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Department of Agriculture, Water and the Environment

Final Report of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia

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Prepared by the Independent Review Panel

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Letter of transmittal

Independent Review of the
Pesticides and Veterinary Medicines
Regulatory System in Australia

Panel chair – Ken Matthews AO

28 May 2021

Dear Minister,

I am pleased to submit to you the final report of the independent Panel established to review the pesticides and veterinary medicines regulatory system in Australia.

The terms of reference for the review asked the Panel to undertake a review of the regulatory framework from first principles, and to provide recommendations for reform to ensure it is contemporary, fit for purpose, reduces unnecessary red tape, and increases the value of Australian agriculture.

As we have tackled the task, the Panel has consulted as widely as possible, engaging with over 200 stakeholders. We released for discussion an Issues Paper and subsequently published for comment a Draft Report. We have considered over 170 written submissions. We established a consultative committee with key stakeholders, and we have met with state and territory officials on nine occasions.

It was important to work in such a transparent way because stakeholder views about Australia's regulatory system are strongly held. For years, key stakeholders have argued, sometimes loudly, that a range of systemic improvements should be made and that reform is overdue.

The Panel agrees. Reform is long overdue. Not only has the Panel identified many opportunities to improve the performance of Australia's regulatory system overall, but if we fail to do so, the critically important social licence to continue to use pesticides and veterinary medicines will be at risk. Community attitudes, especially in urban Australia, to farmers' agricultural chemical use are becoming steadily more demanding. Human health and safety, animal health and welfare, environmental protection, and transparent public processes need to be, and be seen to be, taken very seriously.

There have been many previous attempts to reform Australia's regulatory system. However, reforms suggested by these reviews have tended to be issue-specific and partial, not whole-of-system; they have been episodic, not continuous; and they have been incremental, not ambitious. A number of reforms have either not been implemented at all, or not been effectively implemented. Where there has been implementation, the reforms have often not been utilised to their full potential.

Too often, the previous reviews have focused only on the APVMA – but the Panel considers that Australia's regulatory system as a whole is much more than just the APVMA.

In its initial work, the Panel undertook a 'diagnosis' of the current problems, stakeholder criticisms, and future challenges in the current system. We then developed a 'prescription' to deal with the diagnosis. Some of the key elements of the diagnosis (the case for change) were:

- Growing community concern about the use of pesticides and veterinary medicines and the risk of losing the social licence to continue their use
- A lack of clarity about the purpose and objectives of the regulatory system as a whole
- The absence of a clear point of policy leadership and responsibility for the continuing adaptation and improvement of the system as a whole
- A lack of access for Australian farmers and other users to pesticide and veterinary medicine products and uses approved in competitor countries
- Inconsistency across state and territory borders in the way the system deals with control-of-use
- Reluctance by regulators to give credit to industry's own QA and stewardship programs as a means to strengthen safe chemical use
- Sometimes slow and difficult processes to register pesticides and veterinary medicines and uses
- Poor prioritisation of registration and control-of-use efforts to match actual levels of risk
- A lack of resilience in the regulatory system to deal with change and unexpected events
- Distortions, inequities, inefficiencies, cross subsidies, and a lack of sustainability in the cost recovery arrangements that apply throughout the regulatory system
- Outdated relationships between regulators (both supply and control-of-use) and those they regulate.

The Panel thus concluded that **the status quo is untenable**. It is not a question of whether change is needed but rather, how and how fast to change.

In developing its recommended 'prescription', the Panel has developed for your consideration some bold reform opportunities that will make a real and enduring difference, as well as common sense – sometimes long overdue – improvements to current processes. We have assembled a package of mutually supportive initiatives that, as the reform process unfolds, will transform Australia's regulatory system to enable it to continue to deliver for Australians for at least the next 30 years.

The reform package comprises a great many changes and improvements which need to be made to the regulatory system over the years ahead. Of course, not all the reforms can be tackled at once and the Panel is proposing that you consider launching the package not as a one-time package, but as a multi-year process of reform-by-reform modernisation of the regulatory system.

There will be many opportunities for stakeholders during that process of transformation to give their views about the design of each individual reform as details and legislation are developed.

What are the reforms? The most significant Panel recommendation is the introduction of a single national law to control the use of pesticides and veterinary medicines in all jurisdictions of

Australia. The Panel sees this historic reform as completing – at last – the reform process commenced in the early 1990s when Australia first moved to a single national agvet chemical supply registration process from separate processes in each state. At that time, while **supply** registration was centralised, responsibility for **controlling the use** of registered products was left with the disparate arrangements of the states.

The Panel's second flagship reform is the introduction of an innovative licensing system that, subject to rigorous conditions and comparable regulations, would enable overseas-registered pesticides and veterinary medicines and uses to become available in Australia. The Panel sees this reform as ground-breaking among developed countries, and of enormous potential and long-term value to Australia's farmers and other users of pesticides and veterinary medicines.

Other complementary reforms include:

- A new vision for Australia's regulatory system as a whole (providing guidance for all players about what the system is trying to achieve)
- Nationally consistent arrangements for licensing pesticide-related activities (replacing separate and disparate State-by-State licensing arrangements)
- Strengthening whole-of-chain shared responsibility (including taking advantage of industry's own quality assurance, and stewardship programs – an initiative long-sought by industry)
- Improving the pesticides and veterinary medicines registration process (a range of efficiency improvements)
- Reforming cost recovery (the source of much stakeholder dissatisfaction over the years)
- Building serious arrangements for stakeholder consultation and input (past arrangements have been ad hoc and ephemeral)
- Improved arrangements for monitoring the performance of the regulatory system (so the outcomes and impacts of the system can be seen and public confidence improved)
- Building-in continuous improvement to the regulatory system as a whole (so that unlike previous reviews, the reforms from this review will actually be driven through to completion, and new reform ideas will be added as they emerge in the future).

The Panel has also tried to sharpen up the 'identity' of the system. In addition to its primary role in delivering safety, we have stressed that the regulatory system should consider itself a vital factor in the competitiveness of Australia's farmers. While the safety of all Australians is the ultimate purpose of Australia's regulatory system, internationally competitive Australian agriculture requires an internationally competitive regulatory system for its pesticides and veterinary medicines.

Building respect for farmers into the system will be a progressive process over the years of regulatory transformation ahead. However, an important initial initiative is to give credit to farmers for their own QA and stewardship programs. Where suitably rigorous grower-based programs can strengthen the safety chain, it makes good sense to leverage them. Leveraging them also strengthens the value proposition to farmers of participating in the programs. Both safety and the programs themselves are improved as a result.

In its work, the Panel has been careful to protect the position and reputation of the APVMA. The Panel respects the integrity and professionalism of the Authority. The Panel wants the future regulatory arrangement to be independent, based on science, and trusted by the community. The APVMA currently delivers these objectives.

However, while the APVMA is an important part of Australia's regulatory system as a whole, as a specialised scientific agency with a specific remit, the APVMA cannot provide whole-of-system leadership. As the **supply** registration agency, the APVMA cannot **control the use** of pesticides and veterinary medicines in the field. As an independent scientific assessment agency, the APVMA cannot provide policy advice to the government. As a key player itself in the regulatory chain, the APVMA is not in a position to drive other players in the continuing journey of reform transformation which you may be launching following the Panel's report.

For these and other reasons the Panel is recommending the creation of a new statutory position within the Department – the Commissioner for Pesticides and Veterinary Medicines. The Commissioner would be responsible for whole-of-system leadership and policy advice to you. The Commissioner would put in place arrangements for whole-of-system surveillance and reporting and would provide structured and respectful access for stakeholders, including farmers, to comment and provide suggestions for improvements to the regulatory system as a whole.

Most importantly, the Commissioner would be charged with producing a biennial report for Parliament on progress with the reforms decided by the Government and recommending any adjustments or further reforms to take account of developments in the operating environment.

The Panel is convinced that the latter role would build-in a valuable dynamic of continuous improvement which has been lacking over the last few decades but is a key objective of modern regulatory practice.

It is the Panel's view that the multi-year process of transformation to be embarked upon, must critically include transformation of regulatory attitudes and practice by the authorities responsible for both supply regulation and control-of-use. This is an important opportunity to advance the Government's recently refreshed Deregulation Agenda.

The Panel's report highlights some of the key attitudinal changes we think are required, including:

- a stronger focus on outcomes-oriented regulation
- work prioritisation based more heavily on relative risk
- greater openness to leveraging industry's own quality assurance schemes
- stronger efforts by system regulators to encourage voluntary compliance
- a stronger commitment to transparency of performance, based on published performance indicators and regular public reporting of performance and whole-of-system regulatory outcomes
- a stronger culture of constructive collaboration between separate agencies in the interests of the system as a whole

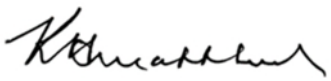
- maximising regulators' accessibility and responsiveness to external stakeholders
- active support for the development of national regulatory and risk management capacity outside the government sector.

Changes like these will be transformational. In assembling its recommendations, the Panel has sought to transform Australia's current system to ensure it will be 'fit for any future' and able to deal with radically new farming systems alongside conventional Australian farming, as well as facilitating the introduction of innovative disease prevention and therapeutic options for livestock, companion animals and a range of other animal species.

Accommodating these futures is not a one-time change; it requires processes to continue transformation, adaptation and flexibility as the future emerges. This necessary process of transformation will be spearheaded by the proposed Commissioner, in its periodic advice to you.

In summary, the Panel is convinced that substantial reform is necessary. The package we are recommending to you will deal with the range of current problems of the system as well as pre-empting many future challenges. The package will need to be implemented over a period of years. Safety will remain the primary purpose, while functional and attitudinal change will transform the system to be fit for any future. We commend the package to you.

Finally, I want to take this opportunity to acknowledge the hard work and commitment by my Panel colleagues, Dr Anne Astin AM PSM, Dr Mary Corbett, and Dr Craig Suann. They have worked tirelessly to produce this blueprint for the progressive transformation of Australia's regulatory system. I also want to thank and commend the high performing team of officials who have supported us, led by Ms Julie Gaglia.



Ken Matthews AO

Panel Chair

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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 (see Annex 1). The Panel is required to 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 (Commonwealth, state and territory), 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 final 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.

Digestible summaries of the Panel's reforms and the benefits they afford key stakeholder groups are included at Annex 13. The information sheets provide tailored information for community groups, chemical companies, consumers, farmer and grower groups, pesticide applicators, and veterinarians.

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, animal welfare and environmental protection.
- Improving the efficiency and timeliness of regulatory decisions.
- 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 that should be embraced to streamline the framework and reduce red tape. Existing tools and systems could be better used, and new processes or systems introduced where needed.
- Shared responsibility – co-regulation is being increasingly adopted in modern regulatory systems and provides for greater accountability on all parties within the system.

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 on the Issues Paper 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 group (HACCUT) network.

The consultation process on the Draft Report involved 21 meetings with 78 stakeholder groups, also mostly via COVID-safe videoconference. The Panel also met with the HACCUT network and the Consultative Committee. The Panel received 72 written submissions on the Draft Report.

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 has met with the CEO and senior officers multiple times throughout the review, including face-to-face meetings in Canberra and Armidale (pre-COVID) which provided the opportunity for staff to contribute to the Panel's deliberations.

Key themes from consultation on the Draft Report

Stakeholder feedback on the Draft Report centred around a number of key themes which focused the Panel's discussion and influenced the final form of recommendations for this report. The key themes raised by stakeholders were:

- principles of the revised pesticide and veterinary medicines regulatory system
- nationally harmonised control-of-use
- the Commissioner for Pesticides and Veterinary Medicines
- compounding of veterinary medicines and the prescription cascade
- international licensing
- monitoring and surveillance.

This report

The Panel is convinced that certain far-reaching changes are necessary to deliver a responsive and adaptive future regulatory system. This final report delivers a number of vital reforms through recommendations. It is based primarily on the recommendations in the Draft Report, which have been refined based on stakeholder feedback and further Panel deliberations.

The Panel received valuable feedback during the conduct of its review and this has helped shape the final recommendations. The Panel understands that some of the recommendations in its Draft Report have sparked strong and not necessarily supportive responses from some stakeholders – and to some extent have been misunderstood.

The Panel has invested significant time and effort in assessing and analysing stakeholder views in finalising its report, and has used this feedback to refine and improve its reforms. The Panel accepts that some of the recommendations will not please all stakeholders. However, the Panel believes its recommendations are not only necessary and viable, they are essential for the future of the pesticides and veterinary medicines regulatory system.

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 the changes proposed.

The rise of biologically based pesticides and GMOs, as well as vaccines for animals means the terminology 'chemicals' is no longer an accurate descriptor. The Panel recognises that the products regulated by the system are not only used in agricultural settings, but are also used in a variety of other contexts, for example in urban and non-urban land management, home and garden settings, domestic pest control and for companion, exotic animals and native fauna.

For these reasons, and a desire to clearly differentiate the current and future regulatory systems, and to mark the start of the recommended regulatory transformation process, the Panel has chosen to update the terminology for the regulatory system from agricultural and veterinary (agvet) chemicals to 'pesticides and veterinary medicines'.

To avoid confusion in this report, the Panel has referred 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, ecosystems, and trade and the safety and welfare of animals when 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 $200 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 potentially extensive 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 Estimated key regulatory savings to industry.

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 (this was not a requirement for this review). The regulatory cost impacts of the Panel's recommendations are presented as a guide only to support stakeholder consideration. This report 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 $200 million return over a decade).

Table 1 Estimated key regulatory savings to industry

Reform	Regulatory saving (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.
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	Improving accessibility to active constituents and increasing 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.

Note: This table highlights the estimated 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 $200 million (see Annex 4 for this detail).

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, and ensuring animal health. These products are critical to agricultural productivity and the competitiveness of Australian primary production, significantly contribute to environmental sustainability, and play a key role in animal 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. 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 system 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 see important opportunities for industry to exercise greater responsibility and accountability for managing the safe manufacture and use of these products in line with modern regulatory practice. This presents opportunities to further strengthen the system.

Community attitudes and expectations have also changed and there is greater awareness and understanding of the potential impact of the misuse of pesticides and veterinary medicines and a greater desire to know the provenance of food and fibre 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):
  - A new vision for the pesticides and veterinary medicines regulatory system, guided by the 6 key objectives of: protecting human health and wellbeing, protecting animal health and welfare, protecting the environment, supporting primary industries, protecting Australia's trade, and contributing to biosecurity preparedness.
  - 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, for both the supply and use of pesticide and veterinary medicine products. The Panel recommends that the Commonwealth have responsibility for developing and maintaining the single national law, while the states and territories will continue to deliver control-of-use regulatory functions. Delivery will be within a consistent framework developed under the single national law. The Panel is also recommending that the Commonwealth provide conditional, additional funding to the states and territories to ensure resourcing for these functions is sustained.
  - 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.

- 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 visibility and understanding of the use of pesticides and veterinary medicines and their impacts in Australia.
  - The Panel recommends a comprehensive 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 advances whereby smart labelling will improve access to tailored information.
  - The Panel recommends better regulation of compounded veterinary products which are playing an increasingly important role in the treatment of companion animals and exotic species. This would be through the adoption of a protocol approach to guide veterinarians in prescribing the most suitable veterinary medicines, and improvements in compounding practice.

  - Additionally, to reduce harm to the environment, the Panel encourages the continuation, expansion and formal recognition of suitably rigorous 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 medicines provides all Australians with flexibility to manage pests and diseases and use products that best suit their unique situation. Alternatives to existing pesticide 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 for 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 would, however, be required to address the risks associated with the use of the product and put in place measures to address any unique Australian circumstances.
  - 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 with equivalent access to their international counterparts.
  - In response to stakeholder feedback on its Draft Report, the Panel has developed an additional approach to provide access to uses for priority pest, disease and animal health needs via supplemental labels. The Panel sees supplemental labels as bridging the gap between permits and registration, and providing a pathway to get minor uses registered while providing the same level of risk assessment and management as exists in the current permit system.
  - The Panel considers that linking the needs of Australian plant and animal health sectors to the supplemental label process will empower and facilitate partnership efforts between growers and the chemicals sector to pursue registration of identified priority needs.

- **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 resources on products of higher risk while maintaining 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 establishing specific criteria for emergency research and minor use permits to better reflect the differences in risks posed by the controlled or limited use allowed through permits relative to the broad scale or generalised uses set out through registration. Additionally the Panel recommends establishing a licensing scheme for entities undertaking multiple research activities to reduce the need for multiple applications for permits to be made to the regulator.
  - 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.

- 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.
  - Finally, the Panel sees opportunities to better support entry to the market, by pre-application third-party assessment, which would also expand the assessment skills base in Australia 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 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 $200 million across all pesticides and veterinary medicines industry sectors over 10 years, with these savings to be ongoing and likely to increase over time 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 58 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.

Overview of the reforms

The Panel has designed its key reforms around the objectives of the new regulatory system (see Chapter 1). Each chapter of the Panel's report recommends reforms that align with the objectives of the future regulatory system, as well as the overarching principles of modernising and streamlining regulation, and the enhanced approach to shared responsibility and co-regulation (Figure 1).

Figure 1 Alignment of reforms to regulatory review vision and objectives

✓ **Primary benefit**
✓ **Secondary benefit**

	Whole of System Vision and Objectives						**Overarching Reform Objectives**	
	Protect human health and wellbeing	**Protect animal health and welfare**	**Protect the environment**	**Support primary industries**	**Protect Australia's trade**	**Contribute to biosecurity preparedness**	Modernising and streamlining regulation	Enhanced approach to shared responsibility/ co-regulation
Establishment of a Truly National Regulatory System: • Single National Law • National Leadership through Commissioner • Whole of System Reporting • Increased engagement and consultation.	✓	✓	✓	✓	✓		✓	
Protecting the Health & Safety of People, Animals and the Environment: • System-wide domestic surveillance • Domestic produce monitoring • Increased environmental monitoring • National Adverse Experience Reporting • Improved chemical reviews • Humaneness Assessment.	✓	✓	✓		✓		✓	✓
Ensuring responsible use • General product obligations • A single national licencing system • Consistent training standards and required completion of accredited education.	✓	✓	✓	✓	✓	✓	✓	✓
Improving choice in pest and disease management tools: • Refocussed scope of what products are regulated • Revised definitions of pesticides and veterinary medicines • Targeted assessment effort by the APVMA • 'Fast track' assessments of particular application types and nationally consistent use patterns • An international licencing scheme.	✓	✓	✓	✓	✓	✓	✓	✓
Contributing to supply chain resilience • Building Australia's supply chain resilience • Active constituents approved at substance level • Third party assessment and expanded skill base.	✓	✓	✓	✓	✓	✓	✓	

1 Introduction

1.1 The role of pesticides and veterinary medicines in modern society

Pesticides and veterinary medicines play a fundamental role in Australia's social and economic wellbeing, are critical to agricultural productivity and competitiveness, and significantly contribute to environmental sustainability through weed, pest, and disease control. Veterinary medicines also play a key role in ensuring animal health and welfare across a wide range of species. Together, pesticides and veterinary medicines contribute enormously to Australia's safe, clean food supply chain.

In our modern society, 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 in the natural and cultivated environment 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 a 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 impact 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 natural ecosystems and crops and seriously affect Australia's livestock industries by preying on stock, competing for pasture, transferring disease, damaging flora and other environmental assets and triggering soil erosion. 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 aim to 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 up to 10% of a broadacre farm cash income (i.e., total cash receipts minus total cash costs), which was $153,000 per farm in 2019-20 (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. Important 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 preventing and managing pest and

disease incursions in Australia both at, and post, the Australian border such as through fumigation, insecticide treatments and vaccinations.

In a similar way, pesticides and veterinary medicines are vital for the continuing success of Australia's agricultural exports which are valued at over $40 billion annually (ABARES 2021). Many of Australia's international trading partners have imposed restrictions on the presence or level of certain chemical residues in their agricultural imports. These restrictions provide a strong incentive for safe and responsible use of pesticides and veterinary medicines employed in Australian agricultural systems.

Responding to community expectations

Overall, pesticides and veterinary medicines play a critical role in animal health and welfare, environmental and ecosystems management, and Australia's agricultural production. Australia's future pesticides and veterinary medicines regulatory system must meet the community's clear expectations that the system will scrupulously protect human and animal health and welfare and the environment. At the same time, the system needs to enable primary producers to produce safe food for Australians while remaining internationally competitive.

To maintain the social licence to continue to use pesticides and veterinary medicines, the regulatory system needs to respond to heightened consumer, community, and user concerns and expectations on matters such as involuntary exposure to harmful chemicals, environmental contamination, reports of mass bee deaths, as well as provenance, and the traceability of food supply chains, to name a few. Demands are increasing for greater transparency about pesticides and their use. Consumers wish to know more about the provenance of their food and fibre and expect traceability in their food supply chains. They are seeking more effective investigations, reporting and corrective action when adverse events occur. Veterinary medicines, particularly those for use in companion animals under the care of veterinarians, do not face the same level of community concern in relation to their ongoing use.

Simultaneously, across the world there are increasing demands for more sustainable and ecological agricultural practices with concomitant reductions in the use of pesticides. This is driving agricultural reform and innovation in several areas, including the development of biological-based pesticides, and the use of technologies such as drones to provide more targeted application, but will require continued focus now and into the future.

There has been an increasingly vigorous community debate about the use of pesticides and, to a lesser degree, veterinary medicines in food production. This has resulted in a sharp divide in parts of the community, with some recognising and valuing the benefits of these chemicals in contributing to a safe, economical and secure food supply while others perceive that most, if not all, pesticides are toxic, harmful, and damaging to humans, animals, and the environment.

Responding to users' expectations

While these community concerns and perceptions need to be responded to, and any evidence of harm investigated thoroughly and transparently, it is important that the regulatory system also continues to deliver the safe use of pesticides and veterinary medicines and recognises their contribution to Australia's food supplies. These products are a vital tool for everyday use in agriculture and landscape management 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 livestock, companion animals and the vast number of other animal species (including fauna).
- control pests and diseases that may otherwise negatively impact our food supply and damage agricultural, fishery and forestry production
- manage weeds, feral animals, pests and diseases threatening our natural environment.

The Panel heard consistently from users of agricultural and veterinary chemicals about the importance of the regulatory system delivering improved access to new, innovative, and potentially safer pesticides (such as the biofungicide Stargus) and veterinary medicine products. Feedback also confirmed that, while access to new products was certainly desirable, access to other uses for existing products was also critical. Such uses were often not registered in Australia simply due to the small market size in Australia (Commonwealth of Australia 2019).

For example, the product 'Luna Privilege' is registered for many uses in the USA (e.g., stem and stalk vegetables, root and tuber vegetables, citrus fruits, cereal grains, berries, and legume vegetables), but only registered for banana crops in Australia.

The benefits of increased access to new products and uses 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
- access to a wider range of products to assist with resistance management
- 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
- protection of native flora and fauna through invasive animal pest and weed control.

The Panel heard from some stakeholders, that notwithstanding their benefits, there can be significant detrimental effects on humans, animals, and the health of ecosystems due to the improper use, or even 'overuse', of pesticides and veterinary medicines. A modern and effective regulatory system must therefore be designed to deliver the recognised benefits of pesticides and veterinary medicines while carefully protecting against the risks of adverse impacts.

In this report, the Panel has sought to develop a regulatory system for Australia's future that enhances access to pesticides and veterinary medicines. At the same time the Panel has sought to encourage safer, more sustainable and ecologically sound solutions to pest and disease management. The system needs to support innovation and to grow our national capacity to manage the use of these products responsibly. It needs to respond to the requirements of pesticide and veterinary medicine users while at the same time building public confidence and supporting the social licence to continue to use pesticides and veterinary medicines.

The design of our future regulatory system is an important opportunity to 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 arrangements 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 then of a single national system for the registration of pesticides 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, changing supply chains or the needs of agricultural and veterinary stakeholders. Where previous reviews have recommended changes to the regulatory system, there has been limited uptake of these reforms (Australian National Audit Office 2017).

Primary producers are increasingly building on scientific developments and adopting technological improvements to maximise their productivity, corporate accountability and product stewardship 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, veterinarians, 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.

At least 24 reviews and inquiries into aspects of pesticides and veterinary medicines regulation have been conducted since the introduction of the National Registration Scheme in 1992 (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 have not progressed to completion.

None of these previous reviews allowed the opportunity to review the regulatory system from first principles. The Panel therefore welcomes the opportunity its Terms of Reference (see Annex 1) provide for such a fundamental first principles review.

The Panel has developed a comprehensive package to achieve a transformation of the regulatory system in Australia. If the future regulatory system's vision, objectives, and principles are to be realised, it will be important that the package be considered as a whole. The Panel strongly believes that all of the mutually-supportive reforms will need to be considered together if a regulatory system fit for the next 30 years is to be achieved.

Concerns about the current regulatory system

What are the fundamental recurring concerns about the current system? Over years leading up to the review and throughout the consultation process, the Panel heard consistent, often vigorous criticisms and complaints about the current system from stakeholders, particularly regarding:

- the lack of national consistency in state-by-state control-of-use regulation
- delays and difficulties in gaining access to new products and product uses including biological-based products
- delays and difficulties in gaining approval for improved application technologies
- the absence of residue surveillance systems and monitoring data
- the often poor and inconsistent response to reported adverse experiences
- multiple concerns about cost recovery and charging arrangements
- the lack of opportunity for industry's own quality assurance and stewardship programs to be utilised to strengthen safe use arrangements
- concerns about stakeholder relationships with the supply regulator including consultation opportunities, particularly for community and non-government organisations.

Stakeholders also highlighted the importance of ensuring the future regulatory system does not lose sight of its primary responsibility to protect human and animal health, and becomes more responsive to the changing chemical landscape, including support for innovative product and delivery technologies, and being more responsive to increasingly demanding community expectations both domestically and in international markets.

Having examined the current regulatory system, against the background of this feedback, and recognising other global changes, the Panel considers the following matters are key drivers for changing and improving the regulatory system over the decades ahead:

- more demanding community expectations of safe chemical use
- more demanding community expectations about animal welfare
- increased public access to data on chemical residues demands for nationally consistent control-of-use arrangements
- demands for better access to products and uses available overseas
- trade and market access pressures
- demands for transparency of decision-making and improved consultation
- new technologies and evolving practices
- pressures to modernise regulatory practice
- implications of climate change
- the ability to address and respond to crises more rapidly
- increasing levels of companion animal ownership and unmet needs for some veterinary medicines and their uses.

Each of these drivers is discussed in more detail in the rest of this section.

More demanding community expectations of safe chemical use

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

For example, the plight of honey bees and mass bee deaths reportedly due to chemical use (particularly neonicotinoids) has been highlighted in the media. Similarly, there has been an increased focus on glyphosate because of well-publicised assertions 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 many 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 intensification of community awareness and concern will be a major driver to ensure Australia's future regulatory system is forward looking, responsive, transparent and accountable. It is vital that the community's concerns be heeded, and that the scrutiny be responded to positively. The growing community attention should be capitalised on to help drive better performance of both users and regulators of pesticides and veterinary medicines.

In the Panel's view, the necessary social licence to continue to use pesticides and veterinary medicines in Australia over the decades ahead will ultimately be dependent on demonstrating that usage is responsible and safe, products are effective, and that community concerns are being heard and considered in the operation of the regulatory system.

Public perceptions and attitudes concerning the human health and environmental impacts of chemicals are also driving significant interest in farming systems and land management practices involving minimal or highly selective use of pesticides. Examples are organic farming systems, use of biological control agents, the uptake of Integrated Pest Management 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'.

Even for conventional farming systems, there is increasing pressure on primary producers to demonstrate through their on-farm quality assurance systems that they are managing their chemical use responsibly, and wherever possible, decreasing their overall use of pesticides. Over the decades to come, community and consumer pressures will continue to 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.

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.

More demanding community expectations about animal welfare

Social attitudes towards the use of veterinary medicines have similarities with those seen for pesticides, as there are increasingly demanding expectations regarding the welfare of production animals (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 injudicious use of antibiotics in animals, including production animals, and the development of antimicrobial drug resistance.

The Panel recognises that community demands for high standards of animal welfare have been intensifying in recent years. Examples are pressures for improvement in live animal export and intensive animal production practices such as feed lotting, egg production, and salmon farming. 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 to also include concern over the treatment of vertebrate pest species.

As new animal husbandry practices emerge, some will likely be contentious. Instant access to a 24-hour news cycle and the increased use and reliance on social media channels will provide the community with speedy publicity about any lapses in standards. Adding to this mix is the potential widening of differences in perceptions between rural and urban communities.

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 and comprises a clear objective in regulatory decisions and usage practices.

Increased public access to data on chemical residues

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, and if necessary, speedy recall action initiated.

Currently, to satisfy consumer expectations, the major Australian grocery retailers implement their own residue standards, monitoring, and recall arrangements for 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 sensitive residue testing as the result of improved analytical technologies and detection methods, will continue to increase the pressures on users to be aware of, and responsible in, their use of chemicals.

As the Panel looks forward, it sees growing demands from Australian consumers to make more testing data publicly available. While such transparency is a positive thing, there is a concomitant risk of public misrepresentation and misunderstandings if the release of data is not accompanied with contextual information about what the data means.

More comprehensive traceability arrangements will need to be implemented so that prompt and effective response measures can be actioned. Any questionable or ad hoc monitoring, traceability, and response measures could 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.

Demands for nationally consistent control-of-use arrangements

From the introduction of the National Registration Scheme in 1992, the Commonwealth replaced 8 separate state and territory systems for the registration (supply) of pesticides and veterinary medicines. However, it was decided at the time that the states and territories would continue to be responsible for controlling the use of nationally registered chemicals (control-of-use).

The historic reform delivering a single national decision on supply continues to be applauded by most stakeholders today. However, the continuation of 8 separate control-of-use regimes across Australia is the cause of a good deal of stakeholder concern. A fundamental requirement for an effective regulatory system is the 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/territory governments, and the community at large.

Many examples of the lack of national harmonisation have been drawn to the Panel's attention. They include:

- arrangements for monitoring of chemical residues in domestic produce
- the registration of veterinarians and veterinary prescribing rights
- licensing of remotely piloted aircraft systems
- licensing of pest control businesses
- compliance and enforcement practices
- off-label use of pesticides and veterinary medicines.

Almost all stakeholders remarked that to date, attempts by the states and territory officials to harmonise control-of-use have been exceedingly slow and have achieved only minor advances in some non-contentious areas. This has been despite clear guidance from ministers that harmonisation was to be pursued.

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 is concerned that the government officials tasked with progressing the harmonisation agenda have been unable to demonstrate to the Panel much confidence in their own state or territory achieving the intent of the harmonisation agenda.

The Panel was concerned that jurisdictions do not consider that the multiyear timeframes adopted by officials to address such critical issues are unreasonable. Reluctance to reach agreement on the most contentious and necessary reforms were seen by some officials as 'pragmatic' or 'politically realistic' depending on the views of their jurisdictional stakeholders.

Well-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.

As the Panel looks forward, it sees the conspicuous need for reform of control-of-use arrangements to be another critical driver for change to the system. The status quo is clearly failing.

Demands for better access to products and uses available overseas

By global standards, Australia is a small market for pesticides and veterinary medicine products. Many stakeholders stated that in comparison to other countries, Australia has access to considerably fewer pesticide products, and even lesser access to registered uses. Stakeholders also expressed concern about the lack of access to certain veterinary medicines including biologicals such as vaccines.

A lack of access to new products as well as 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. Lack of access to products and uses can also adversely impact productivity, health, and animal welfare outcomes.

Australia's disadvantage derives from the size of the Australian pesticides and veterinary medicines 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 too 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, more effective, 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 Australian exporters to gain, or maintain, access to markets with otherwise increasingly prohibitive Maximum Residue Limits (MRL) for older chemistries.

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. While the Panel supports greater access, it is not proposing that all products and uses available overseas should be available in Australia.

However, the Panel is convinced that competitive pressures and opportunities to achieve safety, environmental and other benefits will, and should, drive change in the regulatory system towards improved access to chemicals and uses for Australians.

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 guiding discussions at international forums and influencing global trends towards reducing or removing MRLs so there are no detectable residues, with many countries following their lead. While Australia can and does seek to influence overseas MRLs through multilateral and bilateral negotiations, 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 to or change their destination markets. This pressure will likely intensify in future.

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 regulatory objective of protecting Australia's trade interests is mainly pursued through regulatory measures to ensure conformance with MRLs. Processes in Australia for monitoring changes to MRLs in other countries for minor products and lesser markets are not as rigorous as those for major markets and major commodities. This poses risks for Australian exporters. The economic stakes are high. If Australian exporters breach an MRL in an overseas market, market access could be lost for entire sectors, not just individual businesses.

The Panel therefore considers the management of MRLs to be a continuing driver of change in pesticide and veterinary usage patterns and in regulatory practice in the years ahead.

Demands for transparency of decision making and improved consultation

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. Regular, proactive engagement and input from the regulated industry, users and the community is needed to demonstrate transparency and build public confidence about how policy and regulatory decisions are reached.

In their submissions to the Panel, a wide range of stakeholders called for improvements to current arrangements for transparency, consultation, and accountability of the various players within the Australian regulatory system. Many stakeholders looked for improved channels to provide input and suggestions about the design and operations of the regulatory system as a whole.

The Panel expects that pressures from the community for more system transparency and consultation will continue to increase in the years ahead. There will be growing pressure for the rationale, reasoning, and evidence base for decisions to be made public. This will drive change in both pesticide and veterinary medicine usage and regulatory practice.

If successfully delivered, improved transparency and consultation will strengthen trust and confidence for all connected with the regulatory system. It will also provide opportunities for continuous improvement to the way pesticides and veterinary medicines are regulated in Australia.

New technologies and evolving practices

The entire life cycle of practices related to a pesticide or veterinary medicine product, including design, manufacture, on farm and off farm application, and disposal, continues to change. Changes in technology or practice need to drive corresponding changes to the Australian regulatory system.

Advances in application technology and product delivery on-farm 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 approaches to 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 assist in the development of more effective management in environmentally sensitive areas.

The future regulatory system needs to be flexible and agile to accommodate 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.

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 an increased need for high quality compounded products.

Pressures to modernise regulatory practice

The Panel notes that most governments across Australia have an agenda to deliver better regulation, including reducing duplication and overlap. Meanwhile, the literature and Government guidance material about deregulation has become more sophisticated as new models of good regulatory practice are becoming available (Gunningham, N, Sinclair, D 2017). The Panel believes that these insights into contemporary best practice regulation can and should drive substantial improvements to the Australian regulatory system in the years to come.

Given that there have been only incremental reforms to the system since the major reform to chemical supply arrangements in the early 1990s, the regulatory system for pesticides and veterinary medicines in Australia is an obvious candidate for regulatory improvement in line with these more modern concepts. For example, the Panel sees attractive opportunities for:

- re-structuring and simplifying the remaining separate and disparate state and territory and Commonwealth regulatory arrangements into a single integrated national system covering the full product life cycle from supply registration through to control-of-use
- defining clearer whole-of-system performance objectives and performance indicators and mechanisms for quick response to performance shortfalls
- enabling industry to define its own methods to achieve regulator-defined outcomes (rather than the regulator prescribing specifically what is to be done, by whom, and when)

- setting regulatory work priorities based on risk (i.e., focusing on the highest risk issues)
- developing regulatory arrangements in Australia that take account of suitably rigorous registrations in other developed countries
- strengthening risk management by taking advantage of suitably rigorous industry quality assurance schemes, industry stewardship practices, industry training and competency standards, and other industry-based standards
- developing regulatory arrangements to accredit external assessors to assist and complement the work of the APVMA and to build regulatory resilience by strengthening national regulatory capacity outside the Authority
- improving arrangements for transparency, consultation, and stakeholder input
- designing arrangements to monitor and report publicly on the impacts and outcomes of the system as a whole
- designing structures and processes to yield ideas for continuous adaptation, improvement, and reform into the future (rather than the slow or episodic changes to the system as has been the case in the past).

The Panel expects these, and other modern regulatory practices will be important drivers for continuing improvement of the system throughout the process of transformation being recommended by the Panel, and into the decades beyond.

The current coverage of pesticides and veterinary medicines in the Australian regulatory system means that there are various substances that are regulated under multiple frameworks, other than under the APVMA, due to their label claims or intended use. This leaves scope for duplication and overlap with other regulatory systems. Examples include the possible crossover with regulatory bodies such as the Therapeutic Goods Administration (TGA), the Australian Competition and Consumer Commission (ACCC), the Office of the Gene Technology Regulator (OGTR), the Australian Industrial Chemicals Introduction Scheme (AICIS) and Safe Work Australia, plus a range of state and territory regulatory bodies.

This complex array of Commonwealth and state and territory relationships increases regulatory burden, is costly to industry (and ultimately to consumers), has the potential to deter companies from introducing newer and safer chemistries, and can cause confusion and lack of clarity to industry about its obligations.

A number of stakeholders asked 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 give it the authority to make recommendations for wholesale changes to other regulatory systems that interact with the pesticides and veterinary medicines system. However, it has nevertheless made suggestions for improvement where implementation should be of assistance to both schemes involved.

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 modernisation and improvement will (and should) be an enduring driver of change.

Implications of climate change

Climate change presents significant challenges for pest and disease management now and into 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 and environmental land managers, impact human and animal health 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.

Climate change is likely to impact agricultural production differently across Australia's extensive geographical expanse depending on region, and farmers will 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, all of which are predicted to become more variable with climate change (Scott et al. 2014).

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 means of increasing the flexibility of the future regulatory system to respond to changing environmental conditions.

The Panel recognises that farming and land management practices will evolve as climate change impacts are felt. It will be important that the regulatory system adapts in step.

Increasing levels of companion animal ownership and unmet needs for certain veterinary medicines and their uses

The number and importance of companion animals has continued to grow since the inception of the pesticides and veterinary medicines regulatory system. Today, almost 29 million pets are owned by almost two-thirds of Australian households which include an estimated 5.1 million dogs, 3.8 million cats, 11.3 million fish, 5.6 million birds, 614,000 small mammals, 364,000 reptiles and 1.8 million 'other' pets. Companion animal owners spend an estimated $2.6 billion per year on veterinary services, up 19% since 2016 (Animal Medicines Australia 2019). Due to Australia's relatively small market size and the cost of registration, there is an unmet need for a range of veterinary medicines and uses, particularly for companion animals, wildlife, exotic species and in aquaculture.

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

1.3 Vision for the new system

The current regulatory system, as a whole, lacks focus, 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.

It also makes the necessary regulatory transformation process difficult. The substantial process of change now being recommended by the Panel will require clarity of strategic purpose and strong and consistent whole-of-system leadership.

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 on the Draft Report clearly confirmed protection of human, animal, and environmental health as the primary objective of a new regulatory system. This has always been the foremost aim of the Panel's vision and so, to avoid doubt, the vision and objectives have been further strengthened from the Draft Report to highlight this overarching intent.

The Panel considers that the vision for the new system should focus on 2 key concepts:

- protecting people, animals, plants, and Australia's ecosystems to ensure human, animal, and environmental health and wellbeing
- enabling Australians to have equivalent access to suitable and safe chemical and biological tools and uses as their overseas competitors.

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 the responsible and safe use of effective pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to new 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 need confidence that pesticide and veterinary medicine products and the manner in which they are used are effective and will 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 the responsible and safe use of effective pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to new products and uses."

Objectives

This vision should be supported by clear objectives which underpin and elaborate on the vision and provide guidance on what the system should deliver. These objectives need to be simple and easy to understand and provide clear direction for the regulatory transformation process now to be launched, as well as guidance for decision-makers and stakeholders in their day-to-day work.

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.

