise the national licensing arrangements to establish a Special Use Licence to provide additional flexibility for suitably qualified users, while ensuring additional risks are adequately managed by these users.

Special Use Licence holders would be required to hold competencies for chemical use, particularly for hazard identification, risk assessment and mitigation and be allowed to use a product with a reduced REI, WHP or BZ when calculated using an industry developed, government accredited risk assessment tool.

The accredited risk assessment tools would allow the user to identify and develop control measures to manage the risks to workers, consumers of produce and trade, associated with the off-label application.

Industry would be expected to play an active role in designing the risk assessment tool and training module (potentially drawing on existing professional accreditation or QA models) to resolve operational issues such as tools to provide greater flexibility in meeting REI, WHP, ESI and BZ requirements. The APVMA would be responsible for assessing and accrediting the tool, while the Commissioner (advised by the APVMA) will be responsible for issuing Special Use Licences. The Commissioner could provide that certain existing QA activities or professional accreditations are sufficient to meet the competencies required for a Special Use Licence.

50. Recommendation

The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system.

The following are the Panel's proposals for initial licensing schemes under the new national licensing framework:

- **supply of internationally registered products**
- **good manufacturing practice**
- **supply or use of substances for research purposes**
- **supply of hormonal growth promotants**
- **dealings with Stockholm Convention substances**
- **supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)**
- **aerial application of pesticides (pilots and contractors that employ pilots, drone operators)**
- **ground applicators**
- **commercial pest controllers (pest management technicians)**
- **special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.**

4.3 Introducing a nationally consistent training and competency system for users of pesticides and veterinary medicines

User education and training plays a key role in ensuring that pesticides and veterinary medicines are deployed safely and effectively. The use of these products by those who may lack the competency to do so safely has the potential to significantly damage human, animal and environmental safety, and trade.

Currently, there is a variety of competency and licensing requirements which have been developed over the years to assist with the safe use of pesticides and veterinary medicines in Australia. The Panel has been made aware through stakeholder consultations and submissions that training delivery is inconsistent and confusing across the country, adding complexity and cost for users, and introducing risk of poor practice.

For example, jurisdictional control-of-use regulators may require licence applicants to demonstrate successful completion of specific training courses, or industry-based accreditations such as Spraysafe, as evidence of competency to carry out activities authorised under licences. At the same time, employers may require their employees undergo the same or different training to discharge the employers' duty of care under WHS laws.

A number of stakeholders highlighted the value of training to build the skills, knowledge, and competencies for users of pesticides and veterinary medicines.

> *"Specifically, training in the supply of chemicals (and users of chemicals) should be required and be consistent nationally."* (GrainGrowers 2020)

> *"… the organic industry supports assessor accreditation, [and] formal training for all users …"* (NASAA Organic 2020)

> *"The Undergraduate training and continuing professional development of veterinarians provides a solid foundation for the appropriate and responsible use of veterinary medicines, whether the products are registered for animal use or not registered."* (Australian Veterinary Association 2020)

However, not all training leads to positive outcomes.

> *"For some years there has been disquiet among professional groundsprayers about the standards of some applicators in the industry, particularly by insufficiently trained operatives."* (Australian Groundsprayers Association 2020)

During consultation, some stakeholders suggested that, to increase rates of participation, the current accreditation and training system for growers and commercial operators should be more tailored to individual needs. For example, if a participant is only involved in cropping then they should only have to achieve competency requirements for the course components relevant to cropping and not, for example, any livestock components.

Despite the clear value of training and accreditation in assisting with the safe and effective use of pesticides and veterinary medicines, training requirements for users are currently not nationally consistent.

> *"Currently differing training and licence requirements between states increases the cost of training and particularly for fumigation products. Availability of training is also restricted."* (AusChem Training Pty Ltd 2020)

In 2017, the Agriculture Ministers Forum agreed to minimum training standards developed by HACCUT for users of restricted chemical products (RCPs) and Schedule 7 agvet chemicals (noting these allow the states to add additional requirements in their respective jurisdictions). These minimum standards are largely based on completion of accredited training, otherwise known as Vocational Education and Training (VET) sector units of competency. The minimum standards developed by HACCUT also includes recognition of equivalent industry accreditation schemes, such as Spraysafe and its equivalent in other industry sectors.

However, the Australian Environmental Pest Managers Association (AEPMA) submission to this review highlighted the little progress achieved by HACCUT as, 3 years after Ministerial approval, these reforms have still not been fully implemented. In addition, there have been failures of a number of previous attempts to develop and implement nationally consistent training for pesticides and veterinary medicines.

> *"Nothing has happened since in improving and making more efficient the regulatory structure in using Agvet chemicals by qualified operators across state boundaries."* (Australian Environmental Pest Managers Association 2020)

Regulatory oversight of the development and delivery of accredited training courses and units of competency in the VET sector is provided by the Australian Skills Quality Agency (ASQA). Units of competency, and the qualifications within which they sit, are developed and approved under auspices of the Australian Industry and Skills Council, and subsidiary Industry Reference Committees, and are then delivered by Registered Training Organisations. However, some training organisations consider the system currently has limitations.

> *"Accredited training is however limited to some degree by the content and assessment requirements contained in Units of Competency and the training quality framework."* (Tocal College 2020)

The Panel also heard from stakeholders that aspects of the training was out-of-date and difficult to get updated and that more needed to be done to improve existing competencies.

> *"Establish an industry-based, application expert task force from peak bodies to rewrite the national competencies for chemical application to better reflect essential knowledge and skills."* (Aerial Applicators Association of Australia 2020)

Despite the limitations of the VET sector regulatory framework, accredited training is the most common approach for demonstration of competencies, and is widely used in other regulatory schemes, including WHS, and in apprenticeships. The ASQA has national responsibility for ensuring the quality of training developed and delivered under the VET framework.

A minimum standards approach, as developed by HACCUT, still allows a state and territory-based control-of-use regulator to introduce additional requirements over and above the minimum standard. This undermines the logic of national consistency and dilutes the benefits that could arise from harmonisation.

What change is recommended?

Well trained and competent users reduce the risks associated with chemicals use. Having well trained individuals at every point in the supply and use chain reinforces the integrity and strength of the chain as a whole. Good training systems will contribute to building and maintaining community confidence in the appropriate and proper use of pesticides and veterinary medicines. Assurance of competent users will also enable improved access to new chemicals and new uses via alternative pathways such as those outlined in the exemptions and licensing sections of this report (Section 4.2 and 5).

51. Recommendation

The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.

Training standards are an important mechanism for establishing the criteria expected for persons undertaking specified activities involving pesticides and veterinary medicines. The Commissioner needs to drive the establishment of training standards to underpin its responsibility for regulating national control-of-use, including for auditors it engages to ensure compliance with its licensing schemes (see Chapter 5). The APVMA will similarly need suitably trained auditors for veterinary licensing (see Chapter 6), and accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6).

A priority for establishing training standards should be the Panel's recommendation of a nationally consistent licensing scheme covering, amongst others, aerial applicators, and commercial pest operators to take full advantage of the single national law (see Chapter 2). The work of HACCUT to establish the nationally agreed minimum training standards for restricted chemical products and Schedule 7 poisons also remains incomplete. Implementing these initiatives would not mean that operators could ignore any state-based or local requirements, but it would streamline the ability for users to work across borders as well as intra-jurisdiction.

The Panel has also recommended introducing special user licences to allow primary producers to undertake a range of activities including use contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone. However, if such special arrangements were to become available, it would be critical that an applicant for a special use licence demonstrate full competency in risk assessment, chemical handling, and application through completion of rigorous accredited training or industry-based accreditation.

52. Recommendation

The Panel recommends that the Commissioner completes the work of HACCUT to establish training standards for restricted chemical products and Schedule 7 poisons, and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides and veterinary medicines.

53. Recommendation

The Panel recommends that competency standards be established for roles introduced through other recommendations in this review. These include:

- **accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6)**
- **government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.**

The Panel considers there is a significant, under-utilised opportunity to make better use of industry-developed education, training and accreditation programs such as Spraysafe, and similar models, as well as accredited training developed through the VET sector, and other tertiary qualifications. The Panel considers that in some cases, such as for aerial applicators, industry-based accreditation will provide the best outcomes, while for others, VET sector accredited training is likely to be the preferred approach. In establishing the standards, the Commissioner should consider both VET sector accredited training, and industry-based accreditations, and may deem them to be equivalent for certain activities.

54. Recommendation

The Panel recommends that where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Commissioner.

To address stakeholder concerns about training quality and relevance, the Commissioner would engage actively with ASQA and industry associations responsible for industry-based accreditation to ensure timely updating and quality of training outcomes, and that training is adaptable and flexible to meet the needs of pesticide and veterinary medicine users. Industry stakeholders will also have the opportunity to input to these processes throughout the consultative machinery recommended by the Panel in Chapter 2.

The Panel notes with interest the move towards greater use of 'micro-credentialing' which allows for recognition of individual units of competency, or small groups of units of competency, rather than having to undertake and successfully complete a full qualification such as a certificate II or III. The Panel considers that these should be explored in the context of nationally consistent training and competency, particularly as full qualifications are rarely required for users of pesticides and veterinary medicines.

55. Recommendation

The Panel recommends that the Commissioner work with the ASQA and industry associations responsible for industry-based accreditations to ensure quality of training outcomes, and that training is adapted to meet the needs of pesticides and veterinary medicines users into the future. The Panel suggests that the Commissioner examine the benefits of micro-credentials when developing the standards.

Cost of reform

The Panel's recommendation to harmonise training and qualification requirements is not expected to have significant time or financial whole-of-system implications on either user or training industries. The Panel recognises that each state and territory already have existing (albeit inconsistent) requirements, some exceeding or below others. A national approach to

qualifications will likely see some localised increases and decreases, which are considered to balance out at the macro level.

The regulatory cost impacts to users from implementing a single national law, beyond harmonising training and qualification requirements, are considered in Chapter 2.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

4.4 Reforming the approach to labelling

All pesticide and veterinary medicine products are legally required to include information to direct and support the safe use of the product and the response actions in the event of an emergency or unintended exposure. The product label is the primary means to convey this information to handlers and the end user and, importantly, is therefore a valuable safety communication tool for chemical companies and government. Control-of-use agencies also currently rely on the approved physical label as a legal document – what is required is a contemporary source of approved label information that they can compare actual use against.

Advances in technology can support different ways for users of pesticides and veterinary medicines to access, understand and engage with instructions for the safe use of a product. Many industry sectors are increasingly sharing targeted information with users through electronic means, such as quick reference (QR) codes. Internationally, food products are increasingly supplied with labels which make additional information, including traceability and provenance, easily accessible through scanning codes via smart devices (mobile phones, tablets, and commercial scanners etc.). This allows a more responsive approach to information sharing that is tailored to a user's needs and interests. It also provides scope – not previously available – for the simplification of the printed label.

It is not uncommon for the instructions for a pesticide or veterinary medicine product to be updated over time – such as adding new safety instructions, to address a new concern or new application rate, instructions to deal with matters including emerging resistance or new residue restrictions (e.g., reflecting change in overseas market requirements). As a result, different labels for the same product can sometimes be found in the supply chain, and more importantly, within the user's chemical or veterinary medicine store. Should this occur, some users may not have access to the most current information or be able to identify differences easily and quickly in label instructions for how the product should be used safely.

Traditional labels have limited space for instructions, especially on containers that are physically small and therefore only present these instructions in English. This makes it difficult for farm workers from culturally and linguistically diverse communities to understand. Confusion in comprehending a use or safety instruction can pose significant risks. Electronic labelling offers the opportunity for instructions to be available in languages in addition to English or to include pictorial and other visual indicators.

Some stakeholders advised the Panel of instances where physical labels have deteriorated i.e., fallen off the container in the field (particularly the increasing number of labels relying on booklet attachments to capture all the required information). Having a copy of instructions available electronically could not only reduce the user's reliance on bulky physical label formats, but it would also ensure that a copy of the instructions is still accessible.

> *"Growers often report the fragility in product labels, citing they become easily damaged during transit, and degrade upon exposure to sun and rain. As such, it is not uncommon for labels to become damaged to the extent that product identification becomes inherently difficult or even impossible."* (GrainGrowers 2020)

Additionally, many labels include instructions that cover a range of commodities and pests, across a diverse range of circumstances. This can lead to excessively long, detailed labels, in which much of the information is not relevant to individual users' specific needs on the day.

A wide range of stakeholders have expressed the view that there are many, currently unrealised, opportunities offered by electronic labelling (e-labels or smart labels).

> *"Advances to labelling technologies have the potential to improve safety, efficacy, and compliance, as well as mitigate risks associated with label degradation, including unintentional misuse of a product. Further, data capture through applications of this technology could improve product traceability throughout the supply chain, as well as monitoring of sales and other data provisions."* (GrainGrowers 2020)

Smart labels offer benefits such as easier access to information relevant to a given situation and specific conditions (e.g., specific crop details and/or weather conditions, particularly for aerial applications) and the ability to provide updated information when label particulars change. Smart labels can include embedded digital tools to assist users to calculate mixes, application rates and other requirements. They can also improve user experience by making instructions available in different languages and pictorially rather than through written descriptors, or through interactive augmented reality labels to give users additional information.

> *"A shift to smart labelling for agvet chemicals would be supported where it improves users' understanding of their legal requirements and best practice product handling and use – by making the information more clearly and readily available. It would also enable more rapid and efficient updates to label information and instructions and importantly, would facilitate the adoption of local risk assessment tools for chemical users, without compromising safety."* (National Farmers' Federation 2020)

Smart labels may also improve on-farm adoption of technology, allowing machines to scan for application rates as well as simplify and automate record keeping and, in future, meeting increased consumer expectations of traceability and provenance requirements.

> *"There is potential for smart labels to allow for integration of the pest management planning with mixing, application, record keeping and traceability. Integration and automation of planning, tracking and record keeping systems are relatively frontier in horticulture in 2020 but will very soon be mainstream in all agricultural sectors and labelling and record keeping systems should be designed with that in mind."* (Citrus Australia 2020)

> *"GRDC supports the concept of smart labelling as outlined in the discussion paper. In addition to the points made the development of suitable smart label technology would enable for enhanced record keeping and compliance throughout the supply chain including the completion of Vendor Declaration Documents and any other*

> *documentation needed to meet contract requirements."* (Grains Research and Development Corporation 2020)

However, some stakeholders expressed caution about the use of smart labelling for pesticide and veterinary medicine products, wanting to ensure users received the necessary information for safe use of the product.

> *"The organic sector supports the current prescriptive labelling scheme because it provides readily available, onsite information that can be accessed and read at the moment of use. Current prescription labelling does not require an additional device or steps in the process to becoming familiar with the warnings and risks, appropriate handling, and application of the chemical product. The organic sector prefers that a combination of smart labels and the current prescriptive labelling scheme would afford the highest level of protection and risk mitigation."* (NASAA Organic 2020)

> *"The Western Australian Government believes more research is required in this area [smart labelling] before support can be given to the review panel's recommendations."* (WA Government 2020)

Stakeholders also raised concerns about the implications of smart labelling and the legal status of the label under jurisdictional control-of-use legislation.

> *"Labelling and control of use differences between states have varying requirements regarding what has to be on the package."* (Dairy Australia 2020)

> *"It is understood that in some State jurisdictions there is a legal requirement for use instructions to be contained on a label."* (Horticulture Innovation 2020)

This issue of varying jurisdictional requirements for control-of-use is addressed by the Panel in Chapter 2

In addition to the considerable opportunities offered by smart labelling, the Panel recognises the existing approach to approving label content in Australia needs significant reform. Currently, there is duplication of regulatory requirements due to product label content needing to meet multiple legislative obligations, including pesticides and veterinary medicines, Workplace Health and Safety (WHS), poisons scheduling, and dangerous goods laws. These obligations are often identical or near identical to the labelling statements required by the APVMA. Stakeholders encouraged the Panel to seek reforms to these regulatory overlaps and noted duplication.

> *"Currently, agvet chemicals which are workplace chemicals are subject to labelling requirements under both agvet and WHS laws."* (Safe Work Australia 2020)

> *"Importantly, some label content (e.g. dangerous goods, poisons scheduling and GHS) fall outside the jurisdiction of the APVMA and should also be considered in terms of control of use and compliance."* (CropLife Australia 2020)

> *"We encourage the panel to seek efficiencies in the interface between regulators in areas such as poison scheduling, GHS labelling, gene technology regulation, and biosecurity."* (Syngenta Australia 2020)

Presently, there are separate labelling codes for pesticide and veterinary medicine products which outline differing legislative requirements for each. In 2014, legislative amendments provided the opportunity for the APVMA to make an inclusive labelling standard that would rationalise regulatory effort and avoid operational delays by removing regulatory practices that duplicate assessment of information already regulated by other entities. However, 6 years later, the APVMA has not progressed the development of a labelling standard and continues to rely on current labelling codes and existing operational practices.

Stakeholders noted that the current label approval process is complex and inflexible. The demanding processes for approval of label content, even where changes are minor, may unnecessarily constrain innovation and restrict communication between manufacturers and users.

> *"The existing mechanisms for updating labels with minor changes are cumbersome and there does not appear to be a simple and cost-effective process for change and updating of all labels held by registrants. Therefore, any changes to the method of providing label directions, review and update should be explored as a matter of priority to ensure directions are up to date as possible."* (GrainGrowers 2020)

> *"Accord supports a risk-based approach to product assessment and product labelling. However, we also support allowing flexibility in labelling to allow hazard statements where there is no detriment to the end user."* (Accord 2020)

During consultations, some stakeholders argued that registration holders should be able to add additional precautions (over and above those required by the APVMA) – such as additional personal protective equipment requirements – to labels. The APVMA currently does not allow any such additions for home garden and domestic pest-control products. These stakeholders argued that the registration holder, not the APVMA, bears the liability for adverse impacts of a product's use, and the current prohibition is particularly problematic.

What change is recommended?

The label represents the essential instrument for communicating critical information to users of chemical products. In the future regulatory scheme, the Panel considers this protective measure must remain the primary source of information to support safe and responsible use of a pesticide or veterinary medicine. Nevertheless, the Panel sees opportunities to improve the effectiveness and value of labels and their primary purpose of providing essential information, while recognising the opportunities for reducing costs and regulatory burden.

Adoption of technology

Looking to the future, the Panel recognises technology will offer significant opportunities in the next 30-years. With the potential for increased automation and machine learning and support for Australia's agriculture industry, the need for machine readable labels is clear. The Panel recommends that future legislation should provide for the adoption of smart labelling (such as QR codes and machine-readable labels), in order to capture the full benefit of current and emerging technologies. The Panel considers these benefits include, but are not limited to:

- Improved user experience with label instructions. For instance, this may include easy access to up-to-date, best practice chemical use instructions allowing users to access relevant label information to remove confusion leading to improvements in chemical handling and use. It

may also provide information in multiple languages, adopt visual and virtual technologies and other targeted instructions to customise use for specific circumstances.

- Reducing labelling (and re-labelling) costs to industry, and avoiding delays in disseminating information (currently, a label variation may not reach the market until stocks of products bearing old labels are exhausted).
- Providing an electronic means for amending label content, allowing holders to update their label following authorisation from the APVMA. This could improve the regulator's handling of communication of changes to instructions for use in real time e.g., following product variation, recall or cancellation or to indicate changes to scheduling, storage, or disposal instructions.
- Supporting increased on-farm automation and reduced regulatory load on farmers by ensuring labels are machine readable. This will allow for automation of spray rates and spray diaries and easy integration with record keeping requirements and systems as they develop in future.
- Directing users to additional information sources and management tools such as a manufacturer's calculation tool for spray buffer zones, reduced withholding periods for produce or re-entry periods for treated areas. The Panel has separately recommended the creation of a special use licence (SUL) to ensure that users are competent when using these tools.
- Exploiting the connectivity of QR type technologies to assist users in fulfilling their regulatory requirements, such as auto filling fields for record keeping purposes. It may also facilitate other automated monitoring, such as the types of products undergoing disposal or recycling at any given location, which would support future biosecurity, environmental and future national recycling obligations.

The Panel considers that pesticide and veterinary medicine products should continue to be supplied with an attached label. The label must communicate, at a minimum, adequate instructions to enable the use of the product for the purpose for which it was designed and manufactured. The fundamental information that relates to safety, first aid, disposal, application, dosage instructions and critical use restrictions (e.g., aerial application, seasonal restrictions for sensitive crops or other local environmental or urban issues) would remain affixed to the container as well as being able to be accessed electronically.

56. Recommendation

The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart-label content.

57. Recommendation

The Panel recommends that with the implementation of a single national law, all barriers to the inclusion of smart-label content on labels is omitted, while retaining minimum standards for information on the label to support safe use and handling. The result should be safer use, a more informed user as well as an improved user experience.

58. Recommendation

The Panel recommends that the Commissioner continues to scan the technology horizon to identify additional emerging technologies that may assist with labelling reform.

Labelling standard as a condition of registration

The Panel considers it is timely to eliminate the longstanding overlap between different regulators with various interests in a pesticide or veterinary medicine's label.

Accordingly, the Panel considers that the APVMA's assessment of the label (see Annex 6) in future be limited to that information which is not covered by other regulatory systems. Label elements assessed by the APVMA will be referred to as 'regulatory assessed elements'. The label will contain instructions for use to manage risks to safety (human, animal, plant, and the environment), trade and effectiveness. The label must also include labelling requirements imposed by other regulators, but these will not be subject to APVMA assessment. A failure to meet labelling requirements, whether these are APVMA's requirements or those of another Australian regulatory system (such as poisons scheduling or work health and safety) would be grounds for the pesticides and veterinary medicines national regulatory system to take remedial action (such as suspend or cancel a product registration, or licence to supply overseas-registered products).

The elements of the label to be regulated in future by other entities, and which will no longer be approved by the APVMA, include signal headings and alert phrases as mandated by poisons scheduling requirements and WHS legislation. First aid and safety instructions should follow the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) labelling statements required under WHS law. The Panel considers this streamlined approach to the APVMA assessed elements of a product label will result in timelier and streamlined decisions by the regulator.

The GHS labelling system is adopted internationally and is the basis for preparing Safety Data Sheets for pesticides and veterinary medicines supplied in Australia. All workplace chemicals in Australia have long been required to be labelled in accordance with the GHS labelling system.

Commented [SPE18]: The AVA understands that veterinary medicines, in common with human medicines, are exempt from this requirement. The risk assessment currently undertaken by APVMA and risk management measures currently included on the label (for example see APVMA Risk Assessments) is a system that appears to fulfil the need without the introduction of significant changes to veterinary practice.

This system has been characterised as a hazard-based system and the Panel understands this may appear inconsistent with its commitment to risk-based regulation. However, the GHS labelling requirements derive from the same hazard profile as relied on by the APVMA when conducting its worker health risk assessments.

GHS labelling requirements provide information for users to ensure compliance with WHS duties and obligations. This approach can be viewed as allowing the regulator and end users to take appropriate risk-based actions consistent with their role in the regulatory framework. Further, the risk mitigation statements currently required by the APVMA to be included on the label align well with the GHS statements required to be included in Safety Data Sheets and would now be consistently reflected on labels. To that extent, the Panel considers both approaches of regulatory control are achieving equivalent outcomes.

59. Recommendation

The Panel recommends that the regulatory assessed elements of the label approved by the APVMA be limited to that information which is not assessed by other regulatory systems.

60. Recommendation

The Panel recommends the product label must comply with general conditions of registration to ensure the risks of the product can be managed. To implement this, the Panel recommends the establishment of general statutory conditions of registration to which the product label must comply, along with urgent completion of a labelling standard. Where relevant, compliance with the labelling standard would be made a condition of registration (or form part of the licence to supply overseas registered products). More details of these proposed conditions are provided in Annex 6.

A general condition of registration (or equivalent for a licence to supply overseas registered products) should be that the label must include adequate instructions for safe use and must comply with other regulatory systems. This includes matters that the APVMA would no longer assess or require on the label.

The Panel also considers that manufacturers should not be prevented from including additional information on their labels provided this is consistent with the essential regulatory assessed elements of the label. For example, there should be no prohibition on the inclusion of additional safety instructions the manufacturer deems necessary to reduce its risk exposure. In the Panel's view, this is another way to advance the concept of more evenly shared responsibility for safety assurance between government and non-government participants in the regulatory system.

61. Recommendation

The Panel recommends manufacturers should be permitted to (and indeed, should be encouraged to include) include additional personal protective information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

Under the Panel's future arrangements, failure to supply a product with an approved label will continue to be an offence. Representations (including advertising and claims) made about the product must not be contrary to activities detailed in the National Rules for the use of pesticides or veterinary medicine products (see Chapter 2 and Annex 8 and 9), namely, that a product must be used according to label directions unless an exemption is applied for, in statute or by the APVMA.

There are currently no requirements for registration holders to ensure information on the label is correct, and up-to-date, either periodically or when new information becomes available. The Panel proposes to introduce requirements for the holder to review labels at least once every 5 years, or when new information becomes available. The holder must then declare to the APVMA this information is accurate. This timeframe for periodic label review aligns with the obligation to review Safety Data Sheets under WHS legislation and alignment of these timeframes would reduce both costs and duplication for registration holders. As outlined in Chapter 5 registration holders should notify the APVMA of the removal of jurisdiction-specific use patterns at the first 5-year review point.

62. Recommendation

The Panel recommends that every 5 years, at a minimum, the registration holder must conduct a review of label content to ensure the information on the label is current and remains correct – noting that emerging scientific evidence or consumer concerns could

also trigger a review, including a labelling review, at any time (see chemical review discussion in Chapter 3).

Compliance and enforcement in accordance with label claims

The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the 'regulatory assessed elements' of the label. For this to occur efficiently and effectively, it is vital that all pesticide and veterinary medicine product labels in the market reflect the latest instructions. This ensures users do not inadvertently misuse products (such as may occur if an old application rate is no longer suited to deal with an emerging resistance or trade residue concern). It will also reassure users that the instructions they are following reflect current legal obligations.

While control-of-use agencies currently rely on the approved label as a legal document, what is required in the future regulatory system is a contemporary source of label information (the regulatory assessed elements) against which regulators are able to compare actual use. The current requirement for the label to contain all the approved label information, without reference to any external sources or supporting material constrains the adoption of new technologies such as smart labelling. Therefore, the Panel considers a balance is needed between, on the one hand, label information that is a sufficient foundation to trigger compliance action for alleged misuse, while on the other, label information to meet the many needs of users. To this end, the Panel recommends the label should no longer be considered a static document nor represent the totality of legal instructions.

63. Recommendation

The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the regulatory assessed elements of label requirements and not against the 'approved label'.

These reforms to labelling will mean that APVMA will in future be confined to considering only those matters that are specifically related to the regulation of pesticides and veterinary medicines under a revised regulatory scope of definitions (see Chapter 5). This simplifies the APVMA's role and removes unnecessary duplication of effort in information already assessed by other regulators. The reforms also capitalise on the opportunities for automation of record keeping. They enable speedier updates of safety information and instructions. They will permit/allow more user-friendly labelling practices and reduce less critical information and instructions which add to costs and increased non-compliance risk.

Cost of reform

The Panel's recommendations do not mandate the use of technology (such as QR codes) in labelling therefore costs of implementing would only apply to those entities or individuals who choose to foster this technology. While the Panel expects that changes to how the APVMA assesses label information would result in time savings for the regulator, as the label assessments run concurrently with other assessments, time savings (as the regulatory cost impact to the manufacturing, importing and supplying industries) are difficult to measure.

The Panel does consider there are regulatory cost savings in terms of printed labels (in particular those labels represented as a multipage booklet attached to the container) for those that do choose to foster this approach. The Panel has conservatively estimated an industry

saving of approximately $400,000 per annum, or $4 million over 10 years. Greater use of emerging label technology in the future will continue to increase savings to industry.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

4.5 Enhancing stewardship of pesticides and veterinary medicines wastes

Australia's approach to waste and recycling is currently undergoing a major transformation. Waste is now viewed as a resource, and there is greater focus on the national and international aspects to waste management, recycling, and re-use. Waste management is currently the responsibility of state governments, but the Australian Government is increasing its role in policy development and strategic approaches to waste management and recycling with introduction of new legislation, strategies, and other incentives.

The '2018 National Waste Policy: less waste, more resources' was agreed by Australia's Environment Ministers and the President of the Australian Local Government Association in December 2018. The policy provides a framework for collective, national action on waste management, recycling, and resource recovery to 2030. It applies principles for a circular economy related to waste management to support better and repeated use of Australia's resources.

> *"The wine sector is committed to the concept of striving for a more 'circular economy' that favours more effective use of previously discarded parts of agricultural production. Many businesses already take a lifecycle approach to measuring their waste and emissions and we are beginning to see businesses seek innovative opportunities to value- add parts of the waste stream."* (Australian Grape and Wine 2020)

The 'National Waste Policy Action Plan 2019' (Australian Government, state and territory Governments and the Australian Local Government Association 2019) presents targets and actions to implement the 2018 National Waste Policy. The plan complements and supports the implementation of national packaging targets developed and agreed by Australian businesses and industry through the Australian Packaging Covenant Organisation, as well as separate policy commitments by every state and territory jurisdiction.

A key action of the Australian Government is the introduction of the 'Recycling and Waste Reduction Bill 2020' to create a framework for prohibiting export of problematic, unprocessed, or contaminated waste streams, including plastics, glass, paper, cardboard and tyres. The legislation also incorporates the existing *Product Stewardship Act 2011* with recommended changes following its review (Department of Agriculture, Water and the Environment 2020). The proposed reforms include:

- bringing sustainable product design and reparability into the objects of the Act
- allowing for expanded schemes to deal with material streams rather than individual product categories

- strengthening the Minister's priority list so it can recommend actions and set deadlines for companies to establish voluntary product stewardship schemes through co-regulatory approaches and prior to mandatory regulation by government
- providing the Minister with the ability to table a statement about the operation, performance and coverage of accredited voluntary arrangements to celebrate schemes and organisations that are doing fantastic work, but also to publicly call out free riders who are not participating in an accredited scheme that's available to them
- being supported by the establishment of a Product Stewardship Centre for Excellence to provide mentoring and advice on schemes, and the National Product Stewardship Investment Fund with a $20 million investment to support the creation of new schemes or the expansion of existing schemes.

The Australian pesticides and veterinary medicines industries have long established industry stewardship programs to manage the end of life cycle impacts, flows, and fates of products or materials. The major programs for the pesticides and veterinary medicines manufacturers, drumMuster and ChemClear, are operated by CropLife Australia's wholly owned subsidiary AgSafe Limited as part of the Industry Waste Reduction Scheme (IWRS).

Participating members in the IWRS are CropLife Australia, Animal Medicines Australia, Veterinary Manufacturers and Distributors Association, the National Farmers' Federation, and the Australian Local Government Association. A number of proprietary programs also exist for the return, reconditioning, and recycling of intermediate bulk containers (IBCs).

> *"AgStewardship Australia … is responsible for the collection and management of levy contributions to fund two voluntary stewardship programs owned and operated by Agsafe Limited – drumMUSTER and ChemClear, which collect empty agvet chemical containers and safely dispose of unwanted agvet chemicals respectively."* (Animal Medicines Australia 2020)

Products participating in the drumMUSTER scheme display the drumMUSTER logo. The logo indicates the user can currently deliver the empty, clean containers to one of 835 national collection sites free of charge, as they have already paid a 6-cent levy per litre/kg towards recycling of the container. If the container does not have a logo it may be because the manufacturer has opted out of the program and therefore no levy has been paid, or because the container does not meet the drumMUSTER eligibility criteria, and is ineligible for collection.

The Panel considers these programs to be excellent examples of successful voluntary stewardship that demonstrate how industry can take responsibility and self-regulate. The Panel is impressed that 80% of the agricultural chemical manufacturing industry takes advantage of these stewardship programs and around 60% of eligible containers are returned.

> *"Agriculture Victoria is aware of concerns from stakeholders of gaps in participation in the ChemClear and drumMUSTER programs by some chemical suppliers and would welcome further consideration of a proposal that addresses this issue."* (Victorian Department of Jobs, Precincts and Regions 2020)

The AgSafe-operated industry schemes already make substantial contributions towards targets in the National Waste Policy Action Plan 2019, including:

- Target 3: 80% average resource recovery rate from all waste streams following the waste hierarchy by 2030.
- Target 5: Phase out problematic and unnecessary plastics by 2025.

In the Panel's view, disposal arrangements for the pesticides and veterinary medicines sector need to go beyond simply ensuring plastics and metals and any future pesticides and veterinary medicines container materials are recycled. Pesticides and veterinary medicines containers may contain potentially hazardous residual or unused chemicals, and therefore there are risks if empty containers are re-purposed for other uses or abandoned or burnt as there could be leakage and leaching of chemicals from old or damaged drums. There is not only a significant risk to human, animal, and ecosystems health, but also to social licence if such chemical containers or residual chemical products are not handled and managed responsibly. Responsible product stewardship in the sector should therefore aim for as many containers, drums, and residual products as possible being properly processed.

> *"Additionally, irresponsible application on farm, and poor or limited product and container stewardship on the part of manufacturers, pose a high commercial risk for organic producers, the environment, and downstream users. This includes leakage caused by poor on-farm application and management practice, and poor clean-up and waste disposal systems."* (NASAA Organic 2020)

One particular challenge is to ensure adequate coverage of the increasing volume of Intermediate Bulk Containers (IBCs) – large bulk containers up to 1,000 litres, which are being imported. The drumMuster program does not accept bulk containers for recycling and currently the program can only accept containers between 1 litre and 205 litres. The return, reconditioning, and recycling of some IBCs is managed by a number of proprietary programs. However, the return process can be confusing, especially with multiple manufacturers of IBCs each of which has different return policies. There is also trade outside of these stewardship programs due to the utility of IBCs as reusable, stackable containers. Only some of the stewardship programs encourage return through buy- back incentives for IBCs. The Panel is aware that CropLife Australia is taking steps to remedy this problem, but not all importers are CropLife Australia members.

> *"CropLife Australia's mandatory code of conduct is being amended to require all member companies to ensure that all Intermediate Bulk Containers (IBCs) supplied with products are part of a returnable scheme. Already, more than 90 per cent of products supplied in IBCs by CropLife member companies are eligible."* (CropLife Australia 2020)

The Panel is of the view that the introduction of incentives to enhance return, reconditioning and recycling of chemical containers should be a priority for future improvements in product stewardship of pesticides and veterinary medicines to reflect the increased Commonwealth government's policy drivers and focus on waste reduction and management.

What change is recommended?

The Panel is encouraged by industry uptake of the product stewardship schemes but considers more needs to be done to safeguard human, animal, and ecosystems safety, and the sector's social licence.

> *"The NFF strongly supports industry stewardship programs such as ChemClear and drumMUSTER, which provide a pathway for safely disposing of and recycling farm chemical waste and containers. While returnable schemes already exist for a number of other containers, such as intermediate bulk containers for some products, there is appetite among end users to look at the expansion of these programs to other products and container types, and for greater interaction between the programs and state and local regulatory jurisdictions to ensure that the approach to collection is consistent and efficient. Regulatory costs associated with these programs must be minimised, as they are ultimately passed on to farmers and need to be carefully targeted to mitigate unintended consequences."* (National Farmers' Federation 2020)

The high level of participation in the schemes by manufacturers and users shows the success that comes from creating the value proposition that this is 'the right thing to do, the easy thing to do' as well as demonstrating responsible stewardship to the community. As industry-led schemes, they also embody the concept of shared responsibility between industry, users, and Government that aligns with other Panel recommendations including General Product Obligations (see Section 4.1).

> *"Waste disposal and management: The VMDA believes that, subject to further details and costs, manufacturers and the industry generally would benefit from membership of (e.g.) the Industry Waste Reduction Scheme as a condition of registration."* (Veterinary Manufacturers and Distributors Association 2020)

The Panel considers the Government should take a firm role in encouraging responsible disposal, recycling, and stewardship programs to support and encourage this in future.

The Panel's recommendation for a single national law for control-of-use is one means of encouraging improvements to product waste disposal and recycled packaging. This could include imposing licence conditions for certain activities to ensure action. The Panel has also considered whether there is a role for Government in providing incentives or penalties for participation in the industry schemes to avoid the free-rider problem in voluntary product stewardship programs.

> *"The Government will also undertake further detailed policy work and consult on how best to continue supporting voluntary industry-led schemes and will take action to implement regulation where industry fails to act."* (Department of Agriculture, Water and the Environment 2020)

The Panel has considered, but does not support, Government using the levy on sale of pesticides and veterinary medicines to fund container collection by drumMUSTER. The scheme is efficient and flexible because of its industry-led nature. Government levy collection would add a layer of bureaucracy and inflexibility and detract from the success achieved so far by industry taking responsibility. The Panel has also considered requiring non-participants in suitable stewardship schemes to declare their non-participation on labels, unless they can provide argument as to why their products are unsuitable for any stewardship action.

However, labels of products participating in the scheme already bear the drumMUSTER logo. Instead, the Panel recommends that the Commissioner be empowered to publish a list of

companies that are importing or manufacturing pesticides into Australia that are not participating in the current voluntary industry programs, or an equivalent program. This would add further market pressures and incentivise companies to participate. The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reporting on the state of the system (see whole-of-system performance measures in Chapter 2). Publication of such a list is consistent with the Government's intention, announced in conjunction with the introduction of the *Recycling and Waste Reduction Bill 2020* to make public the identities of firms not participating in suitable recycling schemes otherwise available to them.

Participation in the Australian Packaging Covenant Organisation's Australian Recycling Label (ARL) may be considered sufficient; however, adoption of the ARL does not provide for collection and safe processing.

> *"We support initiatives that lead to stronger end-to-end stewardship of AgChem Products wherever these are practical for users and suppliers to implement including: the proposal for packaging of 5kg and above to be recyclable or reusable as a condition of registration. The administration of these schemes needs to be as simple and cost effective, for example such as ChemClear and drumMuster, and lighter than APCO which is complex and costly to administer."* (Syngenta Australia 2020)

The Panel also recommends formal recognition of industry QA schemes which satisfactorily address product stewardship as part of meeting General Product Obligations (see Section 4.1). Many industry QA systems already include requirements and guidance on good disposal practice, such as participating in AgSafe programs. There is evidence that this has already led to increased collections in drumMUSTER. Formal recognition of suitable QA schemes would add incentives both to join schemes (users) and to improve schemes (scheme managers).

> *"The sector is also fortunate to be able to make use of waste disposal and recycling initiatives such as drumMUSTER and ChemClear and certification with our sustainability program requires that chemicals and their containers are disposed of through such systems."* (Australian Grape and Wine 2020)

> *"To some extent, elements of self-regulation are already built into the Freshcare and other quality assurance schemes. … While producers are always reluctant to add more requirements to their accreditation, there is scope to make … waste disposal and management … processes smoother and so less onerous by automating data collection and collation. Smart labelling will facilitate this."* (Citrus Australia 2020)

64. Recommendation

The Panel recommends that the Commissioner be empowered to publicly report a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent.

- **The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reports on the state of the system.**

65. Recommendation

The Panel recommends encouraging industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations (see Section 4.1).

66. Recommendation

The Panel recommends good disposal practice be considered as conditions for relevant licences.

67. Recommendation

The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.

4.6 Managing risks from compounded products

Compounding involves the small-scale 'manufacture' of an animal medication – generally by a veterinarian or pharmacist – to fill a void where no registered product is available with the suitable active constituent, dose, or form (e.g., tablet versus paste). Compounding, therefore, provides flexible animal medicine solutions for uncommon and emergency veterinary needs. In addition to tailored treatments to address specific therapeutic needs, these needs may also include addressing supply issues with registered products.