While the Draft Report contained a revised version of the objectives following the feedback on the Issues Paper, feedback on the Draft Report indicated that the Panel had not sufficiently restated the critical elements of the vision in the objectives, and that human and environmental health had not been included, despite being a key feature of the vision. As such, the Panel has revised the objectives to give greater voice to these elements.

In the Panel's view, the vision for Australia's future pesticides and veterinary medicines regulatory system should be guided by 6 equally weighted objectives to:

- protect human health and wellbeing
- protect animal health and welfare
- protect the environment
- 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 undoubtedly important, these concepts are best acknowledged in other ways.

Human health and wellbeing are key cornerstones of the Panel's vision for the future regulatory system. Users of pesticides and veterinary medicines, whether workers, or the general public, must have confidence that the products, when used in accordance with the label instructions, should not result in adverse effects on their health and wellbeing. Consumers of treated produce also need to be assured that the produce they consume does not pose unacceptable risks to their health and wellbeing.

Animal health and welfare have always been important concerns for farmers, veterinarians, and the public, and are 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.

Protecting the environment is increasingly important to the community and producers alike. Pesticides and veterinary medicines must be used so that they do not adversely impact environmental values, however pesticides or veterinary medicines also perform important roles in protecting the environment by controlling plants or animal pests that may otherwise threaten Australia's fragile ecosystems.

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, and effective 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 sometimes be vital in such circumstances.

2. Recommendation

The Panel recommends that the future pesticides and veterinary medicines regulatory system is guided by the following 6 equally weighted objectives:

- **protect human health and wellbeing**
- **protect animal health and welfare**
- **protect the environment**
- **support primary industries**
- **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 maintaining community confidence.

In contrast, poorly designed regulation – for example, regulation that is ineffective, unenforceable, or inefficient in meeting its objectives – can 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.

The Principles of Best Practice Regulation (Council of Australian Governments 2014) set out, amongst other aspects, that regulation should be proportional to the issue being addressed, be performance based and outcome focussed, unless prescription is essential in high-risk situations, and provide for compliance strategies that ensure the greatest degree of compliance at the lowest cost to all parties. These have been at the forefront of the Panel's mind as it developed its reform transformation package.

Poorly designed regulation can stifle innovation, deter investment, increase costs, constrain the 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 pesticides and veterinary medicines 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.

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.

- The Panel recognises that *any* substance (even water) can be hazardous under the right circumstances. The Panel heard from some stakeholders that given the purpose of pesticides is to kill pests, pesticides should be assessed from a hazard rather than risk basis.
- However, in the Panel's view, 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 chemicals to manage pests and diseases and safeguard animal welfare, safely.
- However, where a risk cannot reasonably be managed, then the product or use should not be permitted.

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 advisers and 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 structured, 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 prescribing in detail 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 'buy-in' and 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 can be made safer by all parties (government, industry, and users), accepting responsibility for their links in the chain, from design to disposal. Safety is not the sole responsibility of the regulators.
- 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 in a timelier manner 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 suitably rigorous processes such as those required by farmers' 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. Multiple sources of supply, and ready access to alternative pesticides and veterinary medicines will add to resilience.
- Special arrangements for access to chemicals and uses in emergencies will assist. Well-developed channels for identifying and communicating special and emergency needs are important. Processes for mobilising emergency production or import access need to be defined in advance. Permits or similar approvals can be provided conditionally in advance of any crisis. Control-of-use regulations can be adapted to accommodate designated emergency situations. The resilience of the supply and control-of-use regulators themselves, can be augmented by strengthening external contract resources. These and other regulatory measures can be of considerable assistance in building resilience into Australia's supply chains for pesticides and veterinary medicines.

Box 1 Principles applying to the whole regulatory system

The single national law will bring together the independent risk-based, scientific decision-making of the APVMA with consistent control-of-use regulation in the same regulatory system.

For the first time responsibility will be shared across all participants in the regulatory system (government, industry and users) to deliver high quality safe produce and experiences for the Australian public and international customers.

The whole of the regulatory system will operate to a single vision and will share common objectives and guiding principles.

The whole-of-system consultation mechanisms, monitoring, and reporting will promote the transparency of the system's goals, operations and effectiveness. The mechanisms will provide access to the full range of stakeholders. These arrangements will allow for the regulatory system to be responsive to stakeholder needs and suggestions, and be adaptive to change.

Changes to authorisation processes for pesticides and veterinary medicines products via standardised pathways, the permits system, the licensing of internationally registered products, use of accredited assessors and single national licensing arrangements will contribute to a resilient supply chain, the efficiency of the regulatory system and a modern outcomes-based focus for the regulatory system.

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 contemporary and fit-for-purpose regulatory practices.**
- **The system should achieve a single nationally consistent model with shared responsibility for managing the risks associated with 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 recognises that the far-reaching regulatory transformation envisaged by the Panel will take some years to implement.

The Panel's aim is 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 meet 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, innovative, 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) will be preferred to detailed specification of the process to be followed.
- Regulation that takes advantage of industry's best practice through suitable rigorous quality assurance and safety-related standards will be utilised.
- Clear channels will be 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 recognises 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 a continuing 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. Outcomes based regulation reduces this risk.

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 APVMA determines the standards and information to be used including the many circumstances of use. As a consequence, product labelling has become highly prescriptive with undesirable overlap, containing content required under multiple regulatory systems including those overseeing 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 unnecessary 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 mainly on reduced rather than better regulation does not give effect to the full range of possibilities available. The Panel has taken a broad and rich approach to the concept of deregulation in developing its recommendations for the future pesticides and veterinary medicines regulatory system, consistent with where the Australian Government is heading in this area.

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, outcomes-based, responsive, and co-regulatory approaches. It embraces flexible regulation, matched to the level of risks posed to humans, animals, and ecosystems. In doing so, it empowers governments, businesses and third parties to deliver regulatory outcomes in ways that best match their circumstances.

This approach supports the principles that underpin the draft Regulator Performance Guide for Commonwealth regulators (PMC 2021). The draft Guide's principles of continuous improvement and building trust, being risk-based and data driven, and collaboration and engagement echo the sentiments of stakeholders and are at the centre of the Panel's reforms. Additionally, the government's emphasis on streamlining regulation and identifying and minimising areas of regulatory duplication and overlap were a key focus for the Panel.

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 safety responsibilities required of participants in the system. At the same time, GPOs will allow the future regulatory system to leverage suitably rigorous industry-operated quality assurance and stewardship programs to demonstrate compliance with the required outcome of safe use of pesticides and veterinary medicines.

These obligations give credit for the intimate knowledge of pesticide and veterinary medicine operations by industry and utilise 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 outcomes.

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. Leading and contemporary 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 is endeavouring to build over the transformation period, a modern 'culture' of shared responsibility between government and industry to meet

regulatory requirements. Engaging all parties to take responsibility for their part in the chemical lifecycle will strengthen rather than reduce safe practice. This is important as the system as a whole will be stronger if all players are committed to and accountable for the responsible production, handling, 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.

Feedback on the Draft Report suggested that some of the Panel's proposals, particularly in respect of general product obligations, recognition of industry QA schemes (see Chapter 4), and the licensing of internationally registered products (see Chapter 5) represented industry self-regulation, rather than co-regulation. The Panel is concerned that these views misunderstand the proposals and emphasises that the Panel's vision of the future regulatory system is very much about utilising industry's expertise and experience to strengthen safety arrangements, not abdicating regulatory responsibility. 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 monitor and ensure compliance with the outcomes required, then this should be supported, with regulators undertaking random system surveillance checks to confirm that the necessary standards and outcomes 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 in operation, resulting in more efficient and effective deployment of regulator and industry resources. It is the Panel's view that 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 products 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 which would be better regulated solely by the Office of the Gene Technology Regulator.

This proposal also creates pathways for exemption from registration for products where suitably rigorous 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 across Australia, including the elimination of the duplication of regulatory effort between jurisdictions. It will reduce regulatory disparities, and as a result reduce 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). The Panel's innovative licensing proposal seeks to leverage, rather than duplicate, regulatory effort – in this case, the effort by equivalent international regulatory systems. The Panel is aware that other regulatory authorities, including those in Canada, are actively providing pathways that rely on the decisions of comparable international regulators. 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, and provided unique-to-Australia risks have been adequately managed.

Identifying and responding effectively to change

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.

1.6 Implementation plan for the reforms of the Independent Review of the Pesticides and Veterinary Medicines Regulatory System in Australia

The Panel views the recommendations in this report as a complete package, designed to work as a whole, to transform the regulatory system to be fit for a 30-year future. The Panel's vision for the transformation of the regulatory system is that it will be a continuing process of improvement, where the system surveillance program recommended by the Panel, and the robust consultation mechanisms it has designed will progressively identify those aspects of the regulatory system that will need to be re-examined, refined and amended over the 30-year future as the needs of the regulatory system evolve.

While the Panel recognises that it is a matter for Government to respond to the recommendations, and to determine the program for implementation, stakeholders requested that the Panel's final report provide information on the implementation of the reforms proposed by the Panel.

The Panel considers that the Department of Agriculture, Water and the Environment (the Department) should be responsible for drafting new legislation and establishing most new regulations and standards. The Panel considers that the transformation agenda can be

implemented in such a way as to have minimal impact on the APVMA, and thus minimise disruption to the APVMA's existing work programs.

To assist stakeholders the Panel has prepared an implementation roadmap (Figure 2) that outlines in broad terms how the key aspects of the regulatory transformation will be undertaken. The roadmap captures the key reforms in each column, and their progression across each stage of the process from left to right.

The Panel has prepared indicative timelines for its reforms, in 2 tranches. The first tranche comprises non-legislative or operational reforms, and reforms that require amendments to existing legislation. The second tranche consists of reforms that are linked to or can only be given full effect through the single national law.

Additionally, the Panel has prepared more detailed indicative timelines for 3 key reforms: the single national law for control-of-use, the Commissioner for Pesticides and Veterinary Medicines, and licensing of internationally registered products. The Panel envisions that other reforms will follow similar processes to implementation, as they will be part of the packages of legislation that deliver these key reforms.

Figure 2 Pesticides and veterinary medicines implementation roadmap

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

Establish Implementation Committee → Establish state and territory control-of-use taskforce → Establish Stakeholder Forums → Establish Whole of System Forums → Establish Expert Advisory Groups

PREPARING FOR REFORM	DESIGNING THE REFORMS	IMPLEMENTING THE REFORMS
• Reforms under the current APVMA legislative framework are commenced, including: o developing and implementing standards to support a lower regulatory effort pathway o substance level active constituent approval o chemical review trigger o revised permit criteria.	• The new legislative framework is drafted by the Department through consultation with the APVMA.	• Reforms under the APVMA legislative framework are enacted, including: o standard for lower regulatory effort pathways o substance specific active constituent approvals o chemical review trigger o revised permit criteria.
• The Commissioner Designate for Pesticides and Veterinary Medicines is appointed, pending the passage of legislation.	• The framework for the Commissioner's functions is developed, including: o establishing the Stakeholder and Whole of System Forums o environmental monitoring o whole-of-system surveillance.	• The Commissioner's roles and functions are fully operational, including: o the Stakeholder and Whole of System Forums o environmental monitoring o whole-of-system reporting.
• A draft single national law for control-of-use is prepared by the Department of Agriculture, Water and the Environment.	• The department collaborates with state and territory governments to refine and finalise a harmonised single national law.	• The single national law is implemented in, and regulated by all Australian states and territories with oversight from the Department.
• The licensing of internationally registered products scheme is developed by the Department.	• The Department collaborates with the APVMA, industry groups, and state and territory governments to refine and finalise the licensing of internationally registered products scheme.	• The international licensing scheme is fully established and implemented.
• Existing processes (including industry QA schemes) are examined to determine how they can be used to support general product obligations.	• General product obligations are developed by the Department, in consultation with industry, and user groups.	• General product obligations are agreed through consultation with industry and incorporated into the single national law.
• Existing data sources are investigated, collated and assessed to build a knowledge-base of the current data landscape on the use of pesticides and veterinary medicines.	• Where needed, new data sources are established to contribute to whole-of-system surveillance and reporting.	• The Commissioner publishes state of the system reports, which include identified trends, on a biennial basis.
• Labelling standards are drafted.	• Labelling standards are refined and finalised in consultation with government and industry stakeholders.	• Labelling standards are implemented and registration holders undertake 5-yearly reviews to ensure label content is current and correct.
• Current produce and environmental monitoring and surveillance programs are benchmarked.	• Sampling priorities, reporting and compliance actions for domestic produce monitoring and an environmental monitoring program are developed.	• National domestic produce and environmental monitoring programs and system surveillance are executed.
• Current IT capability is assessed for suitability for a single system for adverse experience reporting.	• An effective, useable single interface for adverse experience reporting is designed and developed.	• A one-system approach to adverse experience reporting is launched.
MONITORING AND EVALUATION		
• Biennial public reporting of whole-of-system performance	• Rapid response to monitoring and surveillance outcomes	• Consistent and transparent approach to managing matters of non-compliance
• Ongoing evaluation and continuous improvement of policy, practices and processes	• Reputable, national leadership, supported by strong consultative and engagement processes	

Tranche 1 reforms

The Panel anticipates that the following reforms can be implemented within 2 years of Government agreement to the reform package, as they are non-legislative, operational, rely on existing legislation, or require only minor legislative amendments:

- revised permit criteria (see Section 5.3)
- supplemental labels (see Section 5.4)
- licensing of internationally registered products (Figure 5) (see Section 5.2)
- standards for lower regulatory effort pathways (see Section 5.1)
- nationally consistent training competencies (see Section 4.3)
- accredited assessor competencies (see Section 6.2)
- labelling standard (see Section 4.4)
- standard for compounded veterinary medicines (see Section 4.6)
- data protection equivalence for veterinary medicines (see Section 5.9)
- amendments to chemical review triggers (see Section 3.6)
- Commissioner for Pesticides and Veterinary Medicines (see Section 2.2).

Tranche 2 reforms

The Panel's reforms that are highly dependent on the single national law being in place, or other significant change to the legislative framework are:

- single national law for control-of-use (see Section 2.1)
- nationally consistent approach to compliance and enforcement under the single national law (see Section 2.1)
- nationally consistent licensing scheme (see Section 4.2)
- revised cost recovery arrangements (see Section 7.1)
- national adverse experience reporting system (see Section 3.4).

Single national law for control-of-use

The Panel considers the single national law to be one of the keys to its reform package. As described in Chapter 2 the single national law will replace state and territory arrangements with a single national law to control the use of pesticides and veterinary medicines in all jurisdictions. This will provide many benefits to industry, such as consistent regulation of product use in all jurisdictions and a single national licensing scheme.

In the 12 months following Government decision, referral of powers to the Commonwealth or a Commonwealth applied law arrangement should be explored by a high-level Commonwealth, state and territory task group (Figure 3). Should negotiations succeed, legislation to enact the applied law model is to be progressed as a priority and transitional arrangements are to be put in place by the states and territories. Otherwise, after 12 months the Commonwealth should act unilaterally to establish the single national law to the full extent of its constitutional reach. The Panel considers that regardless of the mechanism the single national law should be operational within 5 years of Government decision.

Figure 3 Implementation timeline for single national law

Key Tasks	Year 1	Year 2	Year 3	Year 4	Year 5
A draft single national law is prepared, while the Department negotiates referral of powers with states and territories	■				
The draft single national law is introduced and passed by Parliament		■			
If negotiations fail, the Commonwealth instead uses its constitutional reach to establish the single national law		■			
States and territories enter a transition period to implement the single national law in their jurisdiction			■	■	
The single national law is implemented					■

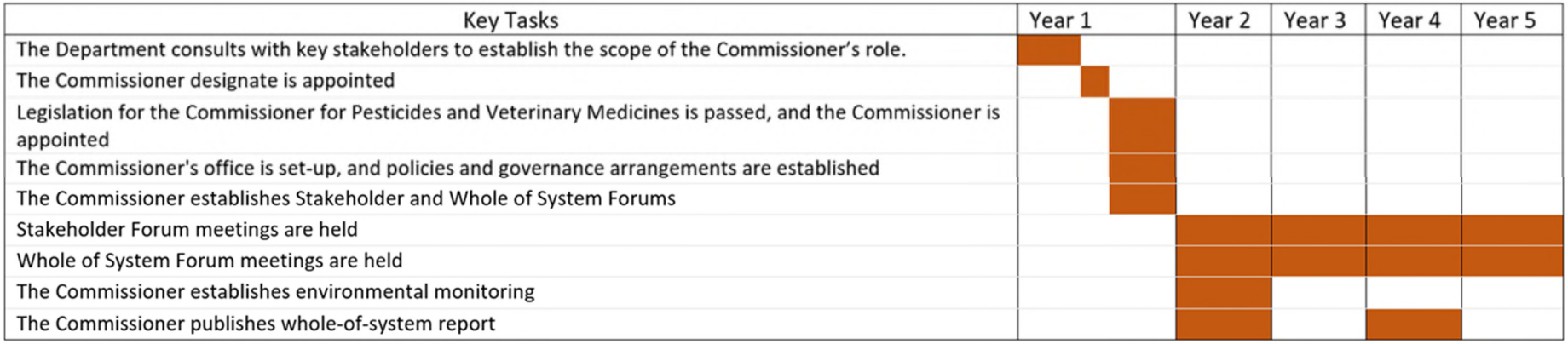
The Commissioner

The Panel recommends creating a new position of Commissioner for Pesticides and Veterinary Medicines to monitor and publicly report on reform progress, and to provide the necessary leadership to drive continuing improvement in Australia's regulatory system over the years ahead.

The Panel considers the Commissioner must be established as the matter of priority and is a key deliverable of an 'early reforms' Bill that will kick-start the regulatory transformation process. The Panel considers that once the scope of the role of the Commissioner has been established through consultation, the Secretary of the Department should appoint a Commissioner designate, to take up the role while the Bill is passed, and the inaugural Commissioner is appointed by the Minister (Figure 4).

Once appointed, the Commissioner for Pesticides and Veterinary Medicines will establish the whole-of-system surveillance and stakeholder engagement functions and design the environmental monitoring program.

Figure 4 Implementation timeline for the Commissioner for Pesticides and Veterinary Medicines



Licensing of internationally registered products

This proposal introduces a licensing scheme to allow safe and effective pesticides and veterinary medicines registered by equivalent international regulators to be supplied and used in Australia – subject to approval of a suitably rigorous risk management plan to deal with unique to Australia issues (see Chapter 5).

The Panel considers that the Department would, in concert with the APVMA, consult extensively with Australian and international stakeholders, including regulators and the Stakeholder forum, to bring the Panel's proposal into a form suitable for progressing into legislation (Figure 5). The Panel considers that this reform should be progressed as part of the legislative package that would implement the single national law for control-of-use.

Figure 5 Implementation timeline for the licensing of internationally registered products

Key Tasks	Year 1	Year 2	Year 3
The licensing scheme is designed by the Department			
The Department collaborates with the APVMA, international regulators, industry groups, and state and territory departments to finalise the scheme			
Legislation providing for the internationally registered products licensing scheme is passed as part of the single national law for control-of-use			
The Department investigates and establishes IT systems and frameworks to support the scheme			
The Department issues the first licences			

2 Establishing a nationally consistent 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.

Compounding this failing is a lack of national leadership for the system as a whole. Leadership is diffused among 8 governments, multiple agencies responsible for different aspects of control-of-use, the national supply regulator, a range of relevant policy advising departments, and Commonwealth/state officials' groups. Consequently, there is no clear point of direction and accountability for the whole system. Stakeholders with views about the system have no clear place to go.

To deal with these failings, the Panel is proposing 3 transformative reforms to build a truly national, integrated, and responsive regulatory system:

- introducing nationally consistent control-of-use
- providing national leadership through the creation of the Commissioner of Pesticides and Veterinary Medicines
- providing channels for meaningful and constructive engagement with the broader community and industry on whole-of-regulatory system matters.

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 (IGA) 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 relating to 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 Australian Pesticides Veterinary Medicines Authority (APVMA)) to regulate supply-side activities. As a result, supply-side controls on pesticides and veterinary medicines are now 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.

The APVMA's core function as the national independent regulator is to assess and register pesticides and veterinary medicines and other non-related chemicals (e.g., 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 product recalls.

The Panel considers the APVMA is well equipped to continue to deliver these activities and does not recommend the transfer of any current functions to any other agency.

Control-of-use

The control-of-use of pesticides and veterinary medicines after registration is currently regulated by each state and territory. Control-of-use activities include ensuring label 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, and veterinary prescribing rights).

The regulatory approach, and the extent of resources and activities deployed to control-of-use differs, sometimes markedly, between each state and territory. This inconsistent national approach causes major issues for growers and businesses operating across jurisdictions, as it results in the same products being allowed to be used in different ways and at different rates of application, depending upon the state or territory of application.

For example, Victorian growers have more flexibility in how they use chemicals as growers outside Victoria require APVMA-issued permits for many of the same uses. In Victoria it would be legal to use a herbicide in a greenhouse which only has approved use patterns for crops in fields, while in other jurisdictions a permit would be required for this use. This difference in approach increases the regulatory burden, adds costs, causes confusion (and therefore risk) among operators working across state boundaries, delays access and may even encourage unauthorised off-label use. There are also differences in approach to veterinary prescribing rights and the scope to treat multiple animals simultaneously.

The lack of a national approach to control-of-use has other significant disadvantages, including that it:

- makes it more complex for the APVMA to put in place effective risk management measures, as the controls on the use of products may vary among the states and territories
- increases complexity and compliance costs for business – particularly those that operate across jurisdictions (including, for example, primary producers, professional ground and aerial spray applicators, agronomists and other advisors, veterinarians, chemical companies, and those that export produce)
- distorts domestic competition by allowing producers in one jurisdiction to use chemicals in ways not allowed in others
- increases costs and complexity of education and training provided by assessors, and risk of non-compliance by users between jurisdictions due to differing training, assessment, 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, as well as making our control arrangements difficult to explain to overseas regulators and customers
- impedes the identification of emerging safety, health, or environmental concerns because of the absence of coordinated reporting, analysis and communication relating to whole-of-system trends
- increases transaction costs for developing and implementing regulations by individual states and territories as well as constraining opportunities for targeting 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 leading to reduced confidence in the regulatory system as a whole.

The need for a single nationally consistent approach to the regulation of 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). A more recent Productivity Commission report (2018) reaffirmed the Commission's continuing view and noted that:

> "*The Australian, state and territory governments should implement a national control-of-use regime…… for agriculture and veterinary chemicals by the end of 2018*".

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. The need to address current problems with control-of-use arrangements was the most consistent message received from all stakeholders in the Panel's broad consultation process.

There have been multiple previous efforts to reduce inconsistencies across 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 by officials is being facilitated at Commonwealth level by the current Department of Agriculture, Water and the Environment (the Department), 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 but jurisdictions have retained the prerogative to add additional requirements for their respective state or territory – again, diminishing the desired outcome of national consistency.

More substantial issues relating to national consistency, such as broader off-label use of chemicals, veterinary prescribing rights and the national coordination of domestic produce monitoring, have remained unresolved since 2009.

A broad range of non-government stakeholders expressed frustration and dissatisfaction with the lack of progress towards nationally consistent control-of-use regulation. In contrast, several state and territory governments argued that the current 'harmonisation' process continues to make appropriate progress and that no change from the current HACCUT process was required, despite scant accomplishments to date in introducing national alignment.

Boundaries to the national law

State and territory legislation covers a range of areas including environmental protection, work health and safety, and public health. For example, in NSW, accountability for most control-of-use legislation for pesticides is the responsibility of the environment portfolio and in many jurisdictions, pest controller arrangements and control-of-use of restricted veterinary medicines 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 its intersection with other state regulatory arrangements, such as dangerous goods, biosecurity, the scheduling of medicines and poisons 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 considers these should remain under the control of the states and territories, and so has made no recommendations about them.

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.

A single national law

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 proposes the use of a Commonwealth-hosted applied 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 integrated regulatory system for pesticides and veterinary medicines.

This should rely on the broadest extent of the Commonwealth's constitutional reach. The Panel considers that the Commonwealth would 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. It considers that the Commonwealth would be able to regulate where interstate and international trade needs to be addressed. 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 is of the view that the most effective way to achieve a single national law would be to work cooperatively with state and territory governments at the legislative and executive level to arrange mutually agreed 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.

The Panel does not favour, as a preference, the alternative, where the Commonwealth would act unilaterally with the states and territories regulating independently in the few remaining gaps not covered by Commonwealth legislation. This would be inefficient and lead to a more fragmented regulatory approach (if states and territories did not refer powers) exacerbating many of the problems of the current system in achieving national consistency for the control-of-use for pesticides and veterinary medicines. However, a precedent does exist 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 legislative instruments.

While there was widespread support from stakeholders for achieving a single national law, in their submissions to the Draft Report, a number of stakeholders expressed misgivings about the Panel's proposal. Some of these stakeholders appeared to have the impression that the Panel's preference was for the Commonwealth to unilaterally and immediately use the constitutional powers available to it to assume responsibility for the regulation of control-of-use through the single national law.

The Panel clarifies that its preference is **for the Commonwealth to work with states and territories to negotiate, within a set timeframe, an agreed national applied law for control-of-use regulation. This would be hosted by the Commonwealth**. The success of this approach for the supply side of the regulatory system suggests that this would also be a viable means to deliver a single national regulatory system for control-of-use to complement the national supply side for the whole system.

Box 2 provides more details of this approach. The proposed nationally consistent approach to control-of-use regulation, while encompassing whole of lifecycle, applies specifically to the activities referenced in Box 2. This box also identifies a number of exclusions for which the Panel considers states and territories and/or other national legislative schemes are best placed to retain responsibility and accountability.

Given the disappointing history of Commonwealth/state negotiations in achieving harmonisation of other aspects of control-of-use, the Panel considers that a strict deadline for the negotiations must be put in place. While progress of harmonisation negotiations to date has been disappointing, the Panel presumes that the issues have already been identified and therefore a solid foundation for finalising discussions already exists.

However, if agreement cannot be reached with the states and territories on an applied law model within 12 months of negotiations commencing, the Panel considers that the Commonwealth should then move unilaterally to use its constitutional powers to assume the regulation of control-of-use of pesticides and veterinary medicines from the states and territories.

Benefits of the single national law

Establishing a single comprehensive suite of legislation spanning the full 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 exposures 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 reputable industry quality assurance (QA) schemes that have been assessed for their rigour and adequacy; 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 Panel considers a single national regulatory system for control-of-use to be an overdue reform, proposed as long ago as 2008 by the Productivity Commission, still widely supported by stakeholders today, and a critical initiative if Australia's regulatory system as a whole is to be transformed as required to meet the long-term needs of the next 30 years.

Box 2 Functions to be covered by the single national law for control-of-use

The Panel's recommended common framework for regulating pesticides and veterinary medicines will be delivered through a single national law covering both supply and use. The Commonwealth will be responsible for developing and implementing this law, in close consultation with the states and territories and stakeholders.

Existing state and territory control-of-use legislation covers a range of areas including biosecurity, animal welfare, environmental protection, poisons, work health and safety, transport, and consumer protection. The successful implementation of the common framework will need to clearly and explicitly define the boundaries between the national control-of-use law and these other state and territory regulations.

The single national law as it applies to control-of-use is intended to cover the core activities associated with the application and use of pesticides and veterinary medicines. This would include the following activities:

- requirements for applying pesticides and using veterinary medicines, and keeping associated records, in accordance with the proposed national rules. This includes applying general product obligations, facilitating recognition of sufficiently robust industry QA schemes, and implementing a veterinary compounding and prescribing rights protocol
- licensing and authorisations (including training and competency assessments), such as for fee-for-service chemical applicators and users of certain highly hazardous chemical products
- controls on off-target movement – including spray drift – in addition to label controls
- compliance and monitoring functions, including audits, inspections, adverse experience reporting, as well as enforcement powers and sanctions
- system surveillance and reporting requirements, including domestic produce and environmental monitoring provisions.

Prescribing these in a single national law will preclude individual jurisdictions from amending, or adding requirements; such actions have diluted the effect of previous attempts at harmonising control-of-use.

There are other activities that relate to control-of-use of chemicals, including pesticides and veterinary medicines beyond those previously listed. The Panel recommends the states and territories and/or other national legislative schemes are best placed to retain legislative responsibility for a number of these other activities including (but not limited to):

- registration of veterinarians and authorising veterinary prescriptions
- dealing with pesticide and veterinary medicine products and containers once discarded
- dealing with contaminated land and produce, including controls on movement and sale of produce and powers to manage contaminated land and produce to prevent the contamination of food
- management of dangerous goods (e.g., transport, storage, record keeping and disposal), biosecurity, public health, the environment, work health and safety, and licensing for the supply and handling of scheduled poisons
- education and extension support that allows users to voluntarily comply and minimise risk.

Some jurisdictions include other farm chemical activities within the same legislation that manages control-of-use. These include matters relating to fertilisers and stock feed. These matters would also continue to be managed under state and territory law.

Successful delivery of the national control-of-use law will require a partnership between the Commonwealth and the states and territories. Subject to successful negotiations with the states and territories, most common requirements would be delivered through the states and territories' established networks of on-the-ground officers. The operations of these officers would be guided by the single national law and national guidance material issued by the Department. This will ensure that control-of-use issues are managed consistently across Australia.

How should control-of-use be administered?

While some stakeholders suggested the APVMA should oversee and manage nationally consistent control-of-use activities, the Panel believes there are many compelling reasons for the Department, representing the Commonwealth, rather than an expert science body, to work with the state and territory governments instead. These include:

- the Department's extensive experience in delivering on the ground regulatory systems similar to control-of-use
- the Department's experience in policy development and new program design
- existing relationships and forums already in place with the states and territories
- many of the reforms related to control-of-use proposed in this review (e.g., general product obligations and recognition of suitably rigorous industry QA schemes) will sit with the Department. The Department will also have responsibility for licensing activities under the single national law for control-of-use
- involvement in the current HACCUT process for national harmonisation can be used as a basis for further negotiations.

Delivery of control-of-use functions

While its Draft Report was not specific about the optimum delivery model for control-of-use regulatory functions, the Panel received significant feedback on this issue. Some stakeholders considered that the on-the-ground operations for control-of-use compliance and enforcement under Commonwealth control would be a significant step backwards and could lead to reduced resourcing for compliance and enforcement functions, loss of expertise and knowledge held by state and territory officers, and poorer outcomes in terms of rapid 'on the ground' responses into adverse events.

While the Department could deliver control-of-use regulatory functions by building on the systems and infrastructure and networks of biosecurity officers, the Panel considers that existing state and territory control-of-use regulators are best placed to deliver 'on the ground' control-of-use regulatory functions. State and territory staff have significant experience and expertise with control-of-use functions, knowledge of the local area, existing relationships with growers, agronomists, spray contractors, and networks within allied regulatory bodies within their jurisdiction.

The Panel heard from some stakeholders that control-of-use operations, particularly in smaller jurisdictions have suffered from reduced resourcing over time, as the responsibilities of staff undertaking control-of-use functions has expanded to include other responsibilities.

The Panel considers that with the Commonwealth taking responsibility for the policy, program design, and legislative functions for control-of-use under the single national law, state and

territory resources available to deliver control-of-use operational functions would increase. Further, a single national law would enable the development over time of more efficient work models designed within a national framework but adapted for local conditions.

The Panel recommends that to ensure that resourcing of control-of-use functions is maintained, and indeed, improved, the Commonwealth should provide a financial contribution to the costs of delivering Commonwealth-specified control-of-use activities undertaken on the Commonwealth's behalf by the states and territories. This financial contribution would be contingent on each state and territory maintaining or increasing its existing resourcing for control-of-use functions, adjusted over time for inflation. The Panel recommends that the quantum of the Commonwealth contribution should be in the order of $5 million per annum divided among the states and territories on the basis of population and agricultural output (see Chapter 7). This Commonwealth financial contribution would be in addition to cost recovered resources such as licence fees.

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 made since 2013, 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 adjusted for inflation). These savings will be especially focused on the chemical user industries, such as farm businesses and commercial spray operators.

The single national law will be funded using existing state and territory resources, bolstered by an additional $5 million per annum of appropriated funding provided by the Commonwealth distributed amongst the states and territories on the basis of population and agricultural output (see Chapter 7).

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 works with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. If agreement cannot be reached with the states and territories within 12 months, the Commonwealth should use its constitutional reach to implement a single national law approach.

5. Recommendation

The Panel recommends that the Department of Agriculture, Water and the Environment have responsibility for policy and legislation for control-of-use as well as associated licensing activities. The Panel also recommends that 'on the ground' control-of-use functions continue to be delivered by the states and territories, but now with the national

guidelines, with increased resources made available through the Commonwealth providing an additional$5 million per annum conditional funding across all states and territories.

Intergovernmental agreement

The National Registration Scheme, including the roles and responsibilities of the Commonwealth and state and territory governments under the scheme, is currently supported by an 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 following the Panel's report. An IGA may be 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/state 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 as it is unlikely to lead to any significant or meaningful change. Without a serious commitment to change by all governments, 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 proposals), the Panel does not believe that a review of the IGA can be meaningfully undertaken 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 at least the following lessons learnt from the current IGA.

For example, under the current IGA, consensus has been difficult to achieve when seeking to harmonise control-of-use arrangements. While included in the current IGA, allocation of adequate resourcing has also been a problem. Timeliness of delivery has not been well managed. There has been a conspicuous lack 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, the decision by 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 compliance and enforcement activities (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 control-of-use statutory functions and obligations
  - the Panel suggests that any future IGA requires each jurisdiction to publish annually the level of resources dedicated to control-of-use
  - the Panel considers that providing clarity and specified resources for regulating pesticides and veterinary medicine use will significantly contribute to community confidence in the future 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 the absence of requirements for 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 (the Commissioner) (see Section 2.2) in the Commissioner's biennial reports on progress with reform and overall performance of the regulatory system as a whole.

6. 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 also recommends the existing IGA be extended until a new IGA is formed.

Any future IGA should:

- **provide that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail**
- **require any jurisdiction that departs from the IGA approach to provide a public reason for such departure**
- **mandate minimum resource levels for regulating control-of-use compliance and enforcement activities, to effectively meet assurance obligations and require publication of those resource levels**
- **require 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**
- **require regular publication (or input to the Department of Agriculture, Water and the Environment'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 in Section 2.1.

However, 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 contributing factor identified by the Panel was the absence of leadership for the system as a whole. The current regulatory system 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 system comprises many moving parts, but no single agency has an overall view of the system as a whole, let alone authority to speak publicly on behalf of the system, to coordinate actions among all players, or to suggest systemic improvements as circumstances change. Responsibility is fragmented and decentralised among many parties. As a result, accountability is unclear, leadership is diffuse and obscure, and change is slow and episodic.

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 continuing effectiveness of the whole regulatory system. As community awareness and concern about aspects of the use of pesticides and veterinary medicines increases, strong and evident leadership is needed to maintain community and market confidence. Without the drive provided

through strong whole-of-system leadership it will also be difficult for the future system to respond 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.

The role of the APVMA

It was apparent from several submissions that some stakeholders have an incorrect perception that the APVMA embodies the entirety of the regulatory system. This derives in part from the shorthand commonly 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 substantial remainder of the system – control-of-use compliance and enforcement functions for pesticides and veterinary medicines – is currently the responsibility of the jurisdictions.

The Panel recognises the APVMA's considerable expertise in product risk assessment and the vital role it plays as a national product registration regulator. However, it is not appropriate for an independent statutory regulator such as the APVMA to play a formal role in setting the Government's regulatory policy framework within which the regulator itself will operate. Rather, its role is implementation, consistent with legislative requirements.

The APVMA is an independent, technical, science-based agency. It is important that this character is preserved to ensure that it can continue as a globally recognised independent agency, well tasked to complete complex regulatory and scientific assessments. As the supply regulator, the APVMA has neither the authority nor 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 and should not be expected to speak publicly for the whole of the regulatory system, as might be required in the event of a regulatory lapse affecting public confidence.

The current range and diversity of agencies directly involved in the regulation of pesticides and veterinary medicines has meant ultimate responsibility for action is dispersed through a bureaucratic collective. This has meant valuable reforms have been too long in development; delivered inefficiently, ineffectively, or not at all; subject to competing policy drivers and resource demands; or have had limited practical effect to users or the community.

Previous efforts at reform have failed to consider the regulatory system as an integrated system comprising many interdependent parts. Reforms have commonly been targeted to address either supply or control-of-use in isolation. Given the multiple agencies involved, with no one entity that can take full responsibility for issues pertaining to the whole regulatory system, there is often confusion about who is accountable and responsible for dealing with matters raised by stakeholders. 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. Through public submissions to the review, (both in response to the Issues Paper and the Draft Report) there was strong stakeholder support for introducing more accountability into the regulatory system.

The Panel heard stakeholders' clear concerns that, without changes to system governance, the vision and recommendations of this Panel would languish with no champion to drive them, as had too often been the case following previous reviews. Over the past 3 decades, at least 24 reviews into aspects of agricultural and veterinary chemicals regulation have been conducted (see Annex 3) but stakeholders reported disappointment with the pace of practical implementation.

The Panel heard mixed views about the performance and effectiveness of the APVMA. There was broad-based recognition among stakeholders of the importance of the APVMA's role in the current regulatory system. The Panel was pleased to hear of performance improvements in APVMA's product registration process since the announcement of this review and the appointment of a new CEO in 2020. The Panel recognises, and agrees with, the strong support from stakeholders for maintaining the APVMA as a structurally separate, independent national regulatory agency whose work is founded on a strong scientific evidence base to make day-to-day decisions for registering pesticides and veterinary medicines.

Consistent with the misapprehension that the APVMA is the totality of the pesticides and veterinary medicines regulatory system, some stakeholders have asked why the APVMA should not have responsibility for driving and delivering many of the Panel's reforms.

The Panel recognises that the APVMA is the trusted regulator of supply, but considers that the fundamental aspects of the transformation process lie beyond the APVMA's role (as the APVMA does not have a role in control-of-use regulation) and capabilities. While ideally there would be a complete institutional separation of policy from regulatory functions, the Panel considers that coupled with the APVMA's lack of policy skills and experience, the APVMA's difficulties in operationalising prior reforms, and the Panel's own engagement with the APVMA via direct discussions about reform options and the Authority's written submissions provide ample reasons why the reforms should be carried out by bodies other than the APVMA.

Accordingly, the Panel has designed the transformation process and the future regulatory system to ensure that the APVMA retains core functions and strengthens its current role as the supply regulator, is not distracted from the delivery of its normal regulatory functions, and can continue to deliver its significant workload.

It is government's role to establish policy and to develop and enact laws. At the Australian Government level, support for these roles is provided by the relevant department. The Panel considers this separation has served the pesticides and veterinary medicines regulatory system 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 has been a tendency for stakeholders to call upon the APVMA when seeking both scientific and policy answers and advocacy for the regulatory system itself. The APVMA has neither the authority, the span of responsibilities, nor the skills and experience to respond satisfactorily. A dedicated system leader is needed to engage in the full policy conversation and protect the independence and scientific focus of the APVMA.

Consultation and advocacy

A related issue identified through stakeholder consultation is the benefit of having an 'advocate' to support the community, industry (users and manufacturers), and governments to engage with the regulatory system.

Currently, individual stakeholders who may have proposals for systemic improvements are unclear about which agency to contact. There is no central liaison point where issues affecting 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, stakeholders were critical of group consultation machinery within the system. They reported that forums have tended to be established, then lapse. Typically, they have been partial rather than whole-of-system. Certain stakeholder groups have felt excluded or unwelcome. Results and outcomes have been variable.

In the Panel's view, the regulatory system is in need of leadership to build and maintain 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 among 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 can address stakeholder concerns and suggestions and can speak publicly on behalf of the entire regulatory system, as essential to the successful implementation of the recommended reforms in this Report. These consultative mechanisms are not intended to take the place of, or duplicate, the APVMA's recently launched Stakeholder Engagement Framework, rather the purpose of the mechanisms is to engage with stakeholders from a broader perspective in relation to whole-of-system matters.

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 (the Commissioner). This statutory position would have its functions and independence defined in legislation. In combination with the single national law, the Panel considers the Commissioner role is critical to the long-term success of the proposed reforms.

The Panel listened to stakeholders' feedback relating to the role of the Commissioner as proposed in the Draft Report. Importantly, the Panel understands that many stakeholders perceived the role would add another layer of bureaucracy, cause confusion, add to costs, have a directive ability over the APVMA, and would even be prone to political interference. None of these concerns is warranted. Rather, the Panel recommends the Commissioner become a key point of responsibility for the whole of the future regulatory system.

The Commissioner will provide much needed national leadership for the entire pesticides and veterinary medicines regulatory system. Through biennial reports to Parliament the position will provide ongoing accountability, as well as driving and coordinating for whole-of-system performance. The biennial reports will also monitor progress in the regulatory transformation process to be initiated following the Panel's report. Similarly, the reports will prompt continuous improvement long into the future. The Commissioner will drive some of the new proposals arising from this review and acting as a key liaison point for stakeholders and governments through formal consultation mechanisms.

In listening to stakeholder feedback, the Panel has reconsidered the assignment of responsibilities among the Department, the APVMA and the Commissioner from those proposed in the Draft Report (see Table 2). The Commissioner's functions have been significantly narrowed.

The Panel considers that the Commissioner will provide a vital role in continuous system improvement well beyond the life of this review. The Commissioner will be empowered to consider suggestions, develop ideas, advise the Minister, and drive change to ensure that the pesticide and veterinary medicines regulatory system continues to respond to new ideas and changing circumstances well into the future.

The Commissioner will take responsibility for:

- strong and independent policy leadership to maintain community and market confidence
- recommending and driving continuous improvement to the system as a whole
- reporting on whole-of-system impacts and outcomes through biennial reports based on whole-of-system performance measures (see Section 2.5)
- whole-of-system surveillance and monitoring, drawing on data from a range of sources (see Chapter 3)
- ongoing open engagement with stakeholders
- establishing and leading the Stakeholder Forum and Whole of System Forum (see Section 2.4)
- establishing a domestic produce monitoring program which would subsequently be run by the National Residue Survey (see Chapter 3).

The position will be a statutory position accountable to the Australian Parliament through the Commonwealth Minister responsible for pesticides and veterinary medicines. Pending the passage of legislation, the Panel recommends the Secretary of the Department make an interim non-statutory appointment. This will ensure the Commissioner can begin setting up systems and stakeholder consultation machinery, driving critical early parts of the reform package, and providing an external face for the reform transformation process.

The model for this position has similarities with other Government commissioner positions, such as the Threatened Species Commissioner.

Table 2 Proposed assignment of responsibilities

Function	Party with current responsibility	Proposed party with responsibility	Report reference
Leadership Strong and independent leadership is needed to maintain community and market confidence, and to drive continuous improvement of the system.	**N/A (new function)**	**Commissioner (new position)**	Section 2.2
Delivering the reform agenda Responsibility for driving the proposed reforms, to ensure they do not lapse and are implemented in a timely and efficient manner.	**N/A (new function)**	**Commissioner** Whole-of-system leadership, continuous improvement and assessing outcomes. **Department of Agriculture, Water and the Environment** Implementing new legislation and delivering new programs of work recommended by the Panel. **APVMA** Continuing to drive and improve chemical registration and reviews.	Chapter 1
Whole-of-system surveillance and reporting Whole-of-system reporting will ensure the pesticides and veterinary medicines regulatory system continues to perform as intended.	**N/A (new function)**	**Commissioner (new position)**	Chapter 3
National Whole of System Forum The establishment of a National Whole of System Forum to discuss operational and administrative practices of the whole system.	**N/A (new function)**	**Commissioner (new position)**	Section 2.4
Stakeholder Forum The establishment of a Stakeholder Forum to consider the impacts and consequences of current and proposed policies.	**N/A (new function)**	**Commissioner (new position)**	Section 2.4
International forums The Department and the APVMA represent Australia at various international forums. These include policy forums and technical forums for pesticides and veterinary medicines.	**Department of Agriculture, Water and the Environment** Policy forums. **APVMA** Technical forums.	**Department of Agriculture, Water and the Environment** Policy forums (no change). **APVMA** Technical forums (no change).	Chapter 2

Function	Party with current responsibility	Proposed party with responsibility	Report reference
Licensing of internationally registered products A new licensing scheme for pesticides and veterinary medicines will allow products registered and approved by selected international regulators to be imported and used in Australia.	**N/A (new function)**	**Department of Agriculture, Water and the Environment**	Section 5.2
Registration, including permits The National Registration Scheme for Agricultural and Veterinary Chemicals will largely continue unchanged.	**APVMA**	**APVMA (no change)**	Section 5.1
Single national law for control-of-use The development of a national law for the control-of-use of pesticides and veterinary medicines, including national policy for control-of-use.	**N/A (new function)**	**Department of Agriculture, Water and the Environment**	Section 4.7
Regulation of control-of-use The use of pesticides and veterinary medicines will be regulated nationwide under the single national law.	**States and territories**	**States and territories (no change)**	Section 2.1
Licensing of activities under the single national law for control-of-use The single national law for control-of-use will include a national licensing scheme. This will allow licence holders to operate in all jurisdictions under a single licence.	**States and territories**	**Department of Agriculture, Water and the Environment**	Section 4.2
Recognition of QA programs Licences to conduct certain activities may require compliance with recognised industry QA programs as part of their licence conditions.	**N/A (new function)**	**Department of Agriculture, Water and the Environment**	Section 4.5
Domestic produce monitoring Domestic produce monitoring is generally undertaken by industry on an ad-hoc basis. The Panel recommends a Government-led national domestic produce monitoring program be established.	**N/A (new function)**	**Department Agriculture, Water and the Environment**	Section 3.2
Develop and establish whole-of-system environmental monitoring The Panel recommends that an environmental monitoring plan be developed through consultation to identify areas of priority for monitoring.	**N/A (new function)**	**Commissioner (new position)**	Section 3.3
Chemical reviews	**APVMA**	**APVMA (no change)**	Section 3.6

Function	Party with current responsibility	Proposed party with responsibility	Report reference
The Panel recommends that legislative triggers be established for reviews of chemical registrations. This will ensure that reviews are carried out as necessary.			
Adverse experience reporting Adverse experience reports (AERs) are currently broken into control-of-use AERs and product AERs. Control-of-use AERs are reported to state and territory regulators, while product AERs are reported to the APVMA.	**APVMA** Responding to product AERs. **States and territories** Responding to control-of-use AERs.	**Department Agriculture, Water and the Environment** Develop and maintain a single national reporting system for AERs. **APVMA** Responding to product AERs (no change). **States and territories** Responding to control-of-use AERs (no change).	Section 3.5

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 (see Section 2.5). The Commissioner will publish a report on system performance 12 months after the release of the Government Response to this review, and then every 2 years thereafter.

The Panel's Draft Report proposed that the Commissioner would have the policy and legislative authority to respond when areas of inefficiencies or deficiencies are identified, keep the single national law as a contemporary document, administer grants programs and be involved in domestic and international policy discussions and fora. However, based on stakeholder feedback and in the interests of ensuring that responsibilities are not duplicated, the Panel has decided that these tasks should remain with the Department, with the exception of Codex and technical fora which most currently sit, and will continue to sit, with the APVMA.

Nevertheless, the Commissioner will be empowered to discuss proposals with and refer areas of inefficiencies or deficiencies, or compliance and enforcement need, to the appropriate areas within the Department or to the APVMA. This will ensure that issues raised in the Stakeholder Forum and Whole of System Forum are heard and actioned appropriately by those with the relevant expertise.

The Commissioner will 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 will manage 2 key engagement groups through the implementation of National Forums:

- The first group will be a two-way stakeholder engagement and consultation review forum (Stakeholder Forum).
- The second group will be an implementation and Whole of System Forum of jurisdictions and regulators including the APVMA, consumer and fair trading, and work health and safety regulators (or their representatives) (Whole of System Forum).

The Commissioner will 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 needed to consider contemporary issues of public concern and provide independent advice on those matters. The Expert Panels would have the option to conduct inquiries to guide their advice.

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

An important function of the Commissioner will be to lead and 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 will build on the future regulatory system's principles (see 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.

Although the APVMA will be required to contribute fully to the Commissioner's biennial reports, it will also continue to report separately on its performance, annually.

It will be important that the Commissioner and the Chief Executive of the APVMA have a mature, cooperative, and collegiate relationship. The importance of this could be made clear in the Minister's Statement of Expectations to the APVMA and in equivalent guidance to the Commissioner.

Chemicals of security concern

During the Panel's work some stakeholders raised concerns about the requirements for managing chemicals of security concern. Concerns included, on the one hand, the adequacy of current arrangements, and on the other hand, the costs these requirements can place on business.

Whilst acknowledging these concerns, the Panel is of the firm view that the management of chemicals of security concern is a national security issue and is best managed by the Attorney General's Department. Additionally, the Panel understands the Attorney General's Department has undertaken its own Regulatory Impact Statement process in developing the National Code of Practice for Chemicals of Security Concern, which has included consultation with industry. Noting that national security issues are outside the Panel's Terms of Reference, the Panel has not made any recommendations to Government about the management of chemicals of security concern except to note that some of the chemicals within the system clearly warrant close management.

7. Recommendation

The Panel recommends the establishment of a position in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines. The Commissioner will have responsibility for:

- **strong and independent policy leadership and responsibility to recommend and drive continuous improvement**
- **reporting on whole-of-system impacts and outcomes through biennial reports based on whole-of-system performance measures**
- **whole-of-system surveillance and monitoring, drawing on data from a range of sources**
- **ongoing open engagement with stakeholders**
- **establishing and leading Stakeholder and Whole of System Forums**
- **establishing a domestic produce monitoring program.**

8. Recommendation

The Panel recommends that the Commissioner advise Government and the public on the performance of the regulatory system as a whole by establishing a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should also establish health-risk indicators for Australia (see Section 2.5).

The Commissioner would be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The Commissioner should

report publicly on the progress of the reforms in its first year, with system wide reporting on performance measures commencing 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Reporting should be informative and educational and include the results of domestic produce residue monitoring and environmental monitoring as well as adverse experience reports, 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. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

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 may change commensurate with the functions. As the new aspects of the future system become operational, the resources for many of these will be supported through appropriation, for example consultation mechanisms (see Section 2.4) expanded system surveillance (see Chapter 3), and domestic produce 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, that is; 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 envisaged by the Panel, 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 APVMA's governance and to its regulatory performance – to be realised from introducing a board to enhance the APVMA's and 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 is 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 adopted by the Government 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 and in the Statement of Expectations.

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 over the years, and that the organisation's dominant culture will be one of continuous improvement rather than a static business-as-usual approach. In ways such as this the board will add value from the point of view of the fee-paying industry.

The role of the board in driving APVMA-relevant reforms in the regulatory transformation process now to be embarked upon, means establishing the board should be an early priority.

Board membership

The Panel considers that board members should be appointed based on 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 sufficient diversity of skills and experiences for the organisation while keeping costs contained. The inclusion of the CEO as an *ex officio* board member will provide the board with the necessary operational insight, strengthen two-way communication between the board and the

authority, 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.

9. 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 its governance arrangements, provide the necessary oversight to support it 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 to emerge was that many stakeholders wanted more structured and effective engagement and consultation arrangements on matters relating to the regulatory system. They 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 need for focused leadership of the system as a whole. The APVMA is an important part of the system, but as a technical regulator with defined responsibilities, it 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 consultations on regulatory matters to date, many groups felt under-represented at best, and excluded at worst. The latter perception was particularly strongly felt by community group stakeholders in relation to APVMA decisions and policy development undertaken by the Department.

The social licence that provides consent to chemical pest and disease management in the production of Australian food and fibre commodities, and in treating companion animals and other species, should never be taken for granted. Ultimately, it is the consumers of produce, and owners and carers of animals, who choose to accept that the use of pesticides and veterinary medicines is safe and responsible. The Panel recognises how fragile this social licence can be. The community is seeking assurance 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 feedback and consultation arrangements can make an important contribution to such public assurance.

The community is also seeking assurances that animal welfare is not being compromised because of a lack of availability of appropriate veterinary medicines to prevent and treat

diseases and ailments in production and companion animals, exotic species, and wildlife. 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, such as horses and deer in national parks.

Past consultation

The Panel is not satisfied that there has previously been adequate consultation on even the limited reforms to the regulatory system to date. The Panel is satisfied there has been an absence of effective continuing dialogue between regulators, industry, users, and the community. Historically, engagement among the system's regulators, policy makers and the broader community has usually occurred on an 'as needed' basis.

For example, the Department, in developing reforms to the regulatory system, has not effectively engaged with stakeholders beyond key industry groups, nor with the broader community. Typically, policy advisors and implementers, including the Commonwealth and other jurisdictions, seek public engagement or comment 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 not sufficiently considered their views or concerns, and this has made them reluctant to continue to engage as they saw little benefit in doing so. They were frustrated at the amount of effort and time they had repeatedly spent to put their views to government with little 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.

Consultation in the future

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 recognises that the diversity of views on the role and place of pesticides and veterinary medicines in food production and pest control and disease management 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 and improved. 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 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 as a whole, but accepts stakeholders' desire for more, and more meaningful, engagement by the government in public discourse.

Improved consultation arrangements will contribute to sustaining the social licence regarding the use of pesticides and veterinary medicines. They may yield good ideas for regulatory improvements. They may accelerate the sharing of good practice among users of chemicals. They may pre-empt public misunderstandings and unnecessary alarm. They may assist in projecting Australia's positive image into export markets. They 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 therefore recommending a range of measures to better inform community, industry, and other stakeholders on the current operations and future of the regulatory system as well as policy reform and national risk management arrangements. Consultation machinery will 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.

What change is recommended?

The Panel recommends the establishment of 2 formal and one ad-hoc consultation and engagement mechanisms to consider the range of opinions and offer advice to ministers and the Department, on the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by the use of pesticides and veterinary medicines. These mechanisms are:

- a Stakeholder Forum
- a Whole of System Forum
- Expert Advisory Panels (as needed).

The Stakeholder Forum

The Stakeholder Forum will establish a channel for constructive dialogue among stakeholders to provide input to the development of policies across the whole regulatory system relating to pesticides and veterinary medicines.

The Stakeholder Forum is to be the primary means for structured government engagement with stakeholders, and stakeholders communicating back to government. The Forum will promote effective ways for all participants in the regulatory system to contribute to ensuring the responsible use of pesticides and veterinary medicines. It will also monitor reform progress. The stakeholder forum will also look at a range of more specific issues relating to pesticides and veterinary medicines. For example, an early item for discussion by the forum should be the appropriate management and consideration of honey bees and the possible synergistic effects of tank mixing.

The Stakeholder Forum will have a broad base invited membership reflecting the range of interests in pesticide and veterinary medicine product use and impacts. The Panel recommends representation be based on a willingness to engage in constructive and collaborative discussions. Membership would be drawn from:

- farming groups
- environmental groups
- animal welfare groups
- consumer and health groups

- pesticide and veterinary medicines manufacturers and organisations
- veterinarians
- chemical applicators
- trade unions
- education and training organisations
- animal sporting organisations
- relevant government agencies.

The Panel acknowledges the United Kingdom (UK) Pesticide Forum as the basis for this Stakeholder Forum. The Stakeholder Forum will provide advice and recommendations to the Commissioner, who may in turn draw on that advice in the development of the Commissioner's biennial assessment reports and recommendations.

To ensure the independence of the Stakeholder Forum, an independent chair should be appointed by the Minister for a 3 year part-time term with an option for renewal for a second term. Secretariat support will 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 and the Board 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 Whole of System Forum

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

The Whole of System 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 Whole of System Forum will identify points of conflict, opportunities, and areas for improvement between regulatory arrangements relating to pesticides and veterinary medicines and develop operational approaches to resolve conflicts.

The Panel anticipates members will be drawn from agencies and departments (Commonwealth, state and territory) with operational or policy responsibility for the environment, work health and safety, biosecurity, fair trading and consumer protections, health, poison scheduling, agriculture (including livestock and other animals), and the APVMA. This forum will also provide advice to relevant ministers on legislative reforms that are needed to improve policies and operational practices related to the regulation of pesticides and veterinary medicines.

Members of the Stakeholder Forum and Whole of System Forum would be chosen as set out in Annexes 10 and 11.

Expert Advisory Panels

The Panel considers that the Commissioner should have the power to convene 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 Expert Advisory Panels within a specified time.

The Expert Advisory Panels will consist of independent experts, with relevant expertise to the topic of enquiry. Like 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. Rather, the Expert Advisory Panels will be convened for the purposes of seeking evidence on critical issues to assist the Commissioner and the Department in the performance of their duties, functions, and powers. This could include advice on the significance of matters identified through surveillance programs, a specific area of regulation, (such as compliance and enforcement where new approaches are established) or advances in chemicals application technology (such as autonomous vehicles). For example, the Commissioner may decide to convene Expert Advisory Panels on topics such as developments in detection of pesticide residues, developing trends in antimicrobial resistance, or specific veterinary issues.

The Panel is strongly of the view that it would not be appropriate for the Expert Advisory Panels to undertake inquiries that relate to APVMA regulatory decisions; rather, it would focus on broader policy issues.

10. Recommendation

The Panel recommends that the Commissioner have responsibility for convening and hosting 2 formal and one ad-hoc consultation mechanisms to consider and offer advice to ministers and the Department of Agriculture, Water and the Environment 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**
- **a Whole of System Forum**
- **Expert Advisory Panels (as needed).**

Terms of reference should be 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 part time chair), and accessible funding for the Expert Advisory Panels. 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 therefore be met through government appropriation.

The Panel considers the Whole of System 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, impacts and outcomes. They provide transparency and accountability 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 currently 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. However, while useful, the APVMA's performance measures are frequently in the form of input or output measures, not outcome measures. Contemporary best practice performance measurement arrangements seek to develop indicators of system outcomes (results) to demonstrate that the system is working effectively.

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

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.

What change is recommended?

The Panel recommends the establishment of a comprehensive set of outcomes focused 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 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 the reform transformation journey 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 Commissioner's 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 provide evidence of performance against the system's endorsed objectives, as described in Chapter 1. Indicators of health and environmental outcomes, industry, and community sentiment, and regulator performance should also be included.

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 (see Recommendation 8).

The Panel recommends that industry measures should encompass the entire life cycle of pesticides and veterinary medicines across the supply chain, from introduction of new chemistries and products through to supply, use, and disposal. Measures would also include Australia's involvement in international forums, trade statistics, and national 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 APVMA and control-of-use regulators 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.

While the Panel has recommended wide range of possible indicators, the Panel reiterates that determination and design of the indicators should ultimately be the responsibility of the Commissioner. This is because designing the performance indicators will be an important means by which the Commissioner can provide leadership and steerage to the regulatory transformation process shortly to be embarked upon.

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 Whole of System Forums (see Section 2.4). and other relevant stakeholders. 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 3 An example of capturing and acting on adverse experience reporting in a future regulatory system

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 from abroad over the internet. Armed with this information, the Commissioner in conjunction with the APVMA developed an information campaign to address this issue.

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) 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 Department and the APVMA), reconsiderations, and responses to recommendations made by the Stakeholder Forum in the future regulatory system to improve transparency and accountability.

It will be important also that efforts are made to build on the APVMA's current output indicators to develop the necessary complementary outcomes indicators. The Panel envisages that the APVMA Board will drive this process.

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 the number one priority of a modern, effective pesticides and veterinary medicines regulatory system. The Panel has, in addition to its other health and safety reforms, targeted 3 key areas for transformation which specifically strengthen this protection: increased surveillance and monitoring; more timely chemical reviews; and a new humaneness indicator for vertebrate pesticides.

The measures proposed will ensure that the system continues to meet increasingly demanding community and industry expectations, builds public confidence, strengthens social licence, and improves protections for people, animals, and ecosystems.

The Panel considers that enhanced safety will be achieved through the implementation of 5 elements:

- system surveillance, data mining and analysis
- domestic produce monitoring
- environmental monitoring
- identifying product related concerns
- greater transparency through public reporting of system surveillance.

These elements will work together to ensure that pesticides and veterinary medicines use is more effectively monitored and that any areas of concern are detected early to limit potential harm and enable a rapid and proportionate response. Credible arrangements to monitor the outcomes and impacts of the regulatory system as a whole are essential to maintain community confidence.

Chemical reviews can offer 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. For this to be achieved, chemical reviews need to be conducted in a timely fashion. The Panel heard that the APVMA, with sole responsibility for chemical reviews, has taken more than 10 years to review some chemicals, while a few are still under review after 15 to 25 years. In fact, paraquat has been under review for 27 years and this cannot be considered reasonable or justifiable by any means.

The transparency and speed of chemical reviews needs to be significantly 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. Unduly extended chemical review processes jeopardise public confidence in the regulatory system.

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 have long been expectations that safe and effective veterinary medicines should be available to treat diseases and conditions of production, companion and other animals. The community is also coming to demand that animal welfare be taken more seriously into account in the management of vertebrate pest animals. Providing consumers with the necessary information to choose more humane treatments for the eradication of vertebrate pests is a rational and measured way to respond to such community demands.

More details of each of these recommended areas for reform, follow.

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 speedy investigation and response. The social licence to continue access to and use of pesticides and veterinary medicines depends on robust and timely data to support public confidence in such arrangements.

There is a vast body of literature available that describes detrimental effects of chemicals in general on human and environmental health worldwide. For example, to complement its own research, the Panel received from the National Toxics Network an array of references to overseas studies describing the impacts of pesticides on human health. Many of these chemicals have similar exposure pathways in Australia and could therefore 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 Australia's environment.

The Panel recognises the importance of this international research. It emphasises the need for careful science-based risk assessment to reject unsafe chemicals or uses, or to design suitable ways of using registered chemicals safely. Indeed, these are the fundamental purposes of regulatory systems in all major developed countries. Without systems structured in this way research findings risk being taken in isolation, an indiscriminate approach that often underpins public disquiet about the use of chemicals. The future pesticides and veterinary medicines regulatory system must build the insights of global science literature into more structured future arrangements for monitoring the impacts and outcomes of chemical use in Australia. The regulatory system needs to take care to present a complete and fulsome picture of the science, risks, and mitigations, so that public confidence in the use and regulation of these chemicals is assured.

In addition to the global science literature, 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, assist in the design of risk management measures, and inform policy discussions and further 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 alone 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. This will improve transparency and enable more meaningful surveillance of trends and developments in chemical use throughout Australia.

Separately, jurisdictional control-of-use legislation currently requires that users record their pesticide and veterinary medicine use, and that these records can be subject to audit by the regulator on request. These record keeping requirements could be a rich source of data but are currently disconnected from any wider scheme to monitor chemical use. The Panel considers commercial and professional (i.e., not home garden or domestic) pesticide use and veterinary medicine use should continue to be recorded but could be better utilised to build a more sophisticated surveillance system.

Many farming industry quality assurance (QA) schemes require chemical use to be recorded (e.g., the myBMP scheme for the cotton industry). 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 monitoring and managing the risks associated with pesticide and veterinary medicine use (GHD 2017). Industry systems and QA programs are existing sources of information that already capture on-farm chemical use through longstanding record keeping requirements (e.g., spray diaries). It is the Panel's strong view that these schemes could, and should, be utilised to support surveillance of the overall performance of the regulatory system.

The APVMA and the states and territories all currently conduct limited post-market compliance checks to assess how effectively pesticides and veterinary medicines risks are being managed. This includes enforcing operator training requirements, certain, but 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, none of these data sources are currently utilised for broader monitoring purposes.

The key issue with all this data is therefore that the many available and potentially valuable information sources are disparate and disconnected. Many of the data sets are passive and not utilised to the extent they could be. A well-designed and comprehensive regulatory system should effectively, collate, curate, and analyse the various sources of post-market information. This would allow regulators to:

- monitor trends and developments in chemical use across Australia
- recognise impacts and outcomes of the regulatory system as a whole
- provide early warning of emerging risks and issues
- confirm whether the current controls are effective or require adjustment
- improve the ability of regulators to target their efforts to detect and respond to non-compliance

- provide the evidence basis for any necessary improvements to Australia's regulatory system as a whole
- provide assurance to the community that effective whole-of-system monitoring was in place.

In the Panel's consultations, a diverse range of stakeholders expressed support for greater use of data from credible sources to inform regulatory decisions.

Collecting and collating such data over a prolonged period would allow a robust and increasingly useful data surveillance system to be established and maintained. Big data techniques offer significant opportunities in the future, to improve our understanding of on-the-ground activities and to discern trends and developments early. This will allow long-term strategies, priorities, and management plans to be developed and more accurately targeted. The current inaccessibility of the various data sets in Australia makes it difficult to prioritise and conduct research in ways useful for product manufacturers, regulators, public good, and end users.

While the case for better utilisation of data is therefore strong, many 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 utilisation of data requires careful consideration of issues relating to intellectual property, confidentiality, and privacy protection. The Panel agrees with these sentiments and notes that governments have processes in place to ensure confidentiality, privacy, and intellectual property. Failure to manage these issues properly would risk discrediting the surveillance system in the minds of stakeholders and the wider community.

Some stakeholders also questioned the way in which an individual grower's data might be utilised, expressing a view that users may be reluctant to participate if their own data may be used for additional compliance purposes or if participation imposed added costs on users to provide data. Again, governments have systems in place to protect an individual's identity and 'de-identify' specific data sources.

These challenges notwithstanding, the Panel considers it is imperative that comprehensive data sets be collected, collated, and curated to build an integrated national data surveillance system. The objective is to enable credible reporting on how the regulatory system as a whole is working, and importantly, what actions needed to be taken where there is evidence of non-compliance, or safety concerns.

Systematic utilisation of available data sets on the use of chemicals is critical to the integrity of the regulatory system. Provided costs are minimised, and confidentiality, privacy, and intellectual property issues are properly managed, users should have no concern in making available such data to the regulator to demonstrate their responsible use. An integrated national data surveillance system will help to build and maintain a robust, effective regulatory system that is both adaptive and responsive.

Box 4 Targeted monitoring and system surveillance

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 support public confidence in such arrangements.

Monitoring and surveillance are intertwined concepts with mutual benefits.

Monitoring is a general concept that can describe the collection, measurement and active analysis of defined populations or activities. In the context of this review, monitoring is a targeted activity to identify pesticide or veterinary medicine residues in domestic produce (food commodities) and environmental samples (water and sediment). Some jurisdictions currently monitor residues in produce however, this reform will deliver a consistent and strengthened approach to monitoring residues across Australia.

System surveillance can be described as continuous observations, analysis, interpretation, and collation of information gathered from multiple data sources. This analysis can then be used to evaluate system performance, inform future planning, develop risk management measures, identify trends, inform compliance actions, and policy discussions. The Panel considers a sophisticated system surveillance model would utilise both produce and environmental monitoring data, adverse experience reports, industry collated data such as QA schemes and university research.

Overall, monitoring is generally a targeted activity whereas system surveillance has a broader remit and assesses data from all relevant sources to inform system improvements.

What change is recommended?

The Panel considers it is critical to establish effective, system-wide surveillance arrangements for pesticides and veterinary medicines. These arrangements would collect, collate, curate, and utilise multiple inputs to build an integrated national data surveillance system. The system would identify areas of concern, provide a basis for compliance action or regulatory change, and provide the evidence basis for designing necessary future improvements to the system as a whole.

Further, the Panel considers that the current lack of comprehensive surveillance and monitoring arrangements undermines the credibility of the existing Australian regulatory system as it makes it difficult to demonstrate how the system is working to protect consumers, animal health and the environment. The Panel considers the difficulty in accessing data about overall system performance is a failing of the current regulatory system and will become increasingly unacceptable to both industry and the community in the years ahead. Conversely, the availability of transparent data and evidence of corrective action to maintain safe performance would provide strong support for the social licence to continue the use of pesticides and veterinary medicines in Australia.

The Panel recommends that the Commissioner for Pesticides and Veterinary Medicines (the Commissioner) (see Section 2.2) develop a cost-effective, integrated national data 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; published literature; changes in market expectations; decisions by overseas regulators; and intelligence or reports from professional bodies and academic institutions (e.g., on anti-microbial drug, anthelminthic or pesticide resistance). In addition, residue detections from monitoring of domestic produce (see Section 3.2), environmental

monitoring data (see Section 3.3), and adverse experience reports (see Section 3.4), would all aid in building a more comprehensive surveillance system.

The Panel recommends the Commissioner 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.

Design and development of the proposed system will be complex and time-consuming. Moving arrangements from the current ad hoc and disconnected data sources to an integrated national system will be part of the extended process of transformation of the national regulatory system over the next few years. The work will need to be conducted in step with other elements of the reform package.

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 recommends these costs should be met through government appropriation.

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

11. Recommendation

The Panel recommends that the Commissioner develop a cost-effective, integrated national data surveillance system fit for the needs of a 30-year future. The Commissioner should also develop arrangements to curate relevant information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes. The Commissioner's biennial report should report on trends identified in system surveillance data.

The surveillance 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, published literature, 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.**

3.2 Domestic produce monitoring

Australia has a well-regarded and longstanding pesticide and veterinary medicine residue monitoring system undertaken by the National Residue Survey. The 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.

While the National Residue Survey does cover a small number of products sold on the domestic market (on a fee for service basis), the Panel considers the lack of a general system for monitoring and reporting on domestic produce to be a serious gap in Australia's current regulatory system.

The states and territories are nominally responsible for monitoring chemical residues as an element of their control-of-use arrangements. However, there is a lack of consistent methodology applied across jurisdictions and the level of resources devoted to the task varies considerably among the states. Currently only 3 states (Queensland, Victoria, and Western Australia) have routine monitoring programs.

Some jurisdictions rely on industry quality assurance schemes to monitor residues, but as these schemes are currently not formally recognised and incorporated within the regulatory system they do not necessarily lead to, or result in, compliance and enforcement action by the jurisdictions. These industry schemes include Freshcare which provides assurance to supermarkets through an annual residues test and FreshTest which conducts tests for wholesalers and their growers in Australia's 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 serious 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. Such community concern almost certainly includes an expectation that residues in domestic food supply are being monitored no less thoroughly than residues in Australian produce sold to consumers in export markets.

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 generally low concentrations of pesticide and veterinary medicine contaminants. The survey results provide valuable data that can be used by state and territory regulators and the APVMA and the Panel supports its continuation. However, the Panel is also aware that the ATDS is not intended to inform compliance measures and does not provide sufficient breadth, granularity, contemporaneity, or regularity in monitoring and traceability to support adequate monitoring of control-of-use regulation.

Moreover, although the ATDS results have generally been reassuring, some of the more targeted industry tests have on occasions yielded results of potential concern.

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 will be real, and Australia's access to export markets could be put in jeopardy. Consumer and export customer alarm could escalate quickly, and perhaps unnecessarily. The Panel therefore considers it important that a credible official national domestic monitoring system be initiated to preserve consumer confidence in Australia's regulatory system. Put simply, the risks of undertaking monitoring of domestic

produce and publishing the results (in context) are far outweighed by the risks to social licence if the status quo continues.

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 regular reports summarising the findings of these programs. A government-led national domestic produce monitoring system would align Australia with international best practice standards.

During the Panel's consultations, stakeholders generally agreed with 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. However, the Panel recognises that there are many complexities associated with establishing and implementing a national produce monitoring system.

The Panel sees enormous opportunities for regulators and other government agencies to collaborate and share monitoring data. With sufficient support and investment, the reforms proposed here could be the start of a collaborative, holistic monitoring system that will enhance policy making and regulatory compliance over the coming decades. While the Panel acknowledges the myriad challenges that must be overcome if such as system is to be established, such a system would significantly benefit industry and lead to a reduction in regulatory compliance costs for businesses and arguably government regulators.

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 and specific information to users 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 continue to build public confidence over time.

What change is recommended?

The Panel recommends the establishment of a comprehensive, cost-effective, and authoritative Government-led national domestic produce monitoring system (see Recommendation 11 in Section 3.1).

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.

Introducing the domestic monitoring scheme will be an important part of the whole-of-system transformation envisaged by the Panel. Design and implementation will not be possible overnight. The Commissioner will design the final aspects of the program, including the multi-year sampling priorities, in consultation with the National Residue Survey, primary producers, the community and state and territory governments (through the Stakeholder Forum and Whole of System Forum (see Chapter 2)), to ensure it aligns with the whole-of-system surveillance scheme. To avoid an open-ended cost, there will need to be careful risk-based targeting of effort. The early years of the program will need to be carefully staged in development and the program extended over time.

The Panel considers that once developed, the domestic produce monitoring scheme should be operated by the National Residue Survey located within the Department of Agriculture, Water and the Environment (the Department), but separately funded through Government appropriation (see Chapter 7).

The Panel considers that the national domestic produce monitoring program could be supplemented and enhanced by existing industry testing programs, such as those led by the Australian Chamber of Fruit and Vegetable Industries or Fresh Markets Australia (e.g., FreshTest). Utilising existing, reputable schemes could greatly simplify the establishment of the national domestic produce monitoring program, resulting in faster access to domestic produce monitoring data and reducing the costs associated with establishing monitoring activities.

The results of the monitoring program will be a key input to the system surveillance outlined in 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. The monitoring program will allow regulators to identify residue violations and provide data to support regulatory action in cases of such violations. The domestic monitoring program will also support the further development of national policy on residue in produce and in production animal commodities and provide the necessary evidence base for any further reforms to the regulatory system as a whole.

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 or veterinary medicines in their production animals. 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 $5 million per annum.

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

3.3 Environmental monitoring

Pesticides have ubiquitous uses, and it is expected that there will be some level of pesticides detected at any given time in the environment, particularly given the increased sophistication in analytical technologies that are now able to detect chemicals in general to a level never before anticipated. This in itself should not necessarily be cause for concern; however, should there be an accumulation or detection of high levels of pesticides in specific ecosystems, such as waterways or soils, this may necessitate remedial action to reduce the possibility of adverse environmental impacts.

The Panel has also heard concerns from various community groups and non-government organisations about the potential for unintended community exposure to pesticides (through urban spraying activities). 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 soils.

In contrast to pesticide contamination, veterinary medicines potentially pose lower risks of environmental contamination, largely due to their different use patterns. Similarly, community groups and non-government organisations generally display less concern about the use of veterinary medicines and the impacts they may have on the environment. However, the risks of environmental contamination posed by veterinary medicines should not be entirely discounted. For example, former sheep dip sites have been areas of public concern in the past. Where veterinary medicines are used in ways and quantities that could foreseeably lead to environmental contamination, they should also be considered for environmental monitoring.

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. The 2021-22 federal budget provided for some $228.8 million in funding. Following an extensive consultation process, the Department is currently exploring opportunities to commence implementation of this strategy, including scoping the development of a national soil monitoring program. If this program were to include a risk-based soil residue monitoring component based on data and insights, 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 intensive chemical use. 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 sampling, analytical methodologies, and other requirements) among them. Most of the water monitoring undertaken by jurisdictions is currently limited to drinking water quality standards only.

Consistent with the many responses the Panel received in favour of 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 supported by comprehensive data, that the Australian environment is being negatively impacted by chemicals. As was the case for domestic monitoring of residues in food, the introduction of credible environmental monitoring should

provide a factual evidence base for public discussion and thus 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 carefully targeted according to risk, in order to minimise cost and to focus on areas of greatest need.

Separate from environmental testing of waterways, drinking water quality is analysed 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 threshold levels, testing frequency is increased 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 during the Panel's stakeholder consultations.

What change is recommended?

The Panel recommends that both water and waterway sediment samples be analysed as a means of monitoring the levels of pesticides and veterinary medicines 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. There would also be benefit in strategic testing of waterways that impact upon aquatic systems that support fisheries and aquaculture.

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 risk profiling.

An 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 industry QA systems and the possibility for co-regulatory approaches in delivering a comprehensive residue monitoring program.

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 sampling and unacceptable residues in soil could provide similar indications about poor agricultural practice or overuse of chemicals. Where environmental monitoring shows unacceptable residue levels (in either water or soil), data will be provided to regulators who can engage with local farmers to encourage better agricultural practices and chemical management or undertake compliance actions if warranted.

The Environmental Monitoring Program will also provide an evidence base for the Commissioner to recommend any further reforms necessary to continue to improve the performance of Australia's regulatory system as a whole (see Chapter 2).

The Panel sees the Environmental Monitoring Program as a good example of the transformative reforms needed to take Australia's current regulatory system to the level necessary to meet the rising expectations of the community and other stakeholders over the next 20 to 30 years. Design and implementation of the program will take time. Implementation milestones will need to be set to guide the journey over the next few years.

The Panel suggests that the Commissioner should explore, with other relevant areas of Government regulators, 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, soils and sediments, represents a public good and should be funded through appropriation. There would therefore be no impact on industry regulatory costs.

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 recently announced National Soil Strategy.

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

12. Recommendation

The Panel recommends increased whole-of-system monitoring by government of pesticides and veterinary medicines in produce and the environment.

Domestic produce monitoring

- **Establishment of a comprehensive, cost-effective, and authoritative Government-led national domestic produce monitoring system. The 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.**
- **A domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residue Survey, primary producers, the community and state and territory governments to ensure it aligns with the whole-of-system surveillance scheme.**

Water and soil monitoring

- **Monitoring water, waterway sediment and soil samples to detect levels of pesticides, parasiticides and antimicrobial drugs in the environment. The testing program should be scalable and targeted, based on risk.**
- **Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.**

Environmental monitoring

- **Development of a government funded, risk based, Environmental Monitoring Plan to identify areas of priority for monitoring 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.**

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 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 product's 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 any issues of concern 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 and allow regulators to react to these concerns 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.

Currently, AER arrangements exist at both national level, and state and territory levels. This is often confusing for parties making the reports. Also, the national and various state schemes do not correlate or integrate well with each other. There is overlap, duplication and confusion.

Adverse experience reporting: veterinary medicines

The majority of AERs received by the APVMA relate to animal health concerns arising from the use of veterinary medicines. During the Panel's consultation with veterinary medicine stakeholders, they drew attention to the opportunity to build on the current (mainly animal health) AERs system to create a best practice pharmacovigilance system to utilise adverse experience reports to collate, monitor, respond to and identify trends.

Many international regulators, including the European Medicines Agency, Health Canada's Veterinary Drugs Directorate, and the United States Food and Drug Administration, maintain national pharmacovigilance systems for veterinary medicines, bringing together data from a variety of sources (including AERs) 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 existing adverse experience reporting program, as discussed previously, is largely utilised for animal health concerns, and could likely provide the foundations for a formal pharmacovigilance scheme.

The Panel is confident there is significant support amongst the veterinary sector for the establishment of such a scheme. For example, 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 further improvements to the AER process that would encourage greater and more streamlined reporting.

Adverse experience reporting: pesticides

The Panel acknowledges that despite all the problems associated with AERs, reporting on veterinary medicines is well developed compared to reporting on pesticides.