Products compounded by a veterinarian, or by a pharmacist as prescribed by a veterinarian, do not fall within the existing legal definition of a veterinary medicine, and therefore are not currently captured by the regulatory system. As a result, they are not subject to the normal safety, quality, efficacy, and risk management controls that apply to registered veterinary medicines. Accordingly, they may not be subject to good manufacturing practice (GMP) controls, APVMA's manufacturing licensing requirements do not apply, and compliance and enforcement measures such as product recalls or suspensions are not available.

This is not to say that compounded products are entirely unregulated; only that the specific laws that have been deemed appropriate for veterinary medicines do not apply. The Panel recognises that there are requirements that veterinarians and pharmacists must comply with for compounding products – such as poisons scheduling and meeting professional standards of the veterinary boards or Pharmacy Board of Australia.

However, because they are not subject to the same suite of regulatory controls as registered veterinary medicines, compounded products may pose greater risks in relation to product efficacy, animal safety, and manufacturing quality. This includes heightened risks of contamination and chemical residues. These risks may have negative impacts on animal welfare, food safety or trade. Contamination and chemical residues are a particular concern for food producing species as well as in some other situations such as horse or dog racing, where unintended contamination of a product has led to positive doping results.

The primary means for managing the risks associated with compounded products is to rely, as much as possible, on APVMA registered or permitted (minor use and emergency) veterinary medicine products and uses in the first instance. The intention is that compounded products are only used where a suitable registered or permitted product or use is unavailable. Using

registered products according to label instructions also ensures that the treatments should comply with food and animal feed laws.

Most stakeholders agreed with the Panel's position that compounded products should only be used when a suitable registered product is unavailable.

> *"When available, veterinarians should use a suitable registered medicine."* (HWL Ebsworth Lawyers on behalf of Bova Australia 2020)

> *"Ceva and the animal health industry in general accepts that there is a clear requirement for compounding where there are no suitable registered veterinary products."* (CEVA Animal Health 2020)

Stakeholders recognised that compounded products are a vital and important component of a veterinarian's therapeutic toolkit. According to information provided by the Australian Veterinary Association, 82% of veterinarians in Australia that responded to a recent survey reported prescribing compounded products (Australian Veterinary Association 2020).

> *"While use of CVMs [compounded veterinary medicines] is much lower than the use of registered products, CVMs nevertheless occupy an important role, which is likely to expand in the decades ahead."* (Australian Veterinary Association 2020)

> *"… Veterinarians treat over 1,000 different species of animal, with wide variations even within a species … However, there are many circumstances in veterinary practice, an order of magnitude more than in human medicine practice, when a registered medicine is not available or is unsuitable for the animal in need of treatment, for example because of dosage size, route of administration or palatability. In these circumstances, compounded medications are an essential part of veterinary practice."* (HWL Ebsworth Lawyers on behalf of Bova Australia 2020)

> *"It is unlikely that registration will be possible for all products needed for veterinary practice so veterinarians must have the flexibility to prevent animal suffering by using vet medicines not registered for that particular species or even compounded or human medicines."* (Submitted by both Small Ruminant Chapter of ANZ College of Veterinary Science and Goat Veterinary Consultancies 2020)

However, stakeholders told the Panel that compounded products are sometimes prescribed, even when an equivalent registered product is available. Compounded products are often less expensive than their corresponding registered counterparts. The Panel is of the view that less expensive products are in the users' interests, provided the safety risks associated with them can be properly managed.

The Panel has also heard of compounded products being prepared in bulk 'in anticipation' of future demand. The Panel accepts that bulk compounding effectively creates a parallel manufacture and supply pathway, that avoids the regulated risk controls that apply to – and are judged appropriate for – registered products. The Panel considers that there are some situations where bulk compounding in anticipation of a future prescription ensures that compounded substances are available when needed e.g., for veterinary hospital use, emergency, after hours or extreme remote location use.

Apart from the additional risks that may be associated with the use of compounded products, these practices may undermine the national regulatory system for veterinary medicines. They may also be considered a market distortion, since compounded products are not subject to the same regulatory overheads as registered veterinary medicine products.

> *"… under the current system veterinarians can prescribe for the compounding of any product, even direct copies of registered veterinary medicines. Compounding pharmacies have recognised this and offer not just their compounding services but have lists of 'products' they can supply, frequently in volume such that would require the manufacture of batches."* (CEVA Animal Health 2020)

The Panel is aware that the Harmonised Agvet Chemical Control of Use Task Group (HACCUT) Veterinary Prescribing and Compounding Rights working group has worked for many years to develop a 'cascade' approach for veterinarians when prescribing compounded products in food producing species (production animals). The responsibilities and progress of HACCUT are explained in more detail in Chapter 2. The HACCUT cascade follows a stepwise approach starting with prescribing a registered veterinary medicine where available as the first step through to prescribing tailored compounded products as a last resort. Veterinary medicine manufacturers supported this approach.

> *"Establishing both a system for regulation of veterinary compounding – such as a cascade system which requires vets to use a registered product where appropriate and a 'low risk' registration system are clear ways to improve the existing APVMA registration system."* (CEVA Animal Health 2020)

Despite support for this proposal, stakeholders expressed frustration at the reform's slow progress. The Panel was concerned at the lack of any sense of urgency in completing the task and proposes that the task now be completed by the Commissioner as part of the implementation of the single national law.

> *"This reform [the cascade approach], originally proposed by the Productivity Commission in 2008, is now at the twelve-year mark."* (Animal Medicines Australia 2020)

> *"We would not be satisfied with a COAG-like structure that became mired in the usual Commonwealth/State impasses, such as has happened with the issue of compounding of veterinary medicines."* (Veterinary Manufacturers and Distributors Association 2020)

What change is recommended?

The Panel recognises the important flexibility that compounding provides to address specialised, uncommon, and emergency problems. Nevertheless, the Panel considers that a registered product should always be the first choice, where reasonably available. It takes the view that the compounding option should be retained where APVMA registered or exempted (see Chapter 5) products and uses, or internationally registered products brought to Australia under licence (see Chapter 5), are not reasonably available for the required animal health outcome. This flexibility is an important aspect of the future regulatory system.

The Panel recommends that products compounded to fill a veterinarian prescription or instruction should be brought within the scope of the future regulatory system but remain exempt from registration. This would apply to compounded products for all animals – including companion animals, non-food producing, and food producing species.

68. Recommendation

The Panel recommends that veterinary medicine products compounded by a veterinarian or a pharmacist, for any animal treatment are brought within the scope of the future regulatory system for veterinary medicines but are exempt from requirements of registration where they comply with prescription by cascade.

While concerned about the 10-year delay in finalising HACCUT's work, the Panel recognises the value of its work to develop a cascade approach for prescribing compounded products in food producing species. The Panel considers it is reasonable that this cascade be extended to all veterinary situations, including companion animals and wildlife. All compounded products would then be subject to the same regulatory oversight in order to manage possible risks such as product and animal safety, underperforming manufacturing quality that requires rectification, and the potential for contamination and residues. The professional codes of conduct established by the veterinary and pharmacy boards in force in each state and territory, also strengthen the post- market compliance regime for compounded products.

The Panel sees significant value to users in retaining the compounding option. However, the Panel also sees a need to improve management of the risks associated with compounding by formalising the rules relating to veterinary prescription of compounded products. This would provide greater assurance that a consistent approach is applied as well as informing decisions about the circumstances in which registered products or compounded substances should be prescribed.

Veterinarians who prescribe compounded products would be required to comply with the prescription cascade (described in this section) and comply with record keeping requirements (addressed in further detail in Section 4.7). A veterinarian or pharmacist must prepare any compounded products. A pharmacist would only be able to supply ('dispense') according to the written instruction of a veterinarian, to treat a specific animal (or animals).

The Panel wants to avoid overreliance on situations whereby a compounded product may be considered unique because it is in a different dosage form to the registered product, or the treatment of a condition requires a combination of active constituents that are readily available in more than one suitable registered product, but not through a single product. To that end, there must be a genuine clinical need to use the compounded form, for example, to facilitate the safe and compliant administration of multiple actives which might be contained in a number of registered products but where such products cannot be practicably or safely combined or split, or if the best treatment outcome requires a compounded preparation in a form different from the registered product (e.g., a suspension instead of a tablet). While it is likely that most veterinarians and compounders operate in good faith, the Panel wants to avoid a niche 'industry' being built around the use of compounded products in situations where the use of one or more registered products is able to safely meet genuine clinical needs.

Commented [SPE19]: It must be recognised that over the 30 year horizon of the agvet review panel consideration the unmet medical needs of non-production animal species is expected to increase considerably and this need wil not be met by registered products for reasons separately outlined by the AVA. As is currently the case, the needs of veterinarians are met by the complementary availability of compounded and registered products.

Prescription cascade for compounded products

The Panel considers that the national rule (see Annex 9) for the use of veterinary medicines use should provide the following cascade approach such that in prescribing a compounded product, a veterinarian must prescribe:

- Firstly, products registered or exempted (currently achieved by issuing a minor use or emergency use permit) for that use by the APVMA, or internationally registered products available in Australia under licence for that use, in the species requiring treatment.
- Secondly, products registered, or internationally registered products available in Australia under licence, for use in a different major animal species (e.g., cattle, sheep, pigs, and chickens for production animals, and cats, dogs or horses for companion animals).
- Thirdly, products registered, or internationally registered products available in Australia under licence, for use in any species, where the product contains the same active ingredient in the same form as a product registered or available under licence in a major animal species.
- Fourthly, unregistered products, including compounded products, containing only 'low risk chemicals' (e.g., bicarbonate soda, common salt, food grade products, and reserved chemical products).

Where no suitable veterinary medicine ~~exists~~ is available in the these categories, a veterinarian may use or prescribe any product of their choosing (including unregistered and compounded products) subject to the following restrictions for products intended for use in production animals:

- the disease or illness being treated is not recurring (for production animals)
- the lack of treatment would result in death or significantly poor welfare
- the product must not contain an antimicrobial of high importance to human health or other prohibited substance(s) for veterinary preparations
- the treatment must not cause injury to human or animal health
- an appropriate withholding period is provided so that use of the product does not violate Australian maximum residue limits (MRL), or international MRLs for export-destined product, in animal products or animal feed
- where no Australian MRL exists, an appropriate withholding period should be provided where required, so that use of the product would not result in detectable residue levels.

The Panel emphasises that the ability to prescribe such products is a professional privilege of a veterinarian, and not available to a lay person, e.g., farmer, horse/dog trainer.

69. Recommendation

The Panel recommends that the prescription cascade provides that registered products must be considered first and compounded products are prescribed ~~as a last resort in order to address an issue that is unable to be addressed through~~only in the absence of a suitable and reasonably available registered or exempted products.

Commented [SPE20]: The abbreviated cascade proposed by AVA (ATTACHMENT C) is consistent with the cascade presented by AVA in its "Guidelines for the preparation and use of compounded pharmaceuticals (2020)" and is further consistent with the cascade in use in the UK. This cascade has a well-established track record of guiding appropriate and responsible use and the AVA cascade is recommended to the panel. A copy of the decision tree or cascade accompanies this submission from the AVA (ATTACHMENT C).

Commented [SPE21]: The AVA has made a number of comments on Annex 9 which should be considered as part of our response to this section on the cascade.

Commented [SPE22]: Refer to comments in Annex 9 – this step of the cascade is irrelevant.

Commented [SPE23]: These restrictions are not appropriate restraints on veterinary prescribing. Apart from being unnecessary they would be difficult or impossible to enforce.

70. Recommendation

The Panel recommends that the prescription cascade is finalised and implemented by the Commissioner under the single national law for control-of-use.

Manufacturing quality for compounded products

The Panel considers that compounded products should be subject to minimum manufacturing standards to help ensure the quality of these substances. The professional expertise of pharmacists, and the limits the prescription cascade imposes on the scale of production and use of compounded products, is such that a full manufacturer licensing scheme would not be appropriate. The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences. Not complying with the standard would require the facility to be licensed under GMP arrangements (see Chapter 6).

The APVMA will need an approved standard to enable the exemption. Currently, there are only Australian guidelines for compounded veterinary medicines (Australian Veterinary Association 2020b, Pharmacy Board of Australia 2017). The Australian Veterinary Association is developing professional standards for compounding veterinary medicines: Good Compounding Practice for Veterinary Medicines (Australian Veterinary Association 2020). The Panel recommends that the APVMA work with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are finalised speedily to enable the exemption.

71. Recommendation

The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

72. Recommendation

The Panel recommends that the APVMA works with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are funded speedily to enable the exemption described in recommendation 68.

Compounded products prepared in bulk

The prescription cascade ensures that registered products, subject to the high-quality controls for bulk production via GMP licensing arrangements, are a veterinarian's first choice for use prior to a compounded product. The Panel considers that there are circumstances where there is a genuine need for bulk compounded products, such as for emergency preparedness or for use in veterinary hospitals. The Panel considers that associated risks can be mitigated through developing and compliance with a suitable standard for good compounding practice for veterinary medicines, in combination with the professional codes of conduct and guidelines applying to pharmacists and veterinarians.

The prescription cascade will ensure that compounded products prescribed by a veterinarian must address a need that cannot be delivered through an APVMA registered or exempted (minor use and emergency) product or use. The Panel considers that bulk production of a compounded product can indicate if a commercial market need exists for that product. Investment in

obtaining a registration or a minor use exemption for such a product would be rewarded through a higher ranking in the prescription cascade.

Cost of reform

Changes to bring veterinary compounding within the pesticides and veterinary medicines regulatory framework are not expected to significantly impact the compounding industry financially. Compounding pharmacies will continue to be subject to the professional standards set by their relevant bodies. The costs associated with increased reporting are considered to be minimal. The Panel considers this reform to be cost neutral.

4.7 National rules for pesticides and veterinary medicines

The Panel has heard that the inconsistencies between state and territory requirements for record keeping about the use of pesticides and veterinary medicine products are a hindrance in the current system. In support of a single national law for pesticides and veterinary medicines, the Panel has developed 2 national rules, the first for pesticides and the second for veterinary medicines (see Annexes 8 and 9). Both rules set out the requirements for a product's responsible, and lawful, use and the records that must be kept for establishing responsible use.

The national rules are based on proposals developed by HACCUT. These rules will replace existing state and territory laws with a single approach that is comprehensive and exerts regulatory action proportionate to the risk profile of the activity being managed. These rules would come into effect for all users who are subject to the single national law (see Chapter 2).

Both national rules draw on the record keeping requirements of existing state and territory laws and establish these as the national standard. The record keeping requirements set out in the rules provide operational flexibility to users by allowing records to be retained in multiple locations, including records under existing QA programs. It is open to users to keep additional records, for example to comply with customer requirements or as part of an industry QA scheme. The Commissioner may recognise QA programs to meet the national record keeping rules, meaning that users will not have any additional burden in meeting the national rules.

Stakeholders highlighted the importance of retaining off-label uses for pesticides, particularly for combatting 'minor use' pests and diseases. Recognising this, the Panel has retained the existing nationally harmonised approaches in the national rule for pesticides. The single approach will allow a user of pesticides to use a product at lower concentrations, frequencies, or rates, or to treat pests other than those stated on the label in the same commodity, or to use a different application technique than stated on the label (subject to compliance with all WHS obligations). To complement these reforms and to support access the Panel has proposed a number of reforms to the current permit system to assist users in seeking new uses more efficiently (Chapter 5).

73. Recommendation

The Panel recommends establishing a national rule for pesticides under the single national law for control-of-use that sets out the requirements for a pesticide product's responsible use, including off-label use, and the records that must be kept for establishing responsible use.

The national rule for the use of veterinary medicines details how a veterinary product may be used by veterinarians and non-veterinarians. The Panel has adopted most aspects that HACCUT developed for its draft proposal for harmonising veterinary prescribing and compounding rights. This includes the proposed cascade approach for veterinarians when prescribing veterinary medicines, which balances risks to animal welfare with the risks to humans, animals, ecosystems, and trade. The Panel also proposes that this cascade applies to all animal use, including companion animal and non-production animals.

74. Recommendation

The Panel recommends establishing a national rule for veterinary medicines under the single national law for control-of-use that sets out the requirements for a veterinary medicine's responsible use, including a prescription cascade that applies to all animal use, and the records that must be kept establishing responsible use.

5 Improving access to pesticides and veterinary medicines

The Panel is of the view that the Australian pesticides and veterinary medicines regulatory system should be a source of competitive advantage. Simplifying regulatory barriers to entry and access for safe chemicals can encourage manufacturers and importers to bring or launch innovative, 'softer' or otherwise inaccessible products in Australia. Better targeting regulatory effort and utilising the work of other domestic and international regulators allows Australia to benefit from international innovation, while maintaining Australia's high regulatory standards.

Improving the levels and timeframes for access to the global pesticides and veterinary medicines market is important for enhancing Australians' choices of state-of-the-art treatments. The Panel recommends creating a licensing scheme to improve access to safe and effective pesticides and veterinary medicines not yet in Australia but registered in comparable international regulatory systems. The scheme provides a pathway for transparently managing risks, including risks that are unique-to-Australia. Taking advantage of international registration processes will facilitate access to products that would otherwise not be available in Australia via the registration pathway, while ensuring products are safe for people, animals, and ecosystems.

The Panel's recommendations within this Chapter are directed towards improving the communication of regulatory outcomes and ensuring regulatory effort is targeted, commensurate with risks, and does not duplicate the work of other domestic or international regulators. Improvements in the regulatory process and transparency of regulatory outcomes can offer a major contribution to solving stakeholders' concerns about access, while continuing to deliver the high safety standards expected by the community.

5.1 Refocusing the scope of the future regulatory system

Scope of products regulated

The risks posed by a product are a function of both the product's intrinsic hazard (for example, its toxicity), and the likelihood and degree of exposure from dealings with it. The level of regulatory concern associated with a product is a function of the risks of dealings with that product, and how well these risks are understood and managed. For example, pool and spa chemicals such as acids, salts, and fungicides may be explosive or highly oxidising but are of low regulatory concern as the associated risks are well understood, and suitable risk management arrangements are well established.

Currently, substances are captured within the scope of the pesticides and veterinary medicines regulatory system based on their intended or represented use, with little differentiation based on their inherent hazard, risk, or level of regulatory concern. This means virtually any product that may control pests or has a therapeutic effect on an animal is within scope of the current regulatory system.

Some stakeholders have told the Panel that the broad scope of products regulated by the APVMA weakens the regulator's focus on managing the real risks associated with pesticide and veterinary medicine products.

> *"... at various times, this loss of focus has compromised a range of work being conducted on agricultural products."* (Aerial Applicators Association of Australia 2020)

Many stakeholders have also suggested – and sound regulatory practice demands – that where a product does fall within the regulatory system, the level of regulatory intervention directed toward it should be commensurate with the risks needing to be managed.

> *"CropLife is pleased that the panel recognises that regulation should not be unnecessarily restrictive and instead be commensurate with the identified risk."* (CropLife Australia 2020)

Over the years, provisions have been added to the existing legislation to enable better targeting of regulatory effort, including via lower regulatory concern pathways and by excluding products or product classes from regulation as a pesticide or veterinary medicine. However, with some exceptions, such as reforms to stock and animal feeds in 2015, the Government has not used these provisions to near their full potential.

The Panel's original Issues Paper identified a range of low regulatory concern products that could potentially be excluded from the scope of the future regulatory system, including consumer products (such as home garden and domestic pest control products), pool and spa chemicals, anti-fouling paints, and over-the-counter companion animal products. The Panel had considered that excluding these products would have enabled a sharper focus on products of higher regulatory concern. It would also provide a stronger 'identity' to the regulatory system, providing a clearer focus on the safety of chemicals primarily used in Australian primary production, by veterinarians, and in non-urban land management.

Some stakeholders were highly supportive of the removal of some of these products from the scope of regulation.

> *"Swimming pool and spa chemicals are products of low regulatory concern which do not warrant being subject to multiple regulatory systems."* (Swimming Pool and Spa Association Australia 2020)

> *"Pool and spa chemicals could readily be regulated by the ACL [Australian consumer law] and the ACC(C) [Australian Competition and Consumer Commission] as outlined, and antifouling paints covered by NICNAS [National Industrial Chemicals Notification and Assessment Scheme]."* (AgriFutures Australia 2020)

> *"The scope should be narrowed to remove chemicals with limited relevance to primary production or animal welfare, such as pool and spa chemicals, anti-fouling paints, dairy sanitisers etc."* (CropLife Australia 2020)

However, while many stakeholders supported re-focusing the scope of the regulatory system, they were clear that this should not be done in a way that compromises safety.

> *"The rationale for removing companion animal medicines from the system is not strong and there are compelling reasons for continued regulation of these products, based on animal safety, animal welfare, user safety, zoonotic disease risks and*

> *adverse consequences, for example, for pets and pet owners from inefficacious flea or tick products."* (Animal Medicines Australia 2020)

> *"Any such proposal to remove products from the scope needs to continue to provide confidence to consumers that the product and its uses are safe. This may be achieved by a different or lighter regulatory touch such as approved standards to which the product conforms and a way to demonstrate the product complies with those standards."* (Syngenta Australia 2020)

In addition, some stakeholders were concerned that excluding broad swathes of products from the regulatory system would simply transfer regulatory responsibility to another regulator, resulting in an increased regulatory burden on the related industries. Still others felt that the pesticides and veterinary medicines regulatory system was best placed to manage product risk. For these reasons they considered that keeping all products within the regulatory system for pesticides and veterinary medicines would be preferable.

> *"Chemistry Australia is concerned that the products that would be removed from the scope of the agvet chemicals regulatory scheme as a consequence of the Review Panel's proposed reform would then fall outside the scope the NRS, requiring separate regulation by each of the States."* (Chemistry Australia 2020)

> *"It would be inconsistent, in terms of consumer protection, for a product used in farming to require regulation and the same, or similar product, used in a home garden to not."* (Horticulture Innovation 2020)

> *"We would prefer to see a lighter touch within the agvet system … This could be an interim measure adopted within the APVMA and consideration as to their removal from the scope of agvet regulation could occur in the future."* (Accord 2020)

The Panel continues to take the view that a sharper regulatory focus will allow the APVMA to direct more attention to areas of greatest regulatory concern. However, the Panel recognises a concomitant need to ensure that risks of all substances currently within the scope of pesticides and veterinary medicines regulation continue to be well managed into the future. The Panel also considers that, with the benefit of various reforms recommended in this report, the future regulatory system for pesticides and veterinary medicines is likely to be better able to regulate these substances more efficiently than other regulatory systems. The Panel's changes to regulatory scope are outlined later in this section.

However, this is not the case for all substances.

Genetically modified organisms

For pesticides and veterinary medicines such as some vaccines that are also genetically modified organisms (GMOs), stakeholders raised issues about regulatory overlap. Dealings with genetically modified organisms are regulated by the Office of the Gene Technology Regulator (OGTR), to manage risks to people and the environment.

If a GMO also has the qualities of a pesticide or veterinary medicine, it is also regulated by the APVMA. As a result (for example), whole GMO plants that express insecticidal qualities are managed by both regulators. Similarly, animal vaccines that do not contain GMOs are regulated solely by the APVMA, while vaccines that contain GMOs fall within the remit of both regulators.

Stakeholders have advised that where both regulators are responsible for a pesticide or veterinary medicine product that contains a GMO, approvals can be duplicative and slow. The Panel is aware that both regulators have had arrangements in place to reduce duplication. For example, the APVMA seeks to maximise the use of OGTR assessments, similarly to the way it uses international assessments. Both organisations also have legislative requirements to consult with the other in relation to certain applications and, in the past, have had a memorandum of understanding (MOU) between them to facilitate cooperation and information sharing. A new MOU may be valuable to set an updated framework for cooperation and information sharing into the future; however, administrative arrangements alone cannot resolve regulatory duplication.

Safety and effectiveness assessment

In addition to the scope of products regulated as pesticides and veterinary medicines, the panel has also explored the scope of the mandatory criteria that should apply to regulated products. Specifically, in its Issues Paper, the Panel identified the APVMA's pre-market assessment of a product's effectiveness (efficacy) as a potential area for reform. The Panel offered a range of approaches to effectiveness assessment, varying across pesticides and veterinary medicines, that were reflective of the risks posed by ineffectiveness.

Through its discussions with stakeholders, the Panel focused on the potential for adopting a model for pesticides similar to that of the US Environmental Protection Agency, where many products are not required to provide evidence of effectiveness at the point of registration, but must be effective when supplied to the market. For veterinary medicines, the Panel was cognisant of the risk an ineffective product may pose to animal welfare, for example ineffective pain medication, and did not anticipate relaxing the need for assessment of effectiveness for such medicines. However, where the risks were lower, the Panel was attracted to a model based on the existing approach of the Therapeutic Goods Administration 'Listed Products' regime and the reliance on the holder's obligation to both supply an effective product and hold information to support that premise.

Stakeholders were very clear in their feedback to the Panel that pre-market assessment of product efficacy should be retained for most veterinary medicines to ensure animal health and welfare outcomes are not compromised. Many users of pesticides also supported the retention of effectiveness as a pre-market assessment.

The Panel understands that efficacy assessments are useful for considering minimum effective application or dosage rates. However, effectiveness assessments are at best, a point-in-time assessment. The Panel also is aware that the effectiveness assessment of many generic pesticides and veterinary medicine products relies on scientific extrapolation based on chemical similarity and, for some veterinary medicines, bio-equivalency to a reference product (i.e., there is no product-specific data showing the product's effectiveness). The process of assessment does not establish a contemporary and continuing indicator of the reference product's effectiveness. The Panel heard repeatedly of the growing threat posed by pest resistance, in both plant and animal sectors. The Panel also heard that with resistance there were products that required increased doses for effectiveness, relative to the levels determined at the date of registration and expressed through the product's static label.

The Panel also heard that there is a general perception that all products registered by the APVMA are assessed for efficacy, and users of pesticides and veterinary medicine products often believe that the APVMA's consideration of a product's effectiveness provides a level of assurance

Commented [SPE24]: The panel should be aware that efficacy and effectiveness are not interchangeable. As outlined in the AVA introduction, efficacy is what the regulator focuses on pre-marketing. Evidence of effectiveness is generally accumulated post-marketing – underpinning the importance of pharmacovigilance and post-marketing surveillance.

Commented [SPE25]: There are many other examples of this point. For example, ineffective antineoplastic medicines would have life ending consequences. Ineffective anticonvulsant drugs, ineffective antimicrobials, antiparasitic agents, infective anaesthetic agents – all could have extremely detrimental effects on animals and humans. Veterinarians rely on Schedule 4 and Schedule 8 medicines and these should always be subject to efficacy and effectiveness review by the regulator. It would be irresponsible for veterinarians to prescribe a registered product that was not supported by evidence. When using unregistered products, veterinarians are expected to investigate available evidence of safety and effectiveness and form a judgement on the balance of risks and benefits to the patient being treated. For registered products it is reasonably expected that the regulator has already assessed the evidence and found that it supports the label claims (indications).

and protection against poor quality and ineffective products. Further, some stakeholders suggested that the APVMA consideration of efficacy leads some users to believe that the current regulatory system provides a means of redress for ineffective products.

The responsibility for supplying effective product rests with the registrant of the product, or the holder of a permit for uses authorised through this mechanism. The existing pesticides and veterinary medicine regulatory system provides no mechanism for users to seek redress for an ineffective product. Australian Consumer Law or contract law are the available legal avenues. The APVMA is immune from civil action in relation to ineffective products – this is a matter between the user and the chemical company. The Panel concurs with this position. The APVMA can respond to the supply of ineffective product, including through product recalls, civil and criminal sanctions.

The Panel sought to reform pre-market assessment of ~~effectiveness~~ efficacy and provide greater clarity to all stakeholders of the responsibilities of the APVMA (low) and of industry (absolute) respectively, in supplying products that will ~~operate~~ perform as claimed. The Panel sees the increasing prevalence of products with caveated label effectiveness, 'may treat/assist with', 'effective against susceptible species' or no listing of specific pests or periods of protection, as only increasing user confusion about what has been assessed through the registration process.

CropLife Australia, Animal Medicines Australia and others told the Panel that given the considerable costs associated with developing new chemistries and bringing them to market, it was unlikely companies would invest in chemistries that are not efficacious with the consequential reputational and market risks. This was an important point for the Panel's deliberations and argument for deregulation of efficacy. Additionally, the Panel noted that efficacy assessments were unusual for other product regulators in Australia, including certain human pharmaceuticals and medical devices.

However, on balance, the Panel recognised that removing effectiveness assessment for a relatively small number of substances meant any reduction in regulatory costs for industry, or in assessment time for the regulatory process, would be minimal at best. Further, this would not contribute to the overarching vision and objectives of improving safety and welfare, protecting ecosystems, or improving access to safe substances for users.

Based on the consistent messages received through consultation, and the limited regulatory benefits and savings, the Panel is not proposing major reforms to the pre-market assessment of effectiveness by the APVMA.

However, the Panel suggests that further consideration be given to this issue in the future. In particular, the Panel suggests that consideration be given to an approach similar to the US EPA (as previously referred to) or the Therapeutic Goods Administration 'Listed Products' model.

In any event, the Panel also recommends that the APVMA establish a more proactive approach to reviewing product-effectiveness post registration. The Panel believes its recommendation for improved whole-of-system surveillance (see Chapter 3) will provide greater and more timely evidence of any ineffectiveness (such as emerging chemical resistance) to support APVMA actions.

Commented [SPE26]: For S2, S3, S4 and S8 products the TGA undertakes a thorough review of the evidence in support of each claimed indication. So it should be for veterinary medicines in S4 or S8. Veterinarians expect and rely on the efficacy assessments of APVMA. They also rely on the manufacture to supply the medicines that have received APVMA approval in the form that it was approved. Inefficacy associated with changing pathogen characteristics is expected. It is also expected that not every product is 100% effective in 100% of patients. However, it is expected that the product will perform otherwise as set out on the label approved by APVMA.

Commented [SPE27]: For veterinary medicines it is absolutely essential that effectiveness is an objective.

Commented [SPE28]: For this consideration it is vitally important that the different classes of veterinary medicines are acknowledged. There is clearly a spectrum of products as reflected in the Scheduling. While current Scheduling criteria are valuable in protecting human health, additional criteria would also enable further protection of animal health.

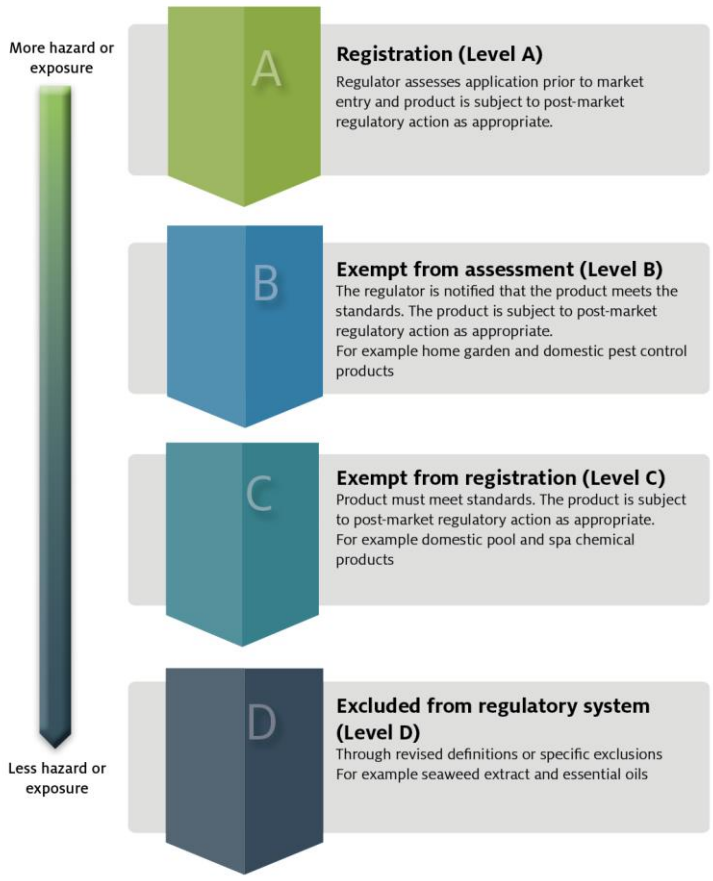
What change is recommended?

Scope of products regulated

Having heard and taken into account stakeholder feedback on the proposed reforms to scope of coverage outlined in the Issues Paper, the Panel recommends a revised approach for the future regulatory system. The new approach is framed around a combination of measures based on the risk profile of the product. This includes revised definitions of pesticides and veterinary medicines to provide a more focused regulatory scope (see Annex 5), removing premarket assessment for products that pose low regulatory concern, and excluding certain substances from the scope of the regulatory system through a 4-level consideration (see Figure 1).

This will allow regulatory effort to be better targeted to those products that pose a measurable risk to the health and safety of humans, animals, plants or ecosystems, or prejudice to trade.

Figure 1 The scope of the future regulatory system including risk-based pre-market assessment measures



Targeting assessment effort

As is currently the case, most categories of pesticide and veterinary medicine products would remain subject to registration based on pre-market assessment (Level A). This would occur where risks to the health and safety of humans, animals, plants, or ecosystems, or which could unduly prejudice trade, are best managed through a bespoke assessment.

Most pesticide and veterinary medicine products containing new active constituents would fall under the Level A registration pathway as the risks associated with handling them would generally be insufficiently supported by a history of safe use.

In addition, the Panel recognises there are risks posed by certain pesticides and veterinary medicines where a higher degree of regulatory oversight of products is always warranted. For that reason, the Panel recommends that, in conjunction with exemption reforms, a Potentially Hazardous or Injurious Substance (PHIS) list be established. The Panel proposes that products or product classes that contain PHIS material would not be eligible for any of the exemption pathways. Such products will continue to be subject to the full registration process. For instance, if a domestic pest control product is categorised as carcinogenic, mutagenic, toxic to reproductive systems or toxic to aquatic ecosystems under the Globally Harmonized System of Classification and Labelling of Chemicals, it will not be exempt from registration or assessment.

However, the Panel recommends some products which pose lower risk (Levels B and C) – but not so low as to warrant being excluded from regulatory scope altogether (Level D) – would continue to remain within the future regulatory system, but with a post-market regulatory focus. This would be achieved by removing the requirement for pre-market assessment undertaken by the APVMA.

The Panel proposes to achieve this by either:

- exempting products (or classes of product) from the need for assessment where it meets an approved standard, allowing registration by notification to the APVMA (Level B)
- exemption from the requirements of registration completely (registration not required) (Level C).

The Panel considers these tailored pathways allow the APVMA to focus its regulatory effort on the areas of highest risk and remove the barrier to market entry that assessment can present. However, it will also ensure these products remain safe to use and would leave the option to undertake regulatory action if risks were not being adequately managed.

Monitoring of the risks associated with these products will be underpinned and supported by the regulatory system's improved surveillance arrangements (see Chapter 3) including adverse experience reporting.

Products with little or no risk which meet the requirements of Level D, for example seaweed extract and essential oils, would be excluded from the regulatory system as described in the 'Revised definition of pesticides and veterinary medicines' section.

Exempt from assessment (registration by notification) Level B
Products that are eligible for this pathway must meet an established standard. Registration would be on the basis of notification to the APVMA by the prospective registrant that the product meets the standard and would thus be exempt from assessment.

The standard would be developed by the Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner) (see Chapter 2), in close collaboration with industry and with public consultation. The Commissioner will also seek advice from the APVMA or other external sources, as necessary.

The Panel considers that the success of this measure depends on the Commissioner, rather than the APVMA, developing these standards. The Government has, for many years, encouraged the APVMA to develop standards to underpin lower regulatory concern routes such as the listed and reserved pathways. The Panel also heard from numerous stakeholders that industry has tried to work with the APVMA to develop standards (such as for dairy sanitisers), with no success. Industry indicated that they had given up trying to get standards developed with the APVMA as they considered that the APVMA consistently made the process far more complicated than in needed to be. The APVMA has failed to produce standards (that industry had been calling for) or even to pursue less intrusive regulatory pathways made available to it under legislation. The Panel therefore does not have confidence that this reform measure would be adequately implemented if it remains the APVMA's responsibility to execute.

As with all registered products, the APVMA would be able to issue product recall notices and substantiation notices (to establish the product's compliance with the standard), take administrative actions such as suspension or cancellation of registered products, and pursue civil and criminal proceedings.

This pathway would be suitable for products of sufficient regulatory concern to warrant registration but whose risks can be mitigated by compliance with a standard. Examples of products that would be exempt from assessment include 'repacked' products (i.e., a product that is identical to another pesticide or veterinary medicine product in the market, just with different packaging/name), diluted versions of authorised products, and home garden and domestic pest control products. An example draft standard for home garden and domestic products is provided at Annex 5.

Exempt from registration (registration not required) Level C
Products that are eligible for this exemption pathway would not be assessed by the APVMA (neither an application nor data submission will be required) nor would they be registered. In addition, there would be no need to notify the APVMA that these products are in the market. The only criterion for market entry would be that the marketer of the product must ensure that it complies with an established standard. These products would be monitored through the adverse experience reporting and surveillance activity, with compliance activities responding to reports.

As with products in the 'exempt from assessment' pathway, the standard would be developed and issued by the Commissioner, consulting with the APVMA, in close collaboration with industry, and would be subject to public consultation.

This pathway would suit products of low regulatory concern but with some associated risk that could be suitably managed by compliance with a standard.

Although the products would be exempt from registration, they would remain within the scope of the regulatory system, so the APVMA would be able to issue product recall notices and substantiation notices (to establish the product's compliance with the standard) and pursue civil and criminal proceedings. Their use would also be subject to the control-of-use arrangements of the single national law.

Products that may be suitable for this category include pool and spa chemicals used for domestic purposes only. An example of a potential draft standard for domestic pool and spa chemicals is at Annex 5.

Genetically modified organisms

The Panel recognises that, in some situations, assessments by OGTR and APVMA can have duplicative elements – with the APVMA and OGTR essentially performing the same types of assessment to manage the risks that a GMO may pose to people and the environment. However, there are also complementary elements as, for example, the APVMA also considers the product and active constituent(s) in their entirety (not just the GMO), the safety of target animals and crops, trade implications and efficacy, which are not assessed by the OGTR.

The Panel considers that there is scope for streamlining interactions between the 2 regulatory systems, which may be achieved through mechanisms such as lighter touch regulatory pathways and exclusion mechanisms. However, it also understands that excluding some live and viable GMOs from the remit of the OGTR may be problematic, as there is public sensitivity to narrowing the coverage of gene technology regulation.

Given these considerations, the Panel recommends a regulatory rationalisation whereby one regulator becomes the decision-maker for an application under legislation. In some cases (depending on the category of the GMO or product and the risks it presents), the APVMA may play no role. For example, whole GMO plants would be excluded from pesticides regulation and the APVMA would play no formal role in their regulation. The Panel does not consider that the risk areas assessed exclusively by the APVMA (i.e., efficacy, residues and trade risks; noting that the assessment of trade risks generally focuses on the risks of residue exceedances in major food commodities) are sufficient to warrant regulating these plants as pesticides. The Panel has proposed a mechanism that would allow substances, including categories of GMO plants, to be brought back into the regulatory system if deemed necessary at a later date; e.g., if the risk profiles of these substances change with new developments in these GMOs in the future; see Annex 5.

In other cases, the other regulator could act in an advisory role and receive notification if and when an application was approved. For example, vaccines containing GMOs are a growing part of the suite of veterinary medicines and stakeholders advised that this growth would accelerate in the decades to come. The Panel considers that these products would be most appropriately regulated and assessed by the APVMA as veterinary medicines, with the OGTR providing advice and receiving notification of application outcomes. This would be on the basis that the APVMA has the expertise to consider those risk aspects that are currently assessed by both agencies. However, the APVMA also considers additional risks associated with the product and its therapeutic use; for example, host animal safety, the safety and stability of the product as a whole (including the effects of any excipients and adjuvants and product sterility), and manufacturing quality (beyond that of the GMO itself).

Biotechnology is advancing rapidly. Apart from whole plants and GMO vaccines, other categories of 'substance', in time, may also be suitable for this lead decision-maker approach. Some specific examples may include:

- a genetically modified (GM) pathogen for the control of a pest species
- a GM bacterium for use as a plant protection product (e.g., against insects in horticulture)
- a GM phage for control of a bacterial plant or animal diseases.

The Panel considers that it is unlikely that both regulators will need to conduct detailed assessments of these, or other new categories of substance that may foreseeably be introduced. However, as the exact risks are not understood at this stage, the only recommendation the Panel makes about them at this time is that duplication and unnecessary regulation should be avoided by applying the approach identified here wherever possible.

This approach would complement the work being undertaken through the National Gene Technology Scheme – coordinated through the Commonwealth Health portfolio – to implement recommendations from the third review of that scheme. That work includes recommendations to introduce additional risk tiering to ensure regulation remains commensurate with the level of risk, as well as streamlining the processing of applications and reducing regulatory burden, where appropriate. The review also recommended clarifying the intersection between the Gene Technology Regulator and other regulators, including identifying any emerging areas where legislative or administrative changes can be made to reduce any unnecessary duplication. The Panel notes that this may provide an opportunity to streamline the assessment of applications for GMOs that are also pesticides or veterinary medicines, as well as the interface between OGTR and APVMA. The Panel has been advised that this work is expected to be completed by 2023.

Revised definition of pesticides and veterinary medicines

The Panel recommends refining the definition of pesticides and veterinary medicines to exclude product classes or uses that are expected to have low regulatory concern (considering both the inherent hazards of the product and the likely exposure from use), or are more efficiently and effectively regulated by other regulators – either as industrial chemicals or genetically modified organisms. Some products (e.g., industrial chemicals) may occasionally be used in ways that would bring them within the scope of regulation (e.g., carbon dioxide as a pest control product); however, this use is incidental to the product's primary use and would be explicitly excluded by regulation.

The legislation would continue to provide for the list of excluded products to be expanded over time by the responsible Minister (or their delegate). The revised definitions described in Annex 5 would exclude the following product classes from the scope of the future regulatory system (noting that the definition provides for excluded substances that are identified as having unmanaged risks, to be brought within the scope of the regulatory system at any time).

- Low hazard or low exposure products would include:
  - whole plants and animals that are naturally occurring
  - pheromones and other semiochemicals
  - biostimulants e.g., seaweed extract

  - surfactants, adjuvants, wetting agents, and spray markers (as products added to the spray tank, distinct from those included within a products formulation – these are regulated as industrial chemicals)
  - those used in small scale, localised research trials (where environmental impact is very limited and there is no entry of treated material into the food chain)
  - pesticide products containing only substances assessed to have limited or no potential for harm, commonly referred to as 'generally recognised as safe' (GRAS) e.g., essential oils, botanical extracts, water, and ethanol
  - products containing Bacillus thuringiensis or its endotoxins as the only active component (a well-characterised, naturally occurring bacterium with insecticidal properties).
- Products regulated by other regulators would include:
  - whole plants or animals that are genetically modified e.g., cotton that has been genetically modified to have insecticidal properties (which would be better regulated by the OGTR)
  - anti-fouling paints (the impact of environmental toxins of the relevant active constituent would be assessed by the industrial chemicals regulator)
  - commodity gases e.g., carbon monoxide, carbon dioxide, nitrogen, sulphur dioxide, acetylene, and liquid petroleum gas.

Cost of reform

The Panel considers a more appropriate allocation of regulatory effort will have significant savings to the product manufacturing, importing and suppling industries, which in turn can benefit product users such as farm businesses through reduced costs.

The Panel's recommendations to improve the focus of the regulatory scheme and assessment activities of the APVMA is expected to reduce regulatory costs by approximately $4.8 million per annum (or $48 million over 10 years). This reduction would be achieved through a combination of fewer registration applications, a reduction in the scope of products subject to renewal fees and levies, less industry effort to overcome the existing regulatory barriers and reduced delay costs.

This is a conservative estimate of savings and the Panel expects that over time, additional products or classes could also be subject to less regulatory intervention, presenting further savings for industry and increased access for users.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

75. Recommendation

The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.

76. Recommendation

The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.

77. Recommendation

The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.

78. Recommendation

The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.

79. Recommendation

The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.

80. Recommendation

In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision-maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary.

5.2 Benefiting from international innovation and accessing alternative products

Australia is a much smaller market for pesticides and veterinary medicines than North America, Europe, and Asia. Because of this Australians often miss out on timely access (and sometimes any access) to new pesticides and veterinary medicines and their uses, compared to their overseas counterparts. This can put Australian exporters at a competitive disadvantage, as well as deny Australians choice in the state-of-the-art treatments or alternatives to existing products with lower impacts on health or easier-to-implement mitigation strategies.

Improving access to internationally registered, safe, and effective products and uses is especially important if Australian primary producers are to successfully compete with their international counterparts and achieve the sector's target of growing a $100 billion agriculture sector by 2030.

The problem of 'access' was one of the major concerns raised by stakeholders consulted in the course of the Panel's work. Chemical users, particularly primary producers, have long seen it as a critical shortfall in the Australian regulatory system.

> *"Comparing chemical crop protection product registrations for the Australian grains industry to those made available within the USA … highlighted that out of the 25 products over 8 years, Australia missed out on 12 chemical products (i.e. Australia is getting about half)."* (Grain Producers Australia 2020)

> *"The regulator, in discussion with industry (chemical and production), needs to determine the reasons for the incongruity between overseas and Australian registrations and seek mechanisms to overcome these."* (Grains Research and Development Corporation 2020)

> *"The size of market is unlikely to change, and hence, AUSVEG recommends an alternative approach to motivate registrants to bring new chemistries [to] the Australian market."* (AUSVEG 2020)

Australia has a world class system for pesticides and veterinary medicines regulation, based upon risk assessment and risk management to protect humans, animals, and ecosystems. This model is not, however, unique to Australia and there are a number of comparable regulators in larger markets, such as the USA, Canada, and Europe, and, of course, in smaller markets such as New Zealand. The Panel has explored options to better utilise the work of these regulators, allowing Australia to benefit from international chemical innovation while maintaining Australia's high regulatory standards.

The Australian Government adopted the principle, in the 'Industry Innovation and Competitiveness agenda: Plan for a stronger Australia 2014' (Department of the Prime Minister and Cabinet 2014), of taking advantage of the decisions of comparably rigorous and credible international regulators, and only imposing additional requirements where there was good reason to do so.

> *"New active ingredients are generally developed and approved in major overseas markets and the cost and complexity of the separate Australian approval process discourages businesses from making these products available in Australia."* (Australian Paint Manufacturers Federation 2020)

> *"Members advise that there is a current disproportionate registration burden locally, compared to comparable overseas markets, to introduce low risk products to meet growing domestic consumer trends."* (Accord 2020)

The Panel considers that the Australian pesticides and veterinary medicines regulatory system should be a source of competitive advantage, rather than another barrier to entry and access for safe chemicals.

> *"Consideration should be taken for registration of products that have been researched and approved for use overseas allowing Australian growers equivalent access to international counterparts."* (Turf Australia 2020)

> *"Supported by clear and transparent environmental assessment requirements, similar recognition [to AICIS reforms] of overseas assessments and approvals under the agvet chemical regulatory scheme has the potential to deliver similar outcomes for agvet chemical users and significantly transform the way the Australian market is viewed by agvet chemical R&D companies."* (Chemistry Australia 2020)

The Panel specifically sought views in its Issues Paper on the use of registration decisions from comparable international regulatory systems that would enable a faster-tracked registration in Australia (subject to any unique Australian conditions being considered). Many stakeholders in their submissions supported the concept of a 'registration by reference' approach especially where the need to assess unique Australian conditions was included.

> *"We are generally supportive of a registration by reference approach with comparable international regulatory systems. This approach would help overcome commercial barriers of Australia's relatively small market size … [and] … would provide Australian agriculture with access to a greater range of crop protection products, however provision would need to be included to address risks unique to the Australian environment."* (Cotton Australia and Cotton Research and Development Corporation 2020)

> *"CropLife and our members support the Panel's view that the Australian regulatory system should take full advantage of the work of comparable regulators and focus regulatory effort on the issues that are unique to Australia."* (CropLife Australia 2020)

> *"Accord supports the Panel's proposal for registration by reference. The Australian Government has a policy of accepting trusted international standards, risk assessments and products. When this policy was announced in 2014, industry was highly supportive as we saw this as an opportunity to remove the burden of unique Australian requirements for products already recognised as safe and available in comparable economies."* (Accord 2020)

Other stakeholders, however, did not support this initiative.

> *"Products registered for use in Australia should be independently assessed by our Federal Regulator … We do not support registration by reference as it would not be in the national or public interest due to environmental and health risks."* (Pesticide Action Group of Western Australia 2020)

> *"AMIC disagrees with this suggested approach, as the risk to trade is significant. … It is imperative that the rigorous standards of the APVMA are not impacted by a registration by reference approach."* (Australian Meat Industry Council 2020)

> *"GrainGrowers does not support registration by reference … [it] … poses challenges associated with the suitability of chemical products to Australian conditions and use patterns, and the extent of scientific rigour applied to international assessments, standards, and decisions."* (GrainGrowers 2020)

The Panel was particularly interested in uniquely Australian issues that may need to be assessed and how these might best be managed. Many stakeholders identified this as their major hesitation about reform in this area, wanting assurance that satisfactory means would be available for consideration of specific Australian circumstances in use. In general, their concerns related specifically to, unique or high value Australian ecosystems (such as the Great Barrier Reef), unique fauna (such as koalas) and the focus on Australian exports for many agricultural commodities. Standards such as those published by the European and Mediterranean Plant

Protection Organisation (EPPO) for determining the comparability of climatic zones between global regions suggest there are few if any truly unique Australian climatic conditions that need to be accounted for.

Information provided to the Panel has shown the high regard the APVMA has for environmental assessments conducted in Canada and Europe for pesticide assessments and their equivalence to Australian assessments. Environmental assessments from the US Environmental Protection Agency were considered by the APVMA (in a document provided to the Panel) as near equivalent to Australian approaches (other than soil). In this sense, the Panel understands that there is no reason environmental assessments from regulators in these countries should not generally be accepted by Australia, because the environmental testing and trials rely primarily on generic tests that are accepted as proxies for a wide range of local conditions. As a result, there would be few unique conditions that are not adequately covered by an international data set from a comparable regulatory system.

The Panel accepts arguments made in relation to the APVMA's consideration of the hazards posed to Australia's trade in registering a product. The Panel understands this assessment, like other areas within the APVMA's remit, considers the risk mitigation strategy proposed by an applicant. Where this mitigation proposal does not adequately address trade risks, the product will not be registered.

The Panel heard from some stakeholders that, if access to the Australian market were to be linked with an overseas registration, it would be possible for future applicants to address any residual 'unique Australian issues' in the design and coverage of their overseas trials and applications. This would streamline the subsequent process for registration in Australia.

It was also acknowledged that there are products (particularly veterinary medicines, e.g., companion animal products and products used for intensive pig and poultry husbandry) where the circumstances of use would not be different in Australia from overseas, so these products would easily suit this approach.

> *"The APVMA could simply require the applicant to provide evidence or argument as to the suitability of the product for the local conditions."* (Veterinary Manufacturers and Distributors Association 2020)

> *"There are certain circumstances, such as products to treat internal or external parasites where there are issues associated with chemical resistance and lack of efficacy, local efficacy trials and assessment will still be required. However, most animal diseases occur globally and do not require specific local efficacy studies or assessment. Similarly, safety studies and safety assessments should not necessarily be repeated within Australia."* (Ceva Animal Health 2020)

There are arrangements in place in other sectors where pre-qualified importers are granted responsibility to manage risks, including for hazardous and sensitive products. For example, biosecurity-approved arrangements and Australian Border Force's 'Australian Trusted Trader' program are voluntary arrangements that allow importers with compliant practices to manage risks and perform documented assessment of goods in accordance with regulators' requirements, using their own sites, facilities, equipment and people, and without daily

supervision by the regulator's staff. Participants are subject to occasional compliance monitoring or auditing.

Such co-regulatory arrangements build on the risk management that companies already undertake to manage their potential company liability, insurance exposure, and reputational risk in the Australian market. Utilising such arrangements in the pesticides and veterinary medicines system may also extend the benefits that the General Product Obligations offer, enlisting the efforts of multiple parties, rather than the regulator alone, to ensure protection of the health and safety of humans, animals, and ecosystems, and avoiding undue prejudice to trade (see Chapter 4).

What change is recommended?

The Panel recommends improving access to safe and effective pesticides and veterinary medicines not yet available in Australia but registered in credible, comparable international regulatory systems, by creating a new licensing scheme for importers and manufacturers, which could also be accessed by grower groups and other users.

The scheme would provide a pathway for the supply of certain internationally registered products into Australia subject to transparent conditions to manage the risks, including unique-to-Australia risks. Risk management would be in the form of a detailed Risk Management Plan lodged by the licensee (see Section 5.3) and approved by the Commissioner.

To address any risk that the licensing pathway could be used to introduce products that have been refused registration by the APVMA, a potential licensee would be required to declare any relevant refusals or withdrawals of product or exemption (permit) applications in the licence application. In addition, to ensure Australia does not get pesticide or veterinary medicine product that users, especially primary producers do not want here, the Panel proposes that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.

The licensing scheme would complement, not replace, the current registration scheme which would continue to be available through the APVMA. The Panel expects the uptake and expansion of the scheme to be incremental and this will need a comprehensive engagement strategy with regulators, industry, and stakeholders.

Under the licensing scheme the equivalent international regulator will have conducted most of the risk assessment and associated risk management actions. The Australian regulatory focus will therefore be on the licensee and their ability to manage the risks through their Risk Management Plan. The focus is on the activities associated with the use of the product rather than on the product itself (given this has already been assessed).

Commented [SPE29]: The AVA understands that there is already a process in place by the APVMA to accept assessments of equivalent regulators in other countries or regions. If there a need for a new system for veterinary medicines OR should the current system be reviewed and improved as appropriate?

The Panel considers that the Commissioner will be best placed to issue and oversee licences given its responsibility for control-of-use under the single national law. These types of judgements go beyond a pure science-based consideration to also take into account usage of industry quality assurance schemes, general product obligations and other co-regulatory approaches to manage risks. These are considerations that are outside of the remit of the APVMA, and the Panel considers it could compromise the well-established and recognised reputation of the APVMA as an independent science-based registration authority if it were

placed in the position of regulating these types of control-of-use activities. Therefore, the Panel strongly considers that the licence scheme should be implemented by the Commissioner.

81. Recommendation

The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.

Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.

82. Recommendation

The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.

The licence holder would bear the responsibility for ensuring aspects unique to Australia are risk assessed and managed, including submitting a detailed plan for how the risks will be managed. Bringing the existing risk management capabilities of an importer or manufacturer into the regulatory system and requiring them to identify and actively manage the range of potential unique Australian conditions and risks across their suite of products will build an additional level of assurance into the regulatory system. Sanctions and penalties for failure will reinforce the onus on the licensee to be duly diligent. The arrangements will encourage and fast-track the availability of safer, more effective pesticides and veterinary medicines to Australians.

The Panel is aware of the potential for criticism that reliance on international decisions reduces the quality of the Australian regulatory system process. The Panel is confident that the dual requirements for both international registration and legally obliged, active risk management by the licensee will ensure the products are safe for use in Australia. These dual requirements will operate in parallel with obligations for work health and safety (WHS) and dangerous goods, fair trading, competition and consumer protection, gene technology legislation, Australia's robust biosecurity requirements and state and territory agriculture, health, and environmental laws.

Managing the risks of a particular product in accordance with the terms of a licence may require the licence holder to fulfil legislated requirements of other regulatory systems. This may include applying for an OGTR licence or biosecurity import permit or applying for amendment to the Poisons Standard or Food Standards Code (to establish a maximum residue limit).

As part of the equivalent international registration process, the licence holder will typically hold and provide the necessary toxicology reports, health-based guidance values and other relevant information needed for any Australian applications. The licence holder will be in control of the timing of these applications, allowing for many to occur in parallel with the equivalent international registration process, unlike with the current Australian registration process where the timing of referrals to these processes is managed by the APVMA.

With the removal of delays due to Australian regulatory assessment and ability for licence holders to directly engage with other regulatory application processes, the Panel sees the potential for Australia to become an immediate joint launch market for a range of new products as they become available in comparable countries overseas. Depending on the level of uptake, this would be a major contribution to solving user groups' concerns about access, while continuing to deliver the high safety standards expected by the community.

The Panel explored this approach to licensing to introduce internationally registered products in terms of benefit for innovative products, or 'softer' products, with manufacturers who had limited or no footprint in Australia. The Panel received positive indications that such a model would encourage manufacturers/importers to bring (and in fact launch) otherwise inaccessible products in Australia. This would provide Australian farmers and other end users with greater diversity in products and flexibility in pest and disease management. The potential was raised with the Panel that the opportunity to simultaneously access the Australian market may increase the priority for registration in overseas markets (benefiting both the originating market and Australia).

Licence holders will be required to make available to Australians all uses for a given chemical approved by the equivalent international regulator. The exceptions would be where the pest, disease, crop or animal is not present or endemic to Australia, or where there is an obligation for the licence holder to notify the Commissioner that the use in Australia would present risks to safety or trade that cannot be managed. Until now, Australian producers have had access to considerably fewer approved uses for chemicals than their overseas counterparts.

> *"Then compare this by crop registrations, where cereals are aggregated into one crop registration group, Australia has 15 new crop, by product, registrations and the USA has 76 registrations … (i.e., Australia has only 20% of the new registrations of the USA)."* (Grain Producers Australia 2020)

The proposed scheme should not generate trade concerns as major trading partners and major exporters are familiar with the use of licensing arrangements including the requirement for risk management plans for products. For example, the export of meat products from Australia is underpinned by industry-administered risk management measures in the form of approved arrangements and meat export licences.

83. Recommendation

The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.

Benchmarking comparable regulatory systems

The Panel recommends that the Commissioner, in consultation with the APVMA, be responsible for assessing the equivalency of international regulators of pesticides or veterinary medicines to deliver outcomes comparable to Australia's standards for registration and use. The Panel considers that the Commissioner should make these decisions as they will be responsible for the issuing of licences under this proposal (see Chapters 2 and 4).

The Commissioner's equivalency assessment would also be informed by stakeholder consultation to include community and industry expectations. The Panel expects this

consultation may form an early topic for consideration by the Stakeholder Forum (see Chapter 2).

Priority should be given to benchmarking the regulatory systems of major launch markets for pesticides and veterinary medicines, although smaller markets may also be relevant to high-value, niche agricultural industries to Australia. The Panel suggests the following markets and regulators at a minimum:

- for pesticides – the UK Chemicals Regulation Directorate and similar pesticide regulators in Germany, Spain and Italy, the Canadian Pest Management Regulatory Agency, the New Zealand pesticides and veterinary medicine products system, and the US Environmental Protection Agency (with a need for specific consideration of environmental risks within a licence holder's risk management plan)
- for companion animal products – the US Center~~re~~ for Veterinary Medicine of the Food and Drug Administration, the US Center~~re~~ for Veterinary Biologicals of the US Department of Agriculture, the European Medicines Agency, the Canadian Veterinary Drugs Directorate, the Japanese Ministry of Agriculture, Forestry and Fisheries, and the New Zealand pesticides and veterinary medicine products system
- for livestock products – the New Zealand pesticides and veterinary medicine products system, the US ~~Centre~~ Center for Veterinary Medicine of the Food and Drug Administration and the US ~~Centre~~ Center for Veterinary Biologicals of the US Department of Agriculture.

For transparency, certainty and accountability, the list of overseas regulators should be prescribed in regulations. This list could also be used as the basis for the APVMA's consideration of overseas data during registration and exemption processes. It is the Panel's expectation that over the next 30 years the listing will increase and include more regional partners.

Commented [SPE30]: Could add the UK Veterinary Medicines Directorate.
There are very few examples of companion animal (or non production animal) products approved by these agencies that are not available in Australia. Often it is Australia that is the source of the innovator product.

Commented [SPE31]: This agency is not usually considered equivalent to the APVMA.

84. Recommendation

The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).

85. Recommendation

The Panel recommends the Commissioner's determination of comparable international regulators:

- **be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders**
- **be conducted by the Commissioner**
- **give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.**

Risk management plan

A key requirement of the licensing scheme will be that licence holders must develop and implement a detailed risk management plan.

The risk management plan will detail the licence holder's business practices for identifying and assessing risks and their control measures for managing risks associated with their supply of internationally registered products. Specific consideration will need to be given in the plan to risk assessments and risk management controls to manage any unique Australian circumstances.

Licence holders will not be bound to conform to a 'one-size-fits-all' set of government delivered tools for managing risks. Instead licence holders will be able to put forward risk management arrangements that leverage and supplement relevant regulatory arrangements in ways best suited to their business and product categories, for example, including additional information on labels, controls on distribution (such as restricting access to specific users under contract or who are trained by the supplier), or providing education, tools and other services to their user base more broadly.

The Panel sees the potential for a more direct relationship between users and product suppliers through this approach which may result in a significant cultural shift in terms of shared responsibility, education, transparency, and market drivers. This highly focused supply approach would augment the minor use exemptions (see Section 5.5) and help to improve access to low volume products by a new collaborative relationship between international manufacturers and their user customers.

For example, a grower group could enter into an arrangement to be the Australian licensee with the manufacturer of a niche product registered in Canada but not available in Australia. The manufacturer could provide the data to the Commissioner to support the application of the grower group to become a licensee. The grower group would develop the risk management plan in consultation with the manufacturer, with the manufacturer benefiting from market access.

It is expected that the risk management plan would, at a minimum, include mechanisms for assessing and controlling as necessary the following Australia-specific risks that may be associated with internationally registered products:

- Australian dietary exposure risks
- Australian environmental exposure risks
- legislation risks, including ensuring that residues in human and animal food do not contravene other Australian laws
- trade risks, including that trade between Australia and other countries is not jeopardised.

Making risk management plans publicly available would ensure the community has confidence that all risks have been identified and are being satisfactorily managed and address any concerns that pesticides and veterinary medicines supplied under licence are not subject to the same regulatory scrutiny as registered products.

86. Recommendation

The Panel recommends that licence holders:

- **must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances**

- **be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions**
- **be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.**

Product labels

Labels on products supplied under licence are expected to retain the same content as that approved by the equivalent international regulator.

The licence holder's risk management plan will need to detail the label elements or content that needs to be amended for the Australian market, such as units of measurement, generation of any missing regulatory assessed elements (see Chapter 4) or management of unique Australian risks. The risk management plan will also detail how these issues will be addressed (such as over-stickering or the use of smart labelling).

Intellectual property protections

The design of the licensing scheme will ensure that intellectual property (IP) arrangements relating to the internationally registered product, and Australia's obligations under international agreements on IP, are respected. The Panel recommends that at a minimum it is a condition that the licence holder must either be the owner of the international registration or have that registration holder's permission.

> *"Supports the proposal to recognise the assessments and approvals of trusted overseas regulatory agencies, subject to a requirement that the Australian proponent is, or has the authority of, the holder of the overseas assessment or approval."* (Chemistry Australia 2020).

An internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product which is subject to an active data protection period (see Section 5.8). Once the data protection period expires, products can be supplied under licence, including internationally registered generic versions of products. Protecting Australian registered products in this way is necessary as data can only be protected where it forms part of decisions by the APVMA. As the APVMA will not make decisions on the individual products while they are supplied under a licence, 'data protection' cannot be applied.

87. Recommendation

The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.

Licensed products will not be eligible for Australian data protection as no suitable data will be provided to the APVMA. The lack of disclosure to the APVMA, but accessible to the Commissioner, means that product information will remain a trade secret of the Australian licence holder, unavailable for use in the Australian registration of other products. Australian common law provisions provide protection for infringement of trade secrets. Licensees may also choose to pursue registered forms of intellectual property rights such as patents and trademarks, as is the case now. The Panel however considers that protection of IP for products

supplied under licence is important to the success of the proposal, and that necessary IP protections should be developed in consultation with industry during implementation.

88. Recommendation

The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

Regulatory safeguards

The Commissioner would provide government oversight of licence holders. Licence holders would be subject to regular audits to ensure they are complying with their risk management plans and other licence conditions. Licence conditions would also require relevant reporting and monitoring data to be provided to the Commissioner so it is informed of products and quantities supplied under the licence and is able to verify that control measures are effective (see Annex 5 for proposed licence conditions).

The Commissioner could take regulatory action against the licence holder for non-compliance with the risk management plan or other licence conditions. Compliance measures available would include injunctions, substantiation notices and enforceable directions, as well as administrative actions including suspending or cancelling licences. Suspension or cancellation of the licence in respect of one product would prevent further supply or use of any other product ranges the licence holder was also supplying in Australia. The Panel considers that these sanctions, impacting all products supplied and used under the licence, provides a significant incentive for the licence holder to act prudentially and in good faith.

Should the risks for an internationally registered product become unacceptable (such as the suspicion of contaminated or adulterated product), protective powers would be available to the Commissioner to require the analysis of products or compel the recall of the product, amongst other post-market regulatory powers. These powers ensure that there will always be a post-market safety net for any supplied internationally registered product. In the case where the international registration is cancelled, it would no longer be eligible under licence (so would be removed), however, it would still be open to the registrant of the internationally registered product to supply product into the Australian market via the registration or exemption pathways.

89. Recommendation

The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).

The initial requirement to implement this licensing scheme is for the Commissioner to undertake an equivalence assessment of one or more equivalent international regulators. The development of equivalency assessments will involve in-depth international collaboration with equivalent international regulators. This kind of informal capacity building has occurred for many years and the licensing scheme would be a practical outcome of this arrangement.

Guidance material to assist industry with expectations for risk management plans and other key aspects of the scheme would also need to be developed through industry and community consultations.

The ability to recognise alternative risk management solutions will also open up innovative approaches to meeting desired regulatory outcomes, including creative new business models for supplying pesticides and veterinary medicines to the Australian market.

Cost of reform

There will be costs to participate in the licensing scheme for international products, however, the scheme is voluntary, and costs therefore will only apply to those who wish to hold a licence to supply internationally registered products. The costs of participating in this scheme would be considerably less than Australia's current registration process and allow significantly faster access to much needed products already registered by comparable international regulators.

Licence fees are expected to be in the order of $2,500 per licence with similar costs payable for licence renewals, with any residual scheme costs collected through a levy on products supplied.

The anticipated industry savings for product supply (and extended through to the product users) of not having to navigate the Australian registration system are expected to be considerable. The Panel has taken a very conservative approach in estimating savings (in terms of number of licensees, number of products supplied, rate of uptake within industry and avoidance of minor use exemptions (permit) costs as a result of broader access to uses already on the label and avoided delay costs) and anticipates industry savings in the order of $5.5 million per year or $55million over 10 years.

In addition, the Panel considers the potential flow-on benefits end users would far exceed this estimate.

Assumptions surrounding the costs to industry as a result of implementing this recommendation are outlined in Annex 4.

5.3 Improving timeliness of (chemical) access through prioritised assessments

In the current regulatory system, there is no formal mechanism by which an application to register a product filling a critical gap or addressing an unmet key agricultural or veterinary need, may be recognised as deserving priority consideration. Instead, each application essentially 'joins the end' of the assessment queue when it is lodged.

There are, however, mechanisms in place to support access in an emergency situation, such as an exotic disease outbreak (see Section 5.5). The APVMA can issue an emergency use permit to allow the use of an unregistered product or unapproved active constituent. In these instances, there must be a genuine belief the use of a product is required because of an emergency or impending emergency.

Separate to emergency situations, there are certain pesticides and veterinary medicines that have highly desirable attributes, for instance:

- more effective pest and disease management (e.g., products with new modes of action)

- enhanced farm viability (e.g., diversified products which allow application earlier or later in the season)
- increased competitiveness in international markets (e.g., alternatives to practices no longer accepted internationally)
- addressing a niche market (e.g., a unique minor use like aquaculture)
- protecting ecosystems (e.g., to manage a weed of national significance).

Prima facie, such products would merit prioritisation over other candidates for registration. Numerous stakeholders supported the concept of prioritisation as it would provide earlier access to products with highly desirable attributes.

> *"A new product or use addressing a significant area of concern, a pest gap, or providing a replacement for a product under reconsideration, could be justification for prioritisation, e.g., an expedited review."* (Horticulture Innovation Australia 2020)

> *"This will increase opportunities for the NSW primary industries sector and more broadly the state of NSW, through more timely access to suitable chemicals for primary production, biosecurity incursions, and pest and weed control on both public and private land."* (New South Wales Government 2020)

There was caution expressed, however, regarding implementation.

> *"The concept of providing a pathway by which the APVMA can better prioritise and manage their workload is supported … Further consultation with industry and the APVMA would be required to determine which application types would be included in the approach and whether the existing application types remain appropriate for a prioritisation process."* (CropLife Australia 2020)

Assessing applications simply in the order in which they are due for completion is the traditional way in which the APVMA work priorities have been set. However, for select pesticide and veterinary medicine products with highly desirable attributes (such as those described previously), more timely access would represent a tangible benefit for Australia's farmers and the environment. The Panel is strongly driven to implement an agile and responsive future regulatory system driven by national needs. For this reason, the Panel's view is that in these limited circumstances, there should be an opportunity for such applications to be prioritised.

What change is recommended?

For pesticides and veterinary medicines that meet prescribed criteria, the Panel recommends 'fast tracking' their application for registration. This will provide more timely access for users where there is a demonstrable need for these products to receive priority. This would be achieved by allowing applications (meeting the prescribed criteria) to be expedited for assessment, enabling these products to enter the market, and become accessible to users earlier than would normally be the case.

The Panel neither expects nor intends that this measure will result in constant reordering of applications (assuming only a small number per year would meet the criteria) and will therefore not delay routine assessments.

The Panel recognises the APVMA will have finite resources (as it does now), but this should not prevent it from being able to prioritise a reasonable number of applications a year over others when these applications would significantly benefit agricultural and veterinary practices, human and animal health, and environmental outcomes.

While not identifying a comprehensive list of criteria for prioritisation, the Panel considers these could include:

- introduction of a new active constituent (e.g., a novel analgesic offering improved post-operative pain relief in companion animals)
- use on a crop group
- uses which are priorities for access to new products (e.g., listed as a chemical under review or for specialised areas that are classed as minor use, including in minor species)
- controlling a pest or weed of national significance (including addressing emergence of exotic pests or diseases).

90. Recommendation

The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.

To allow flexibility and responsiveness to community priorities, the criteria for prioritisation may be determined by the Minister (or their delegate) with the benefit of advice from the Stakeholder Forum (see Chapter 2). This could be put into effect through a priority action list, in addition to the criteria outlined, which may be developed consultatively to address unique needs that are likely to change over time (such as disruptions to the supply chain, or community preferences for lower toxicity or biologically-based products). These would be clearly and transparently communicated and could be prescribed in a legislative instrument.

91. Recommendation

The Panel recommends the criteria for prioritisation be determined by the Minister with advice from the Stakeholder Forum.

Cost of reform

The Panel estimates that a maximum of 5 applications each year are likely to meet the criteria to be considered for prioritisation.

The Panel considers the information required to substantiate the criteria for prioritisation will be easily attainable by registration holders. The process to nominate an application for prioritisation will not be a mandatory requirement, as a result this reform is not expected to incur a cost to industry.

However, allowing these products to enter the market up to 6 months earlier (for instance) than anticipated would reduce delay costs to industry, with an estimated saving of approximately $1 million per annum (or $10 million over 10 years). The Panel also expects that benefits to

product users such as farmers, through earlier access would be considerable but has not estimated what this might be.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

5.4 Improving access and risk management through regionally targeted controls and reduced reliance on jurisdictional borders

Currently, there are variations in the approved use patterns for some pesticides and veterinary medicines between state and territory jurisdictions. These include the crop or animal species to which the pesticides and veterinary medicines can be applied, the pest treated, and application rates for the product. This causes unnecessary complexity, confusion, economic losses, and inequitable access for growers and commercial operators treating the same pests in the same commodities in different jurisdictions.

These differences reflect a historical approach to risk management and use patterns based on jurisdictional boundaries and legislation. As such, these types of arrangements are generally found in older products and their generic derivatives (i.e., products whose registration is based on the older 'pioneer' product's relevant particulars).

The Panel commends the APVMA's efforts in recent years to avoid the approval of jurisdiction-specific use patterns for new registrations, and to take a more rational geographical or climatic approach to managing the risks associated with a product's use. However, consistent feedback was received from stakeholders about unnecessary regulatory burden still remaining when crossing jurisdictional boundaries.

Through the consultation process, many stakeholders advised the Panel that state and territory boundaries represented an arbitrary distinction that may be ineffective for assessing the variable risks of pesticide use. This view was supported by the National Farmers' Federation (NFF), CropLife Australia, Syngenta Australia, and Cotton Australia.

> *"Assessing products by region where there are genuine specific environmental or biological considerations (beyond what already occurs through the APVMA's assessment processes) may be beneficial. However, it would need to be carefully managed to ensure it doesn't lead to confusing or overly complicated label instructions."* (National Farmers' Federation 2020)

Similarly, Cotton Australia emphasised the advantages that include consistency of use and access to pesticides and veterinary medicines:

> *"Merits of considering boundaries other than state boundaries include ensuring consistency of use and access, reducing confusion and ability to identify sensitive areas for restrictions. Boundaries should be clearly described."*
> (Cotton Australia 2020)

What change is recommended?

The Panel recommends that the APVMA provides, in the first instance, nationally consistent use patterns for pesticide or veterinary medicine products (that is, equivalent instructions irrespective of jurisdiction). Nationally consistent use patterns would serve as the default arrangement, with regional variations in use patterns only permitted in specific circumstances.

The APVMA would only be able to vary use patterns of a product on a targeted basis (i.e., in specific regions) where it is necessary to manage specific risks. Targeting use pattern variations to specific regions on the basis of risk, rather than where a jurisdiction's border exists, should result in improved risk management outcomes. Additionally, only permitting variations where necessary to manage specific risks promotes nationally consistent access to pesticides and veterinary medicines, improves economic efficiency, and enables greater and more equitable access for users.

92. Recommendation

The Panel recommends the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted by departmental risks.

The regulation of pesticides based on regional conditions has been well established internationally. The US regulates pesticide use and registration regionally, based on waterways, threatened species habitat, and climatic zones (United States Environmental Protection Agency 2009, 2019, and 2020). Similarly, the EU registers pesticides – and requires Members States to recognise registrations – based on 3 climatic zones (European Commission 2020).

The Panel's opinion is that climatic zones provide the most suitable basis on which to define Australian regions for this purpose.

The range of factors that may necessitate regional variations in a product's use pattern is broad and may not always align with climatic zones (e.g., regional differences in pest susceptibility requiring different application regimes). Therefore, the APVMA would continue to be able to use its discretion to tailor use patterns between regions other than climatic regions, where this would be commensurate with the risks being managed.

93. Recommendation

The Panel recommends targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not correspond to climatic regions.

Determining climatic regions and targeted controls

This approach provides broad coverage of many climate linked factors that can influence the activity of a pesticide or veterinary medicine such as average and extremes of temperature, humidity, precipitation, and sunlight. Different climates can affect half-lives and degradation products of chemicals, and the way chemicals act in the environment. This may, for example, necessitate different application rates or withholding periods.

While climatic zones can be easily defined based on recent conditions (for example, Figure 2), climatic changes could mean that the boundaries for these zones 'move' over time. To manage

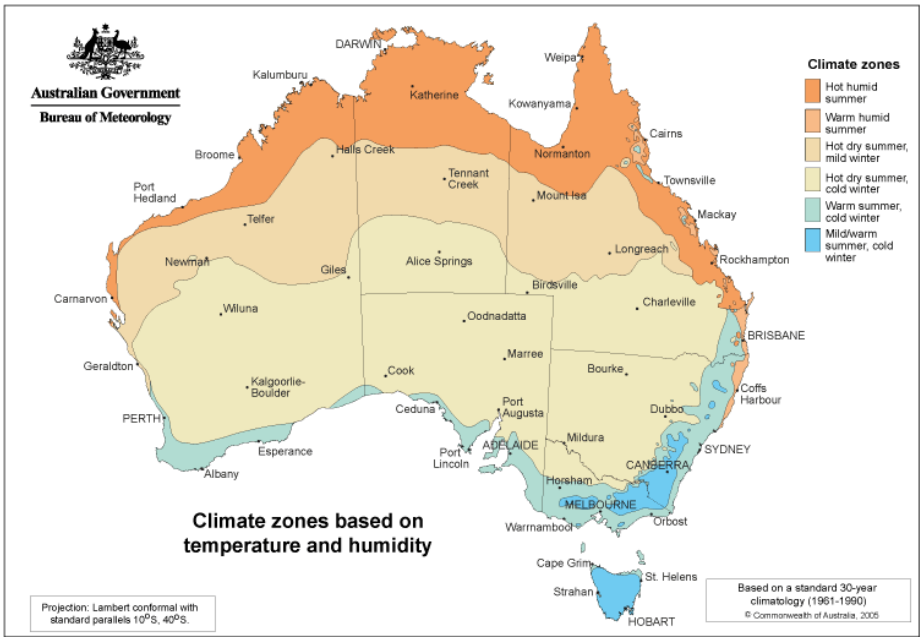
this, climatic zones may need to be defined and managed in a way that allows their boundaries to 'evolve' over time.

The APVMA would have the discretion to define alternative regions to manage the risks posed by the handling and use of a pesticide or veterinary medicine product where necessary. For example, the APVMA may also choose to vary use within a catchment area (such as the Great Barrier Reef catchment) or critical habitat of a listed threatened species.

In addition, risk controls implemented by the APVMA may only be necessary during certain times of year, or for certain application technologies. Targeted controls like this are already employed in Australian jurisdictions. For example, Victoria's Agricultural Chemical Control Areas can specify that regional controls only apply to aerial application of a pesticide during certain periods of the year. This is to protect high-value crops, such as grapes, during sensitive periods of the growing cycle.

The adoption of smart labels (see Chapter 4) would enhance the ability to convey information about appropriate use patterns in different climatic zones, or other regions. Online maps could provide detailed information on regional boundaries and relevant instructions, providing clarity to producers on their regional pesticides and veterinary medicines use obligations.

Figure 2 Australian climate zones based on temperature and humidity



Source: Bureau of Meteorology 2006

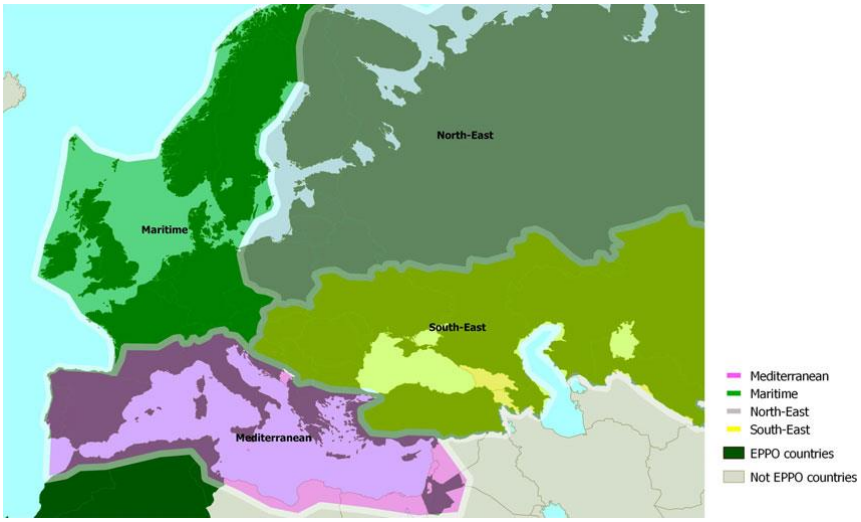
Linking Australian and international climatic zones

Where products registered by a comparable international regulator are to be accepted for licence in Australia, the Commissioner may ask licence holders to address any relevant unique Australian conditions. The linking of climatic zones used in Australia to those used by

comparable international regulators could facilitate the use of international data to address unique Australian conditions relating to climate, promoting improved and equitable access to overseas registered pesticides and veterinary medicines.