The Panel does not accept the argument, put by some, that the smaller number of reports for pesticides is evidence of a smaller number of adverse experiences. Submissions and views expressed by various stakeholders throughout the Panel's consultations suggest that the current adverse experience reporting scheme for pesticides is slow, inconsistent, and cumbersome to use and users see little meaningful action being taken in response to reports. There is confusion for intending users of the scheme about whether to use state or local government reporting channels, or the national reporting channel. Even when the right channels are found, responses to reports can take an inordinately long time.

The Panel sees potential for an important systemic improvement if there were to be 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. More comprehensive analysis and easier reporting processes will yield invaluable intelligence for continuing improvements to Australia's future regulatory system. Reporting on AERs would improve transparency and knowledge and provide users and the community with increased confidence in the regulatory system.

What change is recommended?

The Panel recommends that AERs 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 AERs should be detailed in legislation for both pesticides and veterinary medicines.

The Panel considers it vital that AERs 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 performance of the entire system.

The Panel recommends that under the new single national law for control-of-use, a single national system for reporting all adverse experiences be developed. Reports of adverse experiences would be via a single web-based national portal through which all AERs would be channelled. The Panel expects that such a system would simplify the collection of data and the reporting of AERs to build on advances in technologies that can provide opportunities for more sophisticated and contemporary monitoring and regulatory systems overall.

The Panel considers that as the Department will have responsibility for policy and legislation for control-of-use (under the single national law) it should be assigned responsibility for developing and maintaining the AER web-based national portal. While the APVMA could develop and maintain the single AER system, the control-of-use and performance assessment elements of the scheme go beyond the scope of the APVMA's core responsibilities and would divert resources best used for other purposes.

While the national reporting system would be developed and maintained by the Department, responding to AERs would still be the responsibility of the appropriate regulator (being either the APVMA or the relevant control-of-use regulator). The AER portal would automatically refer AERs to the appropriate authority when they are received, thus acting as a single point of contact and automated AER referral system, while also providing for a national database of AERs.

The Panel is aware of the importance of AERs to regulators' compliance activities and the need for regulators to have continued access to AERs and hence all regulators would have tailored access to the AER dataset.

To improve transparency and accountability, summaries of validated AERs would be published regularly and within designated response timeframes. These public summaries would be prepared by the authority responsible for responding to the AER (generally the APVMA or the relevant state or territory regulator) and include basic information about the adverse experience that was reported, and the regulator's response. AER report summaries would be published as soon as possible (and within 3 months of the date of report).

Holders of active constituent approvals, registrations or permits would be required to submit any AERs to the single national portal. This would occur when they become aware of an unintended safety effect, lack of efficacy, evidence of resistance development, 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) would be obligated to submit AERs.

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 would 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, that the Panel considers to be of high value, 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 equipping the regulators and policy makers with a set of comprehensive information sources.

Any individuals, for example farmers, companion animal owners, gardeners, veterinarians, or members of the public, should also be able to voluntarily submit a report concerning the registration or use of a pesticide or veterinary medicine product to the single national portal for AERs 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). In the case of veterinary medicines, the Australian Veterinary Association could also play a role in coordinating the role of the veterinary profession in the collation and review of AERs. 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 Department 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 by most other developed countries. This would enable state and territory regulators or the APVMA to undertake further investigation or compliance action if it was related to supply (APVMA) or control-of-use (the relevant control-of-use regulator) matters.

This would also help ensure regulatory action is undertaken as soon as an issue is identified and will contribute to the continued safety, quality and effectiveness of pesticides and veterinary medicines. The Panel believes these changes will help address the concerns raised by various stakeholders about the timeliness of AER responses, and provide greater assurance about the continued safety, quality and effectiveness of pesticides and veterinary medicines.

In developing the pharmacovigilance scheme, the Department should consider reporting of antimicrobial resistance, resistance to antiparasitic agents and other parasiticides as part of a more robust scheme. Antimicrobial and antiparasitic drug resistances can be considered as leading to lack of efficacy in the relevant veterinary medicines, and as such may be included in AERs. The Panel sees a need for better monitoring of antimicrobial drug (AMD) use and efficacy, especially in production animals, and expects that this need will only become greater in the coming decades.

The Panel envisions a future where adverse experiences are reported and publicly available following validation and authenticity. As technology progresses and smart labelling (see Chapter 4) becomes more integrated in farming practices, the Panel sees an opportunity to explore user friendly applications that allow instantaneous reporting and recording of adverse experiences.

Cost of reform

The Panel's recommendation to provide structure and a streamlined process to submit adverse experience reports builds on 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.

13. Recommendation

The Panel recommends that adverse experience reporting (AER) be consolidated, improved, and better utilised:

- **The structure and reporting process required when reporting adverse experiences should be detailed in legislation for both pesticides and veterinary medicines.**
- **The Department of Agriculture, Water and the Environment develops and maintains a single national portal for AERs under the single national law for control-of-use. The Department should collate reports to establish a system wide 'pharmacovigilance' approach.**
- **The AER national portal would automatically refer AERs to the appropriate authority when they are received, thus acting as a single point of contact and automated AER referral system, while also providing for a national database of AERs.**
- **The APVMA and state and territory regulators would be provided with tailored access to the adverse experience report dataset and should publicly report on adverse experience reports that fall under their jurisdiction.**

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 support ongoing confidence in the regulatory system.

Publication of this data will 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 further improvements in the future to food safety and 'lifting the bar' where necessary, on residue detection across all produce.

Data gathered through system surveillance will support evidence-based advice to ministers and better inform future recommendations 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 can be better utilised to identify trends. For example, repeat reports of a herbicide not effectively killing a weed in a region may lead to a targeted investigation of resistance patterns. Similarly, consistent reports from the animal husbandry sector will also expedite recognition of emerging resistance to antiparasitic drugs.

What change is recommended?

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 be transparent about the data and to respond speedily to risks and problems that may be indicated by the data, and in so doing buttress the social licence to continue to use pesticides and veterinary medicines.

Residue monitoring results should be collated by the Commissioner and presented annually in an informative, educational, and suitably contextualised 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 recognises that 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 add to the overall base of information for intelligence gathering which could lead to better targeting of compliance actions. More importantly, the Panel considers that this data would demonstrate the effectiveness (or not) of regulatory controls.

3.6 Improving the speed and transparency of chemical reviews

New scientific information emerges frequently 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 is good regulatory practice and 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.

Currently, the APVMA has sole responsible for undertaking chemical reviews (formerly called chemical reconsiderations) in Australia. Many chemical reviews have taken more than a decade to complete, and certain chemicals remain under review after more than 15 to 20 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 adaptability and 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.

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 appear 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, the regulator, or the associated processes.

In contrast, the 're-registration' schemes for pesticide products in 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, such processes come at a very high cost. The Panel understands these international chemical review schemes are running considerably behind schedule in each of the overseas jurisdictions that conduct reviews on a rolling basis.

Stakeholders had mixed views about adopting a rolling review schedule in Australia, with some supporting rolling reviews as a 'safety backup'; and others expressing concerns about diversion of regulatory resources to this work rather than responding to emerging issues. Certainly, being driven by a rolling review process is inconsistent with allocating scarce APVMA work resources according to relative risk.

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 the 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 beneficial in ensuring that access to safe chemicals is not lost unnecessarily.

In some cases, 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 delivered little improvement, largely because the APVMA's resource focus historically has been on timely product registration at the expense of chemical reviews.

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 risk and science-based and designed to confirm or otherwise, the continuing safety and efficacy of the product in question. Properly designed, a good chemical review process will increase public confidence and maintain social licence related to the use of pesticides and veterinary medicines.

The Panel recommends that in future, reviews will be 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 currently has the ability to initiate a chemical review at any time. However, the Panel considers that there is a lack of transparency in relation to the APVMA's decisions not to initiate chemical reviews, particularly when reviews have been undertaken by comparable international regulators.

For this reason, the Panel recommends that a well-defined, legislated review trigger be introduced. The APVMA would be required to commence a review into substances on the basis

of this trigger and would be required to publicly disclose that the review is 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 the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA would not be required to carry out the review. However, in such a case the APVMA would be required to publish, within 6 months of the trigger occurring, a statement of reasons for not conducting the review. The statement would include a summary of the information the APVMA relied on to form its position. The APVMA may not rely on information that would be considered 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's leadership role, coupled with access to system wide surveillance and a whole-of-system reporting program will give them oversight of adverse experience reports, environmental contamination, the outcomes of domestic produce monitoring and other issues. As such, the Panel considers that the Commissioner should be able to refer chemicals to the APVMA for review.

To refer a chemical to the APVMA, the Commissioner will need to be satisfied that there are sufficient reasons for the APVMA to consider a review and will need to provide those reasons to the APVMA when making the referral. Chemicals referred to the APVMA in this way should be publicly reported. These publicly reported referrals should also include the reasons for the chemical being referred to the APVMA for review.

If the APVMA chooses not to initiate a chemical review based on a referral from the Commissioner, it will be required to publish a statement of reasons for not conducting the chemical review within a designated timeframe.

Enhanced and focused process for review

The future process for chemical reviews will 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 permits is relevant to the scope of the review, the holder of the permit 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 will be able to take administrative or other action as necessary, up to and including suspension, cancellation, or amendment of the registration or permit (as commensurate to the risks). This approach will 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 will have a defined and fixed timeframe. A holder of a registration will be able to 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 will be able to collaborate with each other 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 will 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 should, in most instances, conclude within a maximum of 3 to 4 years from commencement, although sooner is preferrable. 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 will be retained.

Timeliness of chemical reviews

Legislative changes that took effect in 2014 require 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 (see Chapter 2). The APVMA's performance in respect of implementing reforms, would also be included in the Commissioner's biennial assessments of reform progress and overall system performance.

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 from reviews but would be subject to similar and independent oversight of risks. The Department will be responsible for setting robust licence conditions and conducting regular audits of licensees. The Department will 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 Department is informed when the overseas regulator identifies an issue with a product brought to Australia under licence. The Department 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.

Additionally, the Commissioner will be able to direct the Department to investigate a licensed product if they consider that there is sufficient evidence to warrant such an investigation. The requirements on the Department to respond to and report on referrals should mirror those described for the referral of a registered product to the APVMA.

Cost of reform

While the Panel is not directly recommending the number of the reviews undertaken by the APVMA be 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.

14. Recommendation

The Panel recommends the transparency and responsiveness of the chemical review process be improved. Reviews should be initiated through one of 3 mechanisms: as the result of a well-defined, legislated trigger (such as a relevant international decision); at the discretion of the APVMA; or on referral from the Commissioner.

If the APVMA is be required to commence a review into substances on the basis of the trigger, it would be required to publicly disclose that the review is commencing. However, the trigger should not result in repeated near identical reviews within a 3 year period, unless APVMA chooses to initiate a review within this time.

Where an international decision would trigger a chemical review but the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA would not be required to carry out the review. However, in such a case the APVMA would be required to publish, within 6 months of the trigger occurring, a statement of reasons for not conducting the review

15. 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. Similarly, the Commissioner should be able to refer substances imported under the international licensing scheme to the Department of Agriculture, Water and the Environment for investigation.

To refer a chemical to the APVMA or Department, the Commissioner would need to be satisfied that there are sufficient reasons to consider a review and would need to provide those reasons to the APVMA or Department when making the referral.

If the APVMA or Department chooses not to initiate a chemical review or investigation based on a referral from the Commissioner, it should be required to publish a statement of reasons for not conducting the chemical review or investigation within 3 months of the referral being made.

16. 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 are increasingly attracting community interest.

These growing community concerns on animal welfare over the impacts of VPCPs are likely to impact on their continued use in the future.

The current situation

Given the growing community expectations about 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.

Stakeholders largely supported the proposal to include relative humaneness on labels of VPCPs when it was discussed in the Panel's Draft Report. In particular, the RSPCA, Australia's peak animal welfare organisation, stated:

> "*The RSPCA believes this will be a significant step in achieving improved welfare of animals affected by vertebrate pest control programs […] overall the inclusion of relative humaneness on product labels will highlight the importance of animal welfare when selecting a particular control method. This should improve welfare outcomes for both target and non-target species. The other benefit will be that*

greater attention will be focused on more humane methods being developed, including non-lethal humane 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. Farmers and other users would continue to make their own decisions about the products they wished to use.

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 the opportunity 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 former Australian Government Department of Agriculture, Fisheries and Forestry, in conjunction with the states and territories and key stakeholders, including the APVMA. The model adopted in the national strategy 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. 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 notes that no comparable international regulator currently requires relative humaneness information to 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 animal welfare.

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 more humane 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 on 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 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, introduction of the requirement can be staged and 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.

17. 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 industries (manufacturing, supply, and user industries) have changed significantly since the inception of the National Registration Scheme in the early 1990s 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 have been made increasingly clear.

The Panel heard repeatedly during the consultation process, that there is strong commitment from Australian industries to manufacture and supply safe and suitable pesticides and veterinary medicines in order to meet community expectations. This commitment is shared between government and industry and given the improved capacity of industry to deliver consistent quality and safety, the Panel considers the system as a whole can be strengthened by placing more responsibility and accountability with industry for risk-managing the high-quality manufacture and safe, and effective use of these products.

General product obligations

There are multiple participants along the supply chain that can take more responsibility for their part of 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; all parties in the supply chain have a responsibility to ensure that their products are safe, and used safely. 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 have ensured that general safety within the system is not compromised or reduced in any way. Indeed, the aggregate effect has been the reinforcement of safety via a system-wide and collective effort to manage risks at every link in the production and use chain.

Mobilising the efforts of non-government individuals and organisations in this way has allowed government regulators to concentrate their efforts on higher risk areas of the regulatory system, improving overall outcomes. Such arrangements are consistent with best contemporary regulatory practice in Australia and around the world.

The Panel considers that one means by which arrangements of this type can be built into the future pesticides and veterinary medicines regulatory system, is by introducing the concept 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 by adopting the approach. Shifting the focus to regulating activities, rather than only the product's

use (noting that the supply of products is regulated), is akin to the approach used in work health and safety legislation.

A national licensing framework

The Panel also proposes introducing 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. This hampers inter-state businesses, adds to costs, is time consuming, and confusing. A single, national licensing arrangement would facilitate greater mobility across borders, reduce risk of error, and reduce administrative burden.

Training and competencies

National licensing arrangements will provide the opportunity to lift training and competency standards to improve the safe and effective use of pesticides. The Panel heard from many stakeholders that approaches to 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 that are based on existing industry programs (such as Spraysafe) and accredited training through the vocational and tertiary education sectors (see Section 4.3). If sufficiently rigorous, these could be referenced in the national licensing framework. More consistent and improved training and competency standards will strengthen safe dealings with chemicals for each link of the handling chain.

Product labelling

The product label is the primary and most effective means of conveying the essential information on safe and effective use of pesticides and veterinary medicines to users. However, the current labelling of pesticides and veterinary medicines is complex, confusing, and inflexible with different labelling codes and information for differing legislative requirements. Labels have become lengthy and detailed, so critical information is sometimes difficult to find. In addition, updating information on labels takes time, sometimes resulting in differing labels in the supply chain for the same product.

The Panel recommends simplifying labelling, and in so doing streamlining label assessment, by focusing pre-market regulatory effort on those label elements that are unique to pesticides and veterinary medicines. Label content which does not require assessment would be subject to post-market compliance by the APVMA.

The Panel also recommends the regulatory system adopt the great potential of 'smart labelling' technology where information can be supplied via electronic means (see Section 4.4). Subject to IT and communications coverage, this will allow targeted data to be provided in real-time including updated information that can be understood by all users including those from the many cultural and linguistically diverse (CALD) communities in Australia.

Disposal and recycling arrangements

At the disposal/recycling stage of the pesticides and veterinary medicines product life cycle, Australian industries have stewardship programs to manage the end-of-life impacts of their 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 ensure their quality assurance schemes and good practice guides include requirements and guidance on good disposal practice as part of being deemed to meet general product obligations. Similarly, good disposal practice could be referenced in licensing conditions (see Section 4.5).

Veterinary compounding

While training and licensing for the safe use of pesticides would be expected to be a key focus for the regulatory system, activities such as compounding veterinary medicines are not subject to the same safety and quality standards and controls as veterinary medicines in the current regulatory 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 recognises this gap in the current system and recommends that products compounded to fill a veterinarian's prescription or instruction should be brought within the scope of the future regulatory system (but remain exempt from registration). This will be achieved by formalising the rules relating to veterinary prescription of compounded products. Such formalisation was widely supported by veterinary medicines manufacturers and veterinarians throughout consultation (see Section 4.6).

National rules for pesticides and veterinary medicines

The Panel heard that the inconsistencies among state and territory requirements for the use of pesticides and veterinary medicine products, and record keeping are a hindrance in the current system.

The Panel proposes new national rules for pesticides and veterinary medicines, built on proposals developed by HACCUT. These rules will form the basis of permissible use of pesticides and veterinary medicines under the single national law.

4.1 Introducing general product obligations

Chemicals have the potential to cause harm to humans, animals, plants, or ecosystems if not manufactured, and used appropriately. Recognising this, the Panel considers that individuals and entities that interact with pesticides or veterinary medicines, from design to disposal, have a basic responsibility to deal with chemicals in a considered and conscientious manner to prevent such harm.

Acknowledging shared responsibility and promoting preventative action

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 (including safety and quality).

Users of pesticides and veterinary medicines also have responsibilities. These currently centre on dealing with products according to the label directions. However, an exclusive focus on compliance with a label risks encouraging a 'set and forget' minimalist mindset. Users may

consider that compliance with the label is a sufficient contribution to responsible use, even when additional, 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 given current regulatory accountability, has less focus on post-market compliance. During its extensive engagement with stakeholders, the Panel was told the APVMA generally applies this pre-market focus consistently, with less apparent regard to the level of risks posed by the product (it was suggested that low risk products are assessed to a similar degree as high-risk products). This reflects, to some degree, the current design of the regulatory system where determining compliance with label directions is undertaken by the states and territories.

The Panel considers that through more sophisticated regulatory arrangements, industry can be empowered to take more active responsibility for safe products, safe handling, and safe user practices. Companies, farmers, and operators can deliver solutions that are more tailored to the practical circumstances and risks of their own operations. Such industry-devised solutions can be more creative, effective, and efficient in delivering the health and safety outcomes required from regulation.

The Panel's objective is to move beyond the 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 and control ('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 who 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 control-of-use is needed and, in the Panel's view, is long overdue (see Chapter 2).

As noted previously, this shared approach to risk management has been successfully applied through work health and safety (WHS) laws in Australia. The 2018 review of the model WHS laws found 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 2020). Currently, some jurisdictions informally rely on certain industry QA schemes for assurance that safety and quality standards regarding the use of pesticides are being met.

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 lift safety standards, increase the opportunities for modern outcomes-based regulation, and reduce costs.

Many stakeholders supported a co-regulatory approach for an additional reason: to capitalise on current, good practice industry-led systems for active risk management. These include industry QA programs, stewardship schemes, good practice guides, standards, and the like. In the current

Australian regulatory system such schemes too often exist alongside regulatory requirements but are not recognised as a legitimate means of delivering on those requirements.

The Panel also heard concerns about the differing capabilities across the agricultural industry and the potential for this to increase regulatory burden in some sectors. In particular, concerns were raised that small and medium sized businesses may not understand how to demonstrate compliance with the co-regulatory approach and that more support may be needed for these businesses.

Introducing general product obligations, and harnessing industry's own quality assurance and standards programs, would, over time, transform Australia's regulatory system from a passive to an active approach that engages all players to manage risks preventatively. This approach consolidates and capitalises on existing chemical risk management practices. As such, it does not add materially to the regulatory burden as users of pesticides and veterinary medicines for production animals are typically already performing the necessary work. For example, spray diary or animal treatment records are already being kept to meet the requirements of their customers, other regulatory systems, or the QA-type programs in which they voluntarily participate.

Importantly, the Panel considers this approach would, over time, incentivise further innovation and investment in risk management 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 various schemes themselves. It would build incentives on the program managers to ensure high standards (to ensure accreditation of their program) 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 products 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, similar to the approach used successfully in work health and safety legislation.

The Panel considers that the obligations placed on chemical users under general product obligations should align with the obligations placed on them under other laws, such as WHS laws, environment protection laws and requirements for on-farm biosecurity. Under WHS laws, businesses that use, store or handle chemicals must manage the risks to worker health and safety associated with using, handling, generating, and storing those chemicals. Similarly, businesses that design, manufacture or import chemicals must ensure that they are without risks to human health and safety, so far as is reasonably practicable. Most existing pesticide and veterinary medicine control-of-use laws prescribe that chemical users must only deal with pesticides and veterinary medicines in certain ways including the storage, transport, use and disposal of chemicals, and must keep records of the use of the chemicals.

Robust, and mature industry QA schemes also provide frameworks for ensuring that pesticides are used in accordance with good agricultural practice, and lead to enhanced stewardship. The Panel considers that rigorously assessed and recognised QA schemes can provide another vehicle to assist growers to meet their general product obligations.

Given these existing legal requirements, and stewardships initiatives, the Panel expects responsible pesticides and veterinary medicines manufacturers, suppliers, and users will already be meeting their obligations, and as such, general product obligations will place little or no additional regulatory impost on businesses and users. However, the standard of safety protection should improve over time as innovative local solutions are designed and implemented. In addition, specifying these obligations will create a more focused approach for compliance, regardless of the flexibility in how the obligations are met, as it provides compliance officers with concrete actions to audit against.

Including these obligations within the pesticides and veterinary medicines regulatory system should improve community confidence in post-registration risk management. It will introduce a performance-based approach for regulating products and their uses while modernising Australia's regulatory system to accommodate contemporary principles of co-regulation. Examples of 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).

In many cases, the practices for complying with the general product obligations could incorporate arrangements already in place for complying with obligations under other laws and schemes. As noted previously, this could include practices that obligation holders already implement through established industry QA schemes and stewardship programs.

Subject to satisfactory Commonwealth/state negotiations, state and territory control-of-use regulators (under the single national law) will be responsible for ensuring compliance with the general product obligations and will be provided with the necessary suite of regulatory tools to allow for proportionate compliance and enforcement actions to be taken if required. The Panel envisages these general product obligations would strengthen 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 and use. Placing general product obligations on businesses should encourage improvements in risk management arrangements in multiple areas, and consequently improve outcomes for workers and the environment.

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. Obligations on users may need tailoring to allow for safe harbours (activities which are deemed to comply with the obligations). This would apply where certain persons using a product would be deemed to comply with the general product obligations if they also comply with the authorised supply and use of that product. For example, safe harbours will 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. In each such case, the person would be deemed to comply with the obligations as they are acting within safe harbours (see Annex 7).

General product obligations would, over time, build a culture of safety and compliance in every business. This will allow industry and all users to demonstrate the care, responsibility, and the attention to safety for animals and humans that the majority of businesses and the industry has at the forefront of its business strategies.

Providing relevant information, such as records of use, or making this information available to the control-of-use regulator on demand, (as is required under existing control-of-use laws), 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.

18. 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. These should enhance current existing industry processes, including codes of practice, work health and safety risk management plans, spray diaries, animal treatment records, industry QA, and

stewardship schemes and be consistent with existing management practices to minimise the regulatory burden in meeting these obligations.

The general product obligations should be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicine products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harm 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, has the necessary management arrangements in place, 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). Supply side 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 the recognition of registration (licensing) of veterinarians in some jurisdictions. National Recognition of Veterinary Registration (NRVR) is in place in NSW, 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 through 'deemed registration'. Under NRVR veterinarians register in the state or territory in which they reside. Registration fees are payable only in one state for states participating in NRVR. In practical terms a veterinarian with full registration who resides in NSW, for example, will be deemed to be registered should they wish to work in NSW, ACT, Queensland, South Australia, Tasmania, or Victoria. While the recognition of veterinary registrations in jurisdictions is beyond the scope of this review, the Panel sees mutual recognition as a sensible rationalisation and simplification of regulatory arrangements. The Panel therefore supports the NRVR currently in place in the majority of jurisdictions and encourages the Western Australian and Northern Territory Governments to participate in the scheme.

For pesticide users who operate across multiple states and territories, the different requirements set by each jurisdiction make working 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, in the pesticides and veterinary medicines sector these challenges will be able to be overcome through implementing the Panel's recommendations for a single national law (see Chapter 2).

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 to introduce a nationally consistent approach to education, training, and competency standards (see Chapter 4).

There have been protracted efforts by the Harmonised Agvet Chemical Control of Use Task group (HACCUT) to align licensing arrangements – or at least to provide for mutual recognition of licences among jurisdictions. However, these 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 and reform would entail significant adjustment to current arrangements.

Throughout the stakeholder consultation phase of this review, 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). Similarly, stakeholder feedback regarding applicator licensing was that state-based regulations pose significant difficulties for spray application businesses and farmers operating across state borders.

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

What change is recommended?

The Panel has recommended the implementation of a single national control-of-use law for 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 considerably superior to mutual recognition, as complex jurisdiction-to-jurisdiction differences remain, and the intergovernmental mutual recognition agreement still allows any 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 modern 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 by 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 more 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).

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 currently 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, to reduce the number of permit transactions currently associated with these substances.

A single national licensing framework

Given this 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*.

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).

Responsibility for delivery

The Department of Agriculture, Water and the Environment (the Department) would issue most licences, with certain exceptions, such as good manufacturing practice licences for veterinary medicines and which would continue to be administered by the APVMA (under the same legislation as the other licensing arrangements). The Panel considers that a central, national body should be responsible for issuing and reviewing licences under the national control-of-use law, and that the Department is best placed to be assigned responsibility for delivery of this function.

The Panel considers delivery of the licensing function could be undertaken in 2 ways. First, the Department could enter into an agreement with a single jurisdiction to issue licences under the single national law as its 'agent', similar to the manner in which frontline services are delivered on behalf of the National Heavy Vehicle Regulator. The second option would be for the Department to issue and review licenses itself, as it already has equivalent systems in place for similar functions (such as authorisation of biosecurity approved arrangements and other authorisations for import and export of certain agricultural commodities).

Recognition of industry QA schemes

Regardless of which approach is taken, proposed national licensing schemes would include mandatory licence conditions, where necessary, to manage risks associated with the relevant

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 satisfying certain requirements for granting a licence. 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.

This 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. It would provide incentives for improved participation in the schemes, raise program 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).

Transitional arrangements

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 staged transitional measures to minimise impacts on existing licence holders. Any new licensing scheme developed to regulate other activities with pesticides and veterinary medicines would operate on a national basis, and within the new national licensing framework, from their commencement.

Special use licences

Some stakeholders have sought additional flexibility in using products. This is because the APVMA risk assessment of a product's use is usually 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 sees a deregulatory opportunity to utilise the national licensing arrangements to establish a Special use licence to provide additional flexibility for suitably qualified users, subject to approval of suitably rigorous arrangements by these users to manage the risks.

Special use licence holders would be required to hold competencies for pesticide or veterinary medicine 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 that are, 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 Department (seeking advice from the APVMA) will be responsible for issuing special use licences. The Department could determine, subject to assessment, that certain existing QA activities or professional accreditations are sufficient to meet the competencies required for a special use licence.

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

Box 5 Recognition of industry quality assurance schemes

Quality assurance schemes (QA schemes) allow farmers to demonstrate that their produce meets the quality standards and production processes demanded by domestic and international markets.

The Panel proposes that the Department establish a program to recognise high quality industry QA schemes. The program will be voluntary. Industry groups will be able to approach the Department with the details of their QA scheme and request the scheme be assessed and formally recognised.

The Department would assess the QA scheme and determine whether the scheme met a pre-determined set of criteria. It would be open to the Department to suggest necessary improvements to the scheme before its decision. Post decision, the Department would undertake periodic audits or spot checks of recognised QA scheme to ensure they continue to meet the required standards.

There are already many industry QA schemes in Australia, of differing standards of rigour across the various sectors. Recognising this, the Panel proposes that the recognition program for industry QA schemes would be implemented in a tailored way, sector by sector, in consultation with industry and control-of-use regulators.

The Panel expects that the recognition program will encourage best practice in industry QA programs, as QA schemes will need to meet high standards to be formally recognised. Importantly, the program will also allow the Department to assess whether a QA scheme meets the general product obligations. In this way, the Panel expects that any farmers who are meeting the requirements of a recognised QA scheme will also be meeting their general product obligations, and in some cases be recognised as providing suitable evidence of competency for certain licences.

The Panel considers that the recognition program for QA schemes will strengthen social licence and be an additional incentive to improve the quality of the schemes themselves.

Licensing of businesses

Stakeholders informed the Panel that because the current system typically licenses individuals, rather than businesses, a single business may employ numerous licence holders. The Panel recommends that in the future, licenses be available to be granted directly to a business. The licensed business will then be responsible for ensuring relevant staff members within the

business have the necessary qualifications, training, experience and competencies. This will simplify the licensing requirements and make the business itself accountable for ensuring safe systems of operation. It will also promote corporate due diligence relating to staff accreditation, education, and training – similar to that required under work health and safety legislation.

Initial licensing schemes

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

- 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
- ground applicators
- commercial pest controllers
- special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone
- supply of internationally registered products (see Chapter 5).

Other licensing schemes could be introduced under the common licensing framework as the regulatory transformation process unfolds over the coming years.

19. Recommendation

The Panel recommends the Department of Agriculture, Water and the Environment develop a single national legislative framework to accommodate all licences, throughout the product life cycle. The single national licensing framework should enable specific, targeted licensing schemes to be created to regulate specific activities irrespective of whether they relate to supply or use activities. All licences for individual schemes created under the national licensing framework would, with the exception of good manufacturing practice and HGP licensing, be issued by the Department of Agriculture, Water and the Environment, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. Licences should be issued to businesses where possible, rather than individuals, with businesses responsible for undertaking due diligence to ensure their operators hold the accredited education, training, competencies, or other relevant qualifications.

Such licences, where relevant, would incorporate mandatory licence conditions that allow for the recognition of suitably rigorous industry quality assurance schemes.

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 handled and deployed safely and effectively. The use of these products by individuals lacking 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 current training delivery is inconsistent and confusing across the country, adding complexity and cost for users, and introducing risk of poor practice.

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

During the Panel's consultations, 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, livestock components.

Veterinarians are professionally trained, required to undertake continuing professional development, and registered by their respective state or territory veterinary practitioner boards. Professional codes of conduct enforced through registration impose strict requirements regarding the responsible use of veterinary medicines, and as such the Panel does not have the same concerns in relation to training of veterinarians. However, the Panel notes that there is only limited training available for non-veterinarian users of veterinary medicines, for example farmers administering parasiticides or vaccines. Veterinary medicines used in production animals are usually administered by non-veterinarians on the advice and with the guidance of a veterinarian.

Despite the clear value of training and accreditation in assisting with the safe and effective use of pesticides, training requirements for users are currently not nationally consistent. The Panel heard that differing training requirements among states and territories can increase costs, complicate cross-border operations, and lead to difficulty in accessing relevant training.

In 2017, the Agriculture Ministers Forum agreed to move towards minimum training standards developed by HACCUT officials for users of restricted chemical products (RCPs) and Schedule 7 pesticides and veterinary medicines (noting these allow the states to include 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 include

recognition of equivalent industry accreditation schemes, such as Spraysafe and its equivalent in other industry sectors.

However, some stakeholders, and particularly the Australian Environmental Pest Managers Association (AEPMA 2020) highlighted the disappointing progress achieved by HACCUT as, 3 years after Ministerial approval, these reforms have still not been fully implemented. There have been a number of previous attempts to develop and implement nationally consistent training for the use of pesticides which have also failed.

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 the auspices of the Australian Industry and Skills Council, and subsidiary Industry Reference Committees; they are then delivered by Registered Training Organisations.

Some training organisations consider the system is limited by the prescribed content, assessment protocols and standards within the VET framework. The Panel also heard from a range of stakeholders that aspects of the training was out-of-date, difficult to get updated, and therefore increasingly unattractive to potential trainees. They argued that more needed to be done, urgently, to lift the standard of existing competencies.

Despite the limitations of the VET sector regulatory system, accredited training is the most common approach for demonstration of competencies, and is widely used in other regulatory systems, including WHS, and in apprenticeships.

The ASQA has national responsibility for ensuring the quality of training developed and delivered under the VET framework. However for the pesticides and veterinary medicines regulatory system specifically, there is a lack of clarity about who is responsible for monitoring training needs and driving improvements to the training arrangements as a whole.

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 especially of pesticides. Assurance of competent users will also enable improved access to new chemicals and new uses via alternative pathways such as those outlined in the permits and licensing sections of this report (see Section 4.2 and Chapter 5).

Training standards are an important mechanism for establishing the criteria expected for persons undertaking specified activities involving pesticides and veterinary medicines. The Panel recommends that the Department should establish training standards, working closely with state and territory regulators, and other stakeholders, including standards for auditors it engages to ensure compliance with the proposed licensing scheme. The APVMA will similarly

need suitably accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6).

To address stakeholder concerns about training quality, relevance, and contemporaneity the Department should 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 through the consultative machinery recommended by the Panel in Chapter 2.

Monitoring and driving any necessary improvements to training arrangements should be a continuing responsibility of the Department over the period of regulatory transformation ahead. In performing this role, it will be supported by the Commissioner's biennial reports on reform progress and opportunities for continuing improvement to the regulatory system as a whole (see Chapter 2).

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 use licences to allow, subject to strict conditions, 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 (see Section 4.2). If such special arrangements are to become available, it will be critical that an applicant for a special use licence demonstrate they and their staff have full competency in risk assessment, chemical handling, and application through the completion of rigorous accredited training or industry-based accreditation.

The Panel considers there is a significant, under-utilised opportunity to make better use of industry-developed education, training, and accreditation programs, as well as accredited training developed through the VET sector, and other tertiary qualifications. While many industry-based programs are not currently recognised, the Panel considers the Aerial Application Association of Australia's (AAAA's) Spraysafe initiative to be a leading example of an industry-based accreditation scheme recognised by regulators. All jurisdictions recognise AAAA's Spraysafe accreditation as the de facto national competency standard for issuing a licence for aerial application to an individual pilot.

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 Department should consider both VET sector accredited training, and industry-based accreditations, and may deem them to be equivalent for certain activities.

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 frequently broader than strictly necessary for users of pesticides and veterinary medicines.

The Panel also considers that the Department should establish standing liaison arrangements with the ASQA and industry associations responsible for industry-based accreditations. The aim is to ensure on-going quality of training outcomes, and that training continues to be adapted to meet the needs of pesticides and veterinary medicines users as circumstances change into the future. The Panel suggests that the Department 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 has existing albeit inconsistent, requirements. A national approach to competency standards and assessment will likely see some short-term localised increases and decreases in costs, which ultimately will 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.

20. Recommendation

The Panel recommends that all businesses who apply pesticides commercially (be it agricultural or domestic) are responsible for ensuring operators 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.

21. Recommendation

The Panel recommends that the Department of Agriculture, Water and the Environment completes the work of HACCUT to establish suitably rigorous 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. Competency standards should be established for roles introduced through other recommendations in this review, including the issuing of special use licences.

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.

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 Department of Agriculture, Water and the Environment.

The Department of Agriculture, Water and the Environment. should also establish standing liaison arrangements with the ASQA and industry associations responsible for industry-based accreditations.

4.4 Reforming the approach to labelling

All registrants of 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 a critical/essential safety communication tool for chemical companies and government. Control-of-use agencies also currently rely on the approved physical label as a legal document – their compliance and enforcement processes require a contemporary source of approved label information as the basis for compliance assessment as well as enforcement action as appropriate.

Smart labelling

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, including quick response (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 a printed label.

It is not uncommon for handling and use instructions for a pesticide or veterinary medicine product to be updated over time – such as adding new safety instructions, to address a new concern, new application rate or new application technology, instructions to deal with matters including emerging resistance or new residue restrictions (e.g., reflecting changes in overseas market requirements). As a result, the same product with different labels can sometimes be found in the supply chain, and more importantly, within the user's individual chemical or veterinary medicine retail supplier. 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. The absence of translation makes it difficult for workers from culturally and linguistically diverse communities to understand. Confusion in comprehending a use or safety instruction can pose significant risks and cause unintended consequences for users.

Many labels also 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 an individual user's specific needs.

A wide range of stakeholders have expressed the view to the Panel that there are many, currently unrealised, opportunities offered by electronic labelling (e-labels or smart labels). In particular, there are many advantages that may come from machine-readable labels. A machine-readable label could allow machines to scan for application rates as well as simplify and automate record keeping and, in future, meet increased customer and consumer expectations of traceability and provenance.

Smart labels offer other benefits such as easier access to information relevant to a specific situation and current conditions (e.g., specific crop details and 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 and compliance by making instructions available in different languages and pictorially as well as through written descriptors, or through interactive augmented reality labels to give users additional information.

Smart labelling also provides an opportunity to convey other information that supports business practices including access to safety data sheets for conducting workplace risk assessments, videos of safe use practices, information on stewardship programs such as drumMUSTER and Bee Connected, or electronic copies of label information in the event of container label deterioration.

However, certain stakeholders expressed caution about the use of smart labelling for pesticide and veterinary medicine products, wanting to ensure users would always receive the necessary information for safe use of the product. For example, they expressed concern about gaps in access to the requisite IT systems and gaps in communications coverage in regional Australia. They argued that to cover these contingencies, fully detailed paper labels should continue to be available.

Stakeholders also raised concerns about other implications of smart labelling such as the legal status of the physical label under current jurisdictional control-of-use legislation. This issue of varying jurisdictional requirements for control-of-use is addressed by the Panel in Chapter 2.

The Panel recognises the sound position presented by many stakeholders that a physical label, detailing instruction for safe use, is essential while Australia's vast geography, and limited telecommunications infrastructure in remote areas, hampers effective access to online information.

However the Panel also sees smart labelling as a good example of future reform improvements which should be pursued with vigour in the years ahead. The process of transformation of Australia's regulatory system being recommended by the Panel should clearly embrace smart labelling as technologies permit. In the meantime, certain actions can be taken now to facilitate smart labelling in the future. The Panel recommends the first steps towards smart labelling.

Label content

In addition to the considerable opportunities offered by smart labelling, the Panel recognises the existing approach to approving label content in Australia as an opportunity for reform.

The Panel notes labelling reform has been a policy goal of Government and the APVMA for some time, and specifically that the 2014 legislative amendments provided the opportunity for the APVMA to make an inclusive labelling standard that would rationalise regulatory effort. Despite this, the development of a labelling standard has not progressed and the APVMA is only able to rely on current labelling codes and longstanding operational practices.

During consultations, some stakeholders argued that registration holders should be able to include on their labels additional precautions (over and above those required by the APVMA) – such as additional personal protective equipment requirements. 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 therefore particularly problematic for holders.

Communicating risks to honey bees and other pollinators

Another issue raised by stakeholders was the lack of warning information for risks to pollinators on pesticide labels. The Panel has referred elsewhere to reports of bee kills attributed to pesticide (mis-) use. The Australian Honey Bee Industry Council requested in its submission on the Draft Report that the Panel recommend the inclusions of statements on labels informing users of the toxicity of certain pesticides to honey bees.

The Panel recognises the important role pollinators play in the environment, in the production of honey, and on a wide variety of crops. Stewardship programs, such as Bee Connected (developed by Croplife and Australian Honey Bee Industry Council) can play a pivotal role in connecting registered beekeepers with registered farmers and contractors, enabling two-way communication on the location of hives and the use of pesticides which pose risks to pollinator health. The Panel accepts that more can and should be done to ensure the protection of pollinators and suggests the use of such stewardship programs should be promoted more widely.