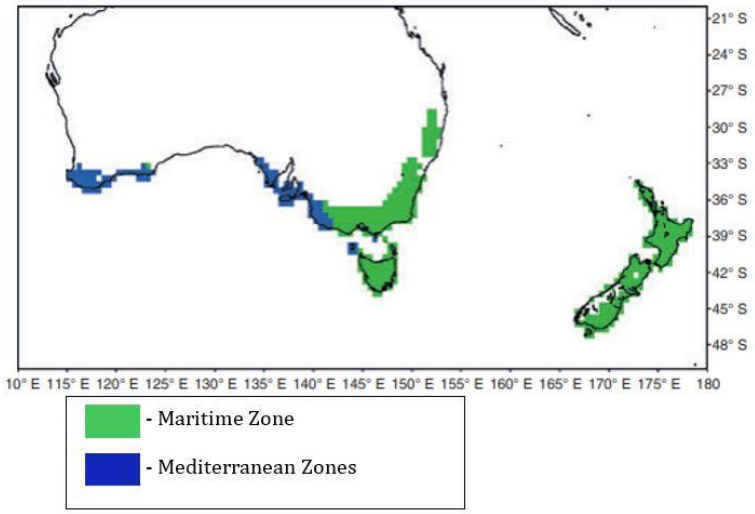
This linking of climatic zones has been demonstrated by the European and Mediterranean Plant Protection Organisation (EPPO). EPPO has published a standard providing guidance to regulatory authorities in determining the comparability of climatic zones between global regions through assessing temperature, dew-point temperature, relative humidity, precipitation, short-range radiation, and frost-free period. Using this methodology EPPO's European maritime and Mediterranean climatic zones (Figure 3) were demonstrated to be comparable to Australian regions (Figure 4).

Figure 3 EPPO European climate zones



Source: European and Mediterranean Plant Protection Organisation (EPPO) 2014

Figure 4 Comparable Australian climatic zones defined by EPPO



Source: European and Mediterranean Plant Protection Organisation (EPPO) 2010

Addressing existing jurisdiction level variations

The Panel agrees with the Agriculture Ministers Forum decision of 25 October 2019 to make any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions. For existing registered products, this regulatory simplification would go some way to enable more equitable access for users of products already registered with jurisdiction-specific use patterns.

Coupled with the Panel's recommendations for nationally consistent use patterns, and a climatic region based approach to risk management of uses, removal of jurisdiction-specific use patterns from existing chemical products would provide further regulatory simplification for users and can be achieved through label updates for pesticide and veterinary medicine products. Labels for pesticide and veterinary medicine products should be updated (at least) every 5 years by holders (see Chapter 4). These label updates will provide for jurisdiction-specific use patterns to be progressively removed within a clearly defined time period of 5-years. The Panel envisages that where a jurisdiction-specific use pattern is removed from a label, a holder would merely be required to inform the APVMA via notification, rather than submitting a full application.

94. Recommendation

The Panel recommends making any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions in line with the 2019 decision of the Agriculture Ministers Forum.

Cost of reform

Removing the need to stipulate individual states and territories for certain uses on labels is expected to have minimal cost impact on industry. The Panel recommends that changes do not need to be made until such time as the registration holder intends to make other label variations

as part of the periodic label review (see Chapter 4) therefore there are no direct regulatory cost impacts for this recommendation.

The benefits that would accrue to users of products through greater access have not been determined.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

5.5 Improving access for emergency, research, and minor uses

The Panel recognises that an effective, contemporary regulatory system must be robust and stringent in assessment of pesticides and veterinary medicines to ensure the safety of humans, animals, and ecosystems. The system must also, however, include sufficient flexibility to permit, on occasion, the use of certain products that are not registered for use on specific animals and crops, when it is deemed vital to health, safety, or viability. Such occasions are currently dealt with under the Minor Use, Emergency Use and Research Use Permit scheme.

The Panel heard strong support for this scheme and fully supports the intent of the current permit scheme in providing access to products.

> *"An efficient approach for assessing permits (minor use and emergency use) is essential and has to date proved valuable to winegrape growers in managing climate change, new pests, seasonal weather events, and a reduced pool of broad spectrum agvet chemical control options. Minor use permits and emergency permits are vital, in the context of the transition to alternatives as certain chemical groups are no longer available, as registration is not renewed, and to act as a buffer when there is a sudden spike in demand."* (Australian Grape and Wine 2020)

The thoroughness of the current product registration assessment process is well suited to registered products and uses that are widespread and with a significant user base. However, the nature of emergency, research and some minor uses is that their use will be restricted in terms of geography, time, or user base.

The Panel also heard that regulatory costs, data requirements and assessment times can be a barrier to access for these latter occasions of need. The Panel considers the operation and practicality of the permit scheme could be considerably improved, without increasing risks to the safety of humans, animals, and ecosystems. Improving access to veterinary medicines for minor species and minor uses should also improve animal health and welfare outcomes.

The current legislation applies the same safety, efficacy, and trade criteria to decisions relating to both registration and permits, although permits do not have to satisfy labelling requirements. This leads to an assumption by permit applicants that equivalent levels of supporting data are required, but for many of these uses there may be less direct data available for the use.

> *"It is expensive and time consuming to obtain a permit and goat, camelid and deer organisations lack the skilled personnel or the funds to employ them to develop and submit them. Also the basic information is either not available due to lack of research*

> *on drugs on goats or lack of public information."* (Small ruminant chapter of ANZ College of Veterinary Science 2020)

In the Panel's view, applying the same level of assessment to permit applications as for registration is unlikely to be commensurate with the level of risks being managed. The APVMA can currently exercise discretion to consider how likely adverse consequences of these restricted uses may be, but the difference in risk consideration between registration and permits is confused through legislation that sets an equivalency in assessment criteria. The Panel is proposing an alternative assessment protocol to that used for registration to manage risks to ensure product availability for emergency, minor uses, and research.

Submissions emphasised that while the APVMA has a good record of promptly dealing with emergency use applications, preparedness is critical to deliver an effective response. While it is possible to currently seek a permit for an emergency use in anticipation of the emergency, it is not possible to publicly differentiate, in respect of the permit, between an anticipatory emergency and an operational emergency. This could cause concerns with trading partners and domestic users as to whether a specific pest or biosecurity threat is active within Australia. Having emergency uses pre-approved and ready to be implemented would enable a faster response in emergency situations without raising undue concerns within the general public or trading partners that Australia has biosecurity challenges that are not yet present.

> *"CropLife commends the APVMA on their approach to assessing and issuing emergency use permits. The recent fall armyworm incursion and the APVMA's swift response to assessing and issuing a range of emergency use permits to control the pest highlight the importance of such a process for managing biosecurity pest incursions."* (CropLife Australia 2020)

> *"Horticulture Innovation believes it would be more efficient to have a mechanism whereby off-label permit applications for biosecurity threats could be assessed but not publicly issued. In the event of an incursion the assessment would have been previously completed allowing its rapid issuance and deployment of corrective action. It would also have the benefit of not unnecessarily confusing, internationally, the Australian status of various biosecurity threats by issuing pesticide approvals for exotic pests and/or diseases not present in Australia."* (Horticulture Innovation 2020) and supported by (Growcom 2020)

Submissions indicated that the current permit scheme can be a barrier to accessing products especially for minor uses.

> *"It would be beneficial to ensure that APVMA staff assessing permit applications for material that differs from the details assessed at registration are empowered to make a decision based on any risk and actions proposed to manage that risk over the duration of the permit. It is rarely possible to demonstrate from the outset that no risk exists. The permit system is of little use if it will not entertain risk and make an informed judgement of proposed risk mitigation actions."* (Bioproperties 2020)

> *"For veterinary minor use permits, the APVMA currently requires virtually the same evidence for the permit as it would for formal registration. Given that the reason for the minor use permit is usually a limited market that would not justify the data*

> *required for registration, and that the need for the product is required to be supported by veterinarians as to the need, we believe that the requirements should be simplified."* (Veterinary Manufacturers and Distributors Association 2020)

Simplifying the tools under the new system

In the Panel's view it is essential that the future regulatory system provides improved and timely access for emergency, research, and minor use purposes.

However, current arrangements are complex and cumbersome. Specifically, the separation between supply (under Commonwealth legislation) and control-of-use (mostly under state and territory legislation) requires the use of 2 functionally similar tools to legalise an activity – permits and exemptions. Both permits and exemptions authorise specific activities that would otherwise not be permitted in relation to use of a pesticide or veterinary medicine, including switching off offences or civil penalty provisions. For example, the APVMA can issue a permit to allow a product to be used in a manner contrary to the label directions without the use being subject to the requirement to only use in accordance with the label direction or any penalties for non-compliance with label directions. Similarly, the APVMA can exempt a product, or class of products from the requirement that only registered chemicals products can be supplied or possessed.

Presently, state and territory laws for regulating control-of-use recognise permits that may be issued by the APVMA, but not all recognise APVMA exemptions. The result is that for some exemptions (such as determining that the supply of an unregistered product is not an offence), the APVMA must also issue a permit to give effect to the exemption in state and territory law (i.e. allowing the lawful use of the same product). In practical terms, an exemption has little practical effect without the issuing of a corresponding permit as there would be no lawful way for a purchaser of the product to use it.

The Panel has recommended there be a single national control-of-use law for regulating the use of pesticides and veterinary medicines through their entire life cycle (see Chapter 2). This new regulatory system provides the opportunity for considerable simplification of the current, somewhat cumbersome exemptions/permit scheme.

The Panel's proposed new single national law would enable a single regulatory instrument (an exemption) to authorise activities for a product throughout its life cycle (from design to disposal). The single instrument would remove the current requirement for additional approvals and regulatory interactions (such as obtaining import consents and exemptions to support the use of a permit). This would assist industry in accessing acceptable products and uses, simplify the legislation, and facilitate compliance without compromising human and animal health and safety.

What change is recommended?

The Panel recommends the following reforms to the current approach to permits. In developing these reforms, the Panel is aware of the importance of permits for protecting animal health and the value they deliver to producers.

> *"As highlighted by the panel, the Improved Access to Agvet Chemicals Initiative has demonstrated a comparable return on investment to international minor use*

programs, at an average return to industry of $117 per government grant dollar or $17 million per project over 20 years." (CropLife Australia 2020)

Greater use of exemptions

The Panel supports the Government's actions to address minor use and support Australian growers' access to safe and appropriate chemical products. The Panel highlights the success of the Improved Access to Agvet Chemicals Initiative. A recent economic analysis (ABARES 2020) of the grants program has shown an average return to industry of $117 per government grant dollar (or $17 million per project over 20 years). These returns are comparable to those achieved for similar international minor use programs. The Panel considers this clear evidence of the value in equipping industries with the necessary tools for pest and disease management.

The Panel favours greater use of exemptions as they are a legislative tool that offers a simplified, streamlined and potentially speedier way of authorising specific activities that would otherwise not be permitted. The Panel is attracted to exemptions in part because exemptions can readily apply conditions for different individuals or groups (e.g., that a user hold an industry accreditation or equivalent competency) or different locations. By contrast, the current regulatory system has limited flexibility as only certain activities can be authorised under permit.

Careful definition of the exemption, and targeted application of exemption conditions would be utilised to ensure that the risks associated with exempted products or uses were properly managed to ensure an equivalent risk management outcome to that achieved by undertaking full product registration.

Exemptions as a legal instrument are already commonly used to support Australian agriculture in the *Export Control Act 2020* and are consistent with international pesticides and veterinary medicines regulatory practices (New Zealand and Canada), where they provide regulatory flexibility.

Exemptions would be made as legislative instruments such as regulations or Ministerial Orders (as is currently the case in the Agvet Code). The APVMA would have authority to make exemptions. The APVMA would continue to assess and grant exemptions for research, emergencies, and minor uses, either on application or on the regulator's initiative, as it does now for permits.

95. Recommendation

The Panel recommends expanding the support by government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing the industries that benefit from access to the necessary tools for pest and disease management.

96. Recommendation

The Panel recommends, through the proposed single national law, implementing an exemptions model as a streamlined way of authorising specific activities that would otherwise not be permitted. Exemptions for minor, emergency and research use may be made as legislative instruments by the APVMA.

Moving from permits to exemptions will only be possible with the implementation of the single national law.

Commencement of the new law would include transitional arrangements to avoid practical impacts to users of existing permits. To ensure there will be no net loss in the access provided by the current permit scheme, permits would be recognised as exemptions under the new system (including having the existing expiry date of the permit carried over to the exemption).

Establishing criteria specific to considering emergency, research, and minor uses

The Panel recommends amending the statutory criteria to establish conditions that are specific to, and reflective of, the real level of risks posed through emergency, research, or minor use.

The Panel proposes that the specific criteria to grant an emergency, research or minor use exemption is that the use of a product would not jeopardise safety or trade and is reasonably expected to be efficacious. In contrast, the registration criteria for safety or trade are that the product does not or would not pose an undue hazard to safety, or does not, or would not, unduly prejudice trade. For efficacy, the registration criteria require that the product is, or would be, effective. This will create a difference, in both policy and legislation, between registration and exemptions. The language reflects the differences in risks posed by a controlled or limited use relative to the broad use set out through registration.

97. Recommendation

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use exemption as long as a use would not jeopardise safety, efficacy, and trade.

The Panel expects these criteria will enable greater use of sound argument in support of emergency, research and minor use applications, and a corresponding reduction in the need for specific data generation prior to consideration of an application for exemption. Sound arguments could include, for example, evidence of a history of safety for comparable uses of the product, or a record of demonstrable safety of the proposed use in an equivalent market overseas.

The Panel is particularly motivated by the potential for the criteria to make greater use of the depth of veterinary knowledge and experience, with exemptions drawing on the existing evidence base from published and well-recognised historical clinical practice.

> *"The permit system does not appear to be well utilised by animal industries, veterinary practitioners, niche plant industries, individual chemical users and agronomists. Utilisation of the permit system appears to be less where there are other avenues for access (e.g., veterinary prescribing or off-label use), lack of industry funding or where individual businesses encounter pest or disease problems that are not common within their industry."* (Victorian Department of Jobs, Precincts and Regions 2020)

As an example of how the exemption scheme may work for minor use applications, an applicant extending the use of an established pesticide product from lettuce to spinach (a minor use) could use a combination of public data and argument, highlighting the extensive use in spinach grown in Canada; where the use pattern is identical and there have been no reported residue violations or impacts on non-target animals. This application could include residue reports from Canadian authorities to substantiate their argument.

> *"Although the predominant use of this [permit] system is to enable new and emergency uses for minor crops, and requires the generation of suitable residue data, there are also identifiable situations where permits can be achieved by extrapolation."* (Growcom 2020)

Supporting biosecurity preparedness through active – and future – emergency exemptions

The Panel recognises the benefit to Australian biosecurity preparedness in establishing emergency exemptions in advance of a pest or disease incursion. The approach currently provided for in emergency permits should be retained.

> *"The emergency permit system also appears to work reasonably well for providing timely access in biosecurity emergencies, although best outcomes are obtained through obtaining permits in advance of any emergency need."* (Victorian Department of Jobs, Precincts and Regions 2020)

To address possible user and export industries concerns over the perception of a pest or disease presence, emergency exemptions, once granted, would be categorised publicly in one of 2 lists: 'active-emergency exemptions' or 'future-emergency exemptions'. Formal triggers would be established within the exemption to make a future-exemption active, such as notice by the Chief Veterinary Officer (CVO), the Chief Plant Protection Officer (CPPO), Animal Health Australia through its AUSVETPLAN, Plant Health Australia through its PLANTPLAN or the Inspector-General Biosecurity.

98. Recommendation

The Panel recommends expanding the authorising of emergency use in advance of the emergency, establishing 2 categories within the public listing of exemptions for 'active-emergency exemptions' and 'future-emergency exemptions'.

99. Recommendation

The Panel recommends that, in granting an emergency exemption in advance of an emergency (a future-emergency exemption), the exemption includes details of the trigger to transition from the 'future' to 'active' exemption category.

The Panel encourages these authorities to take full advantage of this new opportunity from changes in criteria to improve preparedness for contingencies such as exotic animal or plant disease or pest incursions. Preparedness plans, supported by on-the-shelf exemptions, are stronger and can be implemented more speedily. The time to apply for exemptions is before a crisis, not during.

Improving research flexibility

The Panel's separate recommendation for a national licensing scheme (see Chapter 4) provides an opportunity to support research by removing the requirement to seek an exemption for each activity.

The Panel recommends that a licensed entity would be able to undertake research relating to pesticides and veterinary medicines, subject to the condition that a risk management plan is in place along with quality management systems and regular independent assurance checks such

as audits. This would allow an entity to be licensed for multiple research activities under one authorisation. The risk management plan would need to address the potential exposure for humans, animals and ecosystems and the potential for residues to enter the food chain. Research would not be limited by size or quantity, but as either increased, the depth and detail of the risk management plan would also increase.

> *"The minimum area that can be treated under a research permit needs reconsideration. Soft chemistry or biologicals are often most effective when a large area is treated so that edge effect and incursion of new pests is minimised. The current restrictions on trial size have been appropriate for chemistry that has immediate and persistent effect but are not appropriate for some of the newer soft chemistry."* (Citrus Australia 2020)

The licensing scheme for research entities would not preclude anyone, including a licensed entity, from also seeking an exemption for research use.

100. Recommendation

The Panel recommends the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan is in place along with quality management systems and regular independent assurance checks including audits.

5.6 Biologically-based pest and disease management products

Biologically-based products, although not used as widely as chemical-based products, have been a feature of the pesticides and veterinary medicines regulatory system from the beginning. These products have taken many forms, for example, bacillus thuringiensis-based products, extracted plant oils, pheromone attractants, hormones, and many vaccine products. The advice from many stakeholders has convinced the Panel the demand for biologically based products will significantly increase in the decades ahead.

> *"Top international companies directed their R&D spending mostly towards pharmaceutical (65%) and biological (26%) products."* (Animal Medicines Australia 2020)

> *"Many new biological technologies are being developed, including (but of course not limited to) greater focus on the therapeutic use of monoclonal antibodies, CRISPr, micro RNA and other gene therapies."* (Australian Veterinary Association 2020)

The Panel is also persuaded that, while the current regulatory system can work for biologically-based products, there are improvements that can be made to better support biologicals businesses in meeting the demands of users and the expectations of the community especially as the proportion of such products increases in the future.

> *"Australia is missing out on potential productivity improvements through commercial investment in many potential and emerging biological, biochemical and biotechnology based Agvet technologies. It is essential that Australian grain growers*

have access to the same pesticide technologies to remain internationally competitive with other overseas producers." (Grain Producers Australia 2020)

The Panel heard from numerous industry stakeholders that there were several areas where existing regulatory practice, or regulatory duplication, were causing inefficiencies and hindering innovation:

- duplicative arrangements and oversight between the pesticides and veterinary medicines regulatory system, and the system for gene technology
- complex or repetitive biosecurity import assessments for either raw materials or finished product, in particular where a biosecurity permit has previously been granted
- inappropriate or unsuitable standards and approaches for biologically based products, e.g., for satisfying efficacy and manufacturing processes
- 'ill-fitting' application types and assessment expertise within regulators, including the APVMA.

What change is recommended?

Biologically-based products are different from 'conventional' chemical-based products. While their use in pest and disease management might be similar, some of the risks from use are different. Many biological pesticides have a narrow host range, targeting specific pests, and exhibit limited non-target effects. Biologically-based products may degrade relatively readily in the environment, with residues often indistinguishable from natural food components or of no toxicological significance. The Panel recognises that because some biological products pose minimal risk of adverse effects on humans, animals and ecosystems, they may be more desirable than some synthetic pesticide chemicals.

The Panel considered the value of establishing a separate regulatory regime for these products and this was supported by some stakeholders. However, the Panel ultimately determined a 'technology agnostic' regulatory system focusing on the use of pest and disease management products, irrespective of their chemical or biological origins, would best meet Australia's needs. A technology agnostic regulatory system is more flexible than multiple custom regulatory arrangements, and can be adapted to any changing needs over the 30-year timeframe through investing in the relevant expertise and experience for APVMA assessors.

101. Recommendation

The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

The Panel is recommending reforms that will improve the regulation of pesticide and veterinary medicine products. The Panel is confident these same reforms will deliver practical benefit to biologically-based products. Tailored regulatory processes will provide multiple opportunities for improving access for biologically-based products. Specifically:

- enhancing access to overseas biologically-based products through a licensing model for improved access to internationally registered products

- removing certain pre-market assessments by the APVMA will allow pesticide, and veterinary medicine, manufacturers to more readily supply biologically based products that meet the expectations of their customers
- excluding pheromones, semiochemicals, whole plants (including genetically modified plants) that exhibit a pesticidal effect, and products containing bacillus thuringiensis, or some botanical oils from the operation of the pesticides and veterinary medicines regulatory system.
- exempting certain products, or product claims, from the need for registration (while remaining a pesticide or veterinary medicine product within the system) or from the need for pre-market assessment
- reducing cases where a product is subject to separate and duplicative regulatory systems, such as pesticides and veterinary medicines and gene technology; only a single system should have primary regulatory responsibility, as described in the revised regulatory scope.

The Panel is aware of the ongoing efforts of the Department to improve the incorporation of an entity's quality management systems into the decision for import consents in the *Agricultural and Veterinary Chemicals (Administration) Act 1992*. The Panel commends the Department on its efforts.

The Panel is also aware that the *Biosecurity Act 2015 (the Act)* requires that the Department assess biosecurity risks from importing biological material independently from other post-entry regulatory systems. Conditions on the importation of biological material, specified under legislation subordinate to the Act, are based on the level of biosecurity risk associated with goods or classes of goods. As such the Department cannot consider alternatives to these conditions, based on the business practices or industry standards of an importer, without changes to current legislation.

The Panel sees a deregulatory opportunity to allow certain goods (or classes of goods) to be imported under alternative conditions on the basis of recognised international standards for the manufacture of high quality, safe, bulk biological materials. This deregulation would streamline import processes, including border clearance, through the publication of standard alternative conditions and reduce the burden of permit processes benefitting manufacturers, the Government, and users including farmers.

102. Recommendation

The Panel recommends that amendments be made to the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries.

The Panel considers a system performance measure that, over time, tracks the prominence of biologically-based products within the regulatory system would act as a useful measure of the system's responsiveness to these types of products (see Chapter 2).

103. Recommendation

The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.

Cost of reform

While it is difficult to determine the volume of biological material imported for veterinary medicines into Australia each year that would benefit from the Panel's recommendations, the Panel's is confident that an annual reduction in regulatory costs of $100,000 (or $1 million over 10 years) is possible.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

5.7 Allowing consideration of benefits prior to refusing a registration

Some international regulators of pesticides and veterinary medicines, including in Canada, New Zealand, the USA, and the state of California, have incorporated benefit or value considerations into their product assessment systems. In these systems the term 'benefit' is taken to mean a range of things in addition to economic considerations. It includes factors relating to the agronomic (including resistance management), social, health, and environmental consequences of not having access.

The Panel was previously disposed in its Issues Paper to introduce a benefits test as part of the registration process for all products, similar to other countries and there was mixed support for such an approach.

> *"A benefits test would be a useful addition to the regulatory system if it facilitates registration of products to fill gaps or provides an alternative to existing products but with lower risks to users, trade, consumers or the environment."*
> (Citrus Australia 2020)

Some stakeholders recognised that the APVMA may consider benefits to a certain extent now but were aware that there was no formal mechanism to determine this. Some stakeholders were concerned that considering benefits may require an additional statutory test to determine whether the benefits of a product outweigh its risks to humans, trade, animals, or ecosystems. They felt this would add significant regulatory burden during both the preparation and assessment of an application.

> *"AMA is unable to support a Benefits Test as a condition of registration, similar to the process in New Zealand, at this stage. AMA understands that this type of benefits test may pose potential barriers which can significantly delay the registration of products."* (Animal Medicines Australia 2020)

There was also concern that considering benefits associated with a short-term need or that are financially valuable to one sector could overshadow unmanageable risks including long-term negative consequences on ecosystems. For instance, it would be inappropriate to allow a

product to enter the market on the basis that it had a new mode of action, if there were risks that could not be managed – the Panel supports this view.

> *"CBH would support the consideration of 'benefits' in the regulatory framework when considering the registration of a product, however this must be balanced with other concerns or risks that may be raised as part of this same assessment."* (Co-operative Bulk Handling Ltd (CBH Group) 2020)

> *"While in principle, a benefits test may be a consideration in registering a product, the Western Australian Government cannot support the recommendation because information is lacking on how chemical risk would be weighed against economic benefit."* (Western Australian Government 2020)

The Panel acknowledges these concerns and recognises that only in some cases will it be necessary to consider whether a product's benefits outweigh the risks it poses. To this end, the Panel is inclined to allow for consideration of benefits at the critical point where an application may be facing refusal. Restricting application of the test to the point of potential refusal will limit the regulatory burden of the measure, while still allowing the regulator to make a balanced judgement about a registration.

As a hypothetical example, the APVMA may consider an application to use a vertebrate pest poison against feral pigs, to prevent pig predation of the eggs of a threatened sea turtle species. The predation poses a significant threat to the recovery of the turtle species. However, the product is known to have limited off-target impacts on local populations of native fauna. Ordinarily, because of these off-target impacts, the APVMA may decide that this use of the product did not meet the safety criteria (on the basis of unacceptable and unintended negative effect on animals or ecosystems), and so refuse registration for this use. However, by explicitly providing for the benefits of the product to be considered prior to refusal (conservation of the threatened sea turtle species), against the otherwise 'unacceptable' risk of the product's use (limited and localised off-target effects on native fauna), the APVMA may decide that the benefits of the product's use in this particular situation clearly outweigh the risks and approve the use on that basis.

The consideration of human, animal, and ecosystems health and safety is paramount, and it is not the Panel's intent that considering benefits prior to refusal of an application would allow a product to be registered if its risks were unmanageable (for instance, in the previous example, if the off-target effects on native species were extensive and unmanageable, then the application would be refused, irrespective of the benefits). Rather, the Panel is of the view that the introduction of a 'benefit' consideration into the regulatory system will allow for a nuanced and sophisticated regulatory judgement that considers a more complete picture when deciding whether access to a specific product should be granted which would otherwise be refused.

What change is recommended?

The Panel recommends that legislation provides that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration or to suspend or cancel a registration, for example, following chemical review.

The safe dealings with a product are of utmost importance and the product should not be authorised, irrespective of its benefits, if it poses unmanageable risks to the health and safety of humans, animals or ecosystems, or welfare of the target animal. However, there may be scenarios, such as when a product is addressing the outbreak of a blood-borne disease, where overall human health of the population is a consideration. For example, the APVMA would need to balance the benefits of controlling mosquitoes carrying a disease affecting a significant proportion of the population with possible risks to health in some people.

The information that applicants and registrants may supply to the APVMA to support a product's benefits need not be quantitative. As examples:

- In response to notice from the APVMA of possible refusal, applicants may provide a case study to illustrate the unique benefits of their product to demonstrate how the risks are being managed or provide evidence of ecosystem recovery; e.g., a novel pesticide may cause short-term off-target impacts on the local ecosystem but the applicant can show recovery of native plants especially due to a reduction in weed pressure. This provides an opportunity for the future regulatory system to consider bespoke solutions to risk management.
- The APVMA may consider the scenario of a veterinary medicine proposed to be used to control a pest of national significance that causes serious detrimental impacts to ecosystems. A vertebrate pest control product to treat this pest infestation will have a short-term secondary impact on scavenger species. Ordinarily, these short-term off-target impacts may prevent the product's registration, despite the long-term benefit of removing the pest load to allow ecosystems recovery. By allowing the broader, long-term benefits to now be considered as part of the consequences of not registering the product for this use, a balanced end result could be achieved that controls the pest of national significance while delivering a significant net environmental benefit.

Consideration of the consequences of refusal will not occur when a product is suspended or cancelled due to administrative sanctions for inappropriate behaviour or actions by the registrant.

Cost of reform

The APVMA refuses a very small number of applications each year with most applications being revised prior to the point of refusal. The Panel's recommendation to consider benefits at the point of refusal is expected to be cost neutral to the product manufacturing, importing and suppling industries.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

104. Recommendation

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

5.8 Protecting intellectual property

Innovative pesticide and veterinary medicine products and uses are vital to Australian agricultural production, animal health and biosecurity. Generic products also play an important role, such as providing competitive pricing, increased brand choice, and greater diversity and security of supply. A key policy challenge is finding the balance between incentivising product innovation and encouraging the market benefits of generic products.

Innovative new pesticides and veterinary medicines require substantial investment to develop, and have high regulatory costs for approval, yet they are relatively easy to copy. As a result, pesticide and veterinary medicine producers rely on intellectual property (IP) rules to protect their investment and recover their development costs. The smaller the market (i.e., the lower the potential economic returns) and the higher the costs of market entry – including developing the molecule or use, generating data to satisfy the regulator and fulfil the company's duty of care, and regulatory charges – the more valuable this protection is.

Governments around the world recognise that patent arrangements alone do not provide adequate IP protections for pesticides and veterinary medicines. They typically address this by providing a period of protection for confidential information submitted in support of a registration (this is commonly known as data protection). During the protection period, the regulator cannot use one registrant's intellectual property (i.e., confidential information provided to support a registration); or knowledge gained from that information; to support a registration decision on a competitor's application.

Importantly, data protection does not prevent a competitor from generating its own information to support the registration of an equivalent product. Data protection merely prevents the regulator using an innovator's intellectual property as the basis for market entry for a competitor product (without the innovator's consent); that is, it delays free-riding.

Some stakeholders would like to see longer periods of data protection to account for the significant upfront investment required to bring new pesticides and veterinary medicines, or new uses of existing pesticides and veterinary medicines, to market. Others seek shorter periods of protection since data protection effectively provides innovator chemical companies with a monopoly on the market, which typically results in higher product prices and limits the number of comparable products available during the protection period.

Current arrangements

Currently, information is protected if it is provided to, and relied on by, the APVMA for an approval, registration, or variation relating to an active constituent, chemical product, or label. Information is also protected if it is required to be provided to the APVMA because it contradicts information held by the APVMA or shows the active constituent or chemical product may not meet the statutory criteria. The periods of protection are:

- 10 years for information about a new active constituent or a product with a new active constituent
- 5 years for other information about a pesticide containing a previously approved active constituent (such as information provided in support of variation to a registration or label approval; e.g., adding a new use; or a new registration)

- 3 years for other information about a veterinary medicine containing an already approved active constituent.

Protection is also provided for information obtained through trials or laboratory experiments requested by the APVMA in relation to a chemical review of a product or active constituent. A protection period commences from the time the information is provided and ends 8 years after the APVMA makes its decision on the review.

Information provided in support of a permit application is not protected (this is a deliberate policy to encourage parties to use the registration pathway rather than relying on permits).

During the protection period the APVMA may not use the information to assess or make a decision on another chemical review or application unless an exception applies. For example, where it is in the public interest to do so – including where the information would be unfavourable (e.g., would not support the continued registration of a product) – where the owner of the protected information has agreed to its use, or where the information is publicly available.

Importantly, for protected information provided in support of a chemical review, the legislation also contains provisions that entitle a party with protected information to receive compensation from other parties seeking to rely on that information to support the continued registration of their product following a chemical review. The APVMA is required, where necessary, to appoint a mediator or arbitrator who has the power to suspend either party's registration or approval if it considers that one or both parties have not presented a reasonable proposal. The effect of this is that the owner of the information submitted as part of a chemical review must negotiate in good faith with other parties seeking to rely on that information, or risk having their registration suspended. In similar overseas regulatory systems, compensation is generally a private negotiation matter between companies although some regulators (such as the US Environmental Protection Agency) encourage companies to negotiate.

What change is recommended?

The Panel recognises that data protection arrangements are a balance between the competing policy objectives of access to the widest possible range of products and uses at the lowest cost versus sufficient periods of market exclusivity in order to provide the original innovator with a sufficient return on investment.

The Panel proposes that the following principles should underpin Australia's data protection arrangements:

- If a party provides confidential information to a regulator and that if information is used by the regulator for relevant regulatory decisions, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor.
- The limits should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products.
- Equivalent protection periods should be provided for pesticides and veterinary medicines.
- If there is a public interest reason for the regulator to use information, then the regulator should be able to do so irrespective of whether it would otherwise be subject to protection.

- For example, information about a product that is unfavourable should not be treated as protected; such as, information that does not support continued registration of a product or use.
- Similar protections should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application, a chemical review or required because it contradicts information held by the APVMA).

In addition, the Panel recognises that arrangements must remain consistent with Australia's international obligations, such as the US-Australia Free Trade Agreement and the World Trade Organization agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).

The Panel has considered the application of these principles to the various major situations that will arise under the new scheme.

Length of protections for new active constituents and products with new active constituents

Some stakeholders have suggested that Australia's 10-year data protection periods for new active constituents or new products containing new active constituents are too short. The Panel accepts the findings of a 2017 review by ACIL Allen that Australia's current periods are generally comparable with those overseas, are consistent with international obligations, and are appropriate.

The Panel proposes that these protection periods should only be extended beyond 10 years as an incentive to bring priority uses to Australia, as is proposed in the measure in the *Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019* currently before Parliament. This allows for incentives, in the form of data protection extensions of up to 5 additional years, similar to approaches applied internationally. The Panel expects that this will encourage more priority uses to be included on product labels.

Length of protections for other information

Some stakeholders have questioned the disparity between other information periods for pesticides and veterinary medicines:

> *"The key difference is that agricultural chemicals data received 5 years of limited use, whereas veterinary medicines received 3 years. There was, and is, no logical or policy reason for this difference. This lesser period contributes to disincentives for veterinary medicine investment in innovation for Australia and needs to be rectified."* (Animal Medicines Australia)

The Panel sees no justification for different protection periods and proposes that these be aligned to 5 years.

Some stakeholders have also argued that protection periods relating to variations (such as adding a new use) should be longer than 5 years. The Panel has concluded that, given the generally constrained costs for research and development, there does not appear to be a strong argument to extend these beyond 5 years. The 2017 ACIL Allen report suggests that the current 5-year period, which is the same as that applied in New Zealand, is appropriate.

Consistent treatment of chemical review information

The Panel proposes that the current 8-year period for information provided for a chemical review should be reduced to 5 years. This would be consistent with the approach used in New Zealand for reassessments (a process equivalent to chemical review). The Panel is keen to introduce a consistent set of data protection arrangements, including by harmonising the period for chemical review information with the 5-year period for information related to other applications for pesticides and veterinary medicines with established active constituents. The Panel understands that there is very little information that is currently subject to the 8-year protection period so the proposed reduction is unlikely to be of major significance.

The Panel also proposes to expand the scope of chemical review information eligible for data protection to include any confidential information provided by the registrant and relied on by the regulator to support a reconsideration decision. There is no justification to limit protection of information supporting a chemical review to that which results from a specific regulator request and has been obtained because of a trial or laboratory experiment as is currently the case. This harmonises the scope of data protection for chemical review information with the scope of data protection for information associated with approval, registration and variation applications.

The Panel proposes that, with harmonised periods and scope, only a single system of data protection will be needed for the new pesticides and veterinary medicines framework – rather than the current complex arrangements.

Regulator role in arbitrating access to review data

The Panel proposes to discontinue the current mechanism requiring the APVMA to arbitrate data access and compensation agreements between parties with similar products and uses that are under review. The Panel concludes that the negotiation of data access and compensation is a private negotiation matter between companies and should not form part of the new pesticides and veterinary medicines system.

Data protection for minor use and emergency exemptions

Some stakeholders have argued for data protection for information in minor use and emergency use applications. Providing data protection would distort incentives to use the exemptions pathway in place of registration, undermining the policy intent of both the registration, and exemptions for minor and emergency use and cost recovery outcomes. Taxpayer funding is also commonly used to support the generation of such data. The Panel proposes that while certain information in future minor use and emergency use exemption applications may be considered confidential commercial information, these should not qualify for data protection – this is consistent with the current approach for permit applications.

Some stakeholders have also argued the benefits of establishing a data protection credit system for holders who put minor use needs onto product labels. Such holders would be rewarded with an option for a data protection period extension (a voucher) to use on any product (theirs or they could sell it to another company), either immediately or at a later time. The Panel does not support introducing such a voucher system as this would add complexity and may lead to unanticipated consequences. It considers that its other proposals will do more to support improved minor use access.

Data protection for research exemptions

The Panel proposes to provide 5 years data protection for information provided in support of a research exemption. In particular, the Panel considered the experience in New Zealand which applies protection periods for information provided in their research authorisation applications (known as provisional registration). The New Zealand approach is intended to:

- encourage persons to generate local research information as it provides some protection for owners of information
- encourage owners of protected information to pursue registration and include uses on product labels before the protection period ends.

The Panel concludes that such an approach would be a worthwhile addition to the Australian data protection system.

Supply of internationally registered products under licence

The proposal to allow supply of internationally registered products is discussed in Section 5.2. The Panel has considered the data protection issues that might arise out of this new licensing scheme.

The Panel does not consider it is desirable that the APVMA is able to register a product on the basis of similarity to a product supplied under licence, as the APVMA will not hold any of the relevant information for the licence product. The reliance within the licence conditions of the international registration holder consenting to the supply of the product addresses many of IP protection issues posed by stakeholders in response to the international access model proposed in the Issues Paper.

The Panel recommends that the Commissioner be tasked with ensuring that any IP protection measures for the new scheme align with the Panel's principles (including consistency with international obligations).

Active constituent approvals

Protection periods will continue to apply for information provided in relation to active constituents, noting the Panel's proposal that in the future, these will be approved at the substance level and will be underpinned by a standard (Chapter 6).

105. Recommendation

The Panel recommends a simple, consistent approach to data protection for the new pesticides and veterinary medicines regulatory system. The ability to limit the regulator's use of certain information will remain a valuable component of the future system and will continue to be of great importance to industry. This is vital to protect the value of industry investments and ensure that Australians gain access to the latest innovations in pesticides and veterinary medicines.

106. Recommendation

The Panel recommends that if a party provides confidential information to a regulator and that if information is used by the regulator for a relevant regulatory decision, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor's products.

- **These should be consistent with Australia's established international agreements.**
- **Information in minor use and emergency exemption applications are a special case and while this may (as is the case for current permit applications) be considered confidential commercial information, it will not qualify for data protection.**

107. Recommendation

The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products.

- **Equivalent protection periods should be provided for pesticides and veterinary medicines.**
- **The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review).**
- **These periods should only be extended as an incentive to bringing priority uses to Australia, as per the measure in the Bill currently before parliament.**

108. Recommendation

The Panel recommends that the periods of limitation on the regulator's use of information should be:

- **10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent.**
- **5 years for information:**
  - **relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption**
  - **provided in support of a chemical review**
  - **which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria**

109. Recommendation

The Panel recommends that if there is a public interest reason for the regulator to use information, then the regulator should be able to use that information irrespective of whether it would otherwise be subject to protection.

- **For example, information about a product that is unfavourable (does not support continued registration of a product or use) should not be treated as protected.**

110. Recommendation

The Panel recommends that the Commissioner be tasked with ensuring that any intellectual property protection measures for the new scheme to supply internationally

registered products under licence align with the other recommendations (including consistency with international obligations), in consultation with industry.

111. Recommendation

The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a private negotiation matter between companies.

6 Contributing to supply chain resilience

Disruptions can, and do occur, in all global supply chains, regardless of the size of the market or the nature of the goods and services provided. These disruptions can be immediate and far reaching. In Australia we are well aware of the severity of impacts of natural disasters such as cyclones, drought, bushfires and floods. Cyclone Yasi in 2011 caused an estimated $300 million loss in banana crops, resulting in a rise of over 400% in the price of bananas in the following 12 months and a 60% increase in fruit prices in the Consumer Price Index compared to the previous year (ABS 2017). However, such disruptions do not need to occur locally in order to significantly impact a nation's economy and day-to-day living. For example, the 2011 Tōhoku earthquake and tsunami in Japan caused rapid supply chain disruptions to manufacturing sites that resulted in the temporary closure of motor factories in the United States of America (Lohr 2011).

The COVID-19 pandemic has led to supply chain disruptions of unprecedented magnitude, testing the resilience of global supply and logistics arrangements for many essential products. Within Australia, supplies of some pesticides came close to critical levels and for some time, farming groups were seriously concerned. While the challenges were ultimately successfully handled, the vulnerability of pesticide chemical supply chains in particular, was clearly demonstrated.

While the pesticides and veterinary medicines regulatory system cannot, of itself, prevent such disruptions, it is important that the system does not create unnecessary barriers to supply continuity and improves resilience where possible.

> *"The COVID-19 pandemic has highlighted that any potential impediments to the crop protection product supply chain have the potential to significantly impact Australia's food security and should be mitigated."* (CropLife Australia 2020)

The Panel contemplated the feasibility of mitigating the risks associated with disruption of chemical supply chains by means of somehow facilitating stockpiling. However, considering the logistical issues associated with storing, transporting and potentially disposing of large volumes of chemicals, as well as the need for refrigeration (in some instances), work health and safety, and environmental controls the Panel concluded that any type of stockpiling system in Australia was not feasible. Imports currently account for 52% of the Australian market for pesticides and for 11% of veterinary medicines (IBISWorld Australia 2020 and 2020a). Even for a very targeted strategy the volume and diversity of pesticides and veterinary medicines that would need to be stored and the associated logistics and costs make this option non-viable.

However, the Panel considers that other opportunities exist to contribute to improving supply chain resilience, building national capacity, and supporting continuity of supply during periods of disruption.

The Panel recognises the flexible approaches that the APVMA recently employed to meet the supply challenges experienced in the COVID-19 pandemic, such as providing for different

formulations, were valuable for maintaining supply. The Panel considers flexibility of this nature should be built into the future regulatory system.

In light of this, the Panel has examined opportunities for improving access to active constituents, removing unnecessary regulatory barriers, providing flexibility for sourcing active constituents and increasing competition by encouraging new sources of active constituents. Collectively, these measures will improve the resilience of chemical supply in the face of potential disruptions.

In addition, the Panel has developed proposals for alternative approaches to registration that take advantage of comparable international registration processes to facilitate access to products that would otherwise not be available in Australia via the registration pathway, while ensuring products supplied through these alternative approaches are safe for people, animals, and ecosystems (see Chapter 5).

The Panel has also recommended adoption of international standards, such as those for manufacture of veterinary medicines. Such standards can reduce costs, increase opportunities for Australian manufacturers to access international markets, and importantly, allow them to respond quickly to domestic needs where a disruption occurs to an established supply chain overseas.

Finally, the Panel sees opportunities to better support entry to the market, by pre-application third-party assessment, which would also expand the skills base in Australia for assessments beyond the APVMA. This will not only build resilience throughout the regulatory system due to a broader pool of skilled assessors, but also the supply chain. A larger pool of assessors will make it possible to assemble high quality applications more efficiently (i.e., exemption, licence, registration) to meet the demands of the supply chain and reduce time to market.

6.1 Sourcing active constituents

The pesticides and veterinary medicines regulatory system requires that the active constituents in the products are approved, in addition to the products themselves being registered. Currently, it is a requirement that sites of manufacture are approved for both active constituents and pesticide and veterinary medicine products supplied in Australia.

Manufacturers of chemical products often source active constituents from a number of external suppliers and, as a result, registration holders will often have multiple active constituent approvals associated with a single product registration. In addition, once the market is open to generic products, different manufacturers and registrants may use the same active constituent suppliers, which can result in multiple approvals for the same active constituent from the same site of manufacture.

> *"The requirement for a separate approval of the active is costly, delays assessment of the product itself, and unnecessarily absorbs APVMA resources. It does nothing to improve the quality, safety and efficacy of the finished product."* (Veterinary Manufacturers and Distributors Association 2020)

Modern global supply arrangements are flexible and 'just in time' production and diversification of supply sources are common business practices. The legislative requirements constraining site of manufacture instead reflect a time when the same manufacturer frequently produced both the

product and the associated active constituent. The continued existence of these requirements is an example of how the regulatory system has not adapted to changes in the operational environment and leaves product manufacturers constrained in their ability and agility to respond quickly to changes in active constituent supply or price.

What changes are recommended?

The focus of the regulatory system should be on safe and consistent active constituent manufacture. Considering and approving active constituents at a 'substance level' will allow for sourcing from any site of manufacture that can meet the approved standards, including the impurity profile. This approach will avoid unnecessary regulatory barriers that result in multiple approvals for the same active constituent, especially from the same site of manufacture. Providing flexibility of active constituents sources for manufacturers of pesticides and veterinary medicines will improve the resilience of chemical supply in the face of potential disruptions and incentivise competition by encouraging new sources of active constituents.

A reliance on a standard over specific consideration of a site of active constituent manufacture is provided for currently within Agvet Code (but used infrequently by both industry and the APVMA) and is adopted internationally. The latter most frequently for active constituents for veterinary medicines where pharmacopeia are routinely listed as the source of standards.

The obligation on the product manufacturer and registrant to ensure the quality and safety of the active constituents in registered products is also consistent with the Panel's preference to adopt a co-regulatory approach using General Product Obligations (see Chapter 4)

112. Recommendation

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture.

When approving an active constituent, the APVMA would establish a minimum compositional standard including expected (and if necessary, prohibited) impurities. The standard may also set out other specifications as needed or specify compositional requirements (such as for some biological based active constituents). An active constituent in a registered product consistent with the standard could then be authorised, without the need for a further separate approval.

The relevant standards would be developed on the basis of an application for a new active constituent, or by relying on an applicable reference such as an internationally recognised pharmacopoeial standard. This will ensure that the active constituents used in pesticides and veterinary medicines are of suitable quality and continue to protect safety, animal welfare, and trade. A data protection period would prevent the unauthorised use of a standard for a new active constituent.

An applicant or registration holder may wish to use an active constituent that does not comply with the standard; for example, due to differences in impurity profiles arising from different manufacturing processes. In such cases, a new standard could be developed, or the existing standard amended for the active constituent, on application to the APVMA.

113. Recommendation

The Panel recommends that the APVMA establish a standard for each active constituent prior to its inclusion in products. The Panel expects that in establishing standards for

active constituents due regard is given to matters of commercial confidentiality and intellectual property protection.

Registrants would also be required to retain relevant information, including information that verifies compliance with the relevant standard for the source of active constituent in differently manufactured batches of products. This will support the APVMA to take proportionate compliance action where necessary to ensure the quality of active constituents used in pesticides and veterinary medicines to protect safety, animal welfare and trade.

114. Recommendation

The Panel recommends that the APVMA apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard.

Cost of reform

The Panel's recommendation for active constituents to be approved at a substance level, independent of the site of manufacture, is expected to save industry in the vicinity of $4 million per annum by removing the need for data generation and application fees and delay costs.

Reliance on established and agreed standards for active constituents will support the APVMA's current level of rigor while allowing an anticipated saving to industry. The Panel's recommendation would reduce product manufacturers regulatory costs by approximately $4 million a year (or $40 million over 10 years).

Assumptions relating to the development of the costing for this recommendation are outlined in Annex 4.

6.2 International alignment of veterinary manufacturing standards

The majority of manufacturing sites for veterinary medicines supplied in Australia, either domestically produced or imported, must meet specified manufacturing standards to demonstrate consistency in product quality. This ensures veterinary medicines supplied in Australia are safe, reliable and effective for their intended purposes.

Currently, most domestically manufactured veterinary medicines must meet the requirements described in the Australian Code of Good Manufacturing Practice (cGMP) administered by the APVMA. Internationally manufactured veterinary medicines must also meet a manufacturing standard and for many countries this is the Pharmaceutical Inspection Cooperation Scheme (PIC/S). This is a non-binding international co-operative arrangement between regulatory authorities on accepted standards for good manufacturing practice for medicinal products for human or veterinary use. PIC/S is the standard applied by 53 authorities globally, including in Europe, Africa, America, and Asia.

At the time of its inception in 2007, Australia's cGMP met international PIC/S standards (APVMA 2007). However, as PIC/S has evolved, cGMP has not kept pace and therefore no longer aligns with all elements of the international standards. Most crucially, PIC/S requires a first party auditing system (that is, auditors must be government officials) whereas cGMP relies on third party auditors (companies engage an auditor from a list of APVMA-approved commercial

auditors). The Panel is aware that the APVMA has recently announced a review into the cGMP with involvement from the Manufacturers' Licensing Scheme Industry Liaison Committee commencing in 2021.

In order to export Australian-made veterinary medicines to most key Australian markets, manufacturers need to either comply with international manufacturing standards (such as PIC/S) or be subject to quality testing at the point of importation (adding costs and delays to Australian manufactured material). Despite cGMP being recognised by some countries, it is not recognised by key Australian export markets including Canada and the European Union (EU). To export to such markets, Australian manufacturers can currently seek a PIC/S level audit, however, this must be undertaken by the only PIC/S accredited agency in Australia – the Therapeutic Goods Administration (TGA). Despite encouragement from Australian industry over many years, the APVMA has not sought accreditation to carry out such audits.

> *"For the APVMA to genuinely be considered as a world-class regulator, it must make every effort to 'grow into that space' by demonstrating an effort to support our own industry and defending the quality of our manufacturing and regulatory system. Examples include gaining recognition of our quality systems by others such as the EU, USA, and Canada."* (Veterinary Manufacturers and Distributors Association 2020)

Some stakeholders have stated that the TGA audit costs are excessively high and assessment wait times are unreasonably long as the TGA generally prioritises audits of human therapeutic manufacturing sites above veterinary medicine manufacturers (as this aligns more closely with the TGA's core business).

> *"The APVMA insists on using third party auditors who are not in our opinion suitable nor qualified to approve products for export to Europe, Canada, USA or Japan… Our last TGA audit cost us over $70,000 but their closed-off audit cannot go to the European regulator and we have to negotiate with the APVMA and get it passed on, which can take us over our renewal date in the EU. This is bureaucracy gone crazy."* (Jurox Pty Ltd 2020)

Stakeholders have also indicated that it is unclear to which standard, i.e., veterinary or human pharmaceutical standard, the TGA conducts its veterinary medicine manufacturing site audits. It was suggested during consultation by some veterinary medicine manufacturers that they experience difficulties in meeting the TGA's audit requirements under PIC/S as, in their view, they are geared towards the manufacture of human pharmaceutical products rather than veterinary medicines manufacture.

A review commissioned by the APVMA in 2017 recommended a strategy to transition to a full PIC/S model, with an immediate adoption of second party audits (that is, audits undertaken by both an APVMA auditor and an approved private sector auditor), followed by a transition to a first party model to be in place within 5 years. However, the Panel understands that this recommendation had mixed support by industry at that time, and implementation by the APVMA eventually lapsed.

Looking ahead over the Panel's 30-year view for the future regulatory system, there is a fundamental policy question about whether Australia, as a relatively small economy, should

continue to maintain a separate approach to veterinary medicine manufacturing standards that is different from international best practice and alienates significant export markets.

The argument in favour of a separate approach, for Australian-based manufacturers for the domestic market versus export markets, is that domestic market focused manufacturers will initially incur additional costs to comply with international export standards. Whilst acknowledged, the Panel does not consider this cost in itself a sufficiently strong barrier to justify not aligning with the requirements of our key export markets. In addition, the Panel is concerned about the ability for Australia to have an effective voice and influence in future international discussions on veterinary manufacturing standards if it fails to follow a recognised standard that has been adopted by almost all of its major competitors.

The Panel considers the current situation clearly requires regulatory reform. Two standards apply in Australia where only one is necessary. Some manufacturers are required to deal with 2 Australian regulators, rather than one. Maintaining a 'unique to Australia' GMP standard discourages local manufacturers from considering export opportunities. Where an Australian manufacturer does seek to look beyond the local market, it currently encounters time and cost penalties in arranging the necessary audit. In short, while the cGMP may have been satisfactory in years past, the Panel considers movement to PIC/S not only inevitable, but desirable, for the 30-year timeframe ahead.

What change is recommended?

A modern and sophisticated regulatory system addressing veterinary medicine manufacturing must align with international best practice. The Panel strongly recommends that the APVMA becomes PIC/S accredited and that veterinary medicine manufacturers progress towards PIC/S level accreditation over a maximum 5-year time period. This approach is consistent with the view of some stakeholders that it is inevitable that Australian manufacturing will need to achieve this level of accreditation in the future.

Accrediting the APVMA to undertake PIC/S level audits would ultimately yield a significant reduction in time and cost for Australian exporting manufacturers, would remove the need for industry to deal with multiple regulators and would remove market access barriers to key export markets (e.g., the European Union and Canada), affording new opportunities for Australian manufacturers. Moving to a system of direct government audit for domestic manufacturers of veterinary medicines will also enhance public and market confidence in the standards met by domestic veterinary medicine manufacturers.

The Panel acknowledges this recommendation presents an increase in APVMA workload initially. However, in the medium to long term it will generate efficiency and capability within the APVMA, align with international best practice, and free up resources from the TGA to undertake its principal functions. There will also be improved oversight of domestic manufacturing standards through the first party audit system mandated by PIC/S.

115. Recommendation

The Panel recommends the APVMA becomes PIC/S accredited.

For the APVMA, moving from a third party to a first party model required by PIC/S represents a fundamental change to the way veterinary medicines are managed in Australia. The Panel considers it important that guidance material is developed to support industry understanding of

the differences between these systems and to provide industry with a streamlined transition from cGMP to PIC/S.

116. Recommendation

The Panel recommends the APVMA develop guidance material through engagement with industry to support a streamlined transition from cGMP to PIC/S.

The Panel considers that PIC/S requirements for veterinary medicine manufacturers should be introduced over a maximum 5-year timeframe to allow domestic veterinary medicine manufacturers sufficient time to adjust. The Panel understands that for some stakeholders this may constitute a greater burden (especially for currently non-export businesses) than for others who have been increasing their own standards in anticipation of a future move by the APVMA towards a closer alignment of PIC/S. In the intervening period, all Australian veterinary medicine manufacturing sites would continue to meet controls under the cGMP.

117. Recommendation

The Panel recommends both export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.

The Panel considers this proposal will deliver a workable and practical solution that ensures continued production of high-quality veterinary medicines while maintaining the viability of Australia's local manufacturing industry. The Panel would be concerned if implementation action lapsed again, as occurred on the last occasion when a similar recommendation was put forward.

Cost of reform

The Panels' recommendation to require all manufacturers to comply with standards equivalent to PIC/S will incur costs to the veterinary medicines manufacturing industry (estimated at $16.1 million over 5 years). The Panel intention of highlighting the reform in advance of a full transition is intended to allow industry to adopt PIC/S at a manageable rate.

The Panel anticipates that a fully cost recovered PIC/S scheme managed by the APVMA will have similar operational costs to that of the APVMA current cGMP scheme. . These costs, consistent with the current approach from APVMA will be recovered from veterinary manufacturers directly (as licence fees, audit fees or component of the levy).

The total costs over 10 years is estimated at $16.1 million. The Panel considers there is significant offsetting potential for benefit to Australian manufacturers of veterinary medicines through improved access to export markets, however this has not been calculated for this report.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

6.3 Building assessment capacity beyond the APVMA

The assessment of pesticides and veterinary medicines can be complex and lengthy, with some taking well over a year to complete. Assessments must consider a wide range of scientific data and other information to ensure that the product, when used in accordance with the label directions, is safe and does not unduly prejudice trade.

The APVMA has historically undertaken the majority of assessment activities in-house, but currently outsources some work to third-party assessors who are experts in the fields of toxicology, ecotoxicology, efficacy assessment and target animal and crop safety assessments. These contracted experts assess data packages lodged with an application to the APVMA, but the final decision on registration remains with the APVMA.

Although the APVMA contracts external assessors, applicants do not have the opportunity to have their data assessed by independent third-party assessors prior to submission of their application to the APVMA (apart from a now-defunct pilot trial of efficacy (APVMA 2016) and target crop and animal safety assessments), resulting in the APVMA having complete control over the level of service provided. While the Panel heard repeatedly about the diligence and professionalism of the APVMA's staff in providing assessment services, this dominant position neither incentivises efficiency nor encourages innovation by the APVMA. In addition, there are risks for the effectiveness and resilience of the regulatory process where there is such reliance on a small number of assessors with these highly specialised skills sets.

Building national capacity in assessment expertise beyond the APVMA will enable the agency, industry and the broader community to have access to a more extensive pool of expertise and resources than currently exists, including when vacancies may arise within the APVMA, when a chemical company wishes to confirm its data package prior to submission or even when independent comment is needed.

The centralisation of suitable assessment skills and resources has resulted in Australia's limited chemical data assessment skill-base being concentrated within a single organisation. The decision to internalise environmental and health assessments, which the APVMA previously outsourced to the Environment and Health Departments, has further concentrated these skills, leading to additional reductions in national chemical assessment capacity.

The Panel's proposal to extend the network of assessors beyond the APVMA as a means to build national capacity received mixed response from stakeholders. Stakeholders that were in support of an Australian third-party accredited assessor scheme include Australian Groundsprayers Association, CropLife Australia, Syngenta Australia, RSPCA and the Veterinary Manufacturers and Distributors Association, Ceva Animal Health, Grain Producers Australia, National Farmers' Federation and the Swimming Pool and Spa Association Australia.

> *"Ceva supports a third-party accredited accessor scheme. The current NZ MPI uses third-party assessors and this system works very well. There are many experts in Australia who do not work at the APVMA and whose skill and expertise could be utilised in this area."* (CEVA Animal Health 2020)

> *"The Panel's view that increased use of third-party assessors may contribute to building national capacity for regulatory science skills and expertise is supported. CropLife has long advocated for this approach, which would enable the APVMA to formally recognise third-party scientific assessors, as outlined in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018."* (CropLife Australia 2020)

However, some stakeholders including Growcom and Horticulture Innovation Australia had reservations about the private sector performing assessment work.

> *"Growcom does not support third party assessment work. With the exception of efficacy we suspect that there are very few qualified experts who could carry out such work. We are also of the opinion that a third party assessment scheme would have the potential to reduce the capacity in the APVMA for such assessments. The technical teams in the APVMA such as the residues, chemistry and manufacture teams are so small that any reduction in throughput would have ramifications for the national capacity."* (Growcom 2020)

What change is recommended?

The Panel favours a third-party assessor scheme. The Panel considers that establishing an open and transparent pre-application third-party assessment process would expand the skills base in Australia for assessments beyond the APVMA, may lead to decreased costs for applicants, should facilitate higher quality submissions, and decrease timeframes for registration.

This has been demonstrated in New Zealand, where third-party assessors engaged by applicants typically complete data assessments for the applications they will submit to the Ministry of Primary Industries (MPI) within weeks. The scope of these assessments includes residues, efficacy, animal welfare, manufacture, and chemistry. However, the most complex assessments – toxicology and ecotoxicology – are outside the scope of the New Zealand MPI third party accredited assessor scheme (these assessments fall within the remit of the New Zealand Environmental Protection Authority and are sometimes outsourced to external assessors engaged by that agency).

The proposed approach will deliver improved outcomes by enabling a greater range of assessment service providers. This will, in the long term, expand the national pool of chemical assessment and regulatory science skills beyond the APVMA as well as providing a pathway for succession and an environment conducive to growing new opportunities and careers. It will build national capacity and thus strengthen resilience of Australia's regulatory system.

As the current pool of assessors in Australia is small, there may be an initial need to use international assessors (accredited by the APVMA), particularly while the pool in Australia expands or where highly specialised skills are not available locally. This would assist in meeting demand for capacity or specialised skills. For example, assessors in New Zealand already have the underlying skills to provide assessment services, and this pool of assessors could complement those available in Australia.

The MPI requires applications in the form of an assessment. To ensure applications are completed to a high standard, the MPI peer-reviews the third-party assessments it receives. It has a constrained statutory timeframe of 40 days in which to do this – comprising 25 days for appraisal and 15 days for decision. The charge for reviewing a third-party assessment ranges from NZD $150–$250 per hour.

The MPI peer review process is critical to ensuring the quality of assessments received. For example, it identifies information gaps and confirms whether or not assessments are consistent with required standards (including deficiencies identified by the accredited assessor that were not addressed by the applicant prior to submitting the application). Applicants are provided with the opportunity to address any deficiencies that are identified. If applicants do not address any deficiencies, the MPI rejects the application.

Similar to New Zealand, third-party accredited assessors in Australia would provide data assessment services and could also use their skills to work closely with industry stakeholders to provide guidance and assistance when preparing applications (much as regulatory affairs consultants do now).

In providing data assessment, the assessors would also advise clients on identified data gaps and alignment with required standards. These data assessment reports would form part of the application to the APVMA. It would be the responsibility of an applicant to address any deficiencies identified by the assessor.

It is important to note that the APVMA would still be the final decision maker on whether a product is registered – this proposal does not change this.

Given these considerations, the Panel supports the implementation of an accredited assessor scheme, such as that outlined in *the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018*, which lapsed when parliament was dissolved in early 2019. The Panel understands the reason this measure was not revived in the current Bill before Parliament was due to lack of support at the time from the APVMA and some parts of industry; however some industry positions appear to have since moved in favour of this model. Regardless of this history, the Panel is in favour of such a scheme based on its objective merits.

Similar to the New Zealand MPI assessor scheme, the APVMA would peer-review applications undertaken by third-party assessors to ensure their rigour and adequacy.

While the decision to implement an accredited assessor scheme would be made independently of the APVMA, the Authority would have considerable influence over its functional design. For example, the APVMA would establish the framework for assessors and specify requirements for professional experience, insurance, data handling protocols and managing conflicts of interest. Character tests, competency standards and record-keeping arrangements would also be required.

The APVMA could also determine and amend technical requirements and standards for assessment associated with conditions for accreditation. For instance, the APVMA would update the standards and guidance material to keep pace with any changes to international developments in chemical assessment. The APVMA would also be responsible for amending maximum residue limit standards where necessary.

The proposed assessor scheme would be flexible to accommodate the necessary skills sets and functions to be performed. The APVMA already holds guidance material to support its current assessment functions and this could form the basis for instructional material for the external assessor scheme. Using this will minimise the cost and administrative strain on the APVMA when establishing the scheme and ensure the APVMA is transparent about application requirements.

Similar to New Zealand, the proposed assessor scheme would require assessors to declare on a regular basis (potentially annually or with each assessment they submit) any conflicts of interest. Additional measures may include prohibiting an external service provider from assessing an application if, for example:

- they have been employed or directly contracted by the applicant in the past 5 years to undertake work in relation to the production of data, or production of an application to the APVMA
- they were involved in trials or other research and development in relation to the product being assessed
- they were involved in trials or other research and development work with another applicant who has a chemical product that is in direct competition with the product that will be assessed
- they hold shares in the applicant's company, or have any other personal financial involvement with the applicant
- they are aware of a conflict of interest between the application, including the material being assessed and any other review or research work that could adversely impact on an objective review of the material.

A failure to properly disclose a conflict of interest may result in all assessments submitted by the assessor being reviewed, with administrative action taken as necessary against the relevant products pending the outcome of the review.

The APVMA would be responsible for monitoring and overseeing these arrangements to ensure that assessment functions were performed effectively. It would also be responsible for audit and compliance activities, to help ensure quality and consistency to safeguard the integrity of the third-party assessment process.

The APVMA would be able to suspend or cancel accreditations for certain reasons, such as breaches of accreditation conditions. It is also anticipated that there would be criminal and civil sanctions prescribed for contraventions of these conditions, to ensure that accredited persons comply with their requirements.

The scheme would also provide the APVMA with the ability to charge for performing accreditation functions, consistent with cost-recovery principles (Chapter 7).

Cost of reform

The Panel considers all initial costs associated with the establishment of the accredited assessor scheme should be government funded, and that ongoing costs for operation of the scheme (estimated at $3.5 million over 10 years) would be fully recovered through application and renewal fees for assessors and not from broader industry groups.

The Panel also expects that establishing an accredited assessor scheme will have significant potential for benefit to the product manufacturing, importing, and supplying industries (as applicants to the APVMA for registrations or exemptions) by providing greater control of process timeframes. The Panel is aware this has been the experience of the well-established assessor scheme operating in New Zealand.

Assumptions surrounding the development of the costing for this recommendation are outlined in Annex 4.

118. Recommendation

The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.

119. Recommendation

The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

7 Funding of the regulatory system

7.1 Improving transparency and equity by modernising cost recovery

In simple terms, 'cost recovery' is the term for recouping a given expense. From the Australian Government's perspective, cost recovery involves charging for some, or all, of the costs of a government activity. This includes charging the non-government sector for the costs of regulation.

To date, the focus of Commonwealth cost-recovery in the regulation of pesticides and veterinary medicines has been on the operations of the APVMA. The expansion of Commonwealth regulatory activity from supply to also include control-of-use, as proposed in this report, has broader implications for cost recovery. For example, most of the costs associated with control-of-use regulation, which has been the responsibility of states and territories, do not appear to have been recovered from industry (with some exceptions such as applicator licensing). This has constrained the resources available to effectively undertake these regulatory functions.

The Panel's proposed co-regulatory approach will minimise costs to both the regulator and users. For example, greater reliance on established industry quality assurance schemes will assist with ensuring compliance, general product obligations will provide industry with flexibility to achieve the necessary regulatory outcomes, and smart labelling will allow for automated records in spray diaries. Nevertheless, the costs associated with control-of-use activities should not be under-estimated and functions in future will need to be resourced to ensure the continued sustainability and integrity of the regulatory system. The mechanism to make these resources available will, therefore, need to be identified.

Some of the reforms proposed by the Panel, such as introducing licences to supply internationally registered products, will significantly reduce the costs of bringing new products into the Australian market. Other measures on the other hand, such as improvements in whole-of-system surveillance will need to be funded as they comprise necessary new activities as well as existing activities that have not been adequately resourced to date.

The APVMA's cost recovery framework was established in 1996, with only modest adjustments to its basic elements since that time. Despite several reviews, attempts to fundamentally change the cost structure have been largely unsuccessful. In large part, this is because of strongly competing stakeholder views about a preferred cost recovery model.

Importantly, the APVMA's cost recovery arrangements, as currently structured, have not been sustainable. Since 2013, the Authority has run operating losses averaging $2.5 million annually which has led to the drawing down of reserves.

The Panel considers this first principles review of the regulatory system in more than 3 decades needs to find solutions to both the quantum and distribution of funding for the national regulator. In the Panel's view, reforming cost recovery arrangements is a critical requirement if the total reform package for the future regulatory system as a whole is to be implemented successfully.

The Australian Government Charging Framework is the whole-of-government policy that relates to cost recovery. It states that where an individual or organisation creates the demand for a government activity then it should generally be charged for the efficient costs of delivering that activity.

- Fees should be charged where direct costs of a service can be reasonably attributed to the recipient of that service.
- Levies should be used where the costs of an activity are attributable to a group or sector but are not attributable to a specific user – for example, the broad costs for operating compliance, monitoring and enforcement functions.
  - Levies may be tied to a metric such as sales value or volume if the costs for relevant regulatory activities increase in some proportion to the metric; otherwise 'flat' levies (i.e., fixed charges) may be more appropriate.
  - Levies can be targeted if costs can be ascribed to a distinct subset of users (for example, if different classes of products attract different compliance costs as the result of their risk profiles).

Historically, for regulatory activities undertaken by the APVMA, the principle that the costs of an activity should be recovered from those who use or create the need for the activity has been balanced against the policy objective of supporting access to pesticides and veterinary medicines. Although these arrangements pre-date the government's charging framework, the framework does provide for this type of 'deviation' from its core principles if there is a sound policy reason to do so. Previous efforts to bring the arrangements closer into line with the core principles of the Government's Charging Framework have been unsuccessful.

Issues with current funding arrangements

APVMA cost recovery arrangements

The majority of the APVMA's registration application fees are set at levels that recover no more than 40% of its average cost for assessing each class of application. For some other assessment functions (such as minor and emergency use permits), the APVMA charges only a nominal fee.

The Panel has been advised that this fee discount was intended to reduce the barrier to market entry for products, avoid an excessive cost burden on applicants, and incentivise the registration of innovative products. Thus, setting fees to recover 40% of the average cost of the associated service was deliberately intended to 'distort' the market to achieve a policy outcome.

This approach assumes that the 60% fee reduction is an efficient and effective incentive to promote the registration of desirable products. However, there is no robust evidence as to how well, if at all, this untargeted discount has supported the policy goals. Indeed, while innovation takes many forms – including new uses and combinations of established chemicals – the most innovative products are typically introduced by large multinational companies. Fee discounts are less relevant to these large innovators as they are well placed to meet initial registration costs and can offset the cost of new product development across multiple markets.

Nevertheless, it is true that smaller innovators do exist, and may face significant barriers if the full cost of registration were to be recovered at the time of making an application. The number of these smaller innovators is likely to increase as advances in technology become more widely

available, the focus on biological products increases, and as regulatory barriers to market entry are reduced in line with the Panel's proposed reforms.

In addition, application fees are usually only set according to the 'average' volume of work, and hence the average cost, of a particular activity. A similar approach is taken for setting the fees for the current 'modular' application system, which allows the cost and effort of individual assessment components to be more closely tailored to the assessment requirements of an individual application. However, while the 'granularity' of modular applications allows fees to be more reflective of the actual costs of assessment, a degree of imprecision remains. This is because the fees for individual modules are again based on an estimated average cost of the associated work.

However, the key issue with the APVMA's cost recovery arrangements is the 'shortfall' arising from fee collection. At least 60% of the APVMA's average costs for assessing most applications is recovered through wider levies on industry – both a sales-based levy and a flat registration renewal fee (which, although called a fee, funds some activities that would ordinarily be funded through a levy). This leads to a high degree of cross-subsidisation across industry, as the balance of the APVMA's costs for providing a service to an individual or organisation are recovered from the whole industry, including from competitors of those receiving the service.

- The cross-subsidy is exacerbated by the fact that some registrations that benefit from the application fee reduction do not attract sufficient sales levies to ever 'repay' the subsidy. For example, each year approximately one-third of registered products make no sales and so do not contribute to the sales levy. These registered products include 'shelf' products, which the holder never intends to market; for example, because the Australian registration supports access to one or more overseas markets, or to create a 'reference' registration that can be used as a basis for registering multiple generic products.
- Major chemical companies – and, in particular, developers of new chemicals – have opposed this cross-subsidisation. These tend to be larger companies with high product sales that attract substantial levy liabilities. Levy revenue collected from these companies effectively subsidises smaller competitor companies, many of whom produce generic copies of chemistries introduced by the larger companies.

Levies are also used to fund those system wide APVMA activities that are not easily attributable to a particular individual or organisation such as:

- the adverse experience and reporting system
- chemical reviews
- general investigation, compliance, and enforcement activities
- international engagement; for example, with the Codex Alimentarius Commission.

In summary, the Panel is concerned that the current arrangements:

- do not conform to the sound principles of the Australian Government Charging Framework
- result in a misalignment of the real costs of providing services, and corresponding charges
- distort the market as a result of extensive cross-subsidisation among chemical suppliers

- are unsustainable in the sense that the APVMA has regularly run at a loss and may, in the future, run out of options to remain financially viable
- do not enable the adequate allocation of sufficient resources needed for monitoring and compliance.

At the same time, the Panel is keen to ensure that future charging arrangements continue to encourage innovation and access to chemistries, and do not discourage the availability of generic products, which are typically cheaper for farmers and other users.

The current APVMA levy

The APVMA's sales levy applies a proportionate metric and is 'uncapped'. That is, the levy liability associated with a registered product increases in proportion to the value of domestic sales of that product. However, the costs of regulating a product do not always increase with sales value. For example, products with higher sales may have a higher level of adverse experience events because they are used more frequently; in this instance, a proportional metric may be more suitable to recover the costs of adverse experience reporting. However, the costs of providing other regulatory functions, such as operating a chemical review scheme, are largely independent of the value of a product's sales. As such, the linkage between sales value and levy liability is not easy to justify for this activity.

By applying the levy in regressive tiers (i.e., sales below $1 million are charged at a rate of 0.63%; those from $1 million to below $5 million at 0.35%; and those from $5 million at 0.25%), the Government has acknowledged, at least in part, that the link between sales and regulatory costs is not linear. However, it is not clear to the Panel from any available evidence that the current arrangements closely approximate the costs of efficient regulation on a product-by-product basis (which is how the levy is calculated). Rather, it appears to reflect an argument that companies with higher sales can more readily afford contributions to maintain the overall regulatory system; much like progressive personal income tax.

Through the consultation process there were mixed responses about current funding arrangements:

> *"The regulator [the APVMA] and the community have an expectation that technology advances will result in less chemical used. Charging a levy on sales appears to be contrary to this goal. Charging an hourly rate appropriate to the work being undertaken would be a transparent system."* (Agrifutures 2020)

> *"Levy based funding models do little to deliver efficiency. Reform of the cost recovery model to establish the principle that the beneficiary pays will be a crucial element of the current reform process."* (Chemistry Australia 2020)

> *"The cost must not fall entirely on risk creators but instead be funded with appropriate contribution from general revenue."* (Australian Grape and Wine 2020)

Some stakeholders maintain that the historical costs recovered by the APVMA have been excessive and do not reflect the 'efficient' cost of the regulatory effort, although no evidence was provided to the Panel to substantiate this claim. Some stakeholders also argue that many core regulatory functions, including compliance and enforcement, adverse experience reporting, and

chemical review serve a 'public good' and so should be funded through taxpayer funded appropriations.

> *"It is crucial that the APVMA has all necessary powers and ensures that its compliance and enforcement efforts remain focused on the highest threat and risk areas to the community and farming sector. As both the APVMA's and state and territory compliance and enforcement capabilities perform a public benefit function, CropLife Australia recommends it be funded through general revenue."* (CropLife Australia 2020)

> *"We see national initiatives to strengthen the regulator's compliance and enforcement activities as primarily a public benefit which might be funded by Government. Publicly funding monitoring, compliance and enforcement activities will … help to match the size and scope of compliance and enforcement activities to the risks involved."* (Syngenta Australia 2020)

Despite submissions from certain stakeholders, the Panel does not see a strong case for taxpayer funding of these functions. In the Panel's view, most functions argued to be 'public good' are in fact needed as a consequence of the existence and operation of the pesticides and veterinary medicines industry and therefore costs should be recovered from them.

Control-of-use cost considerations

There is little publicly available information about funding for control-of-use activities. However, many stakeholders argued that state and territory resourcing and therefore effort, had declined significantly over the years; some state government representatives echoed this sentiment.

> *"It is likely that competing priorities and resource constraints by all jurisdictions have limited the progression of reforms by HACCUT. … Resources constraints have also impacted funding for policy research and impact analysis."* (Victorian Department of Jobs, Precincts and Regions 2020)

> *"The key current deficiencies that need addressing as soon as possible are … sufficient resources in all jurisdiction to provide effective monitoring of compliance and enforcement if required."* (Grain Growers 2020)

It appears that the control-of-use functions undertaken by the jurisdictions are largely funded through government appropriation, with the costs of only some activities (such as licences) recovered from industry. The Panel is of the view that this reliance on government funding has likely led to diminished resources for control-of-use activities including compliance and monitoring as departmental budgets are reduced and resources reallocated to regulatory activities deemed to be of greater priority.

What change is recommended?

The Panel recognises that the pesticides and veterinary medicines regulatory system is, and will continue to be, complex, with many different functions that will need to be funded. A range of funding mechanisms will therefore be necessary, depending on, and tailored to, the nature of, and risks associated with, activities needed across the whole supply chain.

The Panel considers that the current levels of cross-subsidisation in the supply side distort the market, skew decision-making, are inequitable, and are not consistent with the principle that

where specific demand for an activity is created by identifiable individuals or groups, they should usually be charged for it.

The manner in which cost-recovery arrangements are applied – for example, using levy revenue to subsidise fees – changes the incentives for pesticide and veterinary medicine suppliers to enter the market. This, therefore, has the potential to affect users' access to these substances. Accordingly, the Panel recognises that there are circumstances where a departure from the 'user pays' principle is warranted. However, the Panel is determined to avoid repeating past failures to significantly reform cost recovery arrangements and takes the view that such departures should only apply where there is a strong, clearly identified policy driver. To that end, the Panel has identified a limited set of circumstances in which such a departure may be warranted, which are outlined later in this section.

Given that regulatory costs will not be understood with any certainty until decisions about this review's recommendations are taken, the Panel has determined it can only establish high-level, principles-based recommendations about how to fund various components of the system. The following describes the features of the Panel's preferred cost recovery model.

120. Recommendation

The Panel recommends that in most circumstances the pesticides and veterinary medicines industry should bear the full and reasonable costs of the regulatory functions under the new regulatory scheme.

Cost recovery model

Activities recovered by fees should include, for example, assessments for product registration, licensing of activities, audits undertaken by Government auditors, and accreditation of third-party assessors. Such activities are clearly attributed to the demands of individuals or organisations. Some activities, such as assessment of minor use exemptions, should be recovered by a subsidised fee, supplemented by a component of the sales levy to ensure continued access to minor uses.

A levy on sales should continue, albeit at a reduced level. It should be used to recover 100% of the costs of activities such as chemical reviews, adverse experience reporting and investigation, emergency exemptions, and general compliance and enforcement of supply and control-of-use of pesticides and veterinary medicines. Such activities are generalised, and not easy to attribute to individuals.

The Panel considers a strictly minimum set of activities undertaken by the Commissioner of Pesticides and Veterinary Medicines (the Commissioner), such as policy development, international engagement, support to government, operating consultation forums, and overall system surveillance and monitoring should be publicly funded if agreed by government. Additionally, the Panel considers that the initial establishment costs for functions such as the third-party accredited assessor scheme should be publicly funded to ensure they are successfully introduced into the future regulatory scheme.

Levy principles

While the final implementation details of the levy will need to be developed in consultation with stakeholders, the Panel considers that the following principles should be applied.

The levy should apply to products introduced via both the registration and licensing pathways, to recover relevant costs associated with each of these; for example, the costs associated with control-of-use. Where consistent with providing access, the levy may also apply to products supplied solely via an exemption; in which case the Australian supplier would incur the levy liability. For example, while many minor use permits are held by industry organisations or rural research and development corporations to fill an access gap, some are issued to commercial product suppliers on the basis that the costs of registration are prohibitive. These suppliers derive commercial benefit from the regulatory system and, while they avoid the costs of registration, it is appropriate that they should contribute (through the levy) to the regulatory costs associated with supply of their products.

The levy would be divided into components relating to the costs incurred for undertaking different activities. Splitting the levy into components will reduce cross-subsidisation, although a balance must be maintained to ensure that the levy system doesn't become overly complex and difficult to administer. Each component of the levy will only be charged to those that receive a particular service. For example, if a quality assurance program was introduced for pesticides that involved targeted compliance and enforcement costs that were recovered via a levy, then only pesticides manufacturers, not veterinary medicines manufacturers, should incur a levy liability for that activity.