The Panel considered that mandatory label statements would be a potential solution for communication of risks to pollinators. However, it would be necessary for specific toxicity criteria to be developed, along with data requirements to support assessment against the criteria to inform the label statements before this approach could be implemented. The Panel also considered recommending that voluntary label statements be permitted on products. However, as a voluntary scheme, products posing risks to bees may not include this information on their labels and the Panel is concerned that this may lead to adverse outcomes, including users assuming that the product poses no risks (to pollinators) if a voluntary label statement is not present. Furthermore, products not displaying the label statement would have a marketing advantage over other products which do include such warnings.

The Panel considers the issue of improved communication of risks to pollinators must be addressed in a substantive manner in the future regulatory system and should be explored as a matter of priority by the Commissioner through the stakeholder forum or the establishment of

an Expert Advisory Panel (see Chapter 2). In the interim, the Panel suggests that smart labelling be used to promote the use of Bee Connected.

What change is recommended?

The label attached to the container represents the essential instrument for communicating critical information to users of chemical products. So long as Australia's telecommunication infrastructure is unable to assure high quality internet access for all, the Panel considers the label attached to the container must remain the primary source of information to support safe and responsible use of a pesticide or veterinary medicine. For pesticides, labels affixed to the container will continue to convey 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). Similarly, the label attached to the container must at a minimum present information for major crop groups and representative crops. Uses in all other commodities may then be accessible through smart technology.

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 as connectivity issues and technology developments evolve.

Adoption of technology

Looking to the future, the Panel recognises technology will offer significant opportunities in the next 30 years and beyond. With the growing application of automation and machine learning in Australia's agricultural and food industries, the need for machine-readable labels is clear.

Although there are still telecommunication constraints on the full adoption of smart labelling, the Panel recommends that legislation to facilitate the use of smart labelling and machine-readable labelling be developed without delay. The legislation should allow for progressive implementation of these technologies as telecommunication connectivity improves and remove any other barriers to the adoption of these technologies.

Further, labels should not be prevented from including access to complementary and supporting electronic resources (such as links to a copy of the label, safety data sheet, instructional videos, educational material, and label instructions presented visually or in alternate languages). Access to related services such as Bee Connected could also be provided. The Panel believes the progressive adoption of smart labelling and machine-readable labels will result in safer chemical use, better informed and more confident users, and an improved user experience overall.

While the Panel recommends the adoption of smart labelling and machine-readable labels, the Panel also considers that minimum standards for information on the printed label must be retained to ensure that core labelling information is available to all users, regardless of their access to smart label readers.

The Panel sees that its recommended approach will, in time, 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 rate calculations 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 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. In turn, this would support future biosecurity, environmental and future national recycling obligations, as well as meeting community expectations for transparency in increased provenance and traceability in their food supply chains.

Labelling standard as a condition of registration

The Panel considers it is high time to give full effect to the labelling reforms initiated by the Government in 2014 but which remain incomplete. The Panel recommends that lead responsibility now be assigned to the Department which should consult with the APVMA to finalise a labelling standard.

In its Draft Report, the Panel proposed that where label content is covered by another regulatory system that this content would not be assessed by the APVMA pre-market. Compliance with the requirements of these other regulatory systems would be a condition of registration, and subject to regulatory action if not met.

The proposal drew strong reactions from chemical companies and their peak bodies, particularly due to this approach relying on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as implemented under Australian WHS laws for first aid and safety directions. The Panel recognises that the chemicals industry has long been opposed to the inclusion of GHS label statements on pesticides and veterinary medicines, due to the GHS being based on hazard rather than risk.

The APVMA also opposed the recommended approach because it could not be satisfied that the product could be used safely unless the label had been assessed.

The Panel has carefully considered these views, and developed a revised, standards-based approach offering only some of the reduction in regulatory effort afforded by the proposal in the Draft Report, while still aligning with an outcomes-based approach to regulation.

The Panel considers that label content related to the safe use of the product (such as first aid and safety directions, directions for use, or the statement of claims) should be subject to pre-market assessment by the APVMA, as it can vary by product and it is essential this content is assessed. However, other content would not be subject to pre-market assessment. This would include elements of the label such as net contents, modes of action, anticholinesterase statements, signal words, product name, and supplier. Such elements are fixed and not commonly changed through the APVMA pre-market assessment. These elements would be required to be included on the label as a condition of registration and be subject to post-market compliance measures.

To give effect to this principle, the Panel recommends that the label content is divided into 2 categories; regulatory assessed elements (RAEs) and condition required elements (CREs). The Panel recommends that CREs be those elements that are fixed and not commonly changed as a result of an assessment and would not form part of the APVMA's pre-market assessment. CREs would be required to be included on the label by product registration conditions and therefore be subject to post-market compliance. RAEs would then represent those elements that benefit most from the expert pre-market consideration of the APVMA.

The Panel considers RAEs and CREs would operate in a similar way to that outlined in Annex 6, with the Government giving full effect through the establishment of the labelling standard for pesticides and veterinary medicines. Failure to comply with either a RAE or CRE would constitute grounds for regulatory action, including product recall, product market withdrawal, product suspension, penalty infringement notices, or criminal prosecution.

The Panel sees the recognition of fixed label components from other regulatory schemes as an opportunity to focus pre-market assessment by the APVMA on those matters that are unique to pesticides and veterinary medicines. To that end the Panel recommends that the APVMA allow the inclusion on the label of first aid and safety directions drawn from any established Australian standard to the extent the words would ensure the safe handling of the product. The Panel considers this wording could, at the discretion of the registrant, be drawn from existing APVMA first aid and safety directions, the Poisons Standard, or the GHS. The Panel considers the opportunity to include GHS label statements would support global consistency in label content, and requirements of Australian WHS laws.

The Panel has noted the concerns of stakeholders about enabling the inclusion of GHS content rather than APVMA-determined safety instructions. However, where the language delivers equivalent outcomes the Panel sees no value in preventing the inclusion of GHS content in place of APVMA preferred wording. The Panel's position on this specific labelling simplification issue does not change its general view about the importance of risk based, rather than hazard based, assessments (see Section 1.4).

The Panel also recommends that registrants should not be prevented from including additional information on their labels. The CREs proposed by the Panel provide for this content to be clearly identified as registrant-derived content and would not form part of any regulatory action for users. However, the ability for registrants to go beyond the regulatory requirements should not be constrained. In the Panel's view, this is another way to advance the concept of balanced

shared responsibility for safety assurance between government and non-government participants in the regulatory system.

The Panel considers that sufficient information should be included on the label to identify the person responsible for the product in Australia. This information would be built on the current requirement to identify the party responsible for the marketing of the product.

Periodic review of labels

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 considers it is reasonable to expect the holder of a product registration to maintain an up-to-date understanding of the risks posed by the product, the currency of mitigation strategies for those risks, and that the product is accurately represented in terms of its use.

The Panel therefore proposes to introduce requirements for the holder to review labels at least once every 5 years. The holder must then declare to the APVMA that the information on their label is accurate. The declaration may be included in the product registration renewal process. Certain veterinary medicines are exempt from GHS labelling under WHS regulations. However, the WHS regulations will still require that their safety data sheet be reviewed every 5 years, which may act as a trigger for the review of their label.

The Panel does not consider this obligation will require new testing by a registration holder. It would be part of the general product obligations (see Section 4.1) requiring 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. Where multiple holders identify the need to amend a label to reflect contemporary information this may act as a trigger for the APVMA to undertake a review of all other related products where the risk is the same.

This 5 year timeframe for periodic label review aligns with the obligation to review safety data sheets under WHS legislation. Alignment of these timeframes will 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.

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 will provide increased assurance that 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 RAEs) against which regulators are able to measure and assess compliance. 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 meet these various needs, the Panel recommends the label should no longer be considered a static document nor be the standalone single source of information representing the totality of legal instructions. The single national law will need to provide for these reforms.

Cost of reform

The Panel's recommendations do not mandate the use of technology (such as QR codes) for labelling; therefore, the costs of implementing would only apply to those entities or individuals who choose to utilise this technology.

While the Panel expects that changes to how the APVMA assesses label information would result in worthwhile time savings in pre-market assessment for the regulator, as the label assessments run concurrently with other assessments, time savings (which compromise 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. The Panel sees the opportunity for reduced label sizes (in particular those labels represented as a multipage booklet) for products with multiple commodities and species listed, where only a few are crop groups, representative crops or for major production and non-production animal species. 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 yield further savings to industry over time through improved operation efficiencies.

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

22. Recommendation

The Panel recommends the Department of Agriculture, Water and the Environment, in consultation with relevant stakeholders and consistent with other standard setting approaches, establish the labelling standard under the single national law framework.

23. 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.

24. Recommendation

The Panel recommends that legislation to facilitate the use of smart labelling and machine-readable labelling be developed. The legislation should allow for progressive implementation of these technologies as telecommunication connectivity improves. Further, labels should not be prevented from including access to complementary and supporting electronic resources (such as links to a copy of the label, safety data sheet, instructional videos, educational material, and label instructions presented visually or in alternate languages).

25. Recommendation

The Panel recommends that the label content, i.e., the information constituting the label for control-of-use matters, is divided into 2 categories: regulatory assessed elements (RAEs) and conditional required elements (CREs). The Panel recommends that CREs be those elements that are fixed and do not change as a result of assessment and would not form part of the APVMA's pre-market assessment. CREs would be required to be included on the label by product registration conditions and therefore be subject to post-market compliance. RAEs would then represent those elements for which the expert pre-market consideration of the APVMA is required. RAEs may be communicated, to the extent provided by the labelling standard, through means other than being affixed to the container.

26. Recommendation

The Panel recommends that the APVMA, supported by legislation to the extent necessary, allows the inclusion of first aid and safety directions drawn from any Australian established standard to the extent they would ensure the safe handling of the product. The Panel considers this wording could, at the discretion of the applicant, be drawn from existing standards including APVMA first aid and safety directions, the Poisons Standard, or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

27. Recommendation

The Panel recommends manufacturers should be permitted (and indeed, should be encouraged) to include additional safety information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

28. Recommendation

The Panel recommends that every 5 years, at a minimum, the registration holder conducts its own review of label content to ensure the information on the label remains current and correct – noting that emerging scientific evidence or consumer concerns could also trigger review of the label at any time (see the chemical review discussion in Chapter 3).

29. Recommendation

The Panel recommends that when regulators are determining compliance with responsible stewardship and control-of-use requirements, they should only consider compliance with the regulatory assessed label elements and not against the content on the label not assessed by the APVMA.

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 an essential resource as are other natural resource inputs, and there is greater focus on the national and international aspects to waste management, recycling, and re-use of pesticides and veterinary medicines packaging material and containers. 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 *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.

Waste stewardship in the pesticides and veterinary medicines sector

Australia's pesticides and veterinary medicines industries have long-established industry stewardship programs to manage the end-of-life cycle impacts, flows, and fates of products and materials. The major programs for pesticides and veterinary medicines supply chain, 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.

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 display 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 that equivalent programs put in place by chemical companies, including those operated by Accord member companies, for the management, recycling and disposal of containers also warrant acknowledgement and recognition in the future pesticides and veterinary medicines regulatory system.

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 supply chain takes advantage of these stewardship programs and around 60% of eligible containers are returned.

The AgSafe-operated industry schemes already make substantial contributions to the 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-used for other purposes or are abandoned or burnt as there could be leakage and leaching of chemicals from old or damaged drums. Additionally, risks exist from persistent, residual, and prohibited chemicals that have not been subjected to previous collection and disposal means. 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.

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. Currently, the drumMUSTER program does not accept bulk containers for recycling and 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 distributors 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.

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. This reflects the intensified Commonwealth Government policy drivers and focus on waste reduction and management and sustainability more generally to address increasing consumer and community expectations. It reflects also the particular community interest in good management of containers formerly used for pesticides.

What change is recommended?

The Panel is encouraged by industry uptake of the product stewardship schemes but considers greater intervention is warranted to safeguard human, animal, and ecosystems safety, to retain the sector's social licence and to respond to steadily more demanding consumer expectations.

The high level of participation in the schemes by all participants in the supply chain shows the success that comes from 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).

The Panel considers that in the course of the regulatory transformation process now to be embarked upon, the Government should take a firm role in encouraging responsible disposal, recycling, and stewardship programs.

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 content. This could include imposing licence conditions for certain activities to ensure action. The Panel has also considered whether the Government can incentivise participation in industry schemes to further enhance recycling and sustainability programs, while also introducing enforcement interventions for blatant non-compliance including penalties and potential prosecution.

The Panel has considered, but does not support, Government using the levy on the 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 pressure to incentivise companies to participate. The list would be published on the Commissioner's website or as part of the biennial statutory public assessment reporting on the state of the system (see whole-of-system performance measures in Chapter 2).

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. The Panel notes support in the 2021-22 Federal budget to

support small and medium businesses to adopt the ARL, and additional funding for industry led product stewardship scheme aimed at reducing waste.

The Panel also recommends that when assessing industry QA schemes for their adequacy in meeting the requirements of general product obligations or licence conditions (see Section 4.1) the Department determines how well the schemes address product stewardship. 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 create incentives both to join schemes (users) and to improve schemes (scheme managers).

30. Recommendation

The Panel recommends strengthening good disposal practices (in line with good agricultural practice) by:

- **encouraging industry QA schemes to include requirements and guidance on good disposal practices as part of being deemed to meet general product obligations (see Section 4.1)**
- **responsible and sustainable disposal practices being considered as a condition for relevant licences**
- **publication of a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs or do not have equivalent programs in place, addressing container management, recycling, and disposal.**

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 less common 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 developed to apply to other veterinary medicines do not apply to compounded products. 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 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 assessed and approved product (through registration or permitting by the APVMA) is unavailable. In the future, the Panel's proposal for the licensing of internationally registered products will provide a further avenue for accessing authorised products (see Chapter 5). Using products according to the assessed label instructions also ensures that the treatments should comply with food and animal feed laws.

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 2020a). However, some 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 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 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.

The Panel is aware that the Commonwealth and state officials in the Harmonised Agvet Chemical Control of Use Task group (HACCUT) Veterinary Prescribing and Compounding Rights working group have worked for many years to develop a 'cascade' approach for veterinarians when prescribing compounded products in food producing species (production animals). The responsibilities and (slow) 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.

Despite support for this proposal, stakeholders expressed frustration at the reform's slow progress through HACCUT. 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 Department as part of the implementation of the single national law. The Panel received feedback on the cascade as proposed in the Draft Report and has made revisions to the cascade to recognise the differences in risks between veterinary medicine use in production animals and non-production animals, and to balance the risks to animal welfare with the risks to humans, animals, ecosystems, and trade. The Panel has also taken the decision to rename the cascade a 'protocol' in line with the suggestion of the Australian Veterinary Association.

The Panel acknowledges the skills and expertise veterinarians have and their professional obligations to promote sound animal health outcomes. The protocol provides that veterinarians use their professional judgement in determining suitable treatment options based on clinical need and risk management. Concerns in relation to professional judgement would, in general, remain within the remit of veterinary professional standards and Australia's veterinary practitioners' boards.

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 an assessed and approved product (through registration or permitting by the APVMA, or an internationally registered product available in Australian under licence (see Chapter 5) should always be the first choice, where reasonably suitable or available.

The Panel takes the view that, in the future regulatory regime, the compounding option should be retained where APVMA registered or permitted products and uses, or internationally registered products brought to Australia under licence (see Chapter 5), are not reasonably suitable or available for the required animal health outcome. This flexibility is an important aspect of the future regulatory system. This will apply to both production and non-production animal situations. The prescription cascade developed by HACCUT forms the basis for the Panel's proposed 'prescription protocol'.

The Panel recommends that products compounded to fill a veterinarian's 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 – production and non-production, including exotic species and wildlife. These products would be Level C status (excluded from the need for registration) (see Chapter 5), but subject to controls on their use. The Panel has prepared an example of the standard that would be suitable for implementation of this recommendation (see Annex 5).

Veterinarians who prescribe compounded products, or other non-assessed or unapproved veterinary medicines, would be required to comply with the prescription protocol (described in this section under national rules for veterinary medicines use) 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).

All compounded products would be subject to the same regulatory oversight in order to manage possible risks such as product and animal safety, poor manufacturing quality, 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 wants to promote the use of assessed and approved products over other veterinary medicines, where the products are suitable to the specific therapeutic needs. To that end, there must be a genuine clinical need to use a veterinary medicine that is not registered or permitted by the APVMA, or one that is an internationally registered product available in Australia under licence. This may include facilitating 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).

Products obtaining a registration or a permit for use would be rewarded through a higher ranking in the protocol, in the absence of a specific unaddressed therapeutic need.

Protocol for selecting veterinary medicines

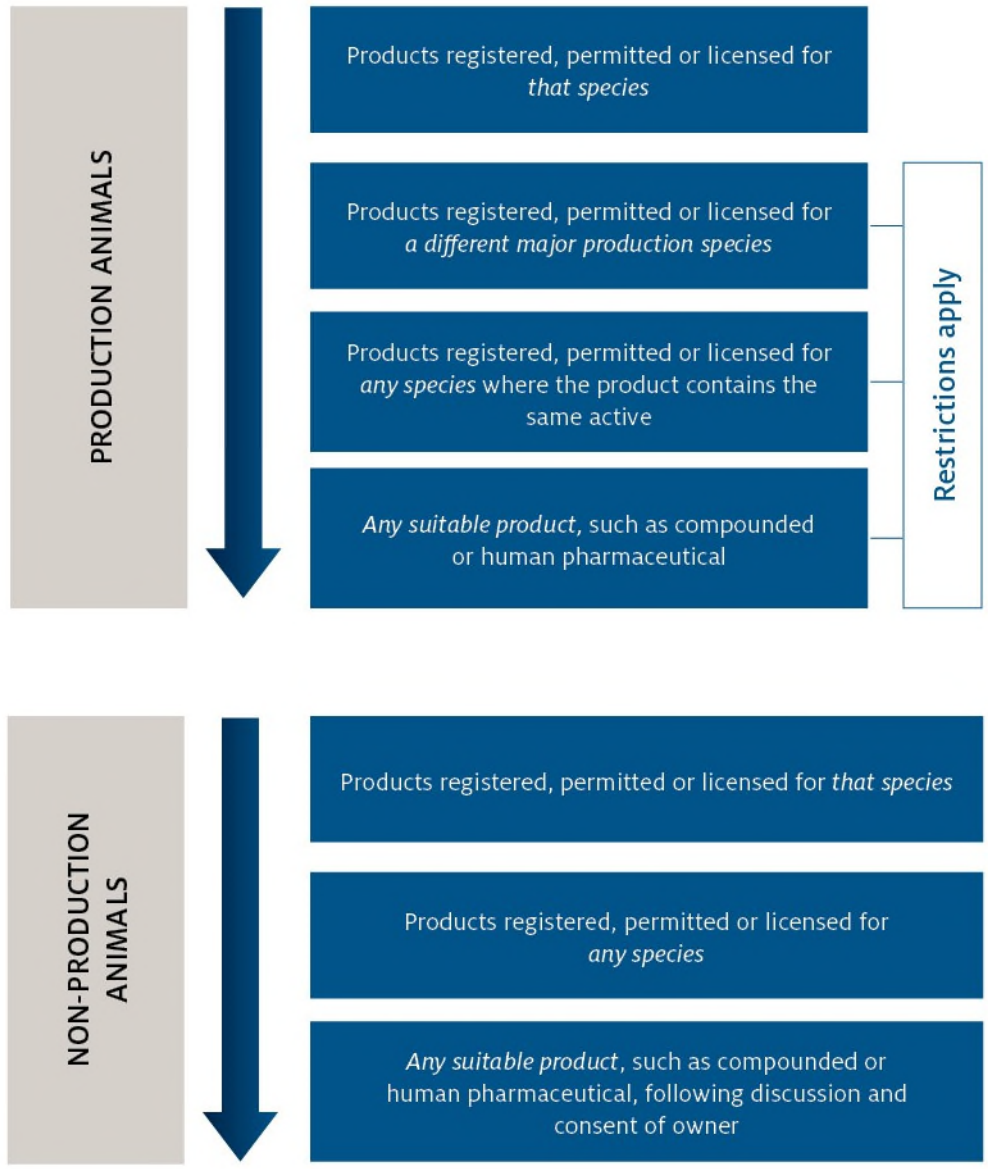
The Panel recommends that the national rule for veterinary medicines should provide a protocol for veterinarians selecting and using veterinary medicines. The protocol should:

- reflect the differences in risks between production and non-production animals
- recognise the professional judgement of veterinarians in determining a suitable product for a therapeutic need
- provide that for production and non-production animals, products registered or permitted for that use by the APVMA (or internationally registered products available in Australia under licence for that use) in the species requiring treatment are to be used where suitable and available, provided that following intermediate steps, where no other product is suitable or available a veterinarian may use or prescribe any product of their choosing (including products not assessed or approved and compounded products) subject to certain restrictions.

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, companion animal owner. The Panel also acknowledges that the proposed national rules would not extinguish the obligations under other legislative schemes, such as dealings with Schedule 4 and Schedule 8 substances of the Poisons Standard.

A simplified version of the Panel's protocol for selecting veterinary medicines is shown in Figure 6. The complete text of the recommended protocol for selecting veterinary medicines is presented in Annex 9.

Figure 6 The protocol for selecting veterinary medicines in production and non-production animals



Manufacturing quality for compounded products

The Panel considers that compounded products should be subject to minimum manufacturing standards to help ensure their quality of production. The professional expertise of pharmacists, and the circumstances set out in the protocol that constrains the use of compounded products to situations where no suitable regulatory assessed products exist, means that a full manufacturer licensing scheme is not warranted. However, these products are veterinary medicines and there is a need to ensure manufacturing quality is sufficient to manage risks to animal welfare, human health, and trade.

The Panel recommends these facilities (be they compounding pharmacies or veterinary practices) are exempt from the requirement for licensing. This exemption should only apply 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 Panel recommends the APVMA, in consultation with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies, establish one or more suitable manufacturing standards for compounded veterinary medicines within 6 months of Government decision. The Panel recognises the work undertaken to date by the Australian Veterinary Association in developing professional standards for the selection and use of compounded veterinary medicines: Good Compounding Practice for Veterinary Medicines (Australian Veterinary Association 2020). The Panel considers this may prove a useful source information in the drafting of an implementable standard.

Cost of reform

Changes to bring veterinary compounding within the pesticides and veterinary medicines regulatory system 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.

31. Recommendation

The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends:

- **registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist**
- **the prescription protocol is finalised and implemented under the single national law for control-of-use**
- **the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.**

32. 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.

4.7 National rules for pesticides and veterinary medicines

The Panel has heard that the inconsistencies among 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 draw on proposals developed by HACCUT, but not yet progressed. These rules are intended to 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 single 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 and forms, 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 Department may recognise QA programs to meet the national record keeping rules, meaning that users may not have to take any additional steps to meet the national record keeping rules if they already meet the requirements of the relevant QA programs.

Stakeholders emphasised 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).

While the Panel recognises that flexibility for farmers must be maintained, there is also a potential for pesticide resistance to develop if pesticides are misused (particularly where pesticides are used at reduced concentrations, frequencies, or rates). The Panel considers that, coupled with general product obligations, the requirements of the national rule address resistance issues. The Panel's other reforms proposed in this report (specifically surveillance, monitoring, and adverse event reporting recommendations) should also contribute to better management of pesticide resistance, helping to address these concerns.

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 (see Chapter 5).

The national rule for the use of veterinary medicines

The national rule for the use of veterinary medicines as previously described details how a veterinary product may be used by veterinarians and non-veterinarians. This includes a protocol for veterinarians to use when selecting veterinary medicines in the treatment of animals under their care.

The protocol provides that veterinarians use their professional judgement in determining suitable treatment options based on clinical need. Concerns in relation to professional judgement would, in general, remain an issue for veterinary professional standards and Australia's veterinary practitioners' boards.

To support veterinarians in making decisions on suitable withholding periods to ensure residues in animal produce do not exceed the MRL or result in detectable residues where no Australian MRL exists, the Panel suggests that the Commissioner for Pesticides and Veterinary Medicines

investigate the establishment of a database to collate and disseminate veterinary scientific and practice knowledge. The Panel understands similar resources exist in international markets, such as the Food Animal Residue Avoidance Databank in the United States of America.

33. Recommendation

The Panel recommends establishing a national rule 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**
- **a veterinary medicine's responsible use, including a prescription protocol that applies to all animal use, and the records that must be kept establishing responsible use.**

5 Improving access and choice in pesticide and veterinary medicine tools

The Panel recognises that plant and animal pest and disease management is essential to farm viability, and public and animal health. The Panel is convinced that a pesticides and veterinary medicines regulatory system that delivers improved access to a diverse range of safe tools, including the latest technology, for plant and animal pest and disease management as well as increased therapeutic options for a range of animal species, can be a source of competitive advantage for Australia.

Simplifying regulatory barriers to entry and access for safe chemicals can encourage manufacturers and importers to bring or launch innovative, 'softer', state-of-the-art treatments or otherwise inaccessible products into Australia. Choice in pest and disease management and therapeutic options allows users to tailor controls and uses to their specific circumstance, and to transition between controls and uses as the market or user needs demand. For pesticides, the Panel understands both the desire from consumers for reduced chemical use and the needs of growers to have access to alternatives. 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.

A central recommendation of the Panel is to create a licensing scheme to improve access to safe and effective pesticides, veterinary medicines and uses not yet available in Australia but registered by comparable international regulatory systems. The scheme will provide 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 traditional 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. As the regulatory transformation proceeds, improvements in regulatory processes and transparency of regulatory outcomes will offer increasing scope for 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

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, many pool and spa chemicals are of low regulatory concern as the associated risks are well understood, and suitable risk management arrangements are well established.

Scope of products regulated

Currently, substances are captured within the scope of the pesticides and veterinary medicines regulatory system based on their intended or represented use alone. The current definitions make little differentiation based on the product's inherent hazard or exposure characteristics (and therefore risk), or the level of regulatory concern the product and its use would pose. This undifferentiated breadth of focus within the whole regulatory system distracts attention from key risk areas.

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 the use of pesticide and veterinary medicine products. 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.

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 APVMA has not used these provisions to near their full potential.

The Panel has identified a range of products of low regulatory concern that should be subject to differing levels of regulatory effort, including in some cases exclusion from the pesticides and veterinary medicines regulatory system. The Panel considers that this will enable a sharper focus on products with specific risks that are not, or cannot be, effectively managed through other regulatory systems.

The Panel sees the improved focus as also providing a clearer 'identity' to the regulatory system, as a system targeting effort on the safety of pest and disease management products used in Australian primary production, by veterinarians and other people responsible for the care of animals, and in non-urban land management, as well as in households across the nation.

The Panel considers that as the benefit of various reforms recommended in this report are realised over the years ahead, the future regulatory system for pesticides and veterinary medicines will more effectively and efficiently regulate these substances. This will include better targeting of effort. The Panel's changes to regulatory scope are outlined later in this section.

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 can use international assessments.

Both organisations have legislative requirements to consult with the other in relation to certain applications. In the past, they have had a memorandum of understanding (MOU) between them to facilitate cooperation and information sharing, which was allowed to lapse. 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. The Panel recommends more substantive improvements later in this chapter.

Safety and effectiveness assessment

In addition to focusing the scope of products regulated as pesticides and veterinary medicines, the Panel also explored varying the scope of the mandatory criteria that should apply to regulated products. Specifically, the Panel identified the APVMA's pre-market assessment of a product's efficacy (effectiveness) as an area for reform to deliver possible savings in time and money. Certain comparable overseas regulators do not assess efficacy as part of their registration process.

As discussed in the Draft Report, the Panel has heard and acknowledges stakeholder concerns and their desire to maintain assessments of effectiveness. As a consequence, the Panel has decided not to progress this reform at this time. However, the Panel still considers that removing efficacy assessment (not safety) should be explored again in the future. This is because efficacy assessments are only a point in time assessment, most products are not assessed (generics) and the existing pesticides and veterinary medicines regulatory system provides no mechanism for users to seek redress for an ineffective product. In addition, the Panel sees strong market incentives to avoid inefficacious products, without the need for regulatory intervention.

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 stronger and more timely evidence of any ineffectiveness (such as emerging chemical resistance) to support APVMA actions.

What change is recommended?

The Panel recommends the scope of pesticide and veterinary medicine products regulated by the future regulatory system be framed around 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) and establishing defined levels (Figure 7) of regulatory consideration in proportion with risk.

This will allow regulatory effort to be better targeted to those products that pose most risk to the health and safety of humans, animals, plants or ecosystems, or prejudice to trade.

Revised definition of pesticides and veterinary medicines

The Panel recommends creating new definitions for pesticides and veterinary medicines (see Annex 5), replacing the existing terminology of agricultural and veterinary chemical products. In

addition to being more intuitive in nature, the new definitions will focus on those products intended to control, or otherwise manage, pest plants and animals, and plant or animal pests and diseases and where the products have the potential for risk to humans, animals, the environment, or Australia's trade.

For the first time, the supply side of the pesticides and veterinary medicines regulatory system will only consider those products which present higher risks by reducing or eliminating pre-market assessment where products have lower hazard and lower exposure potential (or both). **This will establish risk as the core driver of pesticide and veterinary medicine product regulation.**

The revised definitions mean some currently regulated products will transition to other regulatory systems, in particular the Australian Industrial Chemicals Introduction Scheme (AICIS), or become the sole responsibility of another scheme, in particular the *Gene Technology Act 2000*. The majority of products transitioning to AICIS are those with broader industrial uses e.g., commodity gases, or which have substantially similar ingredients besides the active constituents e.g., anti-fouling paints, and so will mostly be already listed within the Australian Inventory of Industrial Chemicals.

The Panel recognises that the specific use of those chemicals as, or in, an agricultural or veterinary medicine product would not be included in AICIS. The Panel considers that to the extent the new chemical use needs to be included into the AICIS, the evaluation by the Executive Director of AICIS (required to list an industrial chemical previously regulated under another law of the Commonwealth) should be greatly reduced by the previous assessment of the substance by the APVMA.

The Panel has heard stakeholders' concerns over the applicability of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) to pesticides and veterinary medicine products in Australia. However, the Panel also notes that GHS is the most widely adopted hazard assessment and communication system in the world which works in conjunction with risk management actions. It is the established and accepted methodology for establishing the inherent hazard posed by a product, especially for workplace use, which can span both pesticides and veterinary medicines. As one component of risk (alongside exposure), an indication of inherent hazard can be used to determine if there is or is not a possible need for risk mitigation to be applied. The Panel expects that over the next 30 years there will also be further refinement to both how hazard is characterised, and the hazards for which risk management is considered necessary. The recommended definitions presented by the Panel for pesticide and veterinary medicine products are designed to allow the hazard components to be amended.

In terms of exposure, the Panel is taking a very conservative approach. Where the use of a pesticide or veterinary medicine product would expose persons or ecosystems, and animals for veterinary medicines, beyond the point of application to either the product or its residues, then that exposure is sufficient to warrant control through the pesticides and veterinary medicines regulatory system.

The Panel's recommended definitions also provide for products that would be outside the revised regulatory scope to be brought back by regulation to the regulatory system at any time.

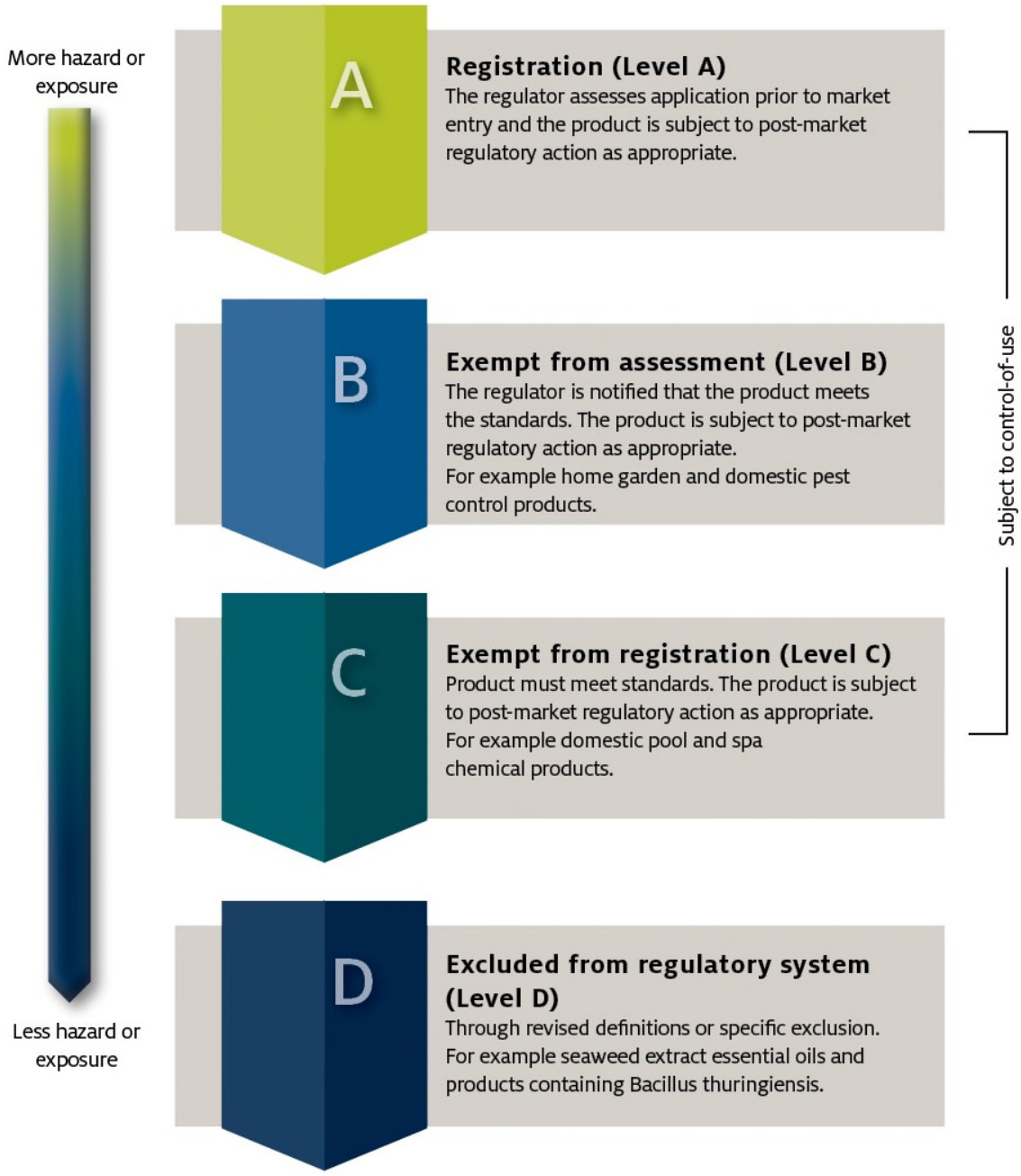
This would occur where clarity is needed on a subjective use pattern (as is the case now) or when unmanaged risks become apparent.

The Panel's recommended definitions similarly provide that where an included product is identified as no longer warranting regulation, these could be excluded from the scheme. For example, pesticide products containing *Bacillus thuringiensis* (a well-characterised, naturally occurring bacterium with insecticidal properties) or its endotoxins as the only active component would be excluded through regulation. The Panel is satisfied the risks of these products can be addressed effectively through approaches other than registration.

Under the new definitions the following product classes would no longer be subject to the requirements of the pesticides and veterinary medicines regulatory system:

- whole plants and animals that are naturally occurring
- insect pheromones and other semiochemicals
- biostimulants e.g., seaweed extract
- surfactants, adjuvants, wetting agents, and spray markers
- products containing *Bacillus thuringiensis* or its endotoxins as the only active component (a well-characterised, naturally occurring bacterium with insecticidal properties).

Figure 7 The scope of the future regulatory system including risk-based pre-market assessment measures



Targeting assessment effort

The Panel recommends establishing within the supply registration arrangements, and flowing through to control-of-use, efficient means to align the regulatory effort for assessment with the risks posed by a pesticide or veterinary medicine and its use. The Panel recommends establishing 4 levels of effort, Levels A to D.

Level A – Full pre-market assessment

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.

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 (i.e., always pre-market assessed within Level A). For that reason, the Panel recommends that a legislative instrument is created and maintained for Products Requiring Pre-market Assessment (PRPA).

The Panel proposes that products or product classes that contain PRPA substances 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 (some of which the Panel proposes are suitable for Level B registration without assessment) 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, that product must enter the Australian market through Level A (pre-market assessment).

The Panel recommends some products which pose lower risk – but not so low as to warrant being excluded from regulatory scope altogether (Level D) – continue to remain within the future regulatory system, but with a greater (or sole) post-market regulatory focus. This would be achieved by replacing the requirement for pre-market assessment undertaken by the APVMA with approved standards (covering matters such as ingredients, labelling, use patterns or other risk management options).

The Panel proposes to achieve this by either:

- exempting products (or classes of product) from the need for pre-market assessment where they meet an approved standard, allowing registration by notification to the APVMA – Level B
- exempting products (or classes of product) from the need for registration where they meet an approved standard – Level C.

Products in Levels B and C would remain within the pesticide and veterinary medicine regulatory system. 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.

Responsibility for these products would sit with the control-of-use regulatory system under the single national law (see Chapter 2), with ability to act for non-compliance. Breaches would include supply of products not complying with an approved standard (effectively an unregistered chemical product), false and misleading claims, and product misuse.

Regulators 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.

Standards would be set by the Department of Agriculture, Water and the Environment (the Department), seeking advice as needed from across the regulatory system including the APVMA, other use and chemical regulators, and in consultation with industry and the community.

The Panel considers that the success of this measure depends on the Department, 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 including the listed and reserved pathways. However, the Panel heard from numerous stakeholders that industry has tried to work with the APVMA to develop standards (such as for dairy sanitisers), without success.

Industry stakeholders indicated that they had 'stopped' trying to get standards developed with the APVMA largely due to the APVMA consistently making the process far more complicated and time consuming than they consider necessary. The APVMA has failed to produce standards (that industry had been calling for and the Government had encouraged) or to pursue other 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 establish the standards.

The Panel considers these carefully calibrated Levels of regulatory attention will allow the regulatory system, and in particular the APVMA, to focus its regulatory effort on the areas of highest risk. This will reduce the barrier to market entry that assessment can present. The tailored Levels will also ensure these products remain safe to use and leave the option to undertake regulatory action if risks are not being adequately managed.

Level B – Exempt from assessment (registration by notification)
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 Panel has provided some initial examples of products and standards that could be suitable for implementation of this recommendation (noting further work would need to be undertaken with industry as part of implementation). Annex 5 includes example standards for:

- domestic pest control and garden pest control products
- repack and dilution products.

Level C – Exempt from registration (registration not required)
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 (although they would remain within the pesticides and veterinary medicines regulatory system). 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.

This pathway would suit products of low regulatory concern but with some associated risk that could be suitably managed by compliance with a standard.

The Panel has provided some initial examples of products and standards that could be suitable for implementation of this recommendation (noting further work would need to be undertaken with industry as part of implementation). Annex 5 includes example standards for:

- pool and spa products (simazine, chlorine dioxide and bromo-chlorodimethylhydantoin if used in pool and spa products would be listed in the PRPA and not eligible for this level.)
- veterinary compounded products
- generally recognised as safe (GRAS) substance products.

Level D – Excluded from regulatory system
Products with little or no risk, for example seaweed extract and essential oils, would be excluded from the regulatory system.

This may be achieved through use of an entry in the regulations or through other legislative instruments such as ministerial orders.