Where the regulatory effort for an activity broadly reflects the amount or value of chemicals sold in Australia, then that component of the levy should be recovered based on the quantity or value of product sales. Otherwise, the levy component should (ideally) take the form of a flat charge. However, the Panel recognises that a flat levy component can impede availability of important 'niche' products and so this principle will need to be tempered; for example, by applying a discount or an 'affordable' base flat charge plus a percentage charge on sales value or volume.

Where a component of a levy is linked to sales, then depending on the relationship between the cost of providing the function and the quantum of product sold, there should be scope to apply tiers, as is currently the case with the APVMA levy. Similarly, if the costs to provide the function associated with a component of the levy does not continue to rise substantially with sales beyond a certain point, then that component of the levy should be capped.

A single levy notice would be issued to cover the costs of relevant activities of both the APVMA and the Commissioner (which will require coordination between the 2 entities). The Panel also proposes that levy notices include a detailed breakdown of levy components to improve transparency and drive regulatory efficiency.

121. Recommendation

The Panel recommends that the existing levy on product sales be continued but at a reduced rate.

122. Recommendation

The Panel recommends that the levy be divided into components relating to the costs incurred for undertaking different activities to minimise cross-subsidisation, with each component of the levy being charged only to those that receive the particular service.

123. Recommendation

The Panel recommends that where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.

Fee principles (application assessments, licences, audits, accreditation, advice requests)
Most regulatory functions that would attract fees in the future regulatory scheme relate to assessments of one type or another, for example, assessing applications for product registration, licences for various activities, exemptions, and third-party accreditations. Audit services provided by the Government are the other major category of services that would attract a fee (such as the proposed audits of manufacturing sites for veterinary medicines needed for PIC/S accreditation). Most others, such as issuing import or export certificates and records searches, are relatively minor activities.

As these activities are attributable to an entity, 100% of their costs should, in most circumstances, be recovered directly from those entities through an assessment fee. While this would minimise market distortion, the Panel is acutely aware that it would significantly increase upfront assessment costs for some applicants. Nevertheless, on current information, assessment fees would still be competitive relative to comparable international regulators. In addition, a number of the Panel's other efficiency proposals should reduce the regulatory effort and cost needed for such assessments; for example, by refocusing the scope of products regulated (see Chapter 5), introducing an accredited assessor scheme (Chapter 6), and especially the proposal to introduce internationally registered products under licence (see Chapter 5).

The Panel recommends that where the amount of work involved in providing a service is highly variable, such as assessing an application for registration, fees should be charged on an hourly basis. Hourly charging will ensure fees reflect true costs, eliminate cross subsidisation, incentivise efficiency by the regulator, and encourage and reward quality applications since these applications will be the most efficient to assess. A scale of rates should apply depending on the service (e.g., administrative vs technical services). An itemised estimate should be provided by the regulator when an application is lodged.

The experience in New Zealand, where hourly charging has been successfully in place for a number of years (along with an external assessor program), has been positive. The Panel considers that this should also be the case in Australia.

Some stakeholders may be concerned that the open-ended nature of this charging arrangement would provide little incentive for the regulator to complete assessments within minimum timelines and cost. The Panel is of the view that the use of accredited third party assessors to improve application quality, a transparent process for providing cost estimates at the time of application lodgement, and pressure from applicants to minimise the charges accrued during an assessment, will ensure costs are kept to an efficient minimum.

124. Recommendation

The Panel recommends that hourly charging should be introduced for activities where regulatory costs are highly variable, while flat fees should be charged where there is little variation.

125. Recommendation

The Panel recommends that the costs for applications for registration be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis.

126. Recommendation

The Panel recommends that where Government audits are routine and predictable the costs of this service should be incorporated into the fees for the parent program for example, via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.

Conversely, where the cost of providing a regulatory service is relatively consistent, then a fixed fee per service should be charged. The predictability of this approach is conductive to improved planning by both the applicant and the regulator.

As these initial application fees could present a barrier to smaller, innovative companies, the regulator should make available mechanisms such as payment plans that allow more significant fees to be paid over time. This would allow the initial sales of a registered product to be realised before the full assessment costs are borne. As this would create some additional administrative complexity for the regulator, some fee adjustment might be required to cover any additional costs.

127. Recommendation

The Panel recommends that mechanisms be developed to allow more significant fees to be paid over time, such as through payment plans.

Elsewhere in this report, the Panel is recommending various licensing schemes, for control-of-use, and licensing to supply internationally registered products to the Australian market. The Panel recommends recovery of 100% of the costs for issuing and maintaining various licences, including all scheduled audit costs and the costs of renewing licences, through fees.

128. Recommendation

The Panel recommends 100% recovery of the costs of issuing and maintaining licences (both for supply side and use activities), including scheduled audits with predictable costs, via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

Accrediting third-party assessors (including renewals of accreditation) will impose an additional cost on the APVMA. The Panel considers that, the costs of accreditations (including any renewal costs) should be recovered from the parties applying for accreditation since this accreditation is required to allow them to provide their services in the marketplace.

129. Recommendation

The Panel recommends that the assessment of applications for accreditation, together with costs to maintain this accreditation, should be 100% recovered from the accredited parties.

While the costs of formal assistance requests relating to applications (pre-application assistance) are already fully recovered through fees, this should be extended to all requests as is already the case in New Zealand. This should be underpinned by clear guidance material, to ensure that application requirements are clearly communicated without the need for unnecessary inquiries to the regulator.

The Panel recommends that full costs should be recovered for advice given by the APVMA in relation to an application, with the first hour's advice provided 'free of charge'. To offset this first hour cost to the regulator, it should be possible to build this cost into application fees as is currently done for some audits or other services in other regulatory systems (for example, the Civil Aviation Safety Authority applies a similar approach for its advice). Clear guidelines would be needed to identify which activities are chargeable, whether this be formal pre-application assistance or more informal interactions. The intention of charging is not to stop applicants seeking the advice of the regulator or clarifying matters but to encourage applicants to use their own resources (including by engaging external service providers) to ensure applications are complete and assessment-ready at the time of lodgement, instead of relying excessively on the regulator for completion of an acceptable application as is sometimes the case, currently.

130. Recommendation

The Panel recommends that full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.

Minor and emergency uses

As set out in Chapter 5, the Panel recommends that exemptions be used to provide access to pesticides and veterinary medicines for minor and emergency uses. The regulatory effort involved in assessing these applications must be funded.

Stakeholders have consistently argued that there is a strong need to maintain substantial subsidies for applications to access minor and emergency uses of pesticides and veterinary medicines.

> *"Minor use permits are a valuable tool for industry and the costs and burdens of obtaining these permits should be kept low."* (Australian Grape and Wine 2020)

> *"With few pesticides registered for use in plantation forestry, the industry relies heavily on minor use permits and supports changes that increase access to softer chemical options, including biopesticides where these could provide alternative solutions. The time and cost of data generation to support minor use permit applications can at times be prohibitive."* (Forest Pest Management Research Consortium 2020)

> *"Generally, the permit application process works well, although additional resourcing given the return on the investment should be considered … Dairy Australia supports the availability of grants to pursue minor uses which would otherwise not be funded. Any attempt at full cost recovery in this area of agvet activity would be self-defeating."* (Dairy Australia 2020)

Reasonable arguments exist for supporting access to minor and emergency use exemptions at a reduced cost where no suitable authorised product for that use is available. This is particularly the case given the importance of these products to primary production (including production of innovative and 'niche' commodities), maintaining animal welfare, protecting the environment, and managing biosecurity incursions. In addition, while the applicant for a minor or emergency use exemption will invariably be easily identifiable, the beneficiaries of the service often will not. This is because many of these exemptions will be issued to persons generally (as is the case with minor and emergency use permits under the current arrangements). Furthermore, in some instances, the 'beneficiary' may be the environment or primary producers and the community generally, such as when it is necessary to combat an exotic pest outbreak.

The Panel, therefore, takes the following view (which largely mirrors the current approach):

- assessment costs for emergency use exemption applications should not be recovered through a fee
- assessment costs for minor use exemption applications should attract a discounted application fee.

While the costs of some of these activities have a public good element (such as exemptions that deal with biosecurity incursions), the Panel expects that most minor and emergency use exemptions will apply to products already available in Australia. This is currently the case through the equivalent permits. Accordingly, the direct financial benefit resulting from the sale of products will generally flow to registration holders, and to those introducing internationally registered products under licence.

Given these considerations, therefore, it would seem reasonable to recover the balance of these costs through a component of the levy on registered and licensed products, supplemented by a small public appropriation in recognition of the public good element (as is the case now).

131. Recommendation

The Panel recommends that a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines is maintained.

132. Recommendation

The Panel recommends that minor use exemption applications should attract a discounted application fee with the balance of the costs recovered as an identified component of the levy on product sales payable by the registrant (or licence holder).

133. Recommendation

The Panel recommends emergency use exemption applications should be fully recovered as a component of the levy. A small appropriation should be sought to offset some of the draw on the levy, in recognition that there is a public good element to this function.

Chemical reviews and APVMA compliance and enforcement

Chemical reviews and general compliance and enforcement activities are both currently funded through APVMA levies. Some stakeholders argue that these activities are a public good and should be publicly funded. However, the whole-of-government charging framework expects that if an industry creates the need for regulation, even if costs cannot be easily attributed to

individual users, it is still appropriate to recover these costs from industry. The Panel accepts this logic – that is, these regulatory activities only exist to manage the risks associated with selling products in the Australian market.

The Panel therefore recommends that the costs of chemical reviews and general compliance and enforcement services (such as investigations of potential issues, random audits, trace back activities, and implementing the graduated range of enforcement tools) should be recovered entirely from industry via components of the levy on sales of products introduced via the registration and licensing pathways.

134. Recommendation

The Panel recommends that as chemical reviews and APVMA compliance and enforcement activities only exist to manage the risks associated with selling pesticide and veterinary medicine products in the Australian market, the costs of these regulatory activities should be recovered entirely from industry via a component of the levy on product sales.

Control-of-use activities

The Panel's single national law proposal (see Chapter 2) would see many control-of-use regulatory activities become Commonwealth responsibilities. While stakeholders have advised that this function is currently under-resourced, the Panel's recommended co-regulatory approach including more formal acknowledgement of industry quality assurance (QA) schemes in legislation (Chapter 4) should ensure that the costs of providing (and complying with) these regulatory activities in future are minimised.

It is clear that the chemical industry is one of, if not the, primary beneficiaries of these regulatory functions. This is because a robust control-of-use system allows the pesticides and veterinary medicines industry to market and supply its products. In addition, a harmonised system (that cannot be achieved by other means) also avoids the need for a 'lowest common denominator' approach to be taken to risk mitigation measures at registration. This reduces and simplifies the chemicals industry's liability risk and increases the practical utility of their products.

Consistent with the Australian Government Charging Framework, the Panel considers that those costs that are not attributable to an individual user should be recovered through a component of the levy on the sales of products introduced via the registration and licensing pathways. This includes the costs associated with adverse experience reporting (which has both supply-side and use aspects). Levying product suppliers, rather than users, is administratively efficient and suppliers are able to recover these costs by distribution across the supply chain.

In limited circumstances (where the recipient of a service can be clearly identified), a fee for service approach will be suitable – for example, licensing primary producers for off-label use. Within these limited circumstances, the Panel recognises there may be certain activities where full cost recovery could result in a perverse outcome (where a barrier presented by full fees would circumvent a critically beneficial outcome). If such circumstances arise, it would be appropriate to consider some subsidy from a levy applied to relevant classes of products.

135. Recommendation

The Panel recommends that the cost of control-of-use regulatory activities should generally be recovered entirely from industry, via a component of the levy on product sales. However, wherever possible, where the beneficiary is clearly identifiable, such as applicators licensing, a fee for services approach would be used.

Expanded system surveillance and monitoring

The Panel recommended in Chapter 3 to expand surveillance and monitoring throughout the pesticides and veterinary medicines regulatory system. These activities will include nationally consistent residues monitoring particularly for produce entering the domestic market, environmental monitoring, and overall systems surveillance. These activities will be overseen by the Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner). The costs of system surveillance and monitoring cannot be attributed to a particular user of the system. The Panel considers that produce monitoring, and environmental monitoring for residues should be publicly funded. Other elements, such as data mining and analysis should also be publicly funded.

136. Recommendation

The Panel recommends that the costs of data mining and analysis for system surveillance and monitoring be publicly funding.

137. Recommendation

The Panel recommends that the costs of environmental monitoring be publicly funded.

138. Recommendation

The Panel recommends that the cost of domestic produce monitoring should be publicly funded.

The Commissioner

The Panel has recommended that the Commissioner perform a number of functions in the pesticides and veterinary medicines regulatory system (see Chapter 2). The majority of the Commissioner's costs will relate to control-of-use, licensing, system surveillance and monitoring responsibilities and will be recovered from a mix of public funds and industry levy as previously described. However, the position will be responsible for additional activities, such as representing the Government at international meetings and consultation, which should be funded through government appropriation. The Commissioner's vital role in assessing and reporting on progress in the overall reform agenda is a mainstream function of government and should therefore also be government funded.

A number of these functions are currently performed by the Department of Agriculture, Water and the Environment. The Panel recommends that these matters, such as the policy development and advisory responsibilities, continue to be funded through appropriations from government. The Commissioners role in representing the Australian Government at international meetings (on policy) should be publicly funded. International engagement currently led by the APVMA (technical fora such as Codex and participating in global joint reviews) should continue to be funded by industry.

139. Recommendation

The Panel recommends that activities of the Commissioner such as driving the reform agenda, policy development, and advisory responsibilities should remain Government funded and that all other Commissioner costs, being activities that only exist to manage the risks associated with selling products in the Australian market, should be 100% recovered from fees (e.g., licensing) or components of the levy as appropriate.

8 List of recommendations

Chapter 1

1. Recommendation

The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system.

'A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to safe products and uses.'"

2. Recommendation

The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives:

- safeguard animal health and welfare
- support primary industries
- protect Australia's trade
- contribute to biosecurity preparedness.

3. Recommendation

The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:

- The regulatory system should be based on risk, not on hazard alone.
- Processes and decisions should be objective, independent and science based.
- Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.
- Risk management measures should be reviewed as new information becomes available.
- The system should be efficient and outcomes-focused by making use of streamlined and fit for purpose regulation.
- The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products.
- The system should be adaptive to new technologies, practices, and knowledge.
- The regulatory system should support a resilient supply chain.

Chapter 2

4. Recommendation

The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation.

This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.

5. Recommendation

The Panel recommends that the need for, and the scope, role and form of a new IGA are considered as part of this review's implementation. The Panel recommends that the existing IGA be extended until this time, recognising that there are some matters, such as those relating to funding, that are unlikely to be resolved in the interim period.

6. Recommendation

The Panel recommends that should there be a need for an IGA in future, it should reflect the lessons learnt from the shortcomings of the current IGA including that it:

- provides that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail
- requires any jurisdiction that departs from the IGA approach to provide a public reason for such departure
- mandates minimum resource levels for regulating control-of-use, to effectively meet assurance and compliance obligations (perhaps as a proportion of each jurisdiction's domestic production value)
- requires regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals
- requires regular publication (or input to the Commissioner's reporting) of performance against these indicators and targets or goals.

7. Recommendation

The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

8. Recommendation

The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.

9. Recommendation

The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.

10. Recommendation

The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.

11. Recommendation

The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.

12. Recommendation

The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.

13. Recommendation

The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.

14. Recommendation

The Panel proposes the establishment of 2 formal and one ad hoc consultation mechanisms by the Commissioner to consider, and offer advice to Ministers and the Commissioner as appropriate on, the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are:

- a Stakeholder Forum
- an Operational Forum
- an Expert Advisory Panel (as needed).

15. Recommendation

The Panel recommends the Stakeholder and Operational forums have terms of reference consistent with those set out in Annex 10 and Annex 11.

16. Recommendation

The Panel recommends that the Commissioner establish a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The biennial reports would review progress in implementing the reforms decided by the Government in light of the Panel's current report. Reporting should commence 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Performance measures, as a minimum, should address:

- health impact
  - establishing formal human, animal, and environmental health risk indicators
  - number and nature of adverse experience reports and pharmacovigilance findings, and time taken to respond to adverse experience reports and any consequential actions.
- industry impact

  - supply, use and disposal of pesticides and veterinary medicines.
- community impact
  - social attitudes
  - community outreach and engagement.
- regulator performance
  - number and type of regulatory decisions by the APVMA and Commissioner
  - number and type of audits and compliance activities, including information and education campaigns.
- responsiveness to community concerns raised.

17. Recommendation

The Panel recommends that the Commissioner establish health risk indicators for Australia, similar to those used in the European Union, and publish outcomes in its reporting of performance measures.

18. Recommendation

The Panel recommends the retention of statutory timeframes for the APVMA to complete its pre-market assessments as a vital input measure to the regulatory system and recommends that statutory timeframes should be expanded to a range of other decisions, such as licensing and responsiveness to the Stakeholder Forum, in the future regulatory system to improve transparency and accountability.

Chapter 3

19. Recommendation

The Panel recommends that the Commissioner be assigned responsibility to build a surveillance system fit for the needs of a 30-year future. The system should:

- Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions.
- Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.

20. Recommendation

The Panel recommends that the Commissioner develop arrangements to curate all such sources of information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes.

21. Recommendation

The Panel recommends the Commissioner consider how to best utilise and capitalise on current record keeping requirements for use of pesticides and veterinary medicines in Australia.

22. Recommendation

The Panel recommends a Government-led national domestic produce monitoring program be established.

23. Recommendation

The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.

24. Recommendation

The Panel recommends the Commissioner finalise the design of the domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residues Survey, primary producers, manufacturers, state and territory governments, and the community.

25. Recommendation

The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.

26. Recommendation

The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.

27. Recommendation

The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.

28. Recommendation

The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.

29. Recommendation

The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.

30. Recommendation

The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of

an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.

31. Recommendation

The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.

32. Recommendation

The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.

33. Recommendation

The Panel recommends sound information sharing practices be established between the APVMA and the Commissioner to allow APVMA access and the opportunity to respond to those matters relating to the registration and exemption of products, or the supply of those products.

34. Recommendation

The Panel recommends the Commissioner establish an interface that provides users and the public with contemporary details of validated adverse experience reports. The Panel also recommends the interface support the streamlining of submission of adverse experience reports.

35. Recommendation

The Panel recommends that trends identified through system surveillance data be reported publicly in the Commissioner's biennial report.

36. Recommendation

The Panel recommends that the residue monitoring results of domestic produce and environmental water and adverse experience reports should be publicly available, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken.

37. Recommendation

The Panel recommends that the results of these programs should be collated and published in an informative and educational manner. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

38. Recommendation

The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.

39. Recommendation

The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.

40. Recommendation

The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.

41. Recommendation

The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.

42. Recommendation

The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.

43. Recommendation

The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.

44. Recommendation

The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.

Chapter 4

45. Recommendation

The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.

46. Recommendation

The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.

47. Recommendation

The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary

medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).

48. Recommendation

The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.

49. Recommendation

The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.

50. Recommendation

The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system.

The following are the Panel's proposals for initial licensing schemes under the new national licensing framework:

- supply of internationally registered products
- good manufacturing practice
- supply or use of substances for research purposes
- supply of hormonal growth promotants
- dealings with Stockholm Convention substances
- supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)
- aerial application of pesticides (pilots and contractors that employ pilots, drone operators)
- ground applicators
- commercial pest controllers (pest management technicians)
- special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.

51. Recommendation

The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage,

risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.

52. Recommendation

The Panel recommends that the Commissioner completes the work of HACCUT to establish training standards for restricted chemical products and Schedule 7 poisons, and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides and veterinary medicines.

53. Recommendation

The Panel recommends that competency standards be established for roles introduced through other recommendations in this review. These include:

- accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6)
- government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.

54. Recommendation

The Panel recommends that where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Commissioner.

55. Recommendation

The Panel recommends that the Commissioner work with the ASQA and industry associations responsible for industry-based accreditations to ensure quality of training outcomes, and that training is adapted to meet the needs of pesticides and veterinary medicines users into the future. The Panel suggests that the Commissioner examine the benefits of micro-credentials when developing the standards.

56. Recommendation

The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart-label content.

57. Recommendation

The Panel recommends that the opportunities to enhance labelling through additional smart-label content be actively pursued and implemented with a stronger sense of urgency than has been the case to date. The result should be safer use, a more informed user as well as an improved user experience.

58. Recommendation

The Panel recommends that the Commissioner continues to scan the technology horizon to identify additional emerging technologies that may assist with labelling reform.

59. Recommendation

The Panel recommends that the regulatory assessed elements of the label approved by the APVMA be limited to that information which is not assessed by other regulatory systems.

60. Recommendation

The Panel recommends the product label must comply with general conditions of registration to ensure the risks of the product can be managed. To implement this, the Panel recommends the establishment of general statutory conditions of registration to which the product label must comply, along with urgent completion of a labelling standard. Where relevant, compliance with the labelling standard would be made a condition of registration (or form part of the licence to supply overseas registered products). More details of these proposed conditions are provided in Annex 6.

61. Recommendation

The Panel recommends manufacturers should be permitted to (and indeed, should be encouraged to include) include additional personal protective information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

62. Recommendation

The Panel recommends that every 5 years, at a minimum, the registration holder must conduct a review of label content to ensure the information on the label is current and remains correct – noting that emerging scientific evidence or consumer concerns could also trigger a review, including a labelling review, at any time (see chemical review discussion in Chapter 3).

63. Recommendation

The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the regulatory assessed elements of label requirements and not against the 'approved label'.

64. Recommendation

The Panel recommends that the Commissioner be empowered to publicly report a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent.

- The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reports on the state of the system.

65. Recommendation

The Panel recommends encouraging industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations (see Section 4.1).

66. Recommendation

The Panel recommends good disposal practice be considered as conditions for relevant licences.

67. Recommendation

The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.

68. Recommendation

The Panel recommends that veterinary medicine products compounded by a veterinarian or a pharmacist, for any animal treatment are brought within the scope of the future regulatory system for veterinary medicines but are exempt from requirements of registration where they comply with prescription by cascade.

69. Recommendation

The Panel recommends that the prescription cascade provides that registered products must be considered first and compounded products are prescribed as a last resort in order to address an issue that is unable to be addressed through suitable and reasonably available registered or exempted products.

70. Recommendation

The Panel recommends that the prescription cascade is finalised and implemented by the Commissioner under the single national law for control-of-use.

71. Recommendation

The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

72. Recommendation

The Panel recommends that the APVMA works with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are funded speedily to enable the exemption described in recommendation 68.

73. Recommendation

The Panel recommends establishing a national rule for pesticides under the single national law for control-of-use that sets out the requirements for a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use.

74. Recommendation

The Panel recommends establishing a national rule for veterinary medicines under the single national law for control-of-use that sets out the requirements for a veterinary medicine's responsible use, including a prescription cascade that applies to all animal use, and the records that must be kept establishing responsible use.

Chapter 5

75. Recommendation

The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and

provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.

76. Recommendation

The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.

77. Recommendation

The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.

78. Recommendation

The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.

79. Recommendation

The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.

80. Recommendation

In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary.

81. Recommendation

The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.

Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.

82. Recommendation

The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.

83. Recommendation

The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.

84. Recommendation

The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).

85. Recommendation

The Panel recommends the Commissioner's determination of comparable international regulators:

- be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders
- be conducted by the Commissioner
- give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.

86. Recommendation

The Panel recommends that licence holders:

- must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances
- be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions
- be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.

87. Recommendation

The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.

88. Recommendation

The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

89. Recommendation

The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).

90. Recommendation

The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.

91. Recommendation

The Panel recommends the criteria for prioritisation be determined by the Minister with advice from the Stakeholder Forum.

92. Recommendation

The Panel recommends the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted by departmental risks.

93. Recommendation

The Panel recommends targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not correspond to climatic regions.

94. Recommendation

The Panel recommends making any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions in line with the 2019 decision of the Agriculture Ministers Forum.

95. Recommendation

The Panel recommends the expanding the support by government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing the industries that benefit from access to the necessary tools for pest and disease management.

96. Recommendation

The Panel recommends, through the proposed single national law, implementing an exemptions model as a streamlined way of authorising specific activities that would otherwise not be permitted. Exemptions for minor, emergency and research use may be made as legislative instruments by the APVMA.

97. Recommendation

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use exemption as long as a use would not jeopardise safety, efficacy, and trade.

98. Recommendation

The Panel recommends expanding the authorising of emergency use in advance of the emergency, establishing 2 categories within the public listing of exemptions for 'active emergency exemptions' and 'future-emergency exemptions'.

99. Recommendation

The Panel recommends that, in granting an emergency exemption in advance of an emergency (a future emergency exemption), the exemption includes details of the trigger to transition from the 'future' to 'active' exemption category.

100. Recommendation

The Panel recommends the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan is in place along with quality management systems and regular independent assurance checks including audits.

101. Recommendation

The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

102. Recommendation

The Panel recommends that amendments be made to the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries.

103. Recommendation

The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.

104. Recommendation

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

105. Recommendation

The Panel recommends a simple, consistent approach to data protection for the new pesticides and veterinary medicines regulatory system. The ability to limit the regulator's use of certain information will remain a valuable component of the future system and will continue to be of great importance to industry. This is vital to protect the value of industry investments and ensure that Australians gain access to the latest innovations in pesticides and veterinary medicines.

106. Recommendation

The Panel recommends that if a party provides confidential information to a regulator and that if information is used by the regulator for a relevant regulatory decision, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor's products.

- These should be consistent with Australia's established international agreements.
- Information in minor use and emergency exemption applications are a special case and while this may (as is the case for current permit applications) be considered confidential commercial information, it will not qualify for data protection.

107. Recommendation

The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products.

- Equivalent protection periods should be provided for pesticides and veterinary medicines.
- The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review).
- These periods should only be extended as an incentive to bringing priority uses to Australia, as per the measure in the Bill currently before parliament.

108. Recommendation

The Panel recommends that the periods of limitation on the regulator's use of information should be:

- 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent.
- 5 years for information:
  - relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption
  - provided in support of a chemical review
  - which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.

109. Recommendation

The Panel recommends that if there is a public interest reason for the regulator to use information, then the regulator should be able to use that information irrespective of whether it would otherwise be subject to protection.

- For example, information about a product that is unfavourable (does not support continued registration of a product or use) should not be treated as protected.

110. Recommendation

The Panel recommends that the Commissioner be tasked with ensuring that any intellectual property protection measures for the new scheme to supply internationally registered products under licence align with the other recommendations (including consistency with international obligations), in consultation with industry.

111. Recommendation

The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a private negotiation matter between companies.

Chapter 6

112. Recommendation

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture.

113. Recommendation

The Panel recommends that the APVMA establish a standard for each active constituent prior to its inclusion in products. The Panel expects that in establishing standards for active constituents due regard is given to matters of commercial confidentiality and intellectual property protection.

114. Recommendation

The Panel recommends that the APVMA apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard.

115. Recommendation

The Panel recommends the APVMA becomes PIC/S accredited.

116. Recommendation

The Panel recommends the APVMA develop guidance material through engagement with industry to support a streamlined transition from cGMP to PIC/S.

117. Recommendation

The Panel recommends both export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.

118. Recommendation

The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.

119. Recommendation

The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

Chapter 7

120. Recommendation

The Panel recommends that in most circumstances the pesticides and veterinary medicines industry should bear the full and reasonable costs of the regulatory functions under the new regulatory scheme.

121. Recommendation

The Panel recommends that the existing levy on product sales be continued but at a reduced rate.

122. Recommendation

The Panel recommends that the levy be divided into components relating to the costs incurred for undertaking different activities to minimise cross-subsidisation, with each component of the levy being charged only to those that receive the particular service.

123. Recommendation

The Panel recommends that where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.

124. Recommendation

The Panel recommends that hourly charging should be introduced for activities where regulatory costs are highly variable, while flat fees should be charged where there is little variation.

125. Recommendation

The Panel recommends that the costs for applications for registration be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis.

126. Recommendation

The Panel recommends that where Government audits are routine and predictable the costs of this service should be incorporated into the fees for the parent program, for example via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.

127. Recommendation

The Panel recommends that mechanisms be developed to allow more significant fees to be paid over time, such as through payment plans.

128. Recommendation

The Panel recommends 100% recovery of the costs of issuing and maintaining licences (both for supply side and use activities), including scheduled audits with predictable costs, via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

129. Recommendation

The Panel recommends that the assessment of applications for accreditation, together with costs to maintain this accreditation, should be 100% recovered from the accredited parties.

130. Recommendation

The Panel recommends that full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.

131. Recommendation

The Panel recommends that a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines is maintained.

132. Recommendation

The Panel recommends that minor use exemption applications should attract a discounted application fee with the balance of the costs recovered as an identified component of the levy on product sales payable by the registrant (or licence holder).

133. Recommendation

The Panel recommends emergency use exemption applications should be fully recovered as a component of the levy. A small appropriation should be sought to offset some of the draw on the levy, in recognition that there is a public good element to this function.

134. Recommendation

The Panel recommends that as chemical reviews and APVMA compliance and enforcement activities only exist to manage the risks associated with selling pesticide and veterinary medicine products in the Australian market, the costs of these regulatory activities should be recovered entirely from industry via a component of the levy on product sales.

135. Recommendation

The Panel recommends that the cost of control-of-use regulatory activities should generally be recovered entirely from industry, via a component of the levy on product sales. However, wherever possible, where the beneficiary is clearly identifiable, such as applicators licensing, a fee for services approach should be used.

136. Recommendation

The Panel recommends that the costs of data mining and analysis for system surveillance and monitoring be publicly funding.

137. Recommendation

The Panel recommends that the costs of environmental monitoring be publicly funded.

138. Recommendation

The Panel recommends that the cost of domestic produce monitoring should be publicly funded.

139. Recommendation

The Panel recommends that activities of the Commissioner such as driving the reform agenda, policy development, and advisory responsibilities should remain Government funded and that all other Commissioner costs, being activities that only exist to manage the risks associated with selling products in the Australian market, should be 100% recovered from fees (e.g., licensing) or components of the levy as appropriate.

Annexes

Annex 1 – Terms of reference

On 5 September 2019 Senator the Hon. Bridget McKenzie, Minister for Agriculture, appointed an independent Panel to undertake a first principles review of the regulatory framework underpinning the National Registration Scheme for Agricultural Chemicals and Veterinary Chemicals (agvet chemicals). The review will examine the framework's aims, structure and operation, and make recommendations to ensure it is contemporary, fit for purpose and reduces unnecessary red tape.

In undertaking the review, the Panel will:

1) assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
2) consider what the goals of Australian agvet chemicals regulation should be
3) consider the current and future requirements of Australia's regulatory framework for agvet chemicals
4) provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture.

The Panel will have regard to regulatory roles and responsibilities at the national, state and territory level; interactions with other regulatory schemes and arrangements; any relevant domestic or international issues; any recent changes to the current framework, including reforms agreed by the Council of Australian Governments; and the government's agenda to reduce red tape wherever possible.

The process will also review the Intergovernmental Agreement (2013) underpinning the National Registration Scheme, which was due to be reviewed in 2018.

Annex 2 – Consultation process

The Panel's intention in this review was to engage broadly and meaningfully with a wide range of stakeholders to seek diverse feedback on reform ideas. The consultation process included the formation of an Agvet Chemicals Review Stakeholder Group, extensive stakeholder consultation and a written submission process.

The Panel commenced its consultation process by convening an Agvet Chemicals Review Stakeholder Group. This Group included pesticide and veterinary medicine companies, farming industry groups, grower and producer groups, the veterinary profession and other related organisations. Non-Government Organisations were invited to participate as part of the group but declined. Nevertheless, many NGOs contributed extensive submissions and were generous with their time during consultation meetings. A list of stakeholder group representatives is in Table 2. The Agvet Chemicals Review Stakeholder Group was asked to raise issues of a regulatory, technical or business nature pertinent to the scope of the review, identify matters of concern and propose constructive options where possible, and provide an avenue for the Panel to communicate with stakeholders about its activities and progress.

In addition, the Panel met with state and territory Governments through the Harmonised Agvet Chemical Control of Use Task group (HACCUT) and with the APVMA CEO and Deputy CEO and then with the APVMA executive team. The output from these early consultations informed the development of the Issues Paper which was publicly released by the Panel on 4 March 2020.

The Panel then consulted extensively to seek stakeholder views and to inform the development of the recommendations in this report. The process involved meetings with 188 stakeholder groups, mostly via 'COVID-19 safe' videoconference, a breakdown of categories of stakeholders consulted is in Table 3. The consultation process, following the release of the Issues Paper started off with a full day meeting with the APVMA in Armidale. The Panel used these meetings to gather views about the regulatory system, to test reform options and to prepare draft findings and recommendations. During the process the Panel again met with HACCUT and with representatives of each jurisdiction separately and following the conclusion of consultations the Panel met with HACCUT and the Agvet Chemicals Review Stakeholder Group to outline where it had landed on reforms to take forward. The Review secretariat also met with the APVMA to outline the major reform proposals that would be included in the Panel's draft report prior to its release.

Table 2 Agvet Chemicals Review Stakeholder Group

Agvet Chemicals Review Stakeholder Group representatives
Accord (hygiene, personal care, and specialty products industry)
Animal Medicines Australia (AMA)
Australian Food and Grocery Council (AFGC)
Australian Meat Industry Council (AMIC)
Australian Veterinary Association (AVA)
Ausveg
Chemistry Australia
CropLife Australia
Dairy Australia

Agvet Chemicals Review Stakeholder Group representatives
Grain Producers
National Farmers' Federation (NFF)
Red Meat Advisory Council (RMAC)
Racing Australia
Seafood Industry Australia
Swimming Pool and Spa Association Australia (SPASA)
Veterinary Medicines and Distributors Association (VMDA)
National Aquaculture Council

The Panel values the time and effort taken by stakeholders to meet with them and in developing formal submissions in response to the Panel's Issues Paper. The Panel has considered all input from stakeholders, including from meetings and submissions, in developing recommendations for this report.

Submissions

On 4 March 2020, the Chair of the Panel called for public submissions addressing the matters contained in its 'Issues Paper: Review of the agvet chemicals regulatory system – future reform opportunities'. The Issues Paper presented the Panel's initial reflections on the efficiency and effectiveness of the current agvet chemicals regulatory system, proposed a number of suggestions for improvement, and posed questions for stakeholders to consider in their responses.

Submissions were initially sought by 26 June 2020. However, in light of the disruption caused by the COVID-19 pandemic, the Minister for Agriculture, Drought and Emergency Management, the Hon. David Littleproud MP, agreed to extend the timeframe for the delivery of the final report to May 2021. Accordingly, the Panel extended the date for submissions until 28 August 2020 to ensure that stakeholders affected by the pandemic had sufficient time to engage in the process. Submissions were accepted through an online form, in email and in hardcopy.

The Panel received 100 written submissions. The public submissions can be found on the **Have Your Say** page of the Australian Government Department of Agriculture, Water and Environment website.

Public consultations

In addition to written submissions, the Panel held 'virtual' one-on-one and round table consultation meetings with 188 groups through 68 meetings. Consultations provided a valuable opportunity for the Panel to hear directly from government agencies (state and territory, and Commonwealth, including the APVMA), peak industry and grower groups, professional associations, pesticides and veterinary medicine companies, non-government organisations and other relevant stakeholders. This allowed the Panel to test its views and ideas with stakeholders whilst also gaining a 'real-world' understanding of the issues affecting those impacted by the current regulatory system and where they considered reform was most critical. Summaries of these meetings can be found on the **Have Your Say** webpage.

Table 3 Groups consulted through one-on-one meetings

Groups	Number
Fisheries	8
Horticulture	18
Livestock	10
Broadacre crops	10
Farm Groups	11
Pesticide and veterinary medicine companies	39
Peak Associations, Professional Associations	28
Government agencies	27
Research and Development Corporations/Other organisations	10
Other industries	11
Non-government organisations	16
Total	**188**

Overview of common views

This section provides a summary of common views expressed in the more detailed submissions to the Panel from key stakeholders, as well as arising from consultation meetings.

While stakeholders put forward a range of views, key common themes included support for:

- nationally consistent and more effective control-of-use arrangements
- need for greater access to products and product uses
- continued implementation of a risk-based regulatory system
- decisions based on sound and contemporary science
- preservation of the independence of the APVMA
- removal of pool and spa chemicals and anti-fouling paints from pesticide and veterinary medicine regulation
- increased monitoring and improved surveillance of residues in domestic produce and the environment
- implementation of effective industry and community consultation forums with clear goals and responsibilities
- improved responsiveness, accountability and transparency of regulatory decision making.

Some of the key areas where stakeholders expressed diverse views were:

- removal of the domestic chemical manufacturing objective
- the value of implementing a statutory duty of care
- implementation of a benefits test
- changes to efficacy assessments

- the registration by reference proposal outlined in the issues paper
- removal of certain consumer veterinary products
- direct involvement of veterinarians (either in administration or under their instruction) for certain products, such as those administered by injection
- whether chemical combinations were worth exploring for pre-market assessment purposes
- mandatory reporting of chemical use data.

The Panel found the examples and information from a range of published research and reports referred to in many of the submissions extremely useful. These were also taken into consideration during the development of this report and its recommendations.

Issues considered through consultation but not pursued

The Panel's Issues Paper, and subsequent consultation, identified many issues and potential areas for reform. Most of these have been further developed and now presented in the Panel's recommendations to establish a fit-for-purpose adaptive regulatory scheme for pesticides and veterinary medicines for the next 30 years. However, not all areas or proposals for reform identified in the Panel's initial Issues Paper were pursued. The following proposals were not pursued at all, or not in their previous form following concerns raised by stakeholders.

Accreditation of holders

The Panel proposed a holder accreditation scheme within the Issues Paper to provide greater incentives for industry compliance. The concepts in this initial proposal evolved through consultation and are integrated in part into the recommended reforms for licensing and general product obligations.

Benefits test

The Panel's initial proposal was to introduce formal consideration of a product's benefit into the assessment process for all applications. This has been replaced with an approach to prioritise specific types of applications for assessment (see Chapter 5). Separately the Panel has recommended that benefits be considered prior to refusal, suspension or cancellation of a registration (see Chapter 5).

Pest groupings

The Issues Paper considered the potential of pest groupings. Through consultation the Panel has concluded that while no specific recommendation should be made in regard to pest groupings, the future scheme will still allow for these if relevant.

Complete removal of products of low regulatory concern

The Issues Paper identified a range of low regulatory concern products that might be excluded from the scope of the future regulatory scheme, including consumer products, pool and spa chemicals, anti-fouling paints, and over-the-counter companion animal products. The Panel has responded to the many stakeholders who raised the potential issues associated with this approach. The Panel has refined its approach to align regulatory effort with risk but keeping most of these products within the regulatory system (see Chapter 5).

Synergistic effects

The Issues Paper considered the potential of addressing synergistic effects. Through consultation the Panel has concluded that while the future scheme will allow for the

incorporation of an assessment of synergistic effects, no specific recommendation should be made at this time given the lack of suitable methods to undertake this type of analysis. Synergistic effects is still in its infancy in the EU, but should be monitored to assess its applicability to Australia as it develops.

Annex 3 – List of previous reviews of the Agvet **Chemicals R**egulatory System

Table 4 List of previous reviews

Dates	Reforms
July 1990	SENATE SELECT COMMITTEE REPORT ON AGRICULTURAL AND VETERINARY CHEMICALS IN AUSTRALIA
June 1998	ARMCANZ – MANAGEMENT OF AGVET CHEMICALS: A NATIONAL STRATEGY
August 1998	BLAIR REVIEW OF FOOD REGULATION
October 1998	ISSUE PAPER – REVIEW OF DATA PROTECTION ARRANGEMENTS UNDER THE AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994
November 1998	ENVIRONMENT AUSTRALIA – NATIONAL PROFILE OF CHEMICALS MANAGEMENT INFRASTRUCTURE IN AUSTRALIA
January 1999	PRICEWATERHOUSECOOPERS – NATIONAL LEGISLATION REVIEW: AGVET CHEMICALS LEGISLATION (FINAL REPORT)
2002	AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING – PESTICIDE USE IN AUSTRALIA
2002	ALLEN CONSULTING GROUP – POSITIONING FOR THE FUTURE – A NATIONAL RISK MANAGEMENT SYSTEM FOR AGVET CHEMICALS: A STRATEGIC REVIEW FOR THE NRA FOR AGVET CHEMICALS
April 2006	MINISTERIAL TASKFORCE ON REGULATORY REFORM – RETHINKING REGULATION: REPORT OF THE TASKFORCE ON REDUCING REGULATORY BURDENS ON BUSINESS
2006–07	AUSTRALIAN NATIONAL AUDIT OFFICE (ANAO) – AUDIT 2006–7
July 2008	PRODUCTIVITY COMMISSION – CHEMICALS AND PLASTICS REGULATION
December 2009	PRIMARY INDUSTRIES MINISTERIAL COUNCIL (PIMC) – NATIONAL SCHEME FOR ASSESSMENT REGISTRATION AND CONTROL OF USE OF AGRICULTURAL AND VETERINARY CHEMICALS DISCUSSION PAPER
August 2010	COAG – NATIONAL POLICY FRAMEWORK (NPF) FOR THE ASSESSMENT, REGISTRATION AND CONTROL OF USE OF AGVET CHEMICALS
November 2010	DEPARTMENT OF AGRICULTURE FISHERIES AND FORESTRY – BETTER REGULATION OF AGRICULTURAL AND VETERINARY CHEMICALS
November 2013	ABARES (DEPARTMENT OF AGRICULTURE) – REVIEW OF SELECTED REGULATORY BURDENS ON AGRICULTURE AND FORESTRY BUSINESSES
June 2014	PROTIVITI – FIRST PRINCIPLES REVIEW OF COST RECOVERY AT THE APVMA
2016	HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON AGRICULTURE AND INDUSTRY – SMART FARMING INQUIRY INTO AGRICULTURAL INNOVATION
August 2016	DELOITTE – CHEMICAL LABELLING DUPLICATION REVIEW
November 2016	PRODUCTIVITY COMMISSION – REGULATION OF AUSTRALIAN AGRICULTURE
June 2017	AUSTRALIAN NATIONAL AUDIT OFFICE – No. 56, 2016–17
October 2017	PwC – REVIEW OF AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY'S COST RECOVERY ARRANGEMENTS
November 2017	ACIL ALLEN – REVIEW OF INTERNATIONAL IP & REGISTRATION ARRANGEMENTS FOR THE REGULATION OF AGVET CHEMICALS
May 2018	PARLIAMENTARY ENQUIRY – APVMA REGULATORY REFORMS
June 2019	REVIEW OF AGRICULTURAL AND VETERINARY CHEMICALS LEGISLATION AMENDMENT ACT 2013

Annex 4 – Overview of regulatory costing estimates and assumptions

The following tables outline costing assumptions, estimates and data sources for the Panel's proposed reforms, demonstrating estimates of the financial implications to industry. This overview is **not** a cost-benefit analysis nor a formal regulatory impact statement. The cost implications have been prepared solely to provide an initial indication of the financial implications to industry of the Panel's proposed reform package.

Where the anticipated cost across industry is less than $100,000 per year, the reform has been identified as being cost neutral.

Unless specifically stated, calculations are exclusive of:

- delay costs which have been calculated as the foregone profits resulting in longer times to access the market (delay costs)
- the value of opportunities that cannot be realised because of the regulatory intervention (opportunity costs)
- efficiency (or other) benefits to businesses, community organisations and individuals resulting from a change in regulation (benefits)
- delay costs and on-boarding costs such as leave provisions and payment of superannuation contributions; and
- direct or flow-on benefits to users, which for some reforms would be significant.

Table 5 Key costings assumptions

Overview of basis for the costing assumptions
Legislative amendments, drafting and implementation will be funded through government appropriation and costings estimated in this report reflect changes in burden post implementation and at full operation.
Quantity of activities, projections and repetition in a period of time – statistics from APVMA performance statistic reports, APVMA annual reports, ABARES data, departmental advice and/or industry feedback.
Costs/fees for activities performed by the APVMA – from the legislative framework (particularly the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* and the Agricultural and Veterinary Chemicals Code Regulations 1995).
Time allocated to activities carried out by the APVMA – from publicly available APVMA statistic reports and legislated timeframes.
APVMA Cost Recovery Impact Statement (CRIS) 1 July 2020 to 30 June 2022.
Future regulatory effort for the APVMA to undertake new, or changed levels of existing regulatory activities – assumes that the APVMA's historic regulatory effort needed to deliver particular activities can be extrapolated.
Salaries and pay rates of government officials – based on the Australian Public Service Act employment salary ranges by classification level (2018-19). For more general estimates of full time equivalent (FTE) staff with no specified classification levels, an average cost of $100,000 per FTE has been assumed. Salaries and pay rates exclude additional costs associated with employment such as leave provisions and payment of superannuation contributions (on-boarding).
Dollar amounts are not exact and have been rounded up to the nearest thousand.

Overview of basis for the costing assumptions

Salaries and pay rates of for industry – based on mid-range award wages drawn from the Fair Work Commission Award 2020.

Costs and timeframes for alignment with international standards – from publicly available information for comparable international regulators, including

- The US Environmental Protection Agency Fee category table – Registration Division – New Active Ingredients for 2020 2021.
- The US Food and Drug Administration guidance document for the Animal Drug User Fee Act for 2020.
- The Canadian Pest Management Regulatory Agency's Pest Control Products Fees and Charges Regulations 2017.
- The Canadian Veterinary Drugs Directorate July 2020 guidance page on fees for veterinary drugs.
- The NZ Environmental Protection Authority fees and charges (as of July 2020) for hazardous substances applications.
- The NZ Ministry for Primary Industries 2019 guidance document to its assessment charges.
- The European Medicines Agency's June 2020 guidance page on fees.

References to quantities of pesticide and veterinary medicine products imported and exported – from within the Department of Agriculture, Water and the Environment.

Costs associated with recruiting executives and panel members – based on previous recruitment processes within the Department of Agriculture, Water and the Environment and the APVMA.

Numbers of products relevant to various reform proposals – derived from the APVMA's PUBCRIS database of chemical products, active constituents and permits.

Where previous costings (undertaken by government under other business) have been relied upon, figures have been adjusted to reflect inflation rates, calculated using the Reserve Bank of Australia inflation calculator.

Costings have not been considered against the OBPR regulatory burden measure tool unless specifically stipulated.

Table 6 Chapter 2 costings: establishing a national regulatory system

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
IMPROVED CONTROL-OF-USE (NATIONAL LAW) Implementing a single national law for agvet chemicals.	The 2013 Regulatory Impact Statement that considered a national scheme for assessment and control-of-use of agvet chemicals was used as a basis for this costing. It was assumed that some level of harmonisation has been achieved since this was completed.	Approximately two-thirds of the 2013 estimates with inflation applied resulting in approximately $75 million saving over 10 years. 25 FTEs will be required to manage national control-of-use functions. Number of FTEs would be commensurate with compliance activity and	Reserve Bank of Australia inflation calculator. 2013 'Decision regulation impact statement on a national scheme for assessment, registration and control-of-use of agricultural and veterinary chemicals' Tim Harding and Associates	**SAVING to industry** To chemical user industries, such as farm businesses and commercial spray operators. **COST** To chemical users and manufacturing industries, for resources to fund national control-of-use activities.	NA	Combination funding: Application fees and component of levy (compliance functions) Appropriated funding (surveillance functions).

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
	Inflation has been applied. Additional Government compliance resources will be required to absorb functions from states and territories.	estimated at $37 million over 10 years. Net saving to industry of $36 million over 10 years 4 FTEs would are estimated to be needed for expanded surveillance. Mixed staffing levels would be required (average of $150,000 per FTE). $6 million in costs over 10 years.	Rivers Economic Consulting Advice from officers within the Department of Agriculture, Water and the Environment specialising in compliance and enforcement.			
COMMISSIONER FOR PESTICIDES, VETERINARY MEDICINES AND STEWARDSHIP Consultation and ongoing stakeholder engagement, policy development, legislation and international engagement.	Industry would not contribute financially to establishment and implementation of consultative mechanisms. Existing departmental resources would absorb new functions until such time as additional resources are required.	Estimated costs for consultative mechanisms of $325,000 per annum or $3.25 million over 10 years, recruitment, remuneration and, associated meeting costs.	NA	No cost anticipated to industry for establishment, implementation or operation.	NA	Funded via government appropriation.

Table 7 Chapter 3 costings: protecting the health and safety of people, animals, and the environment

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
EXPANDING MONITORING AND SURVEILLANCE – MONITORING (ENVIRONMENTAL AND PRODUCE MONITORING)	Produce monitoring at full operation, up to 30 commodities, 300 samples per commodity annually (taken nationally).	Average produce sample cost of $500 Traceback activities for produce residue concerns 10 hours per event, $160 per hour (combined costs).	Advice from officers within the Department of Agriculture, Water and the Environment specialising in contaminations and standards.	NA		Funded via Government appropriation.

Implementation of an environmental and produce monitoring program.	Sediment samples would be undertaken at multiple sites across drainage division across Australia. Sampling is expected to decrease after the first 2 years following establishment of bench marks. Collection of time series data for soil properties and analysis of presence of pesticides and veterinary medicines would be performed in conjunction with the existing National Soil Strategy	Approximate total costs produce resides of $50 million over 10 years. Average water and sediment sample cost of $400 Operational water and sediment monitoring costs $819,000 per annum ($8.2 million over 10 years).				
EXPANDING MONITORING AND SURVEILLANCE – ADVERSE EXPERIENCE REPORTING Formalising adverse experience reporting for both veterinary medicines and pesticide products through legislation – COST NEUTRAL TO INDUSTRY	There are unlikely to be any regulatory cost impacts to most product users, suppliers or licence holders from an increased obligation to report adverse experience reports.	NA	NA	NA	NA	NA
IMPROVED RECONSIDERATION PROCESS Improving the speed and transparency of chemical reviews to increase public confidence and	Assumed 2 additional major reviews each year as a result of international decisions. APVMA resourcing will need to be reallocated	4 additional FTE's $400,000 per annum ($4 million over 10 years)	Extrapolation of current APVMA resources dedicated to undertaking chemical reconsiderations.	NA	FTE's for this proposal are expected to be offset by existing APVMA resources. Data is not available to estimate the cost to industry for	Existing APVMA resources recovered via a component of the levy.

maintain social licence for use of pesticides and veterinary medicines.	to manage increased workload.				responding to individual reviews.	
HUMANENESS ASSESSMENT The incorporation of a humaneness score for vertebrate pest control products on product labels.	That an expert panel will consider new humaneness scores. The expert panel will discuss 3-4 products/product types per meeting. That over-stickers would be used for product labels already in the marketplace. Assessment costs are as indicated by advice from VPRU. Existing registrations will also require an assessment by the VPRU.	One off payment of $2,175 per assessment (additional to APVMA application fees) Estimated to impact an average of 10 applications per year. Applications to amend product labels would be free of charge. Estimated 3 hours of industry time at $33.49 per hour to complete application to vary label. Total cost $2,275 per product. Approximate cost over 10 years $230,000.	Cost and time estimates received from contacts within the Vertebrate Pest Research Unit.	**COST to industry** (one off)	NA	Recovered via application fees and a component of the levy.

Table 8 Chapter 4 costings: ensuring responsible use

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
GENERAL PRODUCT OBLIGATIONS	While GPOs are expected to have a qualitative impact, there is little to no identified cost impact (time or financial) to industry.			COST NEUTRAL TO INDUSTRY		
INTRODUCING NATIONALLY CONSISTENT TRAINING AND COMPETENCY FOR USERS	While nationally consistent training and competency requirements are expected to have a qualitative impact, the			COST NEUTRAL TO INDUSTRY		

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
Reforming existing training and competency requirements to support nationally harmonised training and qualifications.	savings are more likely to be recognised through the proposal for a single national law. An unknown number of operators, allowed to operate with less (or only informal) training under supervision under a person (or organisation) with a master licence, will likely need to meet more formal future training requirements. It is also possible that operators working across borders may require less training (i.e. jurisdictional specific requirements).					
MANAGING RISKS FROM COMPOUNDED PRODUCTS Consistency in regulatory oversight for compounded and manufactured veterinary medicines.	Changes to bring veterinary compounding within the pesticides and veterinary medicines regulatory framework are not expected to significantly impact the compounding industry financially. Compounding pharmacies will continue to be subject to the professional standards set by their relevant bodies. The costs associated with increased reporting			COST NEUTRAL TO INDUSTRY		

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
	are considered to be minimal.					
LABELLING REFORM Changes to labelling assessments and capabilities for agricultural chemicals and veterinary medicines	Assumed 10% of ~8,000 products held by medium and large companies would apply label technology. That leaflets would be printed in runs of 10,000 There would be a time saving for the regulator however as labelling assessments run concurrently with other assessments, this time saving is not able to be measured.	Printing of one, multipage physical leaflet to accompany a product container would cost $2. That using QR technology would reduce leaflet content to 25%. 800 (products) x 20,000 ($2 x 10,000 prints) / 4 (25%) = $4 million over 10 years.	Publicly available figures from printing companies.	SAVING to industry	Use of QR codes, or similar technology on labelling is not mandated therefore any associated costs would only apply to those entities or individuals who participate.	NA

Table 9 Chapter 5 costings: improving access to pesticides and veterinary medicines

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
REFOCUSED SCOPE OF REGULATION – REDUCED SCOPE OF APPLICATIONS Removing various product types and classes from the regulatory system, such as pheromones, whole plants or animals, pool and spa chemicals, anti-fouling paints and domestic pest control products as well as repacked	Assumed ~1800 of currently registered products would be affected. Future projected applications per year no longer required ~160. Quantity of projected application based on average applications finalised by APVMA 2017-2019.	**Timeframes & fees for relevant applications** **Current minimum** Permit 3 months, $350 Product 3 month, $2,632 **Current maximum** Product 18 months, $100,000 **Industry resources for current application**	Public Chemical Registration Information system.	**SAVING to industry** Savings are based on industry no longer being required to submit applications for some products/ product types. And in some cases not having a related levy or/and renewal fee (re excluded products).	Cost impacts for research permits are also considered under 'international licencing'. Estimated costs are based on the panel's current views on what constitutes a pesticide or veterinary medicine product.	NA

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
products and some research permits.		**preparation (per application)** **Simple** 5hrs at $33.49 per hour **Complex** 200hrs at $33.49 per hour Estimated 10-year savings of ~$48 million.				
IMPROVED ACCESS – BENEFITTING FROM INTERNATIONAL INNOVATION AND ACCESSING ALTERNATIVE PRODUCTS Licensing individuals or companies to bring internationally registered products to Australia with only consideration of unique Australian conditions via a Risk Management Plan by the Commissioner.	Licences must be supported by an audit by the Commissioner or other accredited auditor. Audits are repeated every 3 years as a condition of the licence. Assumed $20,000 per audit (Govt.) $15,000 (private). Estimated 5 licences issued in year one with 2 products per licence. Each year thereafter, one new licence issued with each existing licence adding one product to their licence. Additionally, an assumed reduction in minor use permits resulting from new uses coming from international products. Delay costs have been considered for this proposal.	**Fees** **Application fee** $2,500 **Application timeframe** 4 weeks (new app) 2 weeks (renewal) **Application renewal** $1,500 **Annual levies** Current: 0.63% (for sales <$1 million) Proposed: 1% (for sales <$1 million) **Industry resources per application**: Estimated to decrease by approximately 40 hours per application 40hrs at $33.49 per hour $1,340.	Standards store (ISO accreditation) Biosecurity Regulation 2016 Approved arrangements	**SAVING to industry** This scheme is voluntary and costings only apply to entities/individuals who elect to participate. Savings would be a result from removing the need to apply for registration and/or minor use permits in some circumstances.	At the end of a 10 year period, there would be 14 licences and 154 products permitted under licence. Levies would be increased from 0.63% to 1%. Costs recovered under this increase would be dedicated to funding this scheme only, and no other aspects or functions undertaken by the Commissioner.	NA

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
		Delay costs $2.9 million per annum (reduced timeframe 12 months, annual sales $1 million, 20% profit). **Data generation no longer required:** $175,000 (estimated flat rate) **Development of Risk Management Plan:** $50,000 (estimated flat rate) **Midrange minor use permit cost of** ~$80,000 (incl. data generation costs) Estimated up to $5.5 million per year savings or $55m over 10 years.				
REGISTRATION BY REGION Introducing nationally consistent use patterns for pesticide and veterinary medicine products	Manufacturers/registration holders would not be required to update product labels until such time the update could be done in conjunction with another label update therefore there is no cost associated solely with this proposal.			COST NEUTRAL TO INDUSTRY		
IMPROVED ACCESS – BIOLOGICALS	The Department's Animal and Biological Imports team suggest that proposed changes to the current clearance process would			COST NEUTRAL TO INDUSTRY		

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
	incur a cost saving to Industry of approximately $100,000 per year. It is unlikely there will be any significant increase in record keeping or regulatory effort in the border clearance process or on industry's part. Due to the absence of any other statistics or indication of decrease in regulatory burden, savings are estimated at $1 million over 10 years.					

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
IMPROVED TIMELINESS – PRIORITISATION AND/OR CONSIDERATION OF BENEFITS ON REFUSAL A prioritisation mechanism to expedite products through registration, and the consideration of benefits before an application is refused.	Assumptions based on items 1, 2, 3, 4 and 10 being most likely to have a relevant benefit for consideration. Application costs for refusals avoided based on Item 10 as a mid-price range for applications considered in this costing. Quantity of projected applications based on average quantity finalised by APVMA 2017-2020. Assumptions do not include industry costs where products are suspended. That prioritising applications will have some impact on other applications assessment timeframes	**Item 10 application fee with mid-range modules.** $10,626 Estimate 5 applications per year would be eligible for prioritisation. Reduced timeframe 6 months, annual sales $1.5 million, 20% profit. Avoided delay costs $10 million over 10 years. Estimate only 2 applications bound for refusal would be approved each year once benefits are considered. **Cost to substantiate benefit:** 6 hours of industry resource at $33.49 per hour.	APVMA Performance Statistics (refusals)	**SAVING to industry** Through reduced delay costs. **COST to industry** Proving benefits is voluntary and costs only apply to entities/ individuals who elect to participate.	Conservative assumption made that APVMA refuses a small number applications annually. Only a handful of applications are anticipated to meet the criteria for prioritisation each year and savings are likely to be recognised through expedited market access. Allowing these products to enter the market up to 6 months earlier than anticipated would have significant financial benefit to industry.	Recovered via application fees and a component of the levy.
SIMPLIFIED DATA PROTECTION Reforming data protection to introduce a simplified approach.	While simplified data protection arrangements are likely to have an impact on the efficiency of the APVMA's processes, there is little to no identified cost (time or financial) impact on industry.			COST NEUTRAL TO INDUSTRY		

Table 10 Chapter 6 costings: contributing to supply chain resilience

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
IMPROVING RESILIENCE IN THE SUPPLY CHAIN Active constituents considered and approved at a substance level, independent of the site of manufacture.	Assumptions based on removing the need for submission of APVMA application item numbers 15, 16, 17 and 18 as per the definitions provided for in the *Agricultural and Veterinary Chemicals Code Regulations 1995*.	**Annual average whole applications finalised** **Item 18** 60 **Item 17** 230 **Item 16** 2 **Item 15** 2 **Total cost of industry resources per application** **Item 18** ~$1,000 **Item 17** ~$5,100 **Item 16** ~$2,800 **Item 15** ~$7,500 **Total industry hours per application** **Item 18** 30hrs **Item 17** 80hrs **Item 16** 100hrs **Item 15** 150hrs Avoided delay costs $1 million per annum (reduced timeframe 7 months, annual sales $1.5 million, 4% profit low selling sites, 20% profit for innovative sites). Estimated up to $4 million per year savings or $40m over 10 years.	APVMA performance statistics	**SAVING** to industry through reduced delay costs and requirements to submit applications for active constituent approvals.	From 2016/17 changes were implemented for veterinary product manufacturers seeking the approval of sites of veterinary active constituent manufacture which saw an influx in application numbers for 2017/18 and 2018/19. Values for Items 17 and 18 are adjusted to reflect a truer representation of anticipated future applications.	NA

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
OPTIMISING GOOD MANUFACTURING PRACTICES – INTERNATIONAL ALIGNMENT OF VETERINARY MANUFACTURING STANDARDS (PIC/S) Veterinary manufacturing facilities audited at the international standard set by the Pharmaceutical Inspection Cooperation Scheme (PIC/S), including audits being undertaken by directly employed government officials from within the APVMA.	That the APVMA would assume responsibility for audits currently undertaken by the TGA and additional resources would be required. That manufacturers would not be required to comply with this reform for 3-5 years.	Proposed pricing & timeframe structure for PIC/S level manufacturing site audits. **Desk Audit** $2,500 and up to 6 months **Initial Australian site audit** $15,000 and 6–9 months **Initial overseas site audit** $30,000 and 8-12 months **Maintenance audit** (AUS & OS) $10,000 and 3–6 months **Potential time saving:** **Desk Audit** 1–2 months **Initial Australian site audit** 2–5 months **Initial overseas site audit** 1–2 months **Maintenance audit (AUS & OS)** 1–2 months 8 additional staff anticipated to accommodate for increased audits and associated activities ~$800,000 per annum ~$300,000 system maintenance. System operation costs are comparable to existing	Licensed Australian manufacturers APVMA and TGA Memorandum of Understanding NZ MPI approach to veterinary manufacturing audits	**COST to industry (auditing)** Qualitative benefits anticipated through liaison with only one regulator, increased access to export markets, benefit of veterinary specific auditors and transparency in process.	Proposed pricing & timeframes established based on comparable systems, i.e. PICs and current auditing functions of APVMA, TGA and NZ MPI.	Funded by the veterinary manufacturing sector via a levy and application fees.

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as COST or SAVING to industry	Additional factors	Expected funding source
		arrangements for cGMP operation. 161 manufacturers $100,000 over 5 years to update systems in manufacturers. Over a 10 year period $16.1 million in update costs.				
STREAMLINING REGISTRATION AND BUILDING ASSESSMENT CAPACITY – ACCREDITED ASSESSOR SCHEME Establishment of an accredited assessor scheme.	New FTEs to accommodate for: Considering applications for accreditation. Monitoring compliance with accreditation standards and general maintenance. Government appropriation to meet establishment costs. Initial years would see a higher rate of accreditation, before achieving a steady state from year 4.	A mix of staffing levels would be involved with an average of $100,000 per FTE used to give an indication of dollar cost. Estimated total of $3.5 million over 10 years.	NA	**COST to industry** (Assessor industry only) Accrediting third parties will impose additional costs on the APVMA. The APVMA is a cost recovered agency.	Those that use the services of accredited assessors will be subject to whatever fees the assessors choose to charge. Market competition is expected to keep these costs to a minimum but it will remain a free market. The fact that parties can always choose to utilise the APVMA for assessment services will also likely constrain the charging regimes of 3rd party assessors.	Recovered through application and renewal fees for assessors. No cost to broader pesticides and veterinary medicines industry.
IMPROVED ACCESS – EXEMPTIONS (PERMITS) – COST NEUTRAL TO INDUSTRY The current permit system being replaced with exemption provision.	It is anticipated that the process for applying for an exemption would closely mimic that of the permit application process therefore no savings or costs are anticipated as a direct result of implementing exemptions.					

Annex 5 – Definitions, standards and conditions

New definition of pesticide and veterinary medicine

A pesticide product (PP) is a substance or mixture of substances that is represented, imported, manufactured, supplied, or used as a means of directly or indirectly:

1) destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest in relation to a plant, a place, or a thing, or
2) destroying a plant, and
3) both of the following apply:
    a) the use of which will expose persons, or ecosystems other than at point of application, to the product or its residues
    b) the product is classified as in any of the top 3 categories in any hazard class under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

A PP does not include, regardless of representation or use:

1) whole plants
2) whole animals
3) products for vertebrate pest control
4) products declared not to be a PP by legislative instrument.

A PP does include, regardless of hazard classification or exposure, those products:

1) with uses declared to be a PP by legislative instrument.

A veterinary medicine product (VMP) is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly:

1) preventing, diagnosing, curing, or alleviating a disease or condition in the animal or an infestation of the animal by a pest, or
2) curing or alleviating an injury suffered by the animal, or
3) modifying the physiology of the animal, or
4) altering its natural development, productivity, quality, or reproductive capacity, or
5) making it more manageable, or
6) ~~euthanising~~ euthanasing an animal (other than through the application of physical force), and
7) both of the following apply:
    a) the use will expose persons or ecosystems, other than at point of application, to the product or its residues, and
    b) the product is classified as in any of the top 3 categories in any hazard class under the GHS.

A VMP does not include, regardless of representation or use:

1) a product that is a PP
2) a vitamin, a mineral substance, or a feed additive of same, orally administered to or voluntarily consumed by an animal
3) a substance or mixture of substances prepared by, or on the instruction, of a veterinary surgeon, other than substances or mixtures of substances to treat a single animal not intended for food production when accompanied by written instruction of a veterinary surgeon.
    a) instructions of veterinary surgeons must be in writing and precede the creation of the substance or mixture of substances, except where there is no suitable VM registered
        i) instructions must include matters as prescribed
        ii) instructions must be carried out by a registered pharmacist in the course of their practice.
4) products declared not to be a VMP by legislative instrument.

A VMP does include, regardless of hazard classification or exposure, those products:

1) with uses declared to be a VM by legislative instrument
2) products intended or represented as vertebrate pest control.

Commented [SPE32]: It is not clear why the definition of a compounded product has changed from that in the current AgVet Code Act. In view of the recommendation of the panel to include compounded veterinary medicines within the remit of APVMA it is considered appropriate and in the interests of animal health and welfare to revert to the original definitions.

Example – possible draft mandatory standard for home garden and domestic products

Definitions

Active constituent means the substance that is, or one of the substances that together are, primarily responsible for the effectiveness of the product.

Control includes destroy, repel, and prevent.

Domestic pest control products mean products:

1) acting through a chemical or biological means, and
2) used inside, on, or around private dwellings, and
3) for the control of terrestrial arthropod pests such as cockroaches, ants, spiders, silverfish, flies, mosquitoes, and fleas.

But does not include products intended for use as a vertebrate poison.

Garden pest control products means products:

1) acting through a chemical or biological means, and
2) for the control of plant diseases, insect pests, weeds, snails, slugs, and rodents, and
3) for use on vegetables and fruit primarily grown for personal consumption (e.g., not grown on a commercial scale or for sale), or
4) trees, ornamentals, lawns, and other areas around private dwellings.

But does not include products used for pool and spa sanitisation.

Potentially Hazardous or Injurious Substances are defined in a legislative instrument as being any of the following, unless exempted:

1) a formulation containing an active constituent, or ingredient, that meets the criteria of classes Ia or Ib of the World Health Organization (WHO) Recommended Classification of Pesticides by Hazard
2) a formulation containing an active constituent that meets the criteria of classes II of the WHO Recommended Classification of Pesticides by Hazard, other than those with a GHS classification of 4 or higher
3) a formulation that meets the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
4) a formulation that meets the criteria of mutagenicity Categories 1A and 1B of the GHS
5) a formulation that meets the criteria of reproductive toxicity Categories 1A and 1B of the GHS
6) pesticide active constituents listed by the Stockholm Convention on Persistent Organic Pollutants in its Annexes A and B, and those meeting all the criteria in paragraph 1 of Annex D of the Convention
7) pesticides listed under the Montreal Protocol on Substances that Deplete the Ozone Layer.

Private dwelling means a building classified as Class 1a, 1b, 2 or 4 as set out in the National Construction Code (residential buildings) used only for residential purposes. A private dwelling does not include a dwelling to which workplace health and safety laws would apply. For example, boarding houses, hotels, common lodging house or special accommodation house.

Supply to the public means through retail (including online) outlets.

Requirements
A product may be authorised by notification to the regulator where:

1) the product contains active constituent(s) that are not listed in either:
    a) the list of Potentially Hazardous or Injurious Substances
    b) classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard, and
2) one or more of the following applies:
    a) the national regulator has exempted the product from the operation of the national supply legislation
    b) the product is the same as another chemical product in all relevant particulars other than the name of the product, and/or the holder
    c) the product is a diluted version of an authorised chemical product with:
        i) a pack size not exceeding 5 litres or 5 kilograms, and
        ii) a concentration of active constituent not exceeding 400 grams per litre or 400 grams per kilograms, and
        iii) the authorised chemical product is not listed in schedule 7 of the Poisons Standard or is a restricted chemical product

d) the product is a domestic pest control product with:

i) a pack size not exceeding 5 litres or 5 kilograms, and

ii) a concentration of active constituent not exceeding 100 grams per litre or 100 grams per litre and

iii) a formulation that does not meet any of the following categories of the GHS:

1) 1A, 1B and 2 for carcinogenicity, except for petroleum oils, or other hydrocarbons routinely used as fuel, and boron present as boric acid or borax decahydrate

2) 1A, 1B and 2 for mutagenicity

3) 1A, 1B and 2 for reproductive toxicity, or

a) the product is a home garden pest control product with:

i) a pack size not exceeding 5 litres or 5 kilograms, and

ii) a concentration of active constituent not exceeding 400 grams per litre or 400 grams per kilogram, and

iii) a formulation that does not meet any of the following categories of the GHS:

1) 1A, 1B, and 2 for carcinogenicity, except for petroleum oils, or other hydrocarbons routinely used as fuel, and boron present as boric acid or borax decahydrate

2) 1A, 1B and 2 for mutagenicity

3) 1A, 1B and 2 for reproductive toxicity

4) 1 for acute or chronic aquatic toxicity.

Mandatory standard for pool chemical products

Definitions

Pool chemical product means a product or products:

1) acting through a chemical or biological means, and

2) used in pools or spas located in or at a dwelling, and

3) used to control fungal or microbial pests or

4) used for sanitisation, or

5) used to support the effective use of a product to control fungal or microbial pests or sanitisation in pools or spas located in or at a dwelling.

Dwelling means a building classified as Class 1a, 1b, 2 or 3 as set out in the National Construction Code (residential buildings) used only for residential purposes. This includes boarding houses, hotels, common lodging houses or special accommodation houses. This standard does not diminish the operation of workplace health and safety legislation where the dwelling is subject to these obligations.

Exemption statement

A pool chemical product supplied, or intended for supply, to the public is exempt from the requirements for registration where it complies with the requirements set out for ingredients, pack size, user safety statements, packaging, and labelling.

Ingredients
A product must not contain any ingredient listed as a Potentially Hazardous or Injurious Substance under pesticides and veterinary medicines legislation.

Maximum pack size
The product does not exceed 25 litres or 25 kilograms.

User safety statements
The product instructions must not include a need for special precautions or personal protective equipment (other than can reasonably accessed by a non-commercial entity) in the product's preparation, use, or disposal.

For example, none of the following can be required – protective waterproof clothing, PVC or rubber apron, elbow-length PVC gloves, face shield, goggles, impervious footwear, half-or full-face respirator, or breathing apparatus with air supply.

Labelling
The product must at a minimum have attached a prominent, legible label in English with text that details how a user would comply with section 3 of the Australian Standard for Private swimming pools – Water quality (AS3633:1989). This may also be accompanied by additional information available through smart labelling.

Licence conditions for supply of internationally registered products

The prospective licence holder must ensure that the product can be used in Australia for the same uses as those approved by the equivalent international regulator. This condition would not apply in the case of:

- uses for pests and diseases that do not exist in Australia
- uses for crops and animals that are not grown or produced in Australia
- uses that the licence holder:
  - has determined may harm humans, animals or ecosystems in Australia or may prejudice trade between Australia and places outside of Australia
  - has notified the licensor of this determination.

The licence holder must develop and implement a risk management plan that includes an assessment of risks and control measures for managing the risks with internationally registered products and also includes:

- specific risk assessments and risk management controls for unique Australian circumstances, including:
  - that the label of any internationally registered product complies with relevant Australian labelling requirements for pesticides and veterinary medicines, including the generation of any missing regulatory assessed elements (see Chapter 4) and inclusion of information to manage unique Australian risks
  - an assessment of dietary exposure to any internationally registered product in Australia and that the dietary exposure to these residues does not exceed the Acceptable Daily Intake or Acute Reference Dose (if any) for the active constituent(s) in the international registered product

  - an assessment of environmental exposure for any internationally registered product and the control measures for the product that ensure the environmental exposure is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to ecosystems
  - an assessment of the trade risks of any internationally registered product and the control measures for ensuring the use of the internationally registered product would not prejudice trade between Australia and other countries
- the name, qualifications and details of the person having control of dealings with internationally registered products in Australia
- monitoring procedures to verify risk control measures are effective for managing the risks with international registered products e.g. produce residue monitoring data.

Additional conditions would include the licence holder:

- undergoing an audit of the facilities, equipment, systems, processes, procedures, and personnel used in dealing with international registered products; and
- ensuring international registered products are not supplied for use if:
  - the use of product would result in residues in human food that would contravene the Australia New Zealand Food Standards Code
  - the use of the product would result in residues in animal food that would contravene the APVMA MRL Standard
  - the product would contravene state and territory poisons law
  - publishing the risk management plan on the licence holder's website
- making records, and providing these records to the licensor on request, about:
  - all dealings with any international registered products in Australia
  - the procedures and controls employed for international registered products
  - any stability studies that validate the recommended shelf life and appropriate storage conditions of any international registered products
  - any complaint or product failure in relation to any international registered product, and the investigations and actions undertaken in relation to the complaint or product failure
- details of all international registered chemical products dealt with by or on behalf of the holder of the licence during the previous 12 months.

Annex 6 – Summary of label elements for pesticide and veterinary medicine products

The elements assessed and approved by the APVMA are referred to as 'Regulatory Assessed Elements' (RAE).

Table 11 Pesticide products

Label element	Future state
Signal word heading	Omit from the APVMA's assessment for RAE as the APVMA does not set this requirement – it is fully stipulated by poisons scheduling and WHS legislation.
Product name	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or the licence conditions to supply overseas registered products).
Constituent statements, including active constituents and solvents	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or the licence conditions to supply overseas registered products) or WHS legislation.
Net contents	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (the licence conditions to supply overseas registered products) with reference to National Measurement legislation.
Anticholinesterase statement	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Mode of action	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Statement of claims (simplified description of product purpose)	Omit from the APVMA's assessment for RAE as this requirement will instead be established by conditions of registration (or form part of the licence to supply overseas registered products).
Restricted Chemical Product (RCP)	Omit from the APVMA's assessment for RAE as any such requirements will instead be established by specific conditions of registration (or form part of the licence to supply overseas registered products), when product is determined to be Restricted Chemical Product.
Person responsible for marketing the product	Omit from the APVMA's assessment for RAE by the standard set out under the conditions of registration (or the licence conditions to supply overseas registered products) to identify the person responsible for the product (as distinct from marketing) – consistent with General Product Obligations (GPO) arrangements in Chapter 4.
Directions for use	Continue the APVMA's assessment for RAE to include restraints determined by the APVMA (enforceable). This is distinct from non-assessed manufacturer restraints (to limit liability). The APVMA would not generally apply a restraint to a label in terms of application method but must assess safety of all methods proposed by the manufacturer for inclusion on a label. Operates in concert with user GPOs. Information to be presented in a table of Host/Circumstance, Pest, Application rate. Table to be included in publication of RAE and within the APVMA's publicly available register PubCRIS. For products supplied under a licence to supply overseas registered products, the licence will require that all relevant directions for use on the overseas product be reproduced in full in Australia.
Circumstances where product 'not to be used'	Omit from the APVMA's assessment for RAE as this requirement will instead be established through the user GPOs for responsible stewardship.
Other limitations	Combined into single restraint element for RAE directions for use for registered products.

Label element	Future state
Withholding periods	For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any other limitations will need to be added to labels.
Export slaughter interval	Continue the APVMA's assessment for RAE for registered products. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any export slaughter interval information will need to be added to labels.
General instructions	Omit from the APVMA's assessment for RAE as this requirement will instead be established through general statutory conditions of registration or, for environmental statements, standards set out under the conditions of registration (or form part of the licence to supply overseas registered products). Other general instructions may be required by the manufacturer GPOs, or poisons scheduling and WHS legislation.
Resistance statement	Omit from the APVMA's assessment for RAE as this requirement will instead be established by user and manufacturer GPOs.
Compatibility statements	Omit from the APVMA's assessment for RAE as this is currently not a mandatory element.
Precaution statements	Continue the APVMA's assessment for RAE for registered products and include restraints determined by the APVMA. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any precaution statements will need to be added to labels.
Re-entry periods	Continue the APVMA's assessment for RAE for registered products. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any re-entry period information will need to be added to labels.
Vulnerable area statements	Continue the APVMA's assessment for RAE for registered products and include restraints determined by the APVMA. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any vulnerable area statements will need to be added to labels.
Storage and Disposal	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products) and manufacturer GPOs.
Safety statements	Omit from the APVMA's assessment for RAE as this requirement will instead be established by general conditions of registration (or form part of the licence to supply overseas registered products), for environmental statements any standards set out under the conditions of registration (or again form part of the licence to supply overseas registered products), manufacturer GPOs, poisons scheduling and WHS legislation.
First aid statements	Omit from the APVMA's assessment for RAE as this requirement will instead be established by general conditions of registration (or form part of the licence to supply overseas registered products), for environmental statements any standards set out under the conditions of registration (or form part of the licence to supply overseas registered products), manufacturer GPOs, poisons scheduling and WHS legislation.
Batch number	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Date of manufacture	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).

Label element	Future state
APVMA registration number	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Australian Dangerous Goods (ADG) Code	Content not currently considered as is entirely established by ADG obligations to include content on packaging.
WHS hazard statements	Content not currently considered, as these are required under WHS laws. This should remain the case.

Table 12 Veterinary medicine products

Label element	Future state
Signal word heading	Omit from the APVMA's assessment for RAE as the APVMA does not set this requirement – it is fully stipulated by poisons scheduling or, if not scheduled, WHS legislation.
Product name	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Constituent statements, including active constituent and solvents	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Net contents	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products) with reference to National Measurement legislation.
Statement of claims (simplified description of product purpose)	Omit from the APVMA's assessment for RAE as this requirement will instead be established by general statutory conditions of registration (or form part of the licence to supply overseas registered products).
Person responsible for marketing the product	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products) to identify the person responsible for the product (as distinct from marketing) – consistent with GPO arrangements.
Contraindications	Continue the APVMA's assessment for RAE for registered products to include restraints determined by the APVMA. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any contraindications information will need to be added to labels.
Dosage and administration	Continue the APVMA's assessment for RAE for registered products to include restraints determined by the APVMA (enforceable). Information to be presented in a table of Host/Circumstance, Pest, Dose rate. Table to be included in publication of RAE and within public database. For products supplied under a licence to supply overseas registered products, the licence will require that all relevant dosage and administration directions on the overseas product to be reproduced in full in Australia. This is distinct from non-assessed manufacturer restraints (to limit liability). Operates in concert with user GPOs.
Circumstances where product 'not to be used'	Omit from the APVMA's assessment for RAE as this will instead be established by user GPOs for responsible stewardship.
Other limitations	Combined into single restraint element for RAE directions for use for registered products. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any other limitations will need to be added to labels.
Withholding periods	Continue the APVMA's assessment for RAE for registered products.