The Panel has identified all products currently declared not to be an agricultural chemical product or declared not to be a veterinary chemical product by the existing regulations (see Agricultural and Veterinary Chemical Code Regulations 1995) as suitable to continue to be excluded from the scope of the future pesticides and veterinary medicines regulatory system. The Panel has also identified other classes of products more effectively or suitably regulated by schemes outside of pesticides and veterinary medicines:

- anti-fouling paints (the impact of environmental toxins of the relevant active constituent would need to be assessed by the industrial chemicals regulator, the AICIS)
- commodity gases e.g., carbon monoxide, carbon dioxide, nitrogen, sulphur dioxide, acetylene, and liquified petroleum gas.

The Panel recommends that over the years ahead the Government continues to review the products within the scope of the future regulatory system to determine if the risks from a product and its use are correctly located within the Levels. As the regulatory reform transformation process is implemented over the next few years, it is likely there will be further opportunities to better target regulatory efforts for all parties. Regulatory amendments will need to provide for this.

Careful targeting of effort to risk will ensure that Australian farmers, veterinarians, and other people responsible for the care of animals, and land managers have access to the most comprehensive set of tools for pest and disease and therapeutic management, while maintaining, and potentially enhancing safety.

34. Recommendation

The Panel recommends efficiencies for the future regulatory system including:

- **new definitions for pesticides and veterinary medicines that exclude product classes or uses that are expected to be low risk as they have low hazard or low exposure or are effectively and suitably regulated by other regulators (as outlined in Annex 5)**
- **establishment of exemption pathways which remove pre-market regulation for certain low regulatory concern products**

- **development of standards by the Department of Agriculture, Water and the Environment enabling the exemption pathways, utilising input from industry and public consultation**
- **establishment of a Products Requiring Pre-market Assessment (PRPA) list.**

Level D – Genetically modified organisms

The Panel recognises that, in some situations, assessments by the OGTR and the APVMA can have duplicative elements – with the APVMA and the 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 fully 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 judged 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 likely to be 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 disease.

The Panel considers that it is unlikely that both regulators will need to conduct separate detailed assessments of these, or other new categories of substance that may foreseeably be introduced. However, as the exact risks cannot be foreseen at this stage, the only recommendation the Panel makes about them at this time is that regulatory duplication should be avoided and a single regulator approach be made the default arrangement, with departures only when necessary.

35. Recommendation

In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or the OGTR) becomes the decision-maker for an application. Depending on the category of 'substance' and the risks it presents, it 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.

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 unnecessary duplication. The Panel notes that this process of implementation 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 the OGTR and APVMA. This work is expected to be completed by 2023, in accordance with the Forum Action Plan 2018–2023 (Legislative and Governance Forum on Gene Technology, 2018).

This timing would fit well with the overall process of transformation to the pesticides and veterinary medicines regulatory system, now being recommended by the Panel.

Cost of reform

The Panel considers a more rational allocation of regulatory effort will have significant savings to the product manufacturing, importing and supply 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 system 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 the recommendations are outlined in Annex 4.

5.2 Enabling access for Australians to internationally registered 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, available to their overseas counterparts. This can put Australian exporters at a competitive disadvantage. It also denies Australian's choice in state-of-the-art treatments or alternatives to existing products with lower risks to health, or easier-to-implement risk 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 (National Farmers' Federation 2018).

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)

Australia has a world class system for pesticides and veterinary medicines regulation, based on 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.

Were Australia to do so, it would not be without precedent. The Panel is aware that Health Canada is working as part of its Forward Regulatory Plan 2021-2023 to provide a streamlined pathway for the Canadian authorisation of human and veterinary medicines, without an assessment by the Canadian regulator (Health Canada 2021). In the case of veterinary medicines, the streamlined pathway would allow for the authorisation of products which have been authorised by a specified international regulator, have been safely used in the international market, and meet international food safety standards. The pathway is focussed on providing

access to veterinary medicines for minor species and minor uses, which are currently not available on the Canadian market.

More broadly, the OECD has included in its Strategic objectives for 2024 the goal of "*mutual recognition of pesticide reviews [as]… the basis for international cooperation of regulatory bodies*", and "*work sharing…to lead to resource savings and mutual trust*".

The Australian Government has supported the principle of utilising overseas regulatory effort, since at least 2014. In that year it 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 and demonstrable reason to do so.

The Panel considers that the Australian pesticides and veterinary medicines regulatory system should be a source of competitive advantage, rather than a barrier to entry and access for safe chemicals.

> "*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 such a 'registration by reference' approach especially where the need to assess unique Australian conditions was included. Other stakeholders, however, did not support this initiative based on a view that the suitability to Australian conditions and use patterns including trade, health and the environment can only be addressed through assessment by the APVMA, and that the APVMA is unique in the extent of scientific rigour applied when compared to international assessments, standards, and decisions.

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 for use. In general, their concerns related specifically to Australia's climate, unique or high value Australian ecosystems (such as the Great Barrier Reef), unique fauna (such as koalas) and the importance of 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 characteristic Australian climatic conditions would not generally be outside the range considered in other registration processes and thus would not be unduly difficult to accommodate (see Section 5.6 and Figure 8).

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 that 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 residual 'unique Australian issues' in the design and coverage of their overseas trials and applications. This would streamline the subsequent process for approving supply and use in Australia.

Stakeholders supporting reform in this area also argued 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.

> "*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)

The Panel notes that there are arrangements in place in other Australian 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 approved importers with a history of 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 periodic compliance monitoring or auditing.

Utilising such co-regulatory 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, equivalent 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 will provide a pathway for the supply of credibly assessed internationally registered products into Australia subject to transparent conditions to manage the risks, including unique-to-Australia risks. The pathway will not mean automatic acceptance of an overseas decision in whole and without any risk management modifications. Rather the pathway provides for the

tailored translation of a registration by an accredited overseas registration authority into the Australian agricultural, environmental and animal health context in a safe manner.

Building on the safety measures assessed to gain an overseas registration, applicants for a licence will be required to address any unique-to-Australia risks by developing additional, complementary risk management strategies. Such risk management measures will be described in the form of a detailed Risk Management Plan lodged by the licensee for assessment and approval by the Department as the licensor, against suitably rigorous criteria.

The early stages of the regulatory transformation process to implement this licensing scheme will involve the Department undertaking an equivalence assessment of comparable international regulators. While this process progresses, a licensed product prohibited list (discussed later in this section), and guidance material to assist industry understand the rigorous assessment criteria which will apply to risk management plans and other key aspects of the scheme, will be developed. Industry, users, and the community will be consulted.

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 equivalent countries overseas. The ability to recognise alternative risk management solutions will also open up innovative approaches to meeting specified regulatory outcomes, including creative new business models for supplying and managing the use of pesticides and veterinary medicines in the Australian market.

The arrangements will encourage and fast-track the availability of safer, more effective pesticides and veterinary medicines to Australians. 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.

Box 6 An alternative access pathway with robust and rigorous requirements

The proposed licensing scheme for internationally registered products will allow Australia to take advantage of the regulatory expertise already invested in products registered under advanced overseas regulatory systems. The Panel's suite of controls will ensure that in leveraging such decisions, the protections for human, animal and environment safety and trade reflect the robustness expected by all Australians.

The dual requirements for both international registration and active risk management by the licensee (with regulatory oversight by the Department) will provide assurance the products are safe and suitable for use in Australia. A robust equivalency assessment underpins the extent to which the Australian system will place reliance on the overseas product registration, and the required risk management controls that need to be approved. The equivalency of an overseas registration will be strictly limited to those aspects where the regulator's system for regulating pesticides and veterinary medicines is equivalent to that which occurs in Australia.

Licensees will need to meet qualifying criteria and have a risk management plan assessed and approved as part of their licence for supplying overseas registered products in Australia. A particular focus of the risk management plan will be to address any unique-to-Australia risks (such as risks to trade or unique environmental risks) and regulatory requirements (obligations applying in Australia for work health and safety, dangerous goods, poisons, fair trading, gene technology or biosecurity laws).

Specialist risk assessors will rigorously assess the risk management plans as part of licence approval or variation, and periodically audit the licensee to ensure their competence and suitability, compliance with their risk management plan, and confirm the soundness of associated Australia-specific data. Risk management plans will be subject to public consultation which will allow any interested party to see that risks associated with any unique Australian circumstances have been identified and are being satisfactorily managed. For example, it will allow producer groups to identify and inform the Department (as the licensor) of proposed risk management treatments they consider contain unacceptable trade risks (similar to the existing process for product registrations).

It will be a condition of every licence that the licensee implement the risk management plan. Additional conditions can be placed on a licensee where necessary to ensure that any risks are adequately managed. Should a licence holder fail to comply with the conditions of their licence (for example, by failing to manage relevant risks) their licence could be suspended or cancelled. If this happens, the licensee will lose the ability to market its entire range of products introduced under licence, whereas for a registration this will only apply to the specific registered product. This provides a strong incentive for the licence holder to manage their risks effectively.

Coupled with other administrative actions and sanctions (for example, product recall or imposition of extra licence conditions), as well as civil and criminal penalties, the licensing pathway provides a level of rigour at least as strong as that of the registration system.

The licensing scheme will complement, not replace, the current registration scheme which will continue to be available through the APVMA. Both pathways will result in safe and effective products being accessible in the Australian market.

Improving access to products not currently available

The Panel explored its proposed licensing approach with manufacturers who currently have limited or no market presence in Australia to confirm that licensing internationally registered products would provide benefit in terms of improving access to innovative products not currently available to Australians.

The proposed pathway would provide Australian farmers and other end users with greater diversity in products and flexibility in pest and disease management. The Panel received positive indications that such a model would indeed encourage new manufacturers and importers to bring (and in fact launch) otherwise inaccessible products into Australia. In addition, certain chemical companies well established in the Australian market informally indicated their interest in utilising the new licensing pathway. They saw it as attractive to them bringing into Australia a greater range of their products available overseas but not worth the cost and time to register in Australia currently.

Despite these positive indications, the Panel expects the uptake and expansion of the scheme to be incremental. The Panel sees the gradual adoption of the pathway as being another element of the transformation and improvement of the whole Australian regulatory system which will unfold over the years to come.

A comprehensive engagement strategy with regulators, industry, and stakeholders will be required as the scheme is introduced. The Panel also recognises that some product types and uses are well suited to licensing, but others requiring more data to address unique-to-Australia conditions or involving more difficult to manage risks (e.g., trade risks which need to account for a range of countries, multiple human and animal feed Maximum Residue Limits (MRLs), Export Slaughter Intervals (ESIs), and Withholding Periods (WHPs)), may be more suited to registration.

The Panel considers that rather than close the licensing scheme to seemingly difficult product and use types, it should be a commercial decision for the licensee to decide which regulatory pathway – licensing or registration will be best suited to attempt.

Despite Australia's small market size, the Australian registration system is relatively efficient compared to certain international peers. If a registrant intends to use Australia as a launch market for a new product (as sometimes occurs), then the licensing pathway is unlikely to be faster in providing access. The benefit of licensing will be where Australia would otherwise have only received access some time after the launch market, or not at all.

Improving access to new uses for products

However, the benefits of the licensing pathway are not limited to improving access to **products**. Until now, Australian producers have had access to considerably fewer approved **uses** for chemicals than their overseas counterparts. Many products registered in Australia have considerably fewer uses approved in Australia than the same product available overseas.

Under the new licensing pathway, licence holders will be required to make available to Australians all uses for a given chemical approved by the equivalent international regulator, except under specific circumstances. Labels on products supplied under licence are expected to retain the same content as that approved by the equivalent international regulator. The exceptions would be where the pest, disease, crop, or animal is not present or endemic to Australia, the use is on the licensed product prohibited list, or where the Department accepts a representation from the licence holder that the use in Australia would present risks to safety, environment or trade that cannot be managed. Additional uses that may later be added to the international registration would also become available to Australians if they comply with the approved (or varied) risk management plan, and so have unique-to-Australia circumstances addressed.

Opportunities for grower groups and others

The Panel sees an important opportunity in the licensing pathway to change the traditional relationship between growers, as users, and the system regulators. The new licensing pathway provides a unique opportunity for grower groups to take the initiative themselves to gain access rather than, as has traditionally been the case, simply urging 'from the sidelines' that suppliers provide access for them.

Empowering end users (growers) in this way, is consistent with best modern regulatory practice. The Panel sees it as an important means of updating and driving further change in practice in the pesticides and veterinary medicines regulatory system in Australia.

The opportunity arises because the licensing pathway provides a channel for grower groups themselves to apply for licensed access to products. They would do so by developing their own tailored solutions in risk management plans that take advantage of their intimate knowledge of their growers, processors and supply chains, industry practices and environment, as well as access to other experts such as specialist veterinarians in aquaculture.

For example, a grower group could enter into an arrangement with the manufacturer to be the Australian licensee of a niche product registered in Canada but not available in Australia. The manufacturer could provide evidence of the international registration to the Department 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.

Grower group licence holders will be allowed to only make available the subset of internationally approved uses for a given chemical within the scope of their industry sector e.g., a citrus grower group would need to include lemons, oranges, kumquats, yuzu, tangelo, etc., but not grape or pome fruit uses. The Panel considers that if a product has uses for citrus, pome fruit and wine grapes, it is reasonable that the citrus group will only be licensed for the citrus group uses, as these are the uses that a citrus grower group will be reasonably expected to manage.

The Panel considers that it will be a disincentive to grower groups to use this pathway if they are expected to determine suitable risk management arrangements for crops and animals outside their industry sector, or to form coalitions of groups to cover all uses on all products they wish to manage under licence. While this reduces access to uses, grower groups outside the industry sector could follow this example and approach the manufacturer to enter into their own arrangement to gain access under licence. This could also lead to the manufacturer seeking its own licence, thus bringing all uses to the Australian market.

The Panel sees the potential for a more direct relationship between users and product suppliers through this approach which may encourage a valuable cultural shift in terms of through-chain shared responsibility, education, transparency, and market drivers. This highly focused supply approach would augment the minor use permits system (see Section 5.3) and help to improve access to low volume products by a new collaborative relationship between international manufacturers and their user customers.

Box 7 Companion animal hypothetical case study

A company (Zeus Vet Meds) is currently trading in Australia with extensive experience with the Australian regulatory system for veterinary medicines for companion animals. Zeus Vet Meds has an overseas sister company that has registered a range of veterinary medicines for dogs (HappyTails) using an active constituent only registered in Australia for cats. There are no food residue issues, the active constituent is already listed in the Standard for the Uniform Scheduling of Medicines and Poisons for animal use (Schedule 5 – caution), and the HappyTails overseas labelling and information are already in English.

Zeus Vet Meds wishes to supply overseas registered veterinary medicines in Australia, starting with the HappyTails range of products for use in dogs. Zeus Vet Meds has confirmed that the HappyTails range is registered with a regulator on the prescribed list of comparable overseas regulators – Zeus Vet Meds also considers the note from the list indicating that the equivalency assessment for this particular overseas regulator had identified that the trade assessment element of the overseas system differs from the Australian system. Zeus Vet Meds, based on the published guidance material, decides that as the use of HappyTails does not involve a major export species the difference in trade assessment methods will not create a unique-to-Australia risk that would need to be risk managed.

Zeus Vet Meds also confirms that the active constituent and use pattern for HappyTails is not on the prescribed list of prohibited chemistries and classes of products and uses that are not allowed under licence.

Zeus Vet Meds therefore submits a licence application to the Department. Zeus Vet Meds chooses to initially constrain its application to the supply of overseas registered veterinary medicines for companion animals (from any comparable regulator). As required by the application, Zeus Vet Meds draws on its extensive existing history with veterinary medicine supply in Australia to demonstrate that it:

- has the appropriate competency to be able to comply with conditions of a licence to supply overseas registered veterinary medicines
- has the character (qualifying criteria) to manage the risks for an internationally registered product
- is an Australian based entity – there will be an accountable person(s) in Australia for the internationally registered product.

Zeus Vet Meds' licence application is also accompanied by a risk management plan covering the range of products it intends to initially supply (HappyTails). In preparing this plan Zeus Vet Meds followed the available guidance material and (with the assistance of an experienced consultant) drew on its existing experience in developing risk-management measures for previous registration applications to the APVMA. The plan:

- details that the circumstances of use would not be different in Australia from overseas (particularly that there are no food residue issues and the exposure scenarios and limited environmental release potential will be essentially the same as considered by overseas regulator), so there are no unique Australian requirements – Zeus Vet Meds' plan therefore largely relies on reproducing the risk management actions implemented by the relevant overseas regulator including the safety directions.
- explains how Zeus Vet Meds will comply with the licence condition to implement all Australian labelling requirements including matters such as how it will add signal words from scheduling, the Australian poisons information contact phone number, and contact details for Zeus Vet Meds
- explains the role of Zeus Vet Meds' quality assurance schemes, general product obligations and other co-regulatory approaches to manage risks.

The Department, with the assistance of specialist risk assessors, considers and approves the licence application and risk management plan, with appropriate conditions. Zeus Vet Meds begins supplying HappyTails products in Australia.

Zeus Vet Meds is added to the ongoing licence audit program run by the Department, in partnership with the states and territories. The audit confirms:

- Zeus Vet Meds is complying with its approved risk management plan e.g., that it is complying with Australian labelling requirements as proposed
- products supplied in Australia include all the internationally registered instructions for use and safety directions as required by the comparable international regulator
- there have been no refusals or withdrawals of product or permit applications relevant to the types of internationally registered products intended to be supplied
- Zeus Vet Meds has the endorsement of the holder of the international registrations and has access to the data necessary to identify, and address, any risks or issues.

An incident of excess user exposure is subsequently reported through the adverse experience reporting program. Follow up, coordinated by the Department with on-the-ground support from a state or territory compliance officer, confirms that there is no problem – no change is needed to either the licence conditions or risk management plan.

Three years later, the overseas registered product is varied to extend its use to cats as well as dogs. Zeus Vet Meds reviews its risk management plan and confirms that no change is needed. The Australian supplied product's label and instructions are updated to reflect the overseas regulator's changes, as required by the original risk management plan.

Following its success with HappyTails, Zeus Vet Meds decides to bring in another range of companion animal products (SadTails) that meet the conditions of its licence to supply registered overseas veterinary medicines. Zeus Vet Meds sees from its licence conditions and the published guidance that this will require a variation to the risk management plan. Zeus Vet Meds submits the amended risk management plan to the Department which assesses and approves the variations to the plan.

Zeus Vet Meds continues to monitor the status of the relevant overseas product registrations. This reveals that the HappyTails registrations have been cancelled at the request of the overseas registrant as part of a commercial strategy change. Although not cancelled for any safety concern, the conditions of Zeus Vet Meds' licence mean it can no longer supply HappyTails in Australia – such supply was contingent on the ongoing risk mitigation and monitoring provided by an overseas registration (an alternative country registration could be relied on if available). Zeus Vet Meds can still supply SadTails, as this product range remains registered overseas.

Rigour in the licensing scheme

The Panel is aware of concerns among some stakeholders that reliance on international decisions could reduce the quality of the Australian regulatory system process. However, the Panel does not consider it credible that every single pesticide and veterinary medicine presents such unique-to-Australia risks that its safety under Australian conditions will always be different from those in every other country.

In addition, the Panel is confident that the dual requirements for both international registration by an equivalent regulator, and legally obliged, active risk management by the licensee will provide **at least** an equivalent management of risk as the registration scheme to ensure the products are safe and effective when used in Australia. These dual, mutually reinforcing, requirements also operate in concert with obligations for work health and safety (WHS), 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.

Enlisting the active risk management efforts of multiple parties in government and industry, rather than the regulator alone, is a feature of the licensing system that can provide robust assurance of the protection of the health and safety of humans, animals, and ecosystems, and avoid prejudice to trade (see Chapter 4). It is also a Government-endorsed best practice objective of modern regulation.

Rigorous licence approval

Under the licensing scheme, the equivalent international regulator will have conducted most of the risk assessment and decided on associated risk management actions for each product to be supplied under a licence. The focus of Australian regulatory effort will therefore be on the licensee and their ability to manage the risks in the Australian context through their approved risk management plan.

Licensees will need to meet qualifying criteria to ensure that a prospective licensee has the appropriate competency (will be able to comply with the conditions of the licence) and character (fit and proper person) to manage the risks for an internationally registered product.

Only licences which provide equivalent consideration and management of risk as the registration scheme, will be approved, to ensure the products are safe and effective when used in Australia. The Panel reasonably expects that the criteria for licensing will be equivalent to those currently in the Agvet Code for registration with respect to safety, efficacy, trade, and labelling criteria. The key difference for products marketed under licence would be that rather than the registration requirement of being 'satisfied that the criteria are met', the licence issuer would need to be 'satisfied the criteria *will* be met'. This change is because the licence is primarily to regulate the future activities which will be associated with both the supply and use of products. It recognises that a base level satisfaction of the criteria comes from knowing that products can only be supplied under licence when a credible, equivalent international regulator has decided to register the product. The Department's licensor can then assess whether the criteria will be fully met by any further Australian data, assessments, or post-market risk management controls the licensee has additionally set out in their risk management plan.

Assessments of risk management plans will be conducted against a set of rigorous objective assessment criteria. The criteria will be publicly available. It will be open to the Department to seek the advice of independent experts in risk analysis and management. There will be provision for aspects of the plan to be varied, or additional conditions attached, before any approval is granted. Oversight, reporting, and compliance arrangements will be specified. Accountability for performance will be clear and sanctions for non-compliance will be specified.

The Panel considers that the Department will be best placed to issue and oversee licences. The types of judgements involved will go well beyond traditional science-based product supply assessments to also take into account utilisation of industry quality assurance schemes, general product obligations and other co-regulatory and tailored approaches to manage risks. The risk management plans focus on managing use – which will be at the core of the Department's new, reformed, arrangements for managing control-of-use, including on-going monitoring and oversight effort. Such innovative means of managing the risks associated with usage are outside of the usual remit of the APVMA, and the Panel considers it could compromise the recognised reputation of the APVMA as an independent science-based supply registration authority if it were now tasked, in addition, to regulate and monitor these control-of-use activities.

Benchmarking comparable regulatory systems

The design of the licensing model requires that the precise details of international assessment equivalency are established through a regulatory equivalency assessment. The regulatory equivalency assessment is required because 2 regulators may be equivalent for some assessment areas but not others. In simple terms the regulatory equivalency assessment would be expected to examine each of the elements the APVMA considers in relation to the existing statutory criteria. The regulatory equivalency assessment result for each comparable regulator will define where each element of the statutory criteria can be taken to be already met on the basis of the international registration decision and specify the remaining 'unique Australian circumstances' that may still need to be met in a satisfactory manner. Addressing these 'unique Australian circumstances' will need to be addressed through the licensee's approved risk management plan.

Information provided to the Panel by the APVMA demonstrated that it considers environmental assessments conducted in Canada and Europe for pesticide assessments is equivalent to Australian assessments. Environmental assessments from the US Environmental Protection Agency were considered by the APVMA 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 Australian conditions that are not adequately covered by an international data set from an equivalent regulatory system. Nevertheless, the licensing process will need to identify and consider any unique Australian environmental circumstances on a case by case basis.

The Panel recommends that the Department be responsible for assessing the equivalency of international regulators of pesticides or veterinary medicines to deliver outcomes equivalent to Australia's standards for registration and use. The Panel considers that the Department should make these decisions as it will be responsible for the issuing of licences under this proposal (see Chapters 2 and 4). However, the assessment must be conducted in consultation with the APVMA, as determining whether an international regulator's decision would be equivalent to the APVMA's decision requires a detailed knowledge of the data requirements and satisfaction criteria of both regulators. The APVMA has access to that knowledge and is already required to consider it as part of the current system.

Every assessment needs to be a rigorous and intensive process as the assessments are critical steps in determining the unique Australian circumstances to be included in the licensees' risk management plans. They also are important for assuring users, industry, and the community that there has been adequate scientific rigour applied in international assessments, standards, and decisions.

The development of regulatory equivalency assessments will involve in-depth collaboration with equivalent international regulators. This informal capacity building has occurred for many years and the licensing scheme would be a practical outcome of this work. Harmonisation of the regulatory systems and work sharing is a core element of the OECD Programme on Pesticides and Sustainable Pest Management's Vision for the Future. The development of equivalency would contribute towards the OECD Strategic objectives for 2024 of '*mutual recognition of*

pesticide reviews [as]… the basis for international cooperation of regulatory bodies', and '*work sharing…to lead to resource savings and mutual trust*'.

The Department's regulatory equivalency assessment will need to be informed by stakeholder consultation to take account of community and industry expectations. For example, stakeholder input will be important in considering management of cases where the comparable regulator may have a lower risk appetite with regard to some aspects than Australia, such as in the EU, where significantly higher levels of investment are required to obtain and maintain any registration. The Panel expects this consultation may form an early topic for consideration by the Stakeholder Forum, with additional advice on specific aspects from relevant stakeholders e.g., export focused parties in relation to trade (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 in 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
- for companion animal and livestock products – the US Center for Veterinary Medicine of the Food and Drug Administration, the US Center for Veterinary Biologicals of the US Department of Agriculture, the European Medicines Agency, the Canadian Veterinary Drugs Directorate, the UK Veterinary Medicines Directorate, the Japanese Ministry of Agriculture, Forestry and Fisheries, and the New Zealand pesticides and veterinary medicine products system.

The Panel recognises that there will be more unique Australian circumstances for certain product categories than others e.g., conventional chemistries versus biological products, and companion animal products versus production animal or broad acre products. While not providing separate pathways, the regulatory equivalency assessment should assist in streamlining the regulatory process by clarifying the differences in type and number of unique Australian circumstances that actually need to be considered.

For transparency, certainty and accountability, the list of equivalent 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 permit processes. It is also the Panel's expectation that over the next 30 years the listing will increase and include more regional partners.

Risk management plans

A key requirement of the licensing scheme will be that licence holders must develop, gain approval for, and implement a detailed risk management plan. This provides a co-regulatory (as distinct from self-regulatory which the Panel does not support) arrangement that builds on the risk management that companies already undertake to manage their potential company liability, insurance exposure, and risk of reputational damage in the Australian market.

The risk management plan will specify the licence holder's business practices for identifying and assessing risks and detail 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.

The licence holder will bear the responsibility for ensuring aspects unique to Australia are risk assessed and managed, including submitting for assessment and approval a detailed plan for how the risks will be managed. Accountability for the approved risk management plan will rest with the officer responsible for all aspects of the company's business (usually the CEO or Managing Director).

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-to-Australia conditions and risks across their suite of products will build an additional level of assurance into the regulatory system. The licence scheme should also drive licence holders to extend their capability and build even stronger arrangements on these existing foundations. Sanctions and penalties for failure will reinforce the onus on the licensee to be duly diligent.

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. In accordance with contemporary best practice regulation, objectives will be specified as far as possible in outcome terms and licensees will be free to define the best way, in their circumstances, to achieve the specified results.

Example risk management strategies are:

- controls on distribution (such as restricting access to specific users under contract or who are trained by the supplier)
- including additional information on labels
- having an Australian accredited assessor sign off on additional data from several different countries that cover the range of uses and regions in Australia
- providing education, training, risk management and other digital tools to assist users (see smart labelling and special use licences in Chapter 4), and other services to their user base more broadly
- implementing boundary surveillance, monitoring and sampling around usage sites.

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

- risks associated with characteristically Australian farming and work practices
- trade risks, including that trade between Australia and other countries is not jeopardised.

The licence holder's risk management plan will also 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), compliance with the 5 year label review, or changes required for management of unique Australian risks. The risk management plan will also detail how these issues will be addressed (such as over-stickering or, where feasible, the use of smart labelling).

Public consultation

A licensee may propose risk management measures that are not acceptable to industry or the public. Risk management plans will therefore be subject to a period of public consultation so that the licensor can consider any objections, recommended changes, or additional protections. This process will be similar to the APVMA Trade Advice Notices that invite public comment on the trade implications during registration or of a proposed change to the use of a registered product.

The Panel recognises that publication of the risk management plan may provide confidentiality hurdles for companies. However, the Panel considers that making risk management plans publicly available is important for assuring the community that all risks have been identified and are being satisfactorily managed, and to address any concerns that pesticides and veterinary medicines supplied under licence are not subject to the same regulatory scrutiny as registered products.

The licence issuer should have discretion to consider confidential information in support of the public risk management plan. Confidentiality for information that relates strictly to the licence holder, or the licence holder's planned interactions with suppliers and Government agencies would be retained, so long as the lack of disclosure would not modify the risk management actions taken by unrestricted users, processors, exporters, or the public e.g., commercially protected special processing requirements. Where such information is relied on to approve the licence, the licence issuer should provide a public summary statement providing enough non-confidential detail for the public to be informed of how confidential information was considered to address human health, environmental, or other potential concerns.

Trade risks

The proposed scheme itself should not generate trade concerns relating to a lack of rigour, 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 already underpinned by industry-administered risk management measures in the form of approved arrangements and meat export licences.

The Panel recognises the concern expressed by some stakeholders with respect to trade risks. The Panel well understands the considerable value of Australian exports reliant on safe management of residues. The Panel also acknowledges the complexity of current residue management arrangements.

To deal with these issues, the Panel is recommending a structured process of stakeholder and public consultation on the adequacy of the risk management plans. The public consultations will

afford Australian agricultural industries an opportunity to object to a product or aspects of a plan on the grounds of trade risk. Agricultural industries will be able to provide advice about whether the proposed use and associated risk management measures pose an unacceptable trade risk to them and this will be taken into account when deciding whether to approve a risk management plan. This is similar to the approach for registration. Managing potential product trade risks will be an active, ongoing responsibility and commercial decision of the licence holder, with regulatory oversight from the Department's licence issuer.

Managing the risks posed to Australia's trade from a treated commodity is currently achieved through a combination of food and feed MRLs, ESIs, WHPs and prohibitive use statements on a product's label. The Panel recognises the concerns expressed by many stakeholders to ensuring this same level of protection is achieved through the licensing approach. The Panel considers that the established approach of the APVMA may act as a suitable model, namely the applicant proposes suitable risk management strategies, there is public consultation to inform the APVMA, and a decision is made (including, as necessary, amending food and feed MRLs, an authority provided to the APVMA). The Panel considers that the Department as the licensor should have the ability to instigate variations to MRLs as necessary to facilitate safe access to products under licence. This is an authority already provided to the APVMA in terms of the food MRLs maintained by FSANZ, the Panel's proposal will be to extend this to the Department and provide equivalent authority to the Department to amend the feed MRLs maintained by the APVMA. Decisions to vary an MRL would continue to be informed by science and public commentary.

The public and stakeholder consultations on the risk management plan are a key feature of the licence approach. This provides the opportunity (as is achieved by the APVMA Trade Advice Notices) to comment on management strategies such as ESI and WHP. The Panel notes that other markets do set periods that are equivalent concepts, and these may in many cases act as a sound basis for extrapolation.

It would also be open to licence holders to seek to amend the MRLs separate from the licensing approval process, a key feature the Panel believes will deliver greater control of process (but importantly not decision) to industry.

Other regulatory systems

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 the current Australian registration process where the timing of referrals to these processes is managed by the APVMA. This latter constraint was an issue of concern raised by a range of industry stakeholders during the Panel's consultations.

Regulatory safeguards

In developing the licensing scheme, the Panel examined the pre- and post-market regulatory requirements and safeguards for pesticides and veterinary medicine products authorised under

the current APVMA registration pathway, and those that would apply under the Panel's licensing proposal (Table 3 and Table 4). The Panel considers that when examined across both pre- and post-market controls, the proposed scheme for licensing of internationally registered products provides the same protection and level of rigour as those for registered products, but with a greater emphasis on regulator post-market compliance tools, such as regular audits of a licensee's risk management plans initially and evolving to real-time monitoring as technology advances.

Table 3 Comparison of pre-market regulatory safeguards for registration and international licensing

Regulatory criteria	Registration	Licensing of internationally registered products
Regulator guidelines	*Safety, efficacy, trade and labelling:* • data guidelines	*Safety, efficacy, trade and labelling:* • comparable regulators • prohibited lists • risk management plans • unique circumstances • fit and proper person
Application submission	*Safety, efficacy, trade and labelling:* • data and other information addressing legislative criteria	*Safety, efficacy, trade and labelling:* • approval of international registrant • regulatory decision of comparable regulator • risk management plan addressing criteria and unique circumstances
Regulatory assessment	*Safety, efficacy, trade and labelling:* • technical risk assessment of data against criteria	*Safety, efficacy, trade and labelling:* • technical assessment of risk management plan against criteria • unique circumstances • fit and proper person assessment
Public consultation	*Safety and efficacy:* • new active ingredients *Trade and labelling:* • trade consultation	*Safety and efficacy:* • new active ingredients *Trade and labelling:* • trade consultation
Regulatory decision	*Safety and efficacy:* • register (in part or in full) • prescribe conditions • apply unique conditions *Trade and labelling:* • Refuse (National benefits test)	*Safety and efficacy:* • licence (in part or in full) • prescribe conditions • apply unique conditions *Trade and labelling:* Refuse (National benefits test)
Regulatory standards establishment	*Safety and efficacy:* • Health based guidance values *Trade and labelling:* • MRLs (MRL standard and food standards code)	*Safety and efficacy:* • Health based guidance values *Trade and labelling:* • MRLs (MRL standard and food standards code)

Table 4 Comparison of post-market regulatory safeguards for registration and international licensing

Regulatory criteria	Registration	Licensing of internationally registered products
New (adverse) information	*Safety, efficacy, trade and labelling:* • legislation requires notification (s161)	*Safety, efficacy, trade and labelling:* • legislation requires notification
Adverse experience reporting	*Safety, efficacy, trade and labelling:* • AERs will apply	*Safety, efficacy, trade and labelling:* • AERs will apply
Chemical review	*Safety, efficacy, trade and labelling:* • legislated trigger (comparable regulatory decision) • self-initiated • referral from Commissioner • workplan and timeframes • data protection eligible • national benefits test	*Safety, efficacy, trade and labelling:* • legislated trigger (comparable regulatory decision) • self-initiated • referral from Commissioner • workplan and timeframes • data protection ineligible • national benefits test
Non-compliances	*Safety, efficacy, trade and labelling:* • recall • suspend • cancel • conviction • civil penalty	*Safety, efficacy, trade and labelling:* • recall • suspend • cancel • conviction • civil penalty
Testing of product quality	*Safety, efficacy, trade and labelling:* • will apply	*Safety, efficacy, trade and labelling:* • will apply
Compliance monitoring	*Safety, efficacy, trade and labelling:* • random	*Safety, efficacy, trade and labelling:* • regular
Five year label review	*Safety, efficacy, trade and labelling:* • will apply	*Safety, efficacy, trade and labelling:* • will apply

Licensed product prohibited list

To ensure Australia does not access pesticide or veterinary medicine products that users, especially primary producers do not want here, the Panel proposes that the Department establish a list of products not allowed under licence. The licensed product prohibited list will be able to prohibit chemistries, classes of products, and uses so that it can address both existing products that are currently registered overseas and those which are yet to be developed. This list will be developed and maintained in consultation with the Stakeholder Forum, with regular calls for public input.

Government audit and oversight

The Department will provide government oversight of licence holders. Licence holders in the first instance will be subject to regular audits to ensure they are complying with their risk management plans and other licence conditions. The Panel suggests annual audits, but the interval could be varied based on compliance history and level of risk being managed.

Over time, it is likely that more sophisticated compliance monitoring tools will evolve (e.g., real time monitoring) resulting in even more robust systems for providing assurance to markets, users, and the public. Licence conditions will also require reporting and monitoring data to be

provided to the Department, 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 illustrative proposed licence conditions).

The Department will be empowered to take regulatory action against the licence holder for non-compliance with their approved risk management plan or other licence conditions. Compliance measures available will include injunctions, substantiation notices and enforceable directions, as well as administrative actions including suspending or cancelling licences. Substantiation notices will assist the Department to compel licensees to provide evidence of the steps they are taking to manage known or emerging risks (e.g., as identified through surveillance and monitoring, control-of-use, chemical reviews, or any international decisions). This is similar to the role chemical reviews play in relation to registration, but the substantiation notices will be more targeted and dynamic with a fixed response time.

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 prudently 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 will be available to the Department 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 and emergency safety net for any supplied internationally registered product.

In a case where the international registration was cancelled in the original country of registration, it would no longer be eligible under licence in Australia (and so would be removed). However, if the factors leading to cancellation were not applicable to Australia it would still be open to the registrant of the internationally registered product to supply product into the Australian market via an alternative equivalent international regulator's registration, or the Australian registration or permit pathways.

Intellectual property protections

The design of the licensing scheme must ensure that intellectual property (IP) arrangements relating to the internationally registered product, and Australia's obligations under international agreements on IP, are respected. To achieve this, 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 the registration holder's permission for any international registered product for which there is an authorising party (i.e., protected data).

An internationally registered product must also not be able to 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 5.9). 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.

Licensed products will have no Australian data protection as no eligible data will be provided to the APVMA. The lack of disclosure to the APVMA, but accessible to the Department, means that product information will remain a trade secret of the Australian licence holder protected from infringement by Australian common law provisions. The APVMA will hold no protected Australian data that can be used to support the Australian registration of other products. However, the APVMA could rely on a history of safe use under licence to facilitate the registration of an equivalent product. Licensees may also choose to pursue registered forms of intellectual property rights such as patents and trademarks, as is the case now.

The Panel considers that protection of IP for products supplied under licence is important to the success of the proposal. While the Department should not have a role in arbitrating IP disputes, it will have an important implementation role of fully developing the policy and legislative settings for the necessary IP protections, in consultation with industry and other relevant stakeholders.

36. Recommendation

The Panel recommends establishing 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.

In support of this scheme, the Panel recommends:

- **that there be an instrument setting out international regulators determined to be equivalent, and that this be regularly reviewed for currency**
- **that the Department of Agriculture, Water and the Environment, in consultation with the APVMA determine equivalent regulators**
- **establishment of a list of prohibited chemistries and classes of products and uses that would not be allowed under licence**
- **that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.**

The Panel recommends that 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, or a specific grower/producer group only wants to bring in uses associated with their industry sector and within their control**
- **develop, submit for approval, 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 approved 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**

- **cannot supply a product under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active**
- **provide information on request confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions.**

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 will be considerably less than Australia's current registration process and allow significantly faster access to much needed products already registered by equivalent international regulators.

Licence fees are provisionally estimated to be in the order of $2,500 per licence with similar costs payable for licence renewals, and 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 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 $55 million over 10 years.

In addition, the Panel considers the potential flow-on benefits for 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 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 there are clear potential benefits to health, safety, or viability.

The addition of crop groups to the registration process has assisted in extending the benefits of registration to closely related crops. However, such occasions are currently dealt with under the Minor Use, Emergency Use and Research Use Permit scheme.

The Panel heard strong support for this permit scheme and the Panel itself fully supports the intent of the 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 wine grape 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 not be as extensive in terms of geography, time, or user base. In most cases this means the risks are more contained and manageable.

The Panel heard that regulatory costs, data requirements and assessment times can be substantial barriers to access. The Panel considers the operation and usability 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 many permit applicants that equivalent levels of supporting data are required, but for many of these uses there may be less directly applicable data available.

Stakeholder submissions indicated that the current permit scheme can be a barrier to accessing products, especially for minor uses, as it currently requires virtually the same evidence for a permit as for full registration despite the requirement for a limited market.

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 proposes 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 anticipated emergency and an actual operational emergency. This could lead to concerns with trading partners and domestic users as to whether a specific pest or biosecurity threat is active within Australia.

Perhaps more importantly, having emergency uses pre-approved and ready to be implemented would enable a faster and more orderly response in emergency situations.

> "*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)

What change is recommended?

The Panel recommends the following reforms to the current approach to permits. In developing these reforms, the Panel is well aware of the importance of permits for protecting animal health and the value they deliver to producers and has been careful to design the reforms to preserve and increase that value.

Expanding Government's support of minor use programs

The Panel supports the Government's actions to address minor use and support Australian growers' access to safe and effective 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 minor use programs in other developed countries. The Panel considers these rates of return clear evidence of the value in equipping industries with the necessary tools for pest and disease management.

The Panel also supports expansion of the scope and funding of minor use grants to allow the initiative to fund research and development programs for sustainable practices of Integrated Pest Management and animal husbandry. This would align Australia more closely with the levels of support the USA and Canada minor use programs provide to their farmers in these areas.

37. Recommendation

The Panel recommends expanding support by Government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing industries' access to tools for pest and disease management.

Establishing criteria specific to emergency, research, and minor use permits

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. Specifically, the Panel proposes that the criteria to grant an emergency, research, or minor use permit should be 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. The Panel's proposed new criteria for permits will create a clear risk-based difference, in both policy and legislation, between registration and permits. The language reflects the differences in risks posed by a controlled or limited use allowed through permits relative to the broad scale or generalised use provided for through registration.

38. Recommendation

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use permit, as long as the use of the product would not jeopardise safety or trade and is reasonably expected to be efficacious.

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 data to be specifically generated prior to consideration of an application for a permit. Sound arguments could include, for example, evidence of a history of safety for comparable uses of the product (e.g., within a crop group), 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 permits drawing on the existing evidence base from published and well-recognised historical clinical practice.

As an example of how the permit 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.

Supporting biosecurity preparedness through active – and future – emergency permits

The Panel recognises the benefit to Australian biosecurity preparedness in establishing emergency permits in advance of a pest or disease incursion. Advance emergency permits will be one more tool to assist Australia's collaborative, precautionary and prevention-focused response to avoiding impending biosecurity threats. Their ability to raise awareness of potential threats and the required pesticide or veterinary medicine response, may hopefully serve an educative purpose that drives other actions that reduce the need for the emergency permits to be actively used.

To address user and export industries' concerns that the grant of a permit in advance might encourage an incorrect perception that a pest or disease incursion had occurred, emergency permits, once granted, would be categorised publicly in one of 2 lists: 'active-emergency permits' or 'future-emergency permits'. Formal triggers would be established within the permits scheme to ensure 'active' permits are reviewed for reversion to 'future' permits, and to make a future-permit 'active'. Triggers could be a 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 Director of Biosecurity.

The Panel encourages these authorities to take full advantage of this new opportunity, and the Panel's recommended permit-specific criteria, to improve preparedness for contingencies such as exotic animal or plant disease or pest incursions. Preparedness plans, supported by on-the-shelf permits, are stronger and can be implemented more speedily. The time to apply for permits is before a crisis, not during.

39. Recommendation

The Panel recommends expanding the authorising of emergency use permits in advance of the emergency through establishing 2 categories within the public listing of permits for 'active-emergency permits' and 'future-emergency permits'. Future-emergency permits

would include details of the trigger to transition from the 'future' to 'active' permit category and vice versa.

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 current requirement to seek a permit for each research activity not falling within the constraints of the general small-scale research permit (PER7250). Examples are larger scale field trials and product evaluation trials e.g., testing a particular set of label instructions, new packaging, or application technology.

> "*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)

Rather than requiring separate permits for each research activity as currently, the Panel recommends that a licensed research entity will in future be able to undertake research relating to use of either registered or unregistered pesticides and veterinary medicines, subject to the condition that a suitably rigorous risk management plan has been approved, with regular independent assurance checks such as audits.

The risk management plan would need to be supported by research quality and safety management systems, which could be planned to scale with complexity, size, and risk of activities. The risk management plan would need to address the potential exposures for humans, animals and ecosystems, the potential for residues to enter the food chain, the use of trained and accredited applicators in trials, processing, and disposal arrangements, how and when toxicological properties of the product will be evaluated, and first aid, emergency response, and safety directions.

The licence would allow an entity to carry out multiple research activities for multiple classes of products under one authorisation. A university department, CSIRO or state government agricultural research agency might hold a single licence setting out a common research management framework. A grower group might coordinate activities such as resistance management research under a single licence to ensure consistency. Individual research teams within the licensed entities could then focus on research, rather than multiple and repetitive applications to the regulator.

The licensing scheme for research entities would not preclude anyone from seeking a permit for research use, including from a licensed entity for an activity that is outside scope of their licence. This may be desirable to take advantage of the Panel's recommended reform to provide 5 years data protection for information provided in support of a research permit (see Section 5.9).

National research capacity will be strengthened by streamlining all activities across the entire research and development pipeline, as well as the attention to formulating and implementing robust research frameworks. This should enhance Australia's reputation for research quality while building capacity outside Government for dealing with pesticides and veterinary medicines.

40. Recommendation

The Panel recommends building national research capacity through 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 has been approved, supported by research quality and safety management systems, and regular independent assurance checks including audits.

5.4 Improving access to uses through supplemental labels

The high reliance by growers on permits for enabling access to new uses is evidenced by the APVMA's Draft Report submission that acknowledges more than half of all new MRLs they establish result from permits. This is largely attributable to the minor uses needed not achieving product registration status.

The Panel recognises the strong support from growers for the existing permit system, but permits place responsibility on users, rather than the product registrant who ordinarily should be best placed to satisfy regulatory assessment requirements for their product. The APVMA has also been undertaking a project to transfer existing uses approved under permit to product labels. While this was initially supported by funding from the Department, the difficulties of moving a 'user-sponsored' approval (permits) over to a 'registrant-sponsored approval (registration) has proven resource-intensive and the process is ongoing.

Stakeholders stated to the Panel that while they strongly supported permits, they also considered that access to pesticides and veterinary medicines could be improved through reforms that facilitated a greater number of uses being registered, and specifically requested reforms that will:

- address priority needs of producers
- incentivise registrants to expand available uses
- enhance and build on the Government's current Access to Industry Priority Uses of Agvet Chemicals program
- allow for conditional or provisional registration
- facilitate the transition of permit uses to (registered) product labels.

The Panel, taking account of its reform objectives, stakeholder feedback and understanding of the current system, particularly the high reliance of growers on the permit system, has formed the view that there is an opportunity for a targeted reform to registration to address this. The Panel is recommending a reform that encompasses the objectives sought by stakeholders through a mechanism that will facilitate access to minor uses needed by growers, and reduce reliance on permits.

What change is recommended?

The Panel recommends the introduction of supplemental labels for pesticides and veterinary medicines. The reform provides a pathway enabling priority minor uses to be initially registered through a supplemental label, as opposed to issuing a permit. Uses on the supplemental label will transfer to a permanent label following the provision and assessment of any confirmatory data, if and where required.

Improvements and efficiencies will be realised through tying the original consideration for approval to a permanent regulatory outcome, streamlining existing procedures. The reform will replace the need for growers to hold and renew permits and avoid the APVMA needing to undertake the resource intensive permit to label transfer processes. Importantly, it is the alignment of assessing grower needs for permits with those of product registration that affords the greater regulatory efficiency.

The Panel considers this reform will:

- expedite product label registration for minor uses
- facilitate desirable partnership efforts between growers and the chemical sector to pursue label registration
- facilitate bundling multiple minor uses into a single registration application, versus individual permit requests from growers and assessment by APVMA
- incentivise label expansion by the chemical sector including through maximising the use of international data in support of minor uses
- reduce a large and at times sole reliance on permits by growers
- reduce burden on growers and APVMA in processing permit renewals
- provide APVMA with efficiencies to its operations by having those uses registered
- negate the need for separate ad hoc and resource intensive processes to transfer permit uses to label
- be facilitated through smart labelling as also recommended by the Panel
- operate within the established APVMA approaches for risk assessment and risk management.

This reform was not presented as part of the Panel's Draft Report. However, it aligns with suggestions for improving access made by a number of stakeholders in response to the Panel's Draft Report. It also responds to many stakeholders that stated, in written submissions and consultations directly with the Panel, there should have been more consideration of enabling improved access through reforms to the existing registration process.

Delivering priority uses

The Panel considers that the option to place a use on a supplemental label should be provided for the pest, disease, and animal health needs identified as priorities by producers and veterinarians.

Priority needs will be established by requiring the use to be one that has been identified by users. The Improved Access to Agvet Chemicals Initiative, which the Panel is pleased has been extended by the Australian Government, establishes a list of priority needs. The Panel considers this, or an expanded version, could act as the basis for priority needs for supplemental label approval. By linking the needs of Australian users to the supplemental label process it will facilitate desirable and positive partnership efforts between growers, veterinarians and, other users with the chemical sector to pursue registration of identified priority needs. Such collaboration is consistent with contemporary best practice in regulation.

Supplemental label approvals

Registration applications could be sought by either an applicant or by a user group (with support of the registrant). If the APVMA determines that further confirmatory data is necessary, it may approve a priority need (use) via a supplemental label. The APVMA will identify the information necessary to confirm or refine the original decision as a condition of the supplemental label approval. The supplemental label will be approved for a fixed time only. A workplan will be a required condition to ensure delivery of the required information before expiration of the supplemental label. Transfer to the main label will be enabled by providing the further confirmatory data in a subsequent application to the APVMA.

Supplemental labels will not form part of the primary approved label attached to the product container. A supplemental label will contain instructions for use and any conditions specific for that use. The supplemental label will also need to reference the primary approved label where other information relevant to all approved uses exist, similar to permits.

This reform is supported by the Panel's labelling standard reforms and recommendations to increase the use of smart labels. Supplemental labels will be accessible through existing measures such as the APVMA website, the registrant and, in future, using smart label content on the product's primary approved label.

Enabling conservative access

The need for confirmatory data means that supplemental labels should take a conservative approach to approving use patterns, MRLs, etc. The Panel sees the APVMA's existing permit process as a guide for how to safely provide enhanced access to safe and effective products for growers of minor uses where no or limited options exist.

The APVMA in assessing user requested minor uses for approval under permit currently applies a sound approach to risk assessment and management, utilising existing and internationally registered uses, data and, extrapolation. The APVMA may also require data to accompany an application for permit renewal that confirms or refines the instructions in the original permit and movement of MRLs from a temporary to permanent standing.

The Panel in this Chapter has recommended reforms to the permit criteria to reflect and strengthen the application of practical risk management already undertaken by the APVMA. The Panel now recommends this also be applied to product registration of priority uses through supplemental labels.

Regulatory safeguards

The Panel emphasises that this reform will not increase risks as it will mirror the current risk assessment and management principles already being managed and approved under permit for minor uses by the APVMA. This will include that requirements for additional data under a supplementary label will only apply for the purposes of confirming or refining the original decision. This approach is consistent with that applied by the APVMA to minor uses approved under permit.

Supplemental labels and their uses will be subject to the same suspension or cancellation provisions as currently provided in legislation for registered products, approved labels and permits.

41. Recommendation

The Panel recommends the APVMA be empowered to approve a priority need (use) via a supplemental label if it determines that further confirmatory data is necessary. Uses on the supplemental label will transfer to a permanent label following the provision and assessment of any confirmatory data, if and where required.

- **Supplemental labels will not form part of the primary approved label attached to the product container, and will be approved for a fixed time only.**
- **The option to place a use on a supplemental label should be provided only for the priority pest, disease, and animal health needs identified by producers and veterinarians.**
- **The APVMA will identify the information necessary to confirm or refine the original decision as a condition of the supplemental label approval.**
- **A workplan will be a required condition to ensure delivery of the required information before expiration of the supplemental label.**

Cost of reform

The Panel has considered the effort and costs in seeking a supplemental label is the same as that currently expended in terms of permits for the APVMA and applicants. To that extent transferring the point of assessment from a permit to a label will not significantly change the regulatory costs experienced across the system. The Panel considers this reform to be cost neutral.

The Panel notes that the regulatory costs of the APVMA associated with a permit are subsidised through the levy (and effectively drawn from all participants in the regulatory system) while the regulatory costs of the APVMA associated with a label are more directed to a single applicant.

5.5 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 5.3). 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.

In addition to emergency situations, there are certain pesticides and veterinary medicines that have highly desirable attributes and evident national benefits, 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 such as 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)

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. Indeed, many other traditional regulators in Australia use similar, long-established queuing practices.

However, for certain 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, users of veterinary medicines, and the environment. The Panel sees an opportunity to update the culture and practices of the pesticides and veterinary medicines regulatory system by implementing a more agile and responsive work prioritisation system driven by national needs. This would be consistent with the Government's own intentions to drive cultural change and responsiveness in government regulatory practice.

For this reason, the Panel's view is that where tangible benefits can be demonstrated, there should be an opportunity for such applications to be prioritised by the APVMA.

What change is recommended?

For pesticides and veterinary medicines that meet prescribed criteria, the Panel recommends 'fast tracking' their application for registration. Applications would proceed to assessment sooner; but there would be no reduction in the quality and depth of assessments. This will provide more timely access for users where there is a demonstrable justification 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 otherwise have been 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). There should therefore be no undue delay to 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 each year over others when these applications would significantly benefit agricultural and veterinary practices, human and animal health, and environmental outcomes.

A set of criteria to guide prioritisation will need to be established in consultation with stakeholders. However, at this stage, 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 to support access for growers of closely related crops
- 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)
- a new product that offers significantly reduced environmental risks or increased environmental benefits
- controlling a pest or weed of national significance (including addressing emergence of exotic pests or diseases)
- a product that would significantly strengthen the resilience of Australia's supply chains.

To allow flexibility and responsiveness to industry and community priorities, the criteria for prioritisation should be drafted by the Department, and determined by the Minister (or their delegate) (see Chapter 2). The new arrangements 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. These would be clearly and transparently communicated and could be prescribed in a legislative instrument.

42. 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, reduced environmental risks, increased environmental benefits, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.**
- **criteria for prioritisation be drafted by the Department of Agriculture, Water and the Environment, and determined by the Minister.**

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 will result in reduced 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.

5.6 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 among state and territory jurisdictions. These include the crop or animal species to which the pesticides and veterinary medicines can be applied, the pests treated, and application rates for the product. This causes 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 borders.

Through the consultation process, many stakeholders advised the Panel that state and territory boundaries represented an arbitrary distinction that are unlikely to be suitable for assessing geographic differences in the risks of pesticide use. This view was supported by the National Farmers' Federation (NFF), CropLife Australia, Syngenta Australia, and Cotton Australia.

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, consistent 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 will 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, simplifies cross-border businesses, improves economic efficiency, and enables greater and more equitable access for users.

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 regulatory purposes.

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 will continue to be able to use its discretion to tailor use patterns among regions other than climatic regions, where this would be a better match with the risks being managed.

43. 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**
- **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 align with climatic regions.**

Determining climatic regions and targeted controls

The Panel's proposed 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.

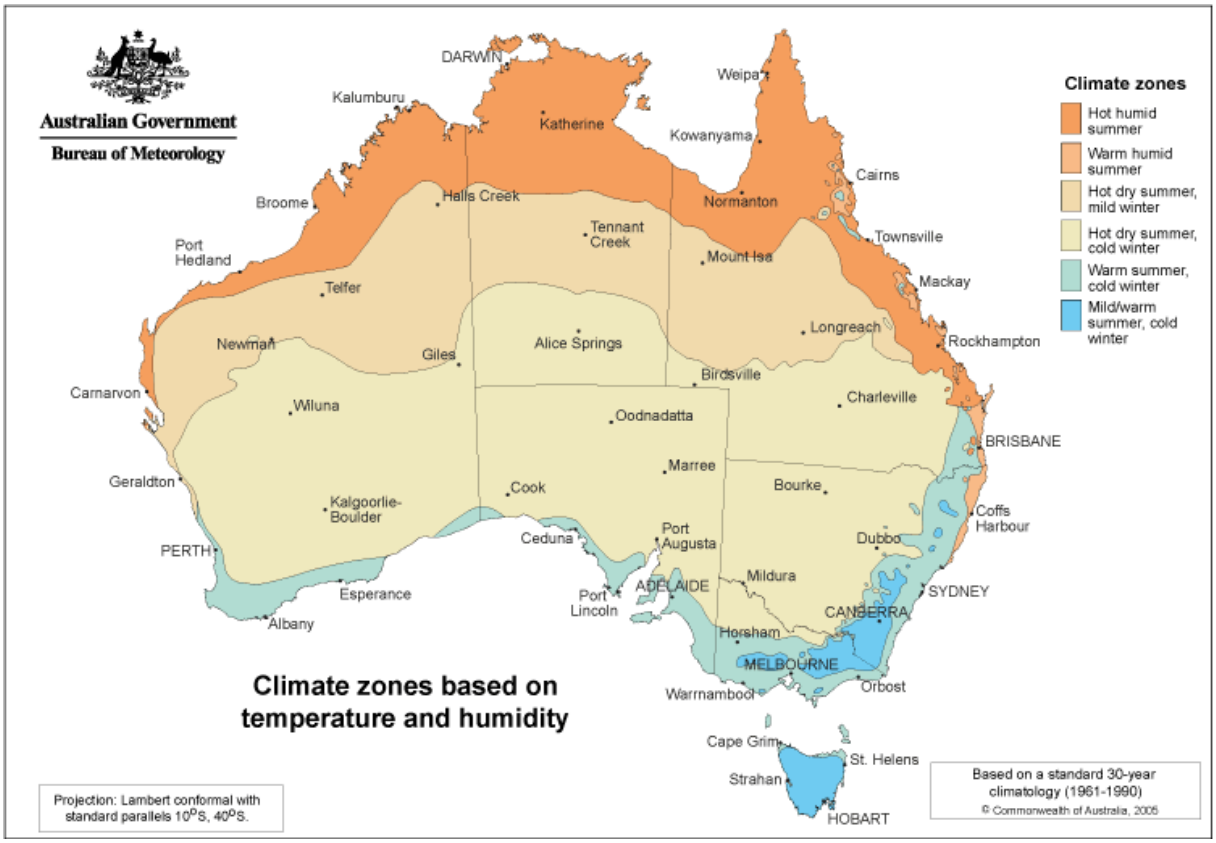
While climatic zones can be easily defined based on recent conditions (for example, Figure 8), climate changes could mean that the boundaries for these zones 'move' over time. To manage this, climatic zones may need to be defined and managed in a way that allows their boundaries to adjust over time.

The APVMA will 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 choose to vary use patterns 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) will enhance the ability to convey information about appropriate use patterns in different climatic zones, or other regions. Online maps will be able to provide detailed information on regional boundaries and relevant instructions, providing clarity to producers on their regional pesticides and veterinary medicines use obligations.

Figure 8 Australian climate zones based on temperature and humidity



Source: Bureau of Meteorology 2006

Correspondence between Australian and international climatic zones

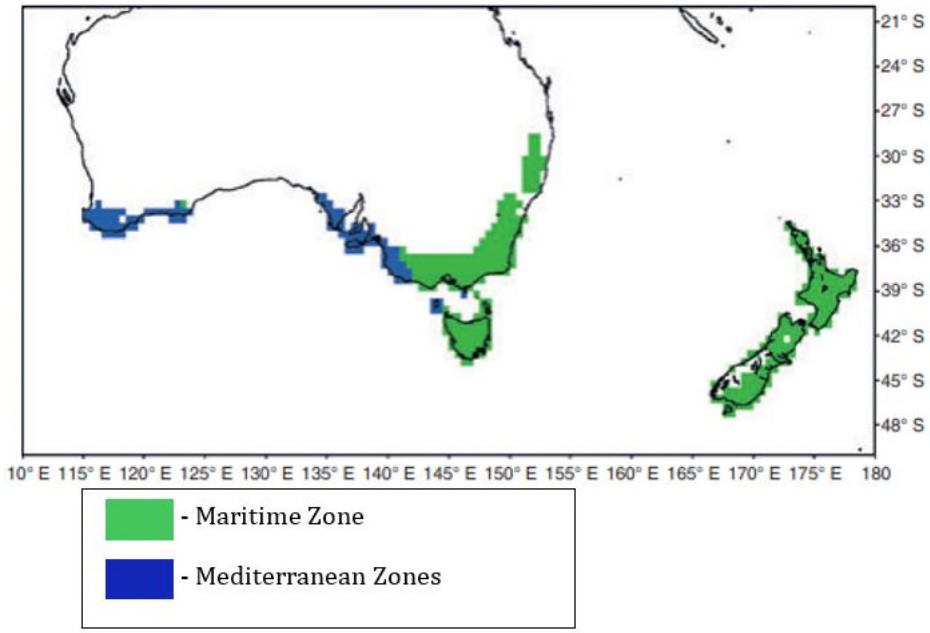
Where products registered by an equivalent international regulator are to be accepted for licence in Australia, the Department may ask licence holders to address any relevant unique Australian conditions. Identifying climatic zones used in Australia which correspond to those used by equivalent international regulators could facilitate the use of international data to address Australian conditions relating to climate, promoting improved and equitable access to overseas registered pesticides and veterinary medicines.

That climatic zones in different parts of the world can correspond 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 (European and Mediterranean Plant Protection Organisation (EPPO) 2014). Using this methodology EPPO's European maritime and Mediterranean climatic zones (Figure 9) were demonstrated to be comparable to Australian regions (Figure 10) (European and Mediterranean Plant Protection Organisation (EPPO) 2010).

Figure 9 EPPO European climate zones

Source: European and Mediterranean Plant Protection Organisation (EPPO) 2014

Figure 10 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 will provide further regulatory simplification for users.

This reform 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 transition period of 5 years. The Panel envisages that where a jurisdiction-specific use pattern is removed from a label, a holder will be required to inform the APVMA via notification, rather than submitting a full application.

Cost of reform

Removing the need to stipulate individual states and territories for certain uses on labels is expected to have minimal cost impact to 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.

5.7 Biologically-based pest and disease management products

Biologically-based products, although not used as widely as chemically 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 of the far-reaching opportunities of biologically based products in the decades ahead.

> "*Top international companies directed their R&D spending mostly towards pharmaceutical (65%) and biological (26%) products.*" (Animal Medicines Australia 2020)

The evidence from use of biotechnology in cotton shows the potential for significant contributions to sustainability, integrated pest management and resistance management outcomes. The improved insecticide and herbicide practices resulting from the deployment of GM cotton have resulted in a 50% reduction in residual herbicides (Constable, 2011) and a 97% decrease in insecticide use since 1992 (Cotton Australia, 2021). Crops are now typically subject to no more than 0 to 3 insecticide treatments per crop. Previously there were typically 10 to 14 treatments per season. These changes in pesticide practice as well as changes in pesticide registrations have been reflected by substantial reductions in pesticides found in river systems in cotton growing areas (Mawhinney, 2011), as well as increased populations of beneficial insects and wildlife in cotton fields, improved farm worker and neighbour safety, a decrease in

labour and fuel usage, and improved soil quality, reduced risks and a further opportunities to grow cotton in areas of high pest infestation (Cotton Australia, 2021).

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 biological-based businesses in meeting the demands of users and the expectations of the community, especially as the proportion of such products increases in the future.

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 of gene technology regulation
- 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 process requirements (which have largely been designed for chemical-based products)
- 'ill-fitting' application types and assessment expertise within regulators, including the APVMA.

What change is recommended?

Biologically-based products are different from 'conventional' chemically-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 pesticides.

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 future needs. A technology agnostic regulatory system is more flexible than multiple customised 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.

A technology agnostic system also emphasises the need for outcomes-based regulation to accommodate the differences between chemical-based and biological-based products.

The Panel is recommending a regulatory reform transformation process that will progressively improve the regulation of pesticide and veterinary medicine products over the years to come. The Panel is confident these reforms will deliver practical benefit to biologically-based products. Tailored regulatory processes will provide multiple opportunities for improving access to biologically-based products.

Specifically, some of the reforms recommended elsewhere in this report that will assist biologically based products include:

- enhancing access to overseas biologically-based products through a licensing model for improved access to internationally registered products that can act as a tailored pathway for addressing the unique aspects of microbial and non-conventional products (see Section 5.2)
- removing certain pre-market assessments by the APVMA to allow pesticide, and veterinary medicine manufacturers to more readily supply biologically based products that meet the expectations of their customers (see Section 4.1)
- excluding insect pheromones and other 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 (see Section 5.1)
- 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 (see Section 1.5)
- reducing cases where a product is subject to separate and duplicative regulatory systems, such as pesticides and veterinary medicines and gene technology; only one system should have primary regulatory responsibility, as described in the revised regulatory scope (see Sections 1.1 and 5.1)
- introducing streamlined permit arrangements for research entities, including biological based research entities in Australia (see Section 5.3).

The Panel is aware of the ongoing efforts of the Department to improve the incorporation of an entity's quality assurance (QA) systems into the decision for import consents in the *Biosecurity Act 2015*. The Panel commends the Department on its efforts.

The Panel is also aware that the *Biosecurity Act 2015* requires the Department to assess biosecurity risks from importing biological material independently from other post-entry regulatory systems. Conditions for 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.

The Panel considers a system performance measure that, over time, tracks the prominence of biologically-based products within the regulatory system will act as a useful measure of the system's responsiveness to these types of products (see Chapter 2).

44. Recommendation

The Panel recommends amendments to the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* to expand alternative conditions for imports of biological pesticides and veterinary medicines. The Panel also recommends the overall pesticides and veterinary medicines regulatory system performance indicators include measuring biologically-based products by quantifying their number and growth over time.

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 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.

5.8 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. The Panel saw it as a way to avoid decisions by regulators which appeared counterintuitive and bureaucratic because obvious benefits could not, by law, be taken into account in the regulator's decision.

There was mixed support for such an approach. 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 use 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.

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.

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 now recommending arrangements to allow for consideration of benefits but only 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.

Box 8 Overriding environmental benefits case study

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 certain, but not extensive, 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 (certain 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.

If the off-target effects on native species were extensive and unmanageable, then the application would be refused, irrespective of the benefits.

The consideration of human, animal, and ecosystems health and safety is paramount, and it is not the Panel's intention that considering benefits prior to refusal of an application would allow a product to be registered if its risks were unmanageable. 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 be amended to provide 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 a 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 the welfare of the target animal of a veterinary medicine. 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 a 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 a limited number of scavenger species. For example, during mouse plagues, scavengers may be affected. Ordinarily, these short-term off-target impacts may prevent the mouse control 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 supply industries.

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

45. Recommendation
The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product when proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

5.9 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 has long been to find 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 its 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 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 situations that will arise under the new scheme.

Length of protection 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 protection 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 2020)

The Panel sees no justification for different protection periods and recommends 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 a chemical review). The Panel is keen to introduce a consistent set of data protection arrangements, including 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 one that 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 intends 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 that the current mechanism requiring the APVMA to arbitrate data access and compensation agreements between parties with similar products and uses that are under review be discontinued. The Panel considers that the negotiation of data access and compensation is a matter to be negotiated between companies and should not form part of the new pesticides and veterinary medicines regulatory system. The APVMA should be free to concentrate on its core business.

Data protection for minor use and emergency permits

Some stakeholders have argued for data protection for information in minor use and emergency use applications. Providing data protection will distort incentives to use the permit pathway in place of registration, undermining the policy intent of both the registration, and permits 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 permit 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 recommendations will do more to support improved minor use access.

Data protection for research permits

The Panel proposes to provide 5 years data protection for information provided in support of a research permit. 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 recommendation to allow supply under licence 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 solely on the basis of similarity to a product supplied under licence, as the APVMA will not hold any of the relevant information for the licensed product. However, as outlined in Section 5.2, the Panel considers that the APVMA could rely on a history of safe use under licence when considering the registration of a product similar to a licensed product. The reliance within the licence conditions of the international registration holder consenting to the supply of the product addresses many of the IP protection issues posed by stakeholders in response to the international access model. The Panel recommends that the Department 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 (see Chapter 6).

46. 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 without needlessly impeding flow-on innovation, competition, and access to alternative chemical products.

- **Equivalent protection periods should be provided for pesticides and veterinary medicines.**
  - **10 years for registration of a new product with a new active constituent or approval of 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, issue a research permit, provided in support of a chemical review, or where information contradicts information in the Record or Register.**
- **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 further extended as an incentive to bringing priority uses to Australia, as per 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.**
- **These limitation periods should not prevent the regulator using information where there is a public interest reason to do so.**

47. 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 matter to negotiate between companies.

5.10 International alignment of veterinary manufacturing standards

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). PIC/S is the standard applied by 53 authorities globally, including in Europe, Africa, America, and Asia.

In order to export Australian-made veterinary medicines to most key Australian overseas 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 significant 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).

In its Draft Report, the Panel recommended that the APVMA become PIC/S accredited and that veterinary medicine manufacturers transition from cGMP to PIC/S accreditation over a 5-year period.

In forming its draft recommendations, the Panel accepted stakeholder views of the high costs of TGA audits and long assessment wait times. The TGA is considered by many veterinary manufacturers to prioritise audits of human therapeutic manufacturing sites above veterinary medicine manufacturers.

The Panel recognised that other, less tangible benefits may also arise from a transition from cGMP to PIC/S. For example, moving to a system of direct government audit for domestic manufacturers of veterinary medicines could enhance public and market confidence in the standards met by domestic veterinary medicine manufacturers. PIC/S standards would facilitate Australian exports and the integration of Australian manufacturers into global supply chains. The Panel's draft recommendations also sought to ensure Australia would have an effective voice and influence in future international discussions on veterinary manufacturing standards.

However, in response to the Draft Report, many stakeholders including peak veterinary medicines industry bodies and veterinary manufacturers raised reasonable concerns with the Panel's proposal to transition to PIC/S, including the high cost of meeting audits and changes to manufacturing facilities and processes required to become PIC/S accredited. Smaller domestic manufacturers highlighted that updating manufacturing sites to meet PIC/S requirements would be so prohibitively expensive that in some cases, it could lead to domestic manufacturing sites closing, further increasing reliance on overseas manufactured veterinary medicine products. The Panel views this as an undesirable outcome, especially considering the small number of

companies that manufacture veterinary medicines domestically, and the even smaller number of companies currently seeking to export to markets requiring PIC/S accreditation.

Taking this feedback into account, the Panel has concluded that there are other ways to support Australian veterinary medicine exporters, without introducing PIC/S certification as a mandatory requirement for all manufacturers of veterinary medicines. One such way would be to pursue the recognition of the Australian cGMP with our key trading partners, such as the EU.

The Panel is therefore no longer recommending that the APVMA become PIC/S accredited or that veterinary medicine manufacturers transition to PIC/S over a 5-year period.

The Panel supports the current plans of the APVMA to improve the Australian cGMP and encourages APVMA to complete its current review of GMP standards in a timely manner. The Panel considers that the Commissioner's first biennial report track progress in this work.

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 vehicle manufacturing 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. For Australia, supplies of a vast range of imported products have been significantly delayed, and importantly for this review, supply of some pesticides dropped to critical levels and for some time, farming groups were seriously concerned about the impacts on product availability. 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 Panel considers it important that as the regulatory system is transformed over the years to come, opportunities to advance resilience are identified and implemented.

The Panel considered the feasibility of mitigating the risks associated with disruption of chemical supply chains by means of 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 a credible stockpiling system in Australia was impractical. Imports currently account for 52% of the Australian market for pesticides and will likely satisfy 11% of the demand for veterinary medicines in 2020-21 (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 depth into our national capacity, and supporting continuity of supply during periods of disruption.

The Panel recognises and applauds the flexible approaches that the APVMA employed to meet the supply challenges experienced in the COVID-19 pandemic. These included providing for

different formulations which proved 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.

The Panel sees opportunities to improve Australia's supply chain resilience by streamlining the approval of active constituents in pesticides and veterinary medicines by the APVMA, and by building assessment capacity beyond the APVMA. These changes will reduce unnecessary bureaucracy and regulation in the supply chain and open the door for more providers to deliver key chemical assessment services, leading to a more resilient supply chain.

The Panel has also developed a proposal for an additional licensing approach to access that takes advantage of comparable international registration processes to facilitate access to products and uses that would otherwise not be available in Australia via the registration pathway. This additional pathway would not be a 'short cut' process, but in fact would utilise extensive and robust data in concert with considering unique Australian conditions, to ensure products and uses available through this supplementary approach are as safe (if not safer) for people, animals, and ecosystems as the registration pathway (see Chapter 5).

Additionally, the Panel sees opportunities to better support speedier 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 by making assessments quicker. A larger pool of assessors will make it possible to assemble high quality applications more efficiently (i.e., permit, licence, registration) to meet the demands of the supply chain and reduce time to market.

6.1 Sourcing active constituents

The current regulatory system requires that in addition to each product being registered, all sites of active constituent manufacture to be used in a registered product must also be separately approved.

For pesticides and veterinary medicines, the current regulatory system effectively requires 3 approvals for each registered product:

1) the product must be registered
2) the active constituent within the product must be approved
3) the manufacturing sites of the active constituent and the product must be approved.

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 opens to generic products, different manufacturers and registrants may use the same active constituent suppliers, which can result in multiple applications, assessments, and approvals for the same

active constituent from the same site of manufacture. This is clearly duplicative and inefficient for both applicants and the APVMA.

Modern global supply arrangements are flexible and 'just in time' production and diversification of supply sources are common business practices. The current legislative requirements are outdated and reflects the past when manufacturers often produced the active constituent and the product at the same site. 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 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 quality active constituent manufacture.

The approval of active constituents at a 'substance level' would remove the requirement for each source to be approved and will allow for sourcing of active constituents from any site of manufacture globally, provided the site can meet the approved and published standard. This approach will avoid unnecessary bureaucracy and regulation that results in multiple approvals for the same active constituent, especially from the same site of manufacture. It will also improve the resilience of chemical supply in the face of potential disruptions and increase competition by encouraging a more diverse range of sources of active constituents.

A reliance on a standard rather than specific consideration of a site of active constituent manufacture is currently provided for within the Agvet Code but has only been used infrequently by the APVMA, which suggests a reluctance to depart from existing practices. However, this practise is commonly used internationally. The most frequent international use of standards for active constituents is for veterinary medicines, where pharmacopeia are routinely utilised as the source of standards.

When approving an active constituent at the substance level, the APVMA would establish a minimum compositional standard including permitted (and if necessary, prohibited) impurities and their permitted levels. 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 from any source could then be used in a registered product, provided the active constituent complied with the standard, 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 pharmacopeial 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.

If an applicant or registration holder wishes 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, it would be possible to apply to the APVMA for a new or amended standard, provided safety and quality standards can be maintained. A data protection period for new active constituents would prevent the unauthorised use of a standard for a new active constituent while the data protection period was in force.

In response to this proposal in the Draft Report, some stakeholders raised concerns that substance level approvals potentially reduce traceability of active constituent sources in cases of recalls and could lead to increased presence of non-compliant active constituents in the Australian market.

The Panel considered these issues when making its original recommendations for substance level approval of active constituents.

Under the existing regulatory system, the quality of the active constituents is assessed at the time of the approval of the site manufacture, and evidence that an approved source of active constituent is being used in the product is required at the time of product registration.

Product registrants are required, as a condition of registration, to keep records of the site of manufacture of the active constituent, batch analysis results that demonstrate that each batch of active constituent used in a product complies with the standard for the active constituent, and the batch number of the active constituent used in each batch of product.

The Panel considers that it is important that these obligations on registrants continue to apply, consistent with the Panel's preference to adopt a co-regulatory approach using general product obligations (see Chapter 4).

Registrants would also be subject to any post-market activities the APVMA considers necessary such as audit of records and testing of products to ensure those products supplied met all conditions of registration including that products only contained active constituents that met published standards.

The Panel considers that these measures will continue to support traceability, allow the APVMA to monitor product quality, and take proportionate compliance action, including timely responses to adverse experience events, where necessary to be assured of the quality of active constituents used in pesticides and veterinary medicines to protect safety, animal welfare and trade.

48. Recommendation

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture. The APVMA should:

- **establish a standard for each active constituent prior to its inclusion in products**
- **ensure due regard is given to matters of commercial confidentiality and intellectual property protection in development of these standards**
- **apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard including in products.**

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 (or $40 million over 10 years) by removing the need for data generation, application fees, and delay costs.

Reliance on established and agreed standards for active constituents will support the APVMA's current level of rigour while allowing an anticipated saving to industry.

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

6.2 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). This results in the APVMA having total control over the level and timeliness of service provided. While the Panel heard from stakeholders about the diligence and professionalism of the APVMA's staff in providing assessment services, the Panel considers that this dominant position neither incentivises efficiency nor encourages innovation by the APVMA. In addition, there are 'key person 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 and assessment is needed. Public confidence in the regulatory system as a whole will be enhanced when authoritative and trusted expertise can be sourced both inside and outside the principal regulator. Universities, other research organisations, and experienced individuals can play a role in Australia, as they do in other countries such as in New Zealand.

The centralisation of suitable assessment skills and resources has resulted in Australia's limited chemical data assessment skill-base being largely 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 as well as impacting process efficiency.

The Panel's proposal to extend the network of assessors beyond the APVMA was generally supported by stakeholders. Stakeholders that were in support of an Australian third-party accredited assessor scheme include Accord, Aerial Application Association of Australia, the Australian Veterinary Association, Ceva Animal Health, CropLife Australia, Grain Producers

Australia, Syngenta Australia, Redcap Solutions, the RSPCA and the Veterinary Manufacturers and Distributors Association.

However, some stakeholders including Growcom, GeneEthics and Animal Medicines Australia had reservations about the private sector performing assessment work, the burden on the APVMA to establish the scheme, and perceived conflict of interest of fee for service assessors to undermine the independence and integrity of the regulatory system.

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 and deepen 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.

Such a system 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 and at less cost. 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 but are sometimes outsourced to external assessors engaged by that agency).

The Panel's 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 a whole.

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 needed 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 to $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 – the Panel's proposal does not change this responsibility or accountability. 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.

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.

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 as the regulatory transformation process proceeds following the Panel's report. 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 example, 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 (see 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 considers the scheme should be implemented within 18 months of the passage of legislation and that the APVMA Board report to the Minister on progress after 12 months. The Panel would also expect that the Commissioner's biennial assessments will also report on progress.

The Panel anticipates 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 and permits) 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.

49. Recommendation

The Panel recommends the establishment, within 18 months, of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA. The model for this scheme should 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 and regulating the supply of products. The extension 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 recouped from industry (with some exceptions such as applicator licensing). This has constrained the resources available to effectively undertake these regulatory functions.

The Panel's proposal to expand opportunities for co-regulation arrangements over the years to come will reduce costs to both the regulator and users. For example, greater reliance on suitably rigorous industry quality assurance schemes will assist with compliance, general product obligations will provide industry with more flexibility to design their own means to achieve the necessary regulatory outcomes, and smart labelling will, as it rolls out, allow for automated records in spray diaries. Nevertheless, the costs associated with control-of-use activities and functions in the future will need to be resourced adequately to ensure continued sustainability and enhanced safety and integrity of the modernised regulatory system.

Some of the reforms proposed by the Panel, such as introducing licences to source internationally registered products and uses, will significantly reduce the costs of bringing new products into the Australian market. On the other hand, improvements in whole-of-system surveillance will need to be funded as they comprise 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 has been because of strongly competing stakeholder views about the preferred cost recovery model.

An important finding by the Panel is that the APVMA's cost recovery arrangements, as currently structured, are simply not sustainable. Since 2013, the Authority has run operating losses averaging $2.5 million annually which has led to the drawing down of its reserves.

The Panel considers this first fundamental 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 a transformative reform package for the whole future regulatory system is to be implemented successfully over the years ahead.

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 costs of delivering that activity.

- Fees should be charged where the 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 of 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 policy objective 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 industry 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 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 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 depart from the principle of full cost recovery 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 continue to be typically introduced by large multinational companies. Fee discounts are less important for these large innovators as they are well placed to meet initial registration costs and can defray the cost of new product development across multiple markets.

Nevertheless, it is true that smaller innovators are active in the Australian market 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 over the Panel's transformation timeframe as advances in technology become more generally available, the focus

on biological products increases, and as regulatory barriers to market entry are steadily 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, 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 – which include 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 the 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 because of extensive and uneven cross-subsidisation among chemical suppliers
- are unsustainable as the APVMA has regularly run at a loss and may, in the future, exhaust any further options to remain financially viable
- do not enable the adequate allocation of sufficient resources needed for monitoring, compliance, and enforcement.

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 does not always increase with sales value. For example, products with higher volume of 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. Additionally, 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 the argument for progressive personal income tax.

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.

Despite submissions from certain stakeholders, it is the view of the Panel that there is insufficient justification for taxpayer funding of these functions. Most functions argued to be 'public good' are in fact needed because of the existence and operation of the pesticides and veterinary medicines industry and therefore costs should be recovered from the industry itself.

Control-of-use cost considerations

There is little publicly available information about current arrangements for funding 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 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 agrees with stakeholder views 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 other regulatory activities deemed to be of greater priority. As such resources decrease, risks to the integrity of the whole system increase.

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. There is no single 'silver bullet' solution. A range of funding mechanisms will 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 associated with supply and subsequent compliance and enforcement of pesticides and veterinary medicines distort the market, skew decision-making, are inequitable, and are not consistent with the general principle that individuals or groups should be charged for the regulatory activities their businesses generate.

The way 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 – these circumstances 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 made, the Panel has determined it can only establish high-level, principles-based recommendations about how to fund various components of the system. Then as the regulatory reform transformation process is implemented over the next few years, the regulatory costs can be more accurately assigned.

The following describes the features of the Panel's preferred cost recovery model.

Cost recovery model

The Panel considers that in most circumstances, the pesticides and veterinary medicines industry should bear the full and reasonable costs of the functions under the new regulatory system.

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 attributable to the demands of individuals or organisations. Some activities, such as assessment of minor use permits, should be recovered by a subsidised fee, supplemented by a component of the sales levy to ensure continued access to

minor uses, as full cost recovery would be a significant disincentive for seeking a permit, and likely promote unlawful use of products.

The Panel considers that 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 reports and investigation, and emergency permits, and general compliance and enforcement of supply of pesticides and veterinary medicines. Such activities are generalised, and not easy to attribute to individuals.

The Panel considers activities undertaken by the Department of Agriculture, Water and the Environment (the Department), such as policy development, and support to government should continue to be publicly funded, and activities undertaken by the Commissioner including operating consultation forums, and overall system surveillance and monitoring should also be publicly funded. Additionally, the Panel considers that the initial establishment costs for functions such as the third-party accredited assessor scheme and the licensing of internationally registered products scheme should be publicly funded to ensure they are successfully introduced into the future regulatory system in the early stages of the regulatory transformation process.

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 a permit; 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 address 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.

Under the Panel's proposed scheme, 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 or expensive to administer. Each component of the levy will only be charged to those that receive the respective 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 would 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.

The Panel proposes that levy notices include a detailed breakdown of levy components to improve transparency and drive regulatory efficiency.

50. Recommendation

The Panel recommends changes to the existing levy on product sales including:

- **that the levy be continued but at a reduced rate with each component of the levy being charged only to those that receive the corresponding service**
- **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 system relate to assessments of one type or another, for example, assessing applications for product registration, licences for various activities, permits, and third-party accreditations. Audit services provided by the Government are the other major category of services that would attract a fee (such as audits of manufacturing sites of veterinary medicines). Most others, such as issuing import or export certificates and record searches, are relatively minor activities.

As these activities are readily 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 could 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 (see 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 high quality applications since assessment of these applications should be more efficient. 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 a completed application is lodged.

The experience in New Zealand, where hourly charging has been successfully in place for many years (along with an external assessor program), appears to have been positive. The Panel considers that this should also be the case in Australia.

Some stakeholders expressed concerns that the open-ended nature of this charging arrangement would provide little incentive for the regulator to complete assessments within minimum timelines and may in fact turn efficient assessments into a revenue raising initiative. The Panel continues to hold 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.

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 conducive to improved planning by both the applicant and the regulator.

The Panel considered that initial application fees could present a barrier to smaller, innovative companies, and thus suggested in the Draft Report mechanisms such as payment plans, allowing more significant fees to be paid overtime. Stakeholder views on this proposal in the Draft Report indicated there was little support for payment plans and the proposal was largely seen as an administrative burden on the APVMA. For these reasons, the Panel has decided not to pursue this suggestion.

Elsewhere in this report, the Panel is recommending various licensing schemes, 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.

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. However as noted, the Panel considers that the initial establishment cost of the accredited assessor scheme should be met from appropriation in the early years of the regulatory transformation process.

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 for applicants, 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, rather 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. This will discourage the excessive reliance shown by some applicants on the regulator.

51. Recommendation

The Panel recommends changes to assessment charging structures including:

- **the introduction of hourly charging for highly variable regulatory activities and flat rates for activities with little variation**
- **that the costs for registration applications be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis**
- **the assessment of applications for accreditation, together with the costs to maintain this accreditation, be 100% recovered from the accredited parties**
- **that the 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'.**

52. Recommendation

The Panel recommends 100% cost recovery for issuing and maintaining licences via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

53. Recommendation

The Panel recommends that where Government audits are routine and predictable the costs of this service 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

Minor and emergency uses

As set out in Chapter 5, the Panel recommends that permits 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. The Panel sees merit in these arguments.

Reasonable arguments exist for supporting access to minor and emergency use permits at a reduced cost where no suitable authorised product for that use is available. This is particularly the case given the importance of many 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 permit will be easily identifiable, the beneficiaries of the service often will not. This is because many of these permits 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 permit applications should not be recovered through a fee
- assessment costs for minor use permit applications should attract a discounted application fee.

While the costs of some of these activities have a public good element (such as permits that deal with biosecurity incursions), the Panel expects that most minor and emergency use permits 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).

54. Recommendation

The Panel recommends changes to the APVMA's permit charging structure including:

- **maintaining a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines**
- **minor use permit applications should attract a discounted application fee with the balance of costs recovered via the levy on product sales payable by the holder**
- **emergency use permit applications should be fully recovered as a component of the levy.**

Chemical reviews and APVMA compliance and enforcement

Chemical reviews and general compliance and enforcement for supply 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.

55. Recommendation

The Panel recommends that the costs of chemical reviews and APVMA compliance and enforcement activities 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, subject to successful negotiations with the states and territories, compliance and enforcement for control-of-use continue to be the responsibility of states and territories at the completion of the regulatory transformation process. The Panel agrees with stakeholders that this function is currently under-resourced.

The chemical industry is a significant, if not the, primary beneficiary of the regulatory control-of-use functions. This is because a robust control-of-use system allows the pesticides and veterinary medicines industry to market and supply its products. Public confidence and social licence are maintained. In addition, a nationally 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.

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.

The Panel recommended in its Draft Report that general compliance and enforcement for control-of-use was 100% cost recovered. However, given the Panel's proposal for a state and territory-based delivery model for these functions, supported by Commonwealth funding (see Chapter 2), a departure from the principles of the Australian Government Charging Framework is warranted. This will better ensure that control-of-use regulatory functions are delivered effectively on the ground and are appropriately resourced,

The Panel considers that in order to ensure a consistent and functional level of resources, state and territories should continue to fund control-of-use compliance and enforcement under their existing (appropriation based) funding arrangements, and that subject to states and territories maintaining these levels, additional Commonwealth appropriation would be provided to support the states and territories in their delivery of control-of-use compliance and enforcement functions under single national law.

The Panel considers that the quantum of the additional Commonwealth Government commitment should be $5 million per annum to support increased compliance and enforcement activities. This contribution combined with a reduction in levies and an increase on reliance of existing QA schemes will avoid cost increases being passed on to industry.

56. Recommendation

The Panel recommends that the cost of general control-of-use compliance and enforcement activities should continue to be funded by states and territories under their current finding arrangements. However, wherever possible or, where the beneficiary is clearly identifiable, such as a licensed operator, a fee-for-service approach would be used. The Panel also recommends an additional Commonwealth Government contribution of $5 million per annum to support the increase in post market compliance and enforcement activities.

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. 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.

57. Recommendation

The Panel recommends public funding for the costs of:

- **data mining and analysis for system surveillance and monitoring**
- **environmental monitoring**
- **domestic produce monitoring.**

The Commissioner

The Panel has recommended that the Commissioner perform a small number of functions in the pesticides and veterinary medicines regulatory system, (see Chapter 2). Most of the Commissioner's costs will arise from system surveillance and monitoring responsibilities and will be appropriation funded. The Commissioner's vital role in assessing and reporting on progress in the overall reform transformation process is a mainstream function of government and should therefore also be appropriation funded.

As described in Chapter 2 the Department will retain policy development and advisory responsibilities. As is currently the case, these functions, and the Department's role in representing the Australian Government at international meetings (on policy) should continue to be funded through appropriations from Government. 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.

58. Recommendation

The Panel recommends that the activities of the Commissioner such as reporting on progress in the transformation process, system surveillance and monitoring, and the cost of stakeholder consultation should be Government funded.

8 List of recommendations

Chapter 1 – Introduction

A new vision, objectives and principles for the future regulatory system

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 the responsible and safe use of effective pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to new products and uses."

2. Recommendation

The Panel recommends that the future pesticides and veterinary medicines regulatory system is guided by the following 6 equally weighted objectives:

- protect human health and wellbeing
- protect animal health and welfare
- protect the environment
- 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 – Establishing a truly nationally consistent regulatory system

Recommendations for a single national approach to control-of-use:

4. Recommendation

The Panel recommends that the Australian Government works with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. If agreement cannot be reached with the states and territories within 12 months, the Commonwealth should use its constitutional reach to implement a single national law approach.

5. Recommendation

The Panel recommends that the Department of Agriculture, Water and the Environment have responsibility for policy and legislation for control-of-use as well as associated licensing activities. The Panel also recommends that 'on the ground' control-of-use functions continue to be delivered by the states and territories, but now with the national guidelines, with increased resources made available through the Commonwealth providing an additional $5 million per annum conditional funding across all states and territories.

6. 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 also recommends the existing IGA be extended until a new IGA is formed.

Any future IGA should:

- provide that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail
- require any jurisdiction that departs from the IGA approach to provide a public reason for such departure
- mandate minimum resource levels for regulating control-of-use compliance and enforcement activities, to effectively meet assurance obligations and require publication of those resource levels
- require 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
- require regular publication (or input to the Department of Agriculture, Water and the Environment's reporting) of performance against these indicators and targets or goals.

Recommendations for the Commissioner for Pesticides and Veterinary Medicines, new consultative forums and an APVMA Board:

7. Recommendation

The Panel recommends the establishment of a position in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines. The Commissioner will have responsibility for:

- strong and independent policy leadership and responsibility to recommend and drive continuous improvement
- reporting on whole-of-system impacts and outcomes through biennial reports based on whole-of-system performance measures
- whole-of-system surveillance and monitoring, drawing on data from a range of sources
- ongoing open engagement with stakeholders
- establishing and leading Stakeholder and Whole of System Forums
- establishing a domestic produce monitoring program.

8. Recommendation

The Panel recommends that the Commissioner advise Government and the public on the performance of the regulatory system as a whole by establishing a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should also establish health-risk indicators for Australia.

The Commissioner would be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The Commissioner should report publicly on the progress of the reforms in its first year, with system wide reporting on performance measures commencing 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Reporting should be informative and educational and include the results of domestic produce residue monitoring and environmental monitoring as well as adverse experience reports, 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. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

9. 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 its governance arrangements, provide the necessary oversight to support it in managing operational, financial and performance matters, and drive the reform agenda.

10. Recommendation

The Panel recommends that the Commissioner have responsibility for convening and hosting 2 formal and one ad-hoc consultation mechanisms to consider and offer advice to ministers and the Department of Agriculture, Water and the Environment 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
- a Whole of System Forum
- Expert Advisory Panels (as needed).

Terms of reference should be consistent with those set out in Annex 10 and Annex 11.

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

Recommendations for new and improved surveillance and monitoring systems:

11. Recommendation

The Panel recommends that the Commissioner develop a cost-effective, integrated national data surveillance system fit for the needs of a 30-year future. The Commissioner should also develop arrangements to curate relevant information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes. The Commissioner's biennial report should report on trends identified in system surveillance data.

The surveillance 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, published literature, 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.

12. Recommendation

The Panel recommends increased whole-of-system monitoring by government of pesticides and veterinary medicines in produce and the environment.

Domestic produce monitoring

- Establishment of a comprehensive, cost-effective, and authoritative Government-led national domestic produce monitoring system. The 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.
- A domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residue Survey, primary producers, the community and state

and territory governments to ensure it aligns with the whole-of-system surveillance scheme.

Water and soil monitoring

- Monitoring water, waterway sediment and soil samples to detect levels of pesticides, parasiticides and antimicrobial drugs in the environment. The testing program should be scalable and targeted, based on risk.
- Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy

Environmental monitoring

- Development of a government funded, risk based, Environmental Monitoring Plan to identify areas of priority for monitoring 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.

Recommendations for streamlined adverse experience reporting:

13. Recommendation

The Panel recommends that adverse experience reporting (AER) be consolidated, improved, and better utilised:

- The structure and reporting process required when reporting adverse experiences should be detailed in legislation for both pesticides and veterinary medicines.
- The Department of Agriculture, Water and the Environment develops and maintains a single national portal for AERs under the single national law for control-of-use. The Department of Agriculture, Water and the Environment should collate reports to establish a system wide 'pharmacovigilance' approach.
- The AER national portal would automatically refer AERs to the appropriate authority when they are received, thus acting as a single point of contact and automated AER referral system, while also providing for a national database of AERs.
- The APVMA and state and territory regulators would be provided with tailored access to the adverse experience report dataset and should publicly report on adverse experience reports that fall under their jurisdiction.

Recommendations for improvements to the APVMA's chemical review process:

14. Recommendation

The Panel recommends the transparency and responsiveness of the chemical review process be improved. Reviews should be initiated through one of 3 mechanisms: as the result of a well-defined, legislated trigger (such as a relevant international decision); at the discretion of the APVMA; or on referral from the Commissioner.

If the APVMA is be required to commence a review into substances on the basis of the trigger, it would be required to publicly disclose that the review is commencing. However, the trigger

should not result in repeated near identical reviews within a 3 year period, unless APVMA chooses to initiate a review within this time.

Where an international decision would trigger a chemical review but the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA would not be required to carry out the review. However, in such a case the APVMA would be required to publish, within 6 months of the trigger occurring, a statement of reasons for not conducting the review

15. 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. Similarly, the Commissioner should be able to refer substances imported under the international licensing scheme to the Department of Agriculture, Water and the Environment for investigation.

To refer a chemical to the APVMA or Department, the Commissioner would need to be satisfied that there are sufficient reasons to consider a review and would need to provide those reasons to the APVMA or Department when making the referral.

If the APVMA or Department chooses not to initiate a chemical review or investigation based on a referral from the Commissioner, it should be required to publish a statement of reasons for not conducting the chemical review or investigation within 3 months of the referral being made.

16. 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.

Recommendations for a humaneness score for vertebrate pest control products:

17. 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 – Ensuring responsible use

Recommendations for the introduction of general product obligations:

18. 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. These should enhance current existing industry processes, including codes of practice, work health and safety risk management plans, spray diaries, animal treatment records, industry QA, and stewardship schemes and be consistent with existing management practices to minimise the regulatory burden in meeting these obligations.

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

Recommendations for a single national licensing framework:

19. Recommendation

The Panel recommends the Department of Agriculture Water and the Environment develop a single national legislative framework to accommodate all licences, throughout the product life cycle. The single national licensing framework should enable specific, targeted licensing schemes to be created to regulate specific activities irrespective of whether they relate to supply or use activities. All licences for individual schemes created under the national licensing framework would, with the exception of good manufacturing practice and HGP licensing, be issued by the Department of Agriculture, Water and the Environment, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. Licences should be issued to businesses where possible, rather than individuals, with businesses responsible for undertaking due diligence to ensure operators hold the accredited education, training, competencies, or other relevant qualifications.

Such licences, where relevant, would incorporate mandatory licence conditions that allow for the recognition of suitably rigorous industry quality assurance schemes.

20. Recommendation

The Panel recommends that all businesses who apply pesticides commercially (be it agricultural or domestic) are responsible for ensuring operators 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.

21. Recommendation

The Panel recommends that the Department of Agriculture, Water and the Environment completes the work of HACCUT to establish suitably rigorous 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. Competency standards should be established for roles introduced through other recommendations in this review, including the issuing of special use licences.

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.

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 Department of Agriculture, Water and the Environment.

The Department of Agriculture, Water and the Environment. should also establish standing liaison arrangements with the ASQA and industry associations responsible for industry-based accreditations.

Recommendations for improved approaches to product labelling:

22. Recommendation

The Panel recommends the Department of Agriculture, Water and the Environment, in consultation with relevant stakeholders and consistent with other standard setting approaches, establish the labelling standard under the single national law framework.

23. 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.

24. Recommendation

The Panel recommends that legislation to facilitate the use of smart labelling and machine-readable labelling be developed. The legislation should allow for progressive implementation of these technologies as telecommunication connectivity improves. Further, labels should not be prevented from including access to complementary and supporting electronic resources (such as links to a copy of the label, safety data sheet, instructional videos, educational material, and label instructions presented visually or in alternate languages).

25. Recommendation

The Panel recommends that the label content, i.e., the information constituting the label for control-of-use matters, is divided into 2 categories: regulatory assessed elements (RAEs) and conditional required elements (CREs). The Panel recommends that CREs be those elements that are fixed and do not change as a result of assessment and would not form part of the APVMA's pre-market assessment. CREs would be required to be included on the label by product registration conditions and therefore be subject to post-market compliance. RAEs would then represent those elements for which the expert pre-market consideration of the APVMA is required. RAEs may be communicated, to the extent provided by the labelling standard, through means other than being affixed to the container.

26. Recommendation

The Panel recommends that the APVMA, supported by legislation to the extent necessary, allows the inclusion of first aid and safety directions drawn from any Australian established standard to the extent they would ensure the safe handling of the product. The Panel considers this wording could, at the discretion of the applicant, be drawn from existing standards including APVMA first aid and safety directions, the Poisons Standard, or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

27. Recommendation

The Panel recommends manufacturers should be permitted (and indeed, should be encouraged) to include additional safety information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

28. Recommendation

The Panel recommends that every 5 years, at a minimum, the registration holder conducts its own review of label content to ensure the information on the label remains current and correct – noting that emerging scientific evidence or consumer concerns could also trigger review of the label at any time (see the chemical review discussion in Chapter 3).

29. Recommendation

The Panel recommends that when regulators are determining compliance with responsible stewardship and control-of-use requirements, they should only consider compliance with the regulatory assessed label elements and not against the content on the label not assessed by the APVMA.

Recommendations for the better use of, and reliance on, existing QA systems:

30. Recommendation

The Panel recommends strengthening good disposal practices (in line with good agricultural practice) by:

- encouraging industry QA schemes to include requirements and guidance on good disposal practices as part of being deemed to meet general product obligations (see Section 4.1)
- responsible and sustainable disposal practices being considered as a condition for relevant licences
- publication of a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs or do not have equivalent programs in place, addressing container management, recycling, and disposal.

Recommendations for a prescription protocol for veterinary medicines:

31. Recommendation

The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends:

- registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist
- the prescription protocol is finalised and implemented under the single national law for control-of-use
- the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable standards are funded to enable said exemption.

32. 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.

33. Recommendation

The Panel recommends establishing a national rule 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
- a veterinary medicine's responsible use, including a prescription protocol that applies to all animal use, and the records that must be kept establishing responsible use.

Chapter 5 – Improving access and choice in pesticide and veterinary medicine tools

Recommendations for new definitions, exemptions and standards:

34. Recommendation

The Panel recommends efficiencies for the future regulatory system including:

- new definitions for pesticides and veterinary medicines that exclude product classes or uses that are expected to be low risk as they have low hazard or low exposure or are effectively and suitably regulated by other regulators (as outlined in Annex 5)
- establishment of exemption pathways which remove pre-market regulation for certain low regulatory concern products
- development of standards by the Department of Agriculture, Water and the Environment enabling the exemption pathways, utilising input from industry and public consultation
- establishment of a Products Requiring Pre-market Assessment (PRPA) list.

35. Recommendation

In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or the OGTR) becomes the decision-maker for an application. Depending on the category of 'substance' and the risks it presents, it 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.

Recommendations for licensing of internationally registered products:

36. Recommendation

The Panel recommends establishing 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.

In support of this scheme, the Panel recommends:

- that there be an instrument setting out international regulators determined to be equivalent, and that this be regularly reviewed for currency
- that the Department of Agriculture, Water and the Environment, in consultation with the APVMA, determine equivalent regulators
- establishment of a list of prohibited chemistries and classes of products and uses that would not be allowed under licence
- that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

The Panel recommends that 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, or a specific grower/producer group only wants to bring in uses associated with their industry sector and within their control
- develop, submit for approval, 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 approved 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
- cannot supply a product under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active
- provide information on request confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions.

Recommendations for improved access to minor uses:

37. Recommendation

The Panel recommends expanding support by Government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing industries' access to tools for pest and disease management.

38. Recommendation

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use permit, as long as the use of the product would not jeopardise safety or trade and is reasonably expected to be efficacious.

39. Recommendation

The Panel recommends expanding the authorising of emergency use permits in advance of the emergency through establishing 2 categories within the public listing of permits for 'active-

emergency permits' and 'future-emergency permits'. Future-emergency permits would include details of the trigger to transition from the 'future' to 'active' permit category and vice versa.

40. Recommendation

The Panel recommends building national research capacity through 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 has been approved, supported by research quality and safety management systems, and regular independent assurance checks including audits.

Recommendations for supplemental labelling:

41. Recommendation

The Panel recommends the APVMA be empowered to approve a priority need (use) via a supplemental label if it determines that further confirmatory data is necessary. Uses on the supplemental label will transfer to a permanent label following the provision and assessment of any confirmatory data, if and where required.

- Supplemental labels will not form part of the primary approved label attached to the product container, and will be approved for a fixed time only.
- The option to place a use on a supplemental label should be provided only for the priority pest, disease, and animal health needs identified by producers and veterinarians.
- The APVMA will identify the information necessary to confirm or refine the original decision as a condition of the supplemental label approval.
- A workplan will be a required condition to ensure delivery of the required information before expiration of the supplemental label.

Recommendations for 'fast tracking' certain application types:

42. 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, reduced environmental risks, increased environmental benefits, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.
- criteria for prioritisation be drafted by the Department of Agriculture, Water and the Environment, and determined by the Minister.

Recommendations for nationally consistent use patterns with targeted controls:

43. 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

- 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 align with climatic regions.

Recommendations for alternative conditions for importing biological products:

44. Recommendation

The Panel recommends amendments to the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* to expand alternative conditions for imports of biological pesticides and veterinary medicines. The Panel also recommends the overall pesticides and veterinary medicines regulatory system performance indicators include measuring biologically-based products by quantifying their number and growth over time.

Recommendations for consideration of national benefits:

45. Recommendation

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product when proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

Recommendations for data protection periods and data access:

46. 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 without needlessly impeding flow-on innovation, competition, and access to alternative chemical products.

- Equivalent protection periods should be provided for pesticides and veterinary medicines.
  - 10 years for registration of a new product with a new active constituent or approval of 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, issue a research permit, provided in support of a chemical review, or where information contradicts information in the Record or Register.
- 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 further extended as an incentive to bringing priority uses to Australia, as per 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.
- These limitation periods should not prevent the regulator using information where there is a public interest reason to do so.

47. 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 matter to negotiate between companies.

Chapter 6 – Contributing to supply chain resilience

Recommendations for approvals of active constituents:

48. Recommendation

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture. The APVMA should:

- establish a standard for each active constituent prior to its inclusion in products
- ensure due regard is given to matters of commercial confidentiality and intellectual property protection in development of these standards
- apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard including in products.

Recommendations for accredited assessors:

49. Recommendation

The Panel recommends the establishment, within 18 months, of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA. The model for this scheme should be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

Chapter 7 – Funding of the regulatory system

Recommendations for levies, charging and cost recovery:

50. Recommendation

The Panel recommends changes to the existing levy on product sales including:

- that the levy be continued but at a reduced rate with each component of the levy being charged only to those that receive the corresponding service
- 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.

51. Recommendation

The Panel recommends changes to assessment charging structures including:

- the introduction of hourly charging for highly variable regulatory activities and flat rates for activities with little variation
- that the costs for registration applications be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis
- the assessment of applications for accreditation, together with the costs to maintain this accreditation, be 100% recovered from the accredited parties

- that the 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'.

52. Recommendation

The Panel recommends 100% cost recovery for issuing and maintaining licences via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

53. Recommendation

The Panel recommends that where Government audits are routine and predictable the costs of this service 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

54. Recommendation

The Panel recommends changes to the APVMA's permit charging structure including:

- maintaining a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines
- minor use permit applications should attract a discounted application fee with the balance of costs recovered via the levy on product sales payable by the holder
- emergency use permit applications should be fully recovered as a component of the levy.

55. Recommendation

The Panel recommends that the costs of chemical reviews and APVMA compliance and enforcement activities be recovered entirely from industry via a component of the levy on product sales.

56. Recommendation

The Panel recommends that the cost of general control-of-use compliance and enforcement activities should continue to be funded by states and territories under their current finding arrangements. However, wherever possible or, where the beneficiary is clearly identifiable, such as a licensed operator, a fee-for-service approach would be used. The Panel also recommends an additional Commonwealth Government contribution of $5 million per annum to support the increase in post market compliance and enforcement activities.

57. Recommendation

The Panel recommends public funding for the costs of:

- data mining and analysis for system surveillance and monitoring
- environmental monitoring
- domestic produce monitoring.

58. Recommendation

The Panel recommends that the activities of the Commissioner such as reporting on progress in the transformation process, system surveillance and monitoring, and the cost of stakeholder consultation should be Government funded.

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 systems 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 2 written submission processes.

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 (NGOs) 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. The stakeholder group representatives were:

- 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
- 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 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 on the Issues Paper and to inform the development of the recommendations in the Draft 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 A. A number of groups representing the interests of first nations and indigenous people were invited to participate in meetings with the Panel but declined. 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.

Following the release of the Draft Report the Panel held one-on-one consultation meetings with 78 groups (Table A2). During this process, the Panel also met with HACCUT and the Agvet Chemicals Review Stakeholder Group.

Submissions

Two submissions processes were held through the development of the Panel's Final Report. Submissions were invited on the Issues Paper between 4 March 2020 and 28 August 2020. Submissions on the Draft Report were open from 16 December 2020 to 26 February 2021.

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 on the Issues Paper.

On 16 December 2020, the Draft Report of the Independent Review of the Agvet Chemicals Regulatory System was released for public comment. The Draft Report presented and discussed the key areas of reform identified by the Panel and corresponding draft recommendations. The Panel received 72 written submissions on the Draft Report.

The public submissions on the Issues Paper and the Draft Report can be found on the Have Your Say page of the Department of Agriculture, Water and Environment's (the Department's) website.

Public consultation

In addition to written submissions, the Panel held 'virtual' one-on-one and round table consultations with stakeholders after the Issues Paper was released, and again after the Draft Report was released.

Public consultation on the Issues Paper

The Panel held consultations with 188 groups through 68 meetings after the Issues Paper was released. These 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. These consultations helped to inform the Draft Report. Summaries of these meetings can be found on the Have Your Say webpage.

Public consultation on the Draft Report

The Panel held consultations with 78 groups through 21 meetings after the release of the Draft Report. These consultations provided stakeholders with an opportunity to discuss their feedback on the draft recommendations with the Panel, while also allowing the Panel to understand how the draft recommendations were received by stakeholders. These consultations helped to inform the discussions and recommendations presented in this Final Report.

Table A1 Groups consulted on the Issues Paper 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**

Table A2 Groups consulted on the Draft Report through one-on-one meetings

Groups	Number
Fisheries	11
Horticulture	8
Livestock	3
Broadacre crops	2
Farm Groups	4
Pesticide and veterinary medicine companies	11
Peak Associations, Professional Associations	13
Government agencies	10
Research and Development Corporations/Other organisations	7
Non-government organisations	9
Total	**78**

Overview of common themes raised by stakeholders

This section provides a summary of common themes raised in the more detailed submissions to the Panel from key stakeholders, as well as arising from consultation meetings.

Common themes raised by stakeholders on the Issues Paper

During consultation on the Issues Paper, key common themes raised by stakeholders 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.

Common themes raised by stakeholders on the Draft Report

During consultation on the Draft Report, common themes raised by stakeholders included support for:

- nationally consistent and more effective control-of-use arrangements
- increased monitoring and improved surveillance of residues in domestic produce and the environment
- continued implementation of a risk-based regulatory system
- nationally consistent training for commercial chemical operators
- national licensing framework to regulate pesticide and veterinary medicine activities
- maintaining essential information on labels, but enhancing labelling through additional smart-label content
- a 'fast track' application process to improve pesticide and veterinary medicine access in response to priority needs
- specific criteria to formalise the process for granting emergency, research or minor use exemptions
- continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

Some of the key areas where stakeholders expressed diverse views were:

- establishing a Commissioner that would oversee the whole-of-system
- establishing a 5-member, skills-based board for the APVMA
- general product obligations
- new definitions for pesticides and veterinary medicines, and the exclusion of product classes or uses that meet specific criteria
- establishing a potentially hazardous or injurious substance list
- a licensing scheme that allows for the supply and use of internationally registered pesticides and veterinary medicines in Australia.

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, Draft Report, and subsequent consultations 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 system 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 and Draft Report were pursued.

Issues and areas for reform in the Issues Paper that were not pursued

The following proposals from the Issues Paper 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. 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 system, 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).

Efficacy assessments

The Issues Paper considered reducing or removing product efficacy assessments from the pesticides and veterinary medicines regulatory system. As discussed in the Draft Report, due to stakeholder concerns and their desire to maintain assessments of effectiveness, the Panel has not progressed with this reform. However, the Panel still considers that removing efficacy assessment (not safety) should still be explored again in the future.

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. Research

into synergistic effects is still in its infancy in the EU, but should be monitored to assess its applicability to Australia as it develops.

Issues and areas for reform in the Draft Report that were not pursued

The following proposal from the Draft Report was not pursued following concerns raised by stakeholders.

PIC/S accreditation

The Draft Report proposed that the APVMA become PIC/S accredited and that veterinary medicine manufacturers transition from cGMP to PIC/S accreditation over a 5-year period. Through consultation, stakeholders raised concerns that the high costs of meeting audits and changes required to manufacturing facilities could actually lead to domestic manufacturing sites closing, further increasing reliance on overseas veterinary medicine products. The Panel views this as an extremely undesirable outcome, so has made no recommendations regarding the introduction of PIC/S.

Annex 3: List of previous reviews of the Agvet Chemicals Regulatory System

Table A3 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 tables in this annex 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 (these are not required for the review). The cost implications have been prepared solely to provide an 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
- direct or flow-on benefits to users, which for some reforms would be significant.

The basis for the costing assumptions is:

- 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.
- Salaries and pay rates 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.
- Costs associated with recruiting executives and panel members – based on previous recruitment processes within the Department 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 A4 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 control-of-use of pesticides and veterinary medicines. **Recommendations 4-5**	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.	Approximately two-thirds of the 2013 estimates with inflation applied resulting in approximately $75 million saving over 10 years. $5 million a year ($50 million over 10 years) in Commonwealth support to states and territories Four FTEs 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.	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 Rivers Economic Consulting Advice from officers within the Department specialising in compliance and enforcement. Advice received from state and territory regulators during consultation regarding the level of effort and resourcing currently required.	**Saving** To chemical user industries, such as farm businesses and commercial spray operators.	NA	Appropriated funding except for licensing of activities which would continue to be cost recovered.

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
Commissioner for Pesticides and Veterinary Medicines Consultation, reporting, system surveillance and ongoing stakeholder engagement **Recommendations 7-8, 10-11**	Industry would not contribute financially to the 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	**Cost neutral** No cost anticipated to industry for establishment, implementation, or operation.	NA	Funded via government appropriation.
Stronger governance for the regulator – APVMA Board Introducing a governance board for the APVMA, replacing the CEO as the accountable authority **Recommendation 9**	Board members are assumed to be in a range of capital cities. The board is based on the proposal contained in the APVMA Board and Other Improvements Bill currently before parliament. The cost of this recommendation has not been included as a reform cost as the establishment of the Board is already a proposal before government.	**NA**	**NA**	**Cost** The cost of this recommendation has not been included as the establishment of the Board is already a proposal before government.	The cost of this recommendation has not been included as the establishment of the Board is already a proposal before government.	Government appropriation for establishment, with ongoing functions funded through APVMA cost recovery. The cost of this recommendation has not been included as the establishment of the Board is already a proposal before government.

Table A5 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) Implementation a national environmental and produce monitoring program. **Recommendation 12**	Produce monitoring at full operation, up to 30 commodities, 300 samples per commodity annually (taken nationally). Sediment samples would be taken at multiple sites across drainage divisions across Australia. Sampling is expected to decrease after the first 2 years following establishment of benchmarks. 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	Average produce sample cost of $500 Traceback activities for produce residue concerns 10 hours per event, $160 per hour (combined costs). Approximate total produce monitoring costs of $50 million over 10 years. Operational water and sediment monitoring costs $819,000 per annum ($8.2 million over 10 years).	Advice from officers within the Department specialising in contaminations and standards. Advice received from specialists in monitoring during consultation.	**Cost neutral**	**NA**	Funded via government appropriation.
Expanding monitoring and surveillance – adverse experience reporting Formalising adverse experience reporting for both veterinary medicines and	There are unlikely to be any regulatory cost impacts to most product users, suppliers, or licence holders from an increased obligation to report adverse experiences.	**Estimated $1.5 million to establish the system with ongoing maintenance costs estimated at $200,000 per annum**	**NA**	**Cost neutral**	**NA**	**Establishment and maintenance costs are covered by government appropriation.**

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
pesticide products through legislation – **Recommendation 13**						
Improved reconsideration process Improving the speed and transparency of chemical reviews to increase public confidence and maintain social licence for use of pesticides and veterinary medicines. **Recommendations 14-16**	Assumed 2 additional major reviews each year as a result of international decisions. APVMA resourcing will need to be reallocated to manage increased workload.	Four additional FTE's $400,000 per annum ($4 million over 10 years)	Extrapolation of current APVMA resources dedicated to undertaking chemical reconsiderations.	**Cost neutral**	FTEs for this proposal are expected to be offset by existing APVMA resources. Data is not available to estimate the cost to industry for responding to individual reviews.	Existing APVMA resources recovered via a component of the levy.
Humaneness assessment The incorporation of a humaneness score for vertebrate pest control products on product labels. **Recommendation 17**	That an expert panel will consider new humaneness scores. The expert panel will discuss 3 to 4 products/product types per meeting. That over-stickers would be used for product labels already in the marketplace. Existing registrations will also require an assessment by the Vertebrate Pest Research Unit (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.	Assessment cost and time estimates obtained from contacts within the VPRU.	**Cost** (one off)	**NA**	Recovered via application fees and a component of the levy.

Table A6 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 **Recommendation 18**	While GPOs are expected to have a qualitative impact, there is little to no identified cost impact (time or financial) to industry.	**NA**	**NA**	**Cost neutral**	**NA**	**NA**
Introducing nationally consistent training and competency for users Reforming existing training and competency requirements to support nationally harmonised training and qualifications. **Recommendations 19-21**	While nationally consistent training and competency requirements are expected to have a qualitative impact, the 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	**NA**	**NA**	**Cost neutral**	**NA**	**NA**

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
	(i.e. jurisdictional specific requirements).					
Managing risks from compounded products Consistency in regulatory oversight for compounded and manufactured veterinary medicines. **Recommendation 31**	Changes to bring veterinary compounding within the pesticides and veterinary medicines regulatory system are not expected to significantly impact the compounding industry financially. Compounding pharmacies will continue to be subject to the professional standards set by the relevant bodies. The costs associated with increased reporting are considered to be minimal.	**NA**	**NA**	**Cost neutral**	**NA**	**NA**
Labelling reform Changes to labelling assessments and capabilities for agricultural chemicals and veterinary medicines **Recommendations 22-29**	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**	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**

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
Labelling reform Introduction of supplemental labels to improve access to product uses **Recommendations 22-29**	Assumed regulatory effort in seeking a supplemental label will transfer from that of permits to registration.	Regulatory costs for the APVMA to assess a permit are currently subsidised through a levy. The costs will now be recovered from applicants seeking a label.	**NA**	**Cost neutral**	**NA**	**NA**

Table A7 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 Removing various product types and classes from the regulatory system, such as insect pheromones, whole plants or animals and anti-fouling paints, and reducing the regulatory burden experienced in registering pool and spa chemicals, and domestic pest control products as well as repacked products and some research permits. **Recommendation 34**	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 preparation (per application)** **Simple** 5hrs at $33.49 per hour **Complex** 200hrs at $33.49 per hour	Public Chemical Registration Information system (PubCRIS).	**Saving** 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 and/or renewal fee (re excluded products).	Cost impacts for research permits are also considered under 'international licensing'. 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
		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 Department. **Recommendation 36**	Licences must be supported by an audit by the Department 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. That the process of licensing a product for use in Australia will be approximately 12 months faster than the registration process. Additionally, an assumed reduction in minor use permits resulting from new uses coming from international products.	**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. **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)	Standards store (ISO accreditation) Biosecurity Regulation 2016 Approved arrangements	**Saving** 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% (for this proposal only). Costs recovered under this increase would be dedicated to funding this scheme only, and no other aspects or functions undertaken by the Department.	**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 have been considered for this proposal.	**Development of Risk Management Plan:** $50,000 (estimated flat rate) **Midrange minor use permit cost** ~$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 pesticides and veterinary medicine products **Recommendation 43**	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.	**NA**	**NA**	**Cost neutral**	**NA**	**NA**
Improved access – biologicals **Recommendation 44**	The Department's Animal and Biological Imports team suggest that proposed changes to the current clearance process would 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	**NA**	**NA**	**Cost neutral**	**NA**	**NA**

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
	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.					
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. **Recommendation 45**	Assumptions based on APVMA 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	**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:** Six hours of industry resource at $33.49 per hour.	APVMA Performance Statistics (refusals)	**Saving** Through reduced delay costs. **Cost** Proving benefits is voluntary and costs only apply to entities/ individuals who elect to participate.	Conservative assumption made that the APVMA refuses a small number of 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.

Reform	Key assumptions	Costing estimates/ figures relied on	Data source(s)	Identified as cost or saving to industry	Additional factors	Expected funding source
	assessment timeframes					
Simplified data protection Reforming data protection to introduce a simplified approach. **Recommendations 46-47**	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.	**NA**	**NA**	**Cost neutral**	**NA**	**NA**

Table A8 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. **Recommendation 48**	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	APVMA performance statistics	**Saving** 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
		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.				
Streamlining registration and building assessment capacity – accredited assessor scheme Establishment of an accredited assessor scheme. **Recommendation 49**	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** (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.	Establishment of the scheme would be government funded. Application of the scheme would be recovered through application and renewal fees for assessors. No cost to broader pesticides and veterinary medicines industry.

Annex 5: Definitions, standards and conditions

All definitions and standards in this Annex are illustrative only. The Panel accepts that they may need to be refined and amended during implementation of the reforms.

5A: Definitions

New definition