Commented [SPE33]: If contraindications, precautions, dosage and administration, are included then the statement of claims is critically important in order to know the context of the label.

Label element	Future state
	For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any withholding period information will need to be added to labels.
Trade advice	Continue the APVMA's assessment for RAE for registered products. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any trade advice information will need to be added to labels.
Side effects	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
General instructions	Omit from the APVMA's assessment for RAE. Rely on general conditions of registration, the standard set out under the conditions of registration (for environmental statements), manufacturer GPOs, Poisons Standard and WHS legislation.
Precaution statements	Continue the APVMA's assessment for RAE for registered products to include restraints determined by the APVMA. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any precaution statement information will need to be added to labels.
Environmental protection statements	Combined into single restraint element for RAE directions for use for registered products and rely on GHS statement. For products supplied under a licence to supply overseas registered products, the pesticides and veterinary medicines risk management plan for the licence will require consideration of whether any environmental protection statement information will need to be added to labels.
Storage and disposal	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products) and manufacturer GPOs.
Safety statements	Omit from the APVMA's assessment for RAE as this requirement will instead be established by general conditions of registration (or form part of the licence to supply overseas registered products), for environmental statements any standards set out under the conditions of registration (or again form part of the licence to supply overseas registered products), manufacturer GPOs, poisons scheduling and WHS legislation.
First aid statements	Omit from the APVMA's assessment for RAE as this requirement will instead be established by general conditions of registration (or form part of the licence to supply overseas registered products), for environmental statements any standards set out under the conditions of registration (or form part of the licence to supply overseas registered products), manufacturer GPOs, poisons scheduling and WHS legislation.
Batch number	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Date of manufacture	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
APVMA registration number	Omit from the APVMA's assessment for RAE as this requirement will instead be established by the standard set out under the conditions of registration (or form part of the licence to supply overseas registered products).
Australian Dangerous Goods Code	Content not currently considered as is entirely established by ADG obligations to include content on packaging.
WHS hazard statements	Content not currently considered as these required under WHS laws.

Annex 7 – General product obligations

General product obligations will apply for all persons dealing with pesticides and veterinary medicines across the life cycle of a product from design to disposal. Examples of the obligations are below.

First obligation

A person dealing with a product would be required to ensure, so far as is reasonably practicable, that the dealing with the product does not result in, is not likely to result in and, will not result in:

- harm to the health and safety of human beings
- unintended harm to the health and safety of an animal, plant, another thing, or the environment
- undue prejudice to domestic or export trade in produce.

Commented [SPE34]: What is this?

Commented [SPE35]: What is 'due' and "undue"?

Second obligation

A person dealing with a product would be required to carry out, or arrange the carrying out of, any calculations, analysis, testing or examination that may be necessary for demonstrating compliance with the first obligation.

For instance, a manufacturer of veterinary medicines would be required to demonstrate its system ensures manufacturing controls are effective in managing the relevant risks (e.g., quality control records).

Commented [SPE36]: While this given example seems reasonable, the obligations apply to all persons dealing with a product from design to disposal. What examinations etc does a dog or horse owner need to take to demonstrate compliance with the first obligation when using a veterinary medicine? There are an infinitude of similar situations.

Third obligation

A person dealing with a product would be required to document and implement a system for demonstrating compliance with the first obligation, including both regular review of the system and regular review of compliance with the first obligation.

These documented systems would be based on those already in place to meet other obligations, including risk management plans for work health and safety, or those required by professional codes of conduct (e.g., for veterinarians). There is a wealth of guidance material available to users of pesticides and veterinary medicines including codes of practice from work health and safety regulators, advice on compiling with professional codes of conduct, and general guidance material produced by industry groups.

For instance, a grains' producer would be required to have a documented system for managing the risks of applying pesticides. The system would be based on a risk assessment of their operations and reviewed periodically, to ensure that it achieves its purpose. Ideally, the plan would be consistent with a standard industry code of practice which would ensure that compliance with this obligation added little or no regulatory burden.

A cattle producer would be similarly required to document the risk management arrangements for the use of veterinary medicines in the treatment of their herd. This may include input from, or reliance on the expertise of, a veterinary surgeon. Again, the Panel considers existing industry practices, and the realities of business would ensure this obligation added little or no regulatory burden beyond current practice.

Commented [SPE37]: What about owners of non-production animals?

Fourth obligation

A person dealing with a product would be required to keep relevant information for demonstrating compliance with these obligations.

A person dealing with a product, on request from the regulator, must provide current relevant information to the regulator in a timely manner to demonstrate compliance with these obligations.

For instance, a commercial applicator would be required to have a system for managing the risks associated with the use of a particular pesticide. The system would be based on a risk assessment conducted by the commercial applicator of their operations. Relevant information such as spray records may be used to demonstrate the system is being implemented and that the controls are effective in managing the relevant risks.

A sheep producer would be required to have arrangements for managing the risks from veterinary medicine use. The arrangements would be based on the producer's risk assessment of their operations. Relevant information such as treatment records, veterinary surgeon prescription label, and details of any withholding period or slaughter interval may be used to demonstrate the producer's arrangements are being implemented and risks are being managed.

Additional obligation for designers and manufacturers

A designer or manufacturer of a product would be required to ensure, so far as is reasonably practicable, that the product is effective, including carrying out, or arranging the carrying out of, any calculations, analysis, testing or examination that may be necessary for demonstrating the product is effective.

Safe harbour for users – taken to comply measures

A primary producer would automatically comply with the first and second obligation if their use is in accordance with all relevant conditions of an authorised product, including any label instructions. An authorised product would mean a product authorised by a registration, licence, exemption or permit under legislation.

A safe harbour would also apply to a person using a pesticide or veterinary medicine as a consumer good (as per Australian Consumer Law).

Annex 8 – The national rule for pesticides

Requirements for the use of pesticides

The following rules apply to all users of pesticides.

1) A user must use a pesticide according to its label or exemption instructions.
2) A user may use a pesticide, on the same commodity as stated for use by the label or exemption, in the following 'off-label' ways:
    a) at a lower rate than stated on the label or exemption
    b) at a lower frequency than stated on the label or exemption
    c) at a lower concentration than stated on the label or exemption
    d) to treat a different pest than stated on the label or exemption.
3) A user may use a pesticide, on the same commodity as stated for use by the label or exemption or on any other non-food crop, in the following off-label ways, as long as the requirements of (2) are met:
    a) to treat a different pest as stated on the label or exemption
    b) prepared in the container to be used for application in combination with another product ('tank mix')
    c) by a different application method
4) A user must record the use of a pesticide according to the national rule for record keeping requirements of pesticides.

Requirements for the record keeping of pesticides use

1) A user of a pesticide must, within 48 hours of its use, cause a record to be made containing the following:
    a) product name
    b) sufficient details to identify the plant(s) receiving treatment
    c) dosage or rate of application
    d) date of use
    e) location
    f) contact details of the user
    g) contact details of the crop owner (if different to the applicator)
    h) start and finish time of the application
    i) equipment used for application (including aircraft in case of aerial application)
    j) weather conditions at the time of application.
2) A user of a pesticide must keep this record for a minimum of 2 years. Records can be written or electronic and do not need to be stored in a single location.

Definitions for the national rule for pesticides

- Contact details means
  - full name
  - business name
  - business or residential address
  - contact number and email
- Sufficient details to identify the
  - plant(s) means
    - its location within the property
    - common or scientific name
  - animal(s)means
    - any identifying markers
    - intended use of the stock (meat, dairy and/or fibre)
    - common or scientific name
- Weather conditions means
  - wind speed and direction
  - humidity
  - air or ground temperature (depending on land or ground application)

Annex 9 – The national rule for veterinary medicines

Requirements for the use of veterinary medicines

1) A non-veterinarian user must use a veterinary medicine according to its label or exemption instructions.

2) A veterinarian may use, or provide written instruction to another person to use, a veterinary medicine according to List A: Selecting veterinary medicines for use in animals.

3) A non-veterinarian user may use a veterinary medicine in an off-label manner where a veterinarian, with direct responsibility for the care of the relevant animal(s), has provided written or electronic instruction for the off-label use.

4) A user must record the use of a veterinary medicine, or a substance used to treat a disease or condition, in a production animal according to the national record keeping rules for veterinary medicines.

List A: Selecting veterinary medicines for use in animals

A veterinarian must choose the first suitable and available veterinary medicine, to treat animals under their care ~~of the veterinarian~~, ~~that is available~~ from the following ordered list:

1) A veterinary medicine registered or exempted by the APVMA or internationally registered products available in Australia under licence for that use in the species requiring treatment

2) A veterinary medicine registered, or internationally registered products available in Australia under licence, for use in a different major animal species (e.g., cattle, sheep, pigs, and chickens for production animals, and cats, dogs or horses for companion animals).

3) A veterinary medicine ~~products~~ registered, or internationally registered products available in Australia under licence, for use in any species, where the product contains the same active ingredient in the same form as a product registered or available under licence in a major animal species.

4) An unregistered including compounded product~~s~~, containing only 'low risk chemicals' (e.g., bicarbonate soda, common salt, food grade products, and reserved chemical products).

5) If the disease/illness is not recurring (for production animals) and the lack of treatment would result in death or significantly poor welfare, a veterinarian may use or prescribe any product of their choosing (including unregistered products, compounded products and TGA registered products) subject to the following restrictions:

   a) the product must not contain an antimicrobial of high importance to human health or other prohibited substance(s) for veterinary preparations

   b) the treatment must not cause injury to human or animal health

   c) an appropriate withholding period is provided so that use of the product does not violate Australian maximum residue limits (MRL), or international MRLs for export-destined product, in animal products or animal feed

   d) where no Australian MRL exists, an appropriate withholding period should be provided so that use of the product would not result in detectable residue levels.

Commented [SPE38]: The AVA recommends that **LIST A** (seemingly developed for production animal species with non-production species mainly overlooked) be discarded and the AVA veterinary medicine cascade adopted (SEE ATTACHMENT C).

Commented [SPE39]: Low risk chemicals can usually (by virtue of being low risk) be acquired freely without a prescription and it is likely that an animal owner will experiment with such use prior to seeking veterinary attention. It is highly unlikely that a veterinarian would prescribe such over-the-counter (OTC) products.

Commented [SPE40]: There are a number of registered products that contain antibacterial agents considered of high importance by ASTAG. For example, 3rd generation cephalosporins (eg ceftiofur and cefovecin), nitrofurans, polymyxins, quinolones, and streptogramins are all active constituents of registered products. If such products become unavailable but are required to continue or initiate treatment of non-production animals then such use is entirely appropriate under the authority of the prescribing veterinarian. For human use only highly important antibacterial agents, use should still be permitted but only (as set out by ASTAG in the 2018 guidelines) under exceptional circumstances, defined as "Based on culture and susceptibility testing, there are no effective alternate agents and the animal is not destined for human consumption."

Commented [SPE41]: When veterinarians select medicines for treatment of particular conditions, they have diagnosed the benefits and risks are determined to ensure that the benefits can be expected to outweigh the risks and with some prospect of improving the health and welfare of the treated animal(s). However, with significant infections or with advanced neoplasia or significant endocrine disorders it may not be possible to completely eliminate all likelihood of adverse outcomes. In other words, in many situations it would not be possible to comply with a direction "must not cause injury to human or animal health".

Commented [SPE42]: There needs to be some consistency in the approach to calculating WHPs for uses of product with or without MRLs. FARAD (Food Animal Residue Avoidance Databank) is a well-established initiative in the USA that provides free scientific-based services to veterinary practitioners that assist in the prevention of drug residues in animal-derived human foods. An analogous scientifically based system is necessary in Australia to ensure that public health and trade are protected while allowed appropriate dosage regimens to be applied for the benefit of animal health and welfare. Apart from use of products not registered for a particular use, the greater issue is the need to vary the dose rate of registered products. This situation is exemplified most by the use of antibacterial agents, many of which have labels approved many decades ago, that now set out dose regimens that are known to be not only ineffective but also likely to provide advantages to pathogens with antimicrobial resistance. Currently there is no consistent approach to reliably vary the WHP period "appropriately" as required by 5c and 5d. Working with the NRS as a tissue residue analytical resource may provide a way to assess the appropriateness of WHP recommendations for off-label use.

Requirements for record keeping of veterinary medicines use

Requirements for non-veterinarian users of veterinary medicines in production animals

1) A user of a veterinary medicine must, within 48 hours of its use, cause a record to be made containing the following:
    a) product name
    b) sufficient details to identify the animal(s) receiving treatment
    c) dosage or rate of application
    d) date of use/prescription
    e) location
    f) contact details of the user
    g) route of administration
    h) condition or reasons for treatment
    i) if more than one animal is treated, the number of animals being treated
    j) withholding period/export slaughter interval
    k) if the veterinary medicine is prescribed by a veterinarian, the contact details of the person prescribinged the veterinary chemical (if different to the user).

2) The date the record was created must be recorded as must the author of the record.

2)3) A user of a veterinary medicine must keep this record for a minimum of 2 years. Records can be written or electronic and do not need to be stored in a single location.

Commented [SPE43]: ...must be available for inspection by appropriately authorised parties.

Requirements for veterinarians using veterinary medicines in production animals

1) A veterinary practitioner using a veterinary medicine must, within 48 hours of its use, cause a record to be made containing the following:
    a) product name
    b) sufficient details to identify the animal(s) receiving treatment
    c) dosage regimen (route, dose rate, frequency and duration of treatment) or rate of application
    d) date of use or date of /prescription
    e) location of animals to be treated
    f) contact details of the user/prescriber
    g) active constituent(s) and concentration
    h) dosage form (for compounded products)
    i) if prescribing or applying using off-label
        i) the manner in which the use is different from label instructions
        ii) an appropriate withholding period/export slaughter interval
    j) total quantity of veterinary chemical medicine prescribed.

k) the date instructions are issued, and the final date of validity of the instructions (not more than 12 months from issuing).

~~k) frequency of dosage and length of treatment~~

l) other directions for use

~~including the date instructions are issued, and the date the instructions are valid till (not more than 12 months from issuing).~~

~~including the date instructions are issued, and the date the instructions are valid till (not more than 12 months from issuing).~~

Commented [SPE44]: What is the basis of this 12 month limit?

Commented [SPE45]: What is the basis of this 12 month limit?

Definitions for the national rule for veterinary medicines

- Contact details means
  - full name
  - business name
  - business or residential address
  - contact number and email.
- Production animal means an animal, other than horses and ornamental fish, that is used commercially to produce food, hide, hair or fleece products for human consumption or use, or is used as food for human consumption, and includes, but is not limited to:
  - buffalo, cattle, deer, fish, goat, kangaroo, pig, poultry, rabbit, sheep, bee, crustacean or mollusc or
  - any other animal known to be used for food production or
  - a species that is used as food for a production animal.
- Sufficient details to identify the:
  - animal(s)means
    - any identifying markers
    - intended use of the ~~stock~~ production animal (meat, dairy and/or fibre)
    - common or scientific name
- Suitable veterinary medicine means a product that has the intended therapeutic effect, is practical to administer, and is available to the veterinarian within an adequate timeframe.
- Under the care of a veterinarian means that the veterina~~ry practice~~ian or his practice must have been given responsibility for the health of the animal(s) by the owner of the animal(s), and that:
  - there are records of a veterinarian within the practice ~~of personally~~ having ~~contact with~~examined the animal(s) for the purpose of diagnosis, treatment and of assuming responsibility for the diagnosis, treatment and outcome; and
  - the veterinarian must have a detailed knowledge of the current treatment status of the animal(s) by having either seen the animal(s) or physically visited the premises within the last 6 months, or consulted remotely with the assistance of digital technology and/or clinical records within the same practice.

Commented [SPE46]: The order seems random. Why not major species followed by minor species?

Commented [SPE47]: Why is this now included in the definition of a production animal? Already this will include an unknown number of aquatic animal species, a variety of insect species.

Commented [SPE48]: What does 'marker's include - is this genetic markers or does it include physical marks or identity tags?

Commented [SPE49]: Is the veterinarian responsible for the 'outcome" [given that the outcome can be dependent on many factors beyond the control of the veterinarian] OR for monitoring response to treatment?

Commented [SPE50]: The appropriate period of time for a physical visit to a remote property remains under review within the veterinary profession and by veterinary boards. Until an appropriate time or range of times is agreed it is recommended that the time period be presented as "within an appropriate period of time that can be justified by the veterinary practitioner on the basis of a property veterinary medicine use risk assessment")

Commented [SPE51]: It is not clear what this means in this sentence.

Annex 10 – Stakeholder Forum

Overall aims

To consider the impacts and other consequences of current and proposed policies, laws and other initiatives that are impacted or are affected by, the use of pesticide and veterinary medicine products, and offer advice to Ministers and stakeholders as appropriate.

To provide a forum for exchanging views, and wherever possible seeking general agreement to matters discussed by Stakeholder Forum participants and reporting proposals and recommendations to the Minister.

Terms of reference

- To be the national forum to express and receive views from participants and interested stakeholders involved in all stages of the pesticide and veterinary medicine regulatory system.
- To identify current, emerging, and future interests and concerns related to pesticides and veterinary medicines policy, regulation, use and disposal.
- To establish effective communication mechanisms for the dissemination of policy and legislative development and proposed reform measures.
- To advise government on the development, promotion and implementation of its policies relating to the responsible use of pesticide and veterinary medicine products.

Membership

The Stakeholder Forum could be made up of senior representatives from organisations covering the plant and animal farming sectors (conventional, regenerative and organic), environmental and conservation groups, animal welfare groups, consumer and health advocate bodies, unions, pesticide and veterinary manufacturing industries, education and training (including research institutions), agricultural and veterinary advice sectors, veterinarians, farm suppliers, animal sports authorities (e.g., Racing Australia, Harness Racing Australia, Equestrian Australia, Greyhounds Australasia).

Senior officials from government departments with a direct interest in and responsibility for pest and disease management, including the use of products for this purpose, will also participate in the Stakeholder Forum.

To ensure the independence of the Stakeholder Forum an independent chair will be appointed by the Minister for a 3-year term with the option of renewal for a further term. Secretariat support will be provided through the Commissioner.

Meeting frequency

The Stakeholder Forum will meet biennially (at a minimum) during the implementation period and first 2 years of operation of the reformed regulatory framework, in a mixture of virtual and in-person events. The effectiveness of the Stakeholder Forum will be reviewed by members after its first 2 years of operation.

Stakeholder Forum recommendations

All recommendations (including findings, outcomes, or other conclusions) by the Stakeholder Forum will be provided to the Commissioner. Government representatives will not be compelled to participate in, but may observe, recommendation processes. Government organisations will not be included in the recommendation process.

Communications

The chair of the Stakeholder Forum will meet with the Commissioner, the CEO of APVMA and the Minister at least twice a year, independent from the Stakeholder Forum meetings.

Specific objectives

- To be actively involved in the development of, and review and comment on, the health risk indicators and system performance measures developed by the Commissioner.
- To review and provide comment on proposed annual monitoring and surveillance plans (see Chapter 3).
- To prepare annually, a list of prioritised issues and submit these to the Commissioner. The Commissioner is expected to provide a response to each issue on the list within 12 months of receipt. Both the list and the response from the Commissioner will be published in the Stakeholder Forum's annual report. The report is to be publicly available and provided to the Commissioner, the CEO of the APVMA and the Minister.
- To monitor progress of the reforms decided by the Government following the Panel's report.
- To recommend topics to the Commissioner for consideration by an Expert Advisory Panel (as needed).
- To promote effective ways for all participants in the pesticide and veterinary medicine regulatory scheme to benefit from the responsible use of these products. This includes identifying and promoting measures (policy, operational or legislative) that are consistent with sustainable production and best practice in pest and disease management.
- To contribute to, and comment on, reports prepared and published by the Commissioner, including the biennial 'state of the system' report.
- To report to the Minister and public annually on the deliberations, and actions, of the Stakeholder Forum.

Monitoring impacts

- To contribute to the identification of measures that effectively monitor consequences (impacts and benefits) from the use of pesticides and veterinary medicines.
- To contribute to the public discussion and contextualisation of the issues related to the use of pesticide and veterinary medicine products.
- To conduct data analytics for data management, mining, and analysis relating to the pesticides and veterinary medicines reporting and monitoring systems.

Annex 11 – Operational Forum

Overall aims

To provide a cross-portfolio, interjurisdictional forum to discuss operational policies and practices, and administering legislation related to the regulation of pesticides and veterinary medicines and to provide recommendations to the Commissioner on changes to improve regulatory practices.

Terms of reference

- To identify points of conflict, opportunities, and areas for improvement between regulatory arrangements relating to pesticides and veterinary medicines.
- To address and, as appropriate, develop operational approaches to resolve conflict or provide advice to relevant Ministers on necessary legislative reform.

Membership

- The forum members will consist of senior officials from government (state, territory, and the Australian and New Zealand governments) agencies or departments with a legislative responsibility for pesticide and veterinary medicine product supply and/or use. This may include multiple representatives from each jurisdiction.
- Observers from Government agencies with an interest in pesticide and veterinary medicine product supply and use may also attend.

Meeting frequency

The forum shall meet at least twice a year, in a mixture of virtual an in-person events.

Specific objectives

- To promote effective communication and information sharing on safe and responsible use and associated controls between regulatory and policy agencies across all portfolios and jurisdictions with interest in, or related to, pesticides and veterinary medicines.
- To review compliance and enforcement effectiveness on use of pesticides and veterinary medicines and to recommend improvements.
- To monitor, review and improve the quality and relevance of legislative frameworks and operational policy development for the responsible use of pesticides and veterinary medicines.
- To contribute to, and comment on, reports prepared and published by the Commissioner, including the biennial 'state of the system' report.
- To make recommendations to the Commissioner for improvements and advances on regulatory assurance mechanisms.
- To report to the Minister and public annually on the deliberations, and actions, of the forum.

Annex 12 – Expert Advisory Panel

Overall aims

To provide the Commissioner with independent advice on matters of policy and regulatory theory relevant to the operation of the pesticides and veterinary medicines regulatory system.

Terms of reference

The Commissioner must identify a specific point, or points, of enquiry that can be resolved through consideration of objective evidence. These point(s) will form the scope of the Panel's considerations. Where the Expert Advisory Panel believes calling for submissions, seeking presentations or other public information activities would aid their deliberations, the Expert Advisory Panel may convene an inquiry. The Expert Advisory Panel is under no obligation to conduct inquiry activities for any matter under their consideration.

The points of inquiry must not relate to regulatory decisions of the APVMA.

Membership

The Expert Advisory Panel will be comprised of at least 3 persons with subject matter expertise, one of which will act as chair.

Expert Panel members may be sourced internationally.

Operation of Expert Advisory Panel inquiries

Expert Advisory Panel inquiries will be conducted on an as-needs basis, dependent on the nature and scope of the enquiry.

The Expert Advisory Panel must have regard to the confidential nature of any submissions or evidence it receives, and may act to preserve that confidentiality.

Notice of convening an Expert Advisory Panel

The Commissioner must publish through its website page, Commonwealth Gazette, and any other means considered appropriate, a notice stating that Expert Advisory Panel has been convened. This notice must be at least 30 days before the Expert Advisory Panel's findings submission date to the Commissioner. Where the Expert Advisory Panel intends to conduct inquiries the notice must be at least 90 days before the findings submission date.

The notice must:

- outline the scope of the inquiry
- identify the panel members and their qualifications
- state the timeframe for report submission.

Where an inquiry is to be held, the notice **must** also

- state the manner in which the inquiry will be conducted (i.e., in-person or written evidence alone)
- invite expressions of interest from parties wishing to present evidence to the inquiry
- identify a means for receiving written submissions addressing the terms of reference

- state that the inquiry is not bound by the rules of evidence, or any practices or procedures applicable to courts of record and may inform itself of any matter it sees fit to add
- state any other matters the Commissioner considers appropriate.

Publication of findings

The Expert Advisory Panel's findings, submitted to the Commissioner, must be delivered in 2 parts. The first details the findings, all of which will be publicly accessible information that the findings relied on, and references to any confidential material (including submitter name and brief description of the material) the Panel relied on in its findings. The second part will include all confidential material (including confidential commercial information or material submitted in confidence) the Panel relied on for its findings.

The Commissioner may give directions prohibiting or restricting the publication of submissions or evidence given to the Expert Advisory Panel whether in public or in private, or of matters contained in such submissions or evidence or in documents produced at an inquiry.

Within 45 days of receiving the Expert Advisory Panel's findings, the Commissioner must submit the report to the Minister, cause it to be tabled in Parliament and published on the department's website in a manner consistent with confidentiality requirements.

Glossary

Term	Definition
AAT	Administrative Appeals Tribunal.
AAWS	Australian Animal Welfare Strategy.
ACCC	Australian Competition and Consumer Commission.
ACL	Australian Consumer Law.
Active or active constituent	The substance(s) in a pesticide or veterinary medicine product that ~~are~~ is primarily responsible for a product's biological or other effects.
Acute effect	Adverse effects that develop rapidly from exposure to a toxic substance.
Acute toxicity	
ADG Code	Australian Dangerous Goods Code. The ADG code provides technical requirements for the land transport of dangerous goods across Australia in conjunction with state or territory law
Adverse experiences/effects	Unintended and sometimes harmful occurrences associated with the use of a pesticide or veterinary medicine.
AERP	Adverse Experience Reporting Program AERP is a post-registration quality assurance program established by the APVMA to help facilitate the risk management of pesticides and veterinary medicines.
AGMIN	Agriculture Ministers' Forum The AGMIN membership comprises Australian, state and territory and New Zealand government ministers with responsibility for primary industries and is chaired by the Australian Government Minister for Agriculture, Drought and Emergency Management. The role of AGMIN is to enable cooperative and coordinated cross-jurisdictional approaches to matters of national interest.
AGSOC	Agriculture Senior Officials' Committee AGSOC comprises all department heads and CEOs of Australian, state and territory and New Zealand Government agencies responsible for primary industries policy issues. It also supports the Agriculture Ministers' Forum (AGMIN) in achieving its objectives.
Agvet chemicals	Pesticides and veterinary medicines.
Agvet Code	*Agricultural and Veterinary Chemicals Code* as set out in the schedule to the *Agricultural and Veterinary Chemicals Code Act 1994.* The Agvet Code makes provision for the evaluation, registration and control of agricultural and veterinary chemical (agvet chemical) products and for related matters.
Agvet legislation	Refers to the following group of legislation: • *Agricultural and Veterinary Chemicals (Administration) Act 1992* • *Agricultural and Veterinary Chemicals (Administration) Regulations 1995* • *Agricultural and Veterinary Chemicals Act 1994* • *Agricultural and Veterinary Chemicals Regulations 1999* • *Agricultural and Veterinary Chemicals Code Act 1994* • *Agricultural and Veterinary Chemicals Code Regulations 1995* • *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* • *Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995*
AI	Artificial Intelligence (also active ingredient).
AICS	Australian Inventory of Chemical Substances.

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Term	Definition
	The AICS is a list of industrial chemicals that are available for use in Australia and is administered by NICNAS.
Antimicrobial resistance	The ability of a microbe to resist the effects of medication.
ANZVCS	Australian and New Zealand College of Veterinary Scientists.
Application item	The type (or category) of application made to the APVMA.
Approved active	An approved active is an active constituent approved for use in Australia.
Approved label	The particulars listed on the label of a pesticide or veterinary medicine product that are approved by the APVMA.
APVMA	Australian Pesticides and Veterinary Medicines Authority (the Australian agvet chemicals regulator)
ATDS	Australian Total Diet Study. An assessment of consumers' dietary exposure (intake) to pesticide residues, contaminants and other substances in food.
Authorisation	An approval, registration, licence or permit.
Biological product/control	A product/method that controls pests such as insects, mites, weeds and plant diseases using other organisms.
Biostimulant	A product able to act on plants' metabolic and enzymatic processes to improve productivity and crop quality.
Carcinogenicity	The tendency of a substance to cause cancer.
CCI	Confidential Commercial Information
Chemical review	See 'Reconsideration'.
Chronic effect	Adverse effects that develop slowly from long, continuous exposures of a hazardous substance.
Chronic toxicity	
Citizen science	Scientific research conducted, in whole or part, by non-professional scientists.
COAG	Council of Australian Governments.
Companion animal	An animal kept as a pet and ~~is~~ not used for production of food, fibre or hide.
Compounding	Compounding involves the small-scale manufacture of an animal medication – generally by a veterinarian or a pharmacist – to fill a treatment void where no suitable registered product is available ~~with the suitable active constituent, dose or form (e.g., tablet versus paste)~~.
Consumer products	Goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption.
Control of Use	The regulation of how a pesticide or veterinary medicine can be used. State and territory governments have responsibility for controlling the use of pesticides and veterinary medicines.
Co-regulation/Co-regulatory system	A system whereby industry develops and administers its own arrangement – to demonstrate compliance, quality assurance etc. – but government provides legislative backing to enable the arrangements to be enforced.
CRIS	Cost Recovery Implementation Statement. A document that sets the fees and charges to be paid by industry for regulatory activities.
Crop grouping	Classification of crops according to similarities relevant to pesticide use. Crop grouping enables formal recognition of data generated in a subset of crops to be extrapolated to other related crops of the same crop group.
CSIRO	The Commonwealth Scientific and Industrial Research Organisation.
Cumulative effects	The effects of multiple exposures to the same chemical across different commodities over time.

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Commented [SPE54]: Alternatively:
The ability of microorganisms such as bacteria, fungi and viruses to develop a capability to grow or survive in the presence of antimicrobials, and to pass this trait on via their genes to other microorganisms.
https://www.amr.gov.au/resources/one-health-master-action-plan-australias-national-antimicrobial-resistance-strategy-2020

Commented [SPE55]: This is not the conventional toxicology definition. Suggest using the GHS definition.

Commented [SPE56]: Many companion animals are kept for fibre production – for example, fibre can be harvested from long haired dogs, cats, rabbits and used for knitting and other purposes.

Term	Definition
CVMs	Compounded Veterinary Medicines.
Data protection	Limiting the use of information, including its use in connection with an application for authorisation of another product, or for variation of the relevant conditions of authorisation of another product.
Delay Costs	The foregone profits resulting from longer times to access a market.
Department (the)	The Department of Agriculture, Water and the Environment.
DPI	Department of Primary Industries
ECHA	European Chemical Agency
Effectiveness	
Efficacy	The ability of a product to produce its claimed effects.
EFSA	European Food Safety Authority.
EPA	Environmental Protection Agency.
Epidemiology~~ical~~	The branch of medicine dealing with the incidence, distribution, spread and control of disease.
ESI	Export Slaughter Interval
Exemptions	A measure to provide that a provision in legislation does not apply, either with or without conditions.
FAO	Food and Agriculture Organization of the United Nations
Farm survey data	ABARES long running farm survey program, which annually collects data on the physical and economic performance of Australian farms.
FSANZ	Food Standards Australia and New Zealand.
FTE	Full-Time Equivalent.
GAP	Good Agricultural Practice. The environmental and operational conditions necessary for the production of safe, wholesome food.
GHS	The Globally Harmonized System of Classification and Labelling of chemicals.
GMO	Genetically Modified Organisms.
GMP	Good Manufacturing Practice.
GRAS	Generally Recognised As Safe. A US FDA designation that a chemical added to food is considered by experts to be safe and is therefore exempt from food additive tolerance requirements.
GTA	Grain Trade Australia.
HACCUT	Harmonised Agvet Chemicals Control of Use Task group.
Hazard	The potential of a biological, chemical or physical agent to cause harm.
Hazard assessment	A consideration of the inherent harm something can cause. It does not consider the likely exposure or chance of the harm occurring.
HGP	Hormonal growth promotant.
IGA	Inter-Governmental Agreement on pesticides and veterinary medicines.
IPM	Integrated pest management.
IUCLID	International Uniform Chemical Information Database.
Label particulars	The particulars, including use instructions, to be contained on the label of a pesticide or veterinary medicine.
Levies	An amount paid by registration holders based on volume of registered pesticide and veterinary medicine product sales.

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Commented [SPE57]: Alternatively:
Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.
https://www.cdc.gov/csels/dsepd/ss1978/lesson1/section1.html

Term	Definition
Manufacturing Licence	The authority to manufacture veterinary medicines not listed in section 59 of the *Agricultural and Veterinary Chemicals Code Regulations 1995*.
Limits on use of information	See 'Data protection'.
Listed chemical product	A pesticide or veterinary medicine product prescribed in Schedule 3B – Listed Chemical Products of the Agvet Code Regulations.
Minor use	A minor use is the use of a product or constituent that does not produce sufficient economic return to make it worthwhile for an applicant to seek registration on their own.
MoU	Memorandum of understanding.
MRL	Maximum Residue Limit. A maximum residue limit (MRL) is the highest amount of an agricultural or veterinary (agvet) chemical residue that is legally allowed in a food product sold in Australia whether it is produced domestically or imported. https://www.foodstandards.gov.au/consumer/chemicals/maxresidue/pages/default.aspx
Mutagenicity	The tendency of a substance to permanently alter the genetic structure of cells or organisms.
NGO	Non-government organisation.
NICNAS	National Industrial Chemical Notification Assessment Scheme.
Non-urban land management	The caretaking of areas in a rural or environmental zone.
NRA	National Registration Authority for pesticides and veterinary medicines (former name of the APVMA).
NRS	National Registration System The National Registration Scheme for Agricultural and Veterinary Chemicals (National Registration Scheme (NRS)) was established under Commonwealth and state and territory legislation.
NWPGP	National Working Party on Grain Protection.
NZEPA	New Zealand Environmental Protection Agency.
NZ MPI	New Zealand Ministry of Primary Industries.
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
Panel	The group of individuals appointed by the former Minister for Agriculture to undertake the review of the agvet chemicals framework.
Parasiticide	Any substance capable of destroying parasites.
Permit	An authorisation allowing ~~for~~ the legal use of pesticides and veterinary medicines that would otherwise be unlawful e.g., A permit for the limited use of an unregistered pesticide or veterinary medicine product.
Prescription	A written instruction provided by a Veterinarian to allow the dispensing of a veterinary medicine, including compounding.
Pesticide	See Annex 5.
PHAA	Public Health Association of Australia
Pharmacovigilance	The collection, detection, assessment, monitoring, and prevention of adverse effects from pharmaceutical products.
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMRA	The Pest Management Regulatory Agency in Canada

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Commented [SPE58]: This is not the conventional toxicology definition. Suggest using the GHA definition or that of

Commented [SPE59]: Alternatively:
A substance that can inhibit the growth, reproductive capacity or can kill a parasite. Also known as an antiparasitic agent. Includes agents active against helminths (nematodes, cestodes, trematodes), protozoa, and arthropods (insects, arachnids etc)

Commented [SPE60]: Does this include Vaccinovigilance?

Term	Definition
Poisons schedule	Poison schedules provide a means of classifying poisons on the basis of potential of harm to humans to identify the degree of control to exercise over their availability to the public. Scheduling is undertaken ~~by~~ within the TGA.
Post-market (regulation, compliance, information)	Regulatory activities undertaken, including information gathering, after a product is registered by the APVMA.
Pre-market (assessment, regulation)	Regulatory activities undertaken before a product is registered by the APVMA.
Primary producer	An individual or entity whose business activities involve plant or animal cultivation, fishing, pearling, or forestry.
Produce Monitoring	The testing for pesticide of veterinary medicine residues in food commodities.
Production Animal	An animal that is farmed for food, fibre or hide.
Prophylactic product	A product intended to prevent disease.
Protected information	See 'Data protection'.
PubCRIS	Public Chemical Registration Information System PubCRIS is a publicly facing database for registered products, approved active constituent and permits. It contains the product name, product category, host and pest information and in most cases, a products label (or list of relevant label particulars).
QA scheme	Quality Assurance scheme.
QR codes	Quick Reference codes. A machine readable optical label that contains information about the item to which it is attached.
R&D	Research and Development.
RAE	Regulatory Assessed Elements. The elements of the label assessed and approved by the APVMA.
Reconsideration	The formal process of reviewing a pesticide or veterinary medicine where new information suggests a change in the risks to human health, the environment, animal or crop safety, and trade.
Record (the)	The Record of Approved Active Constituents for Chemical Products kept under section 17 of the *Agricultural and Veterinary Chemicals Code Act 1994.*
Reference product	A registered pesticide or veterinary medicine product referred to in an application for another product because information for that registered product is relevant to the application.
Register (the)	The Register of Agricultural and Veterinary Chemical Products kept under section 18 of the *Agricultural and Veterinary Chemicals Code Act 1994*.
Registered product	A pesticide or veterinary medicine product contained in The Register of Agricultural and Veterinary Chemical Products.
Repack	A product, or application for a product, that is the same in all particulars including site and method of manufacture as a registered pesticide or veterinary medicine product but registered with a different name and/or owner.
Reserved chemical product	A pesticide or veterinary medicine product in Schedule 3C – Reserved Schedule of the *Agricultural and veterinary Chemicals Code Regulations 1995.*
Residue	Any components, derivatives, metabolites or degradation products of a pesticide or veterinary medicine remaining in a commodity following use.
Resistance	The decreased susceptibility of a pest or disease agent to a product that was previously effective at controlling that pest or disease agent.
Restricted Chemical Product (RCP)	A highly hazardous product which may only be supplied to authorised persons. RCPs are declared by the APVMA under the AgVet code.
RIS	Regulatory Impact Statement

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Commented [SPE61]: It is now more broadly known as MEDICINES AND POISONS SCHEDULING. The TGA definition of SCHEDULING is:
Scheduling is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety.
https://www.tga.gov.au/scheduling-basics

Commented [SPE62]: What about free roaming animals (eg goats or kangaroos) that are harvested but not farmed?

Term	Definition
	A RIS assesses the costs and benefits to the Australian community of a policy or regulatory proposal.
Risk	The probability of an agent (hazard) causing an adverse effect and the magnitude of that effect (expressions of risk can be quantitative or qualitative, and should include consideration of any uncertainties). (JETACAR Report, 1999, p222)
Risk assessment	~~A r~~Risk assessment considers both the hazards posed by a product, ~~and~~ the likely exposures of humans, animals and the environment to these hazards, to estimate the likely risks to human, animal or environmental health associated with each of the various exposure scenarios.
RSPCA	Royal Society for the Prevention of Cruelty to Animals.
Rolling review	A regulatory tool used to speed up the assessment of a product.
Scheduling	The process by which medicines and poisons are classified, controlling how they are made available to the public.
Slaughter interval	The minimum period that needs to elapse between: (a) the last use of the product in relation to an animal; and (b) the slaughtering of the animal for human consumption
Social licence	The acceptance granted to a company, organisation or activity by the community.
Statutory criteria	The list of criteria that the APVMA must be satisfied is met before approving an application. The statutory criteria include: • safety criteria • trade criteria • efficacy criteria • labelling criteria
Statutory office holder	A person who holds a position to which duties and function are specifically assigned in legislation.
Synergistic effects	The effects that 2 or more chemicals have in combination, that are ~~different~~ superior to~~from~~ the effects caused by sum of the individual substances.
TGA	Therapeutic Goods Administration The TGA is the regulatory body for human therapeutic goods in Australia. It is a Division of the Australian Department of Health.
Timeframe performance	The proportion of applications determined within the period required for the application.
Veterinarian/Veterinary Surgeon/Veterinary Practitioner	A person qualified and authorized to practice veterinary medicine.~~A person qualified to treat diseased or injured animals.~~
Veterinary medicines	Products to treat or prevent disease in animals.
VPCP	Vertebrate Pest Control Product
VPRU	Vertebrate Pest Research Unit (New South Wales Department of Primary Industries)
WHO	World Health Organization
WHP	Withholding Period [add definition]
WHS	Work health and safety

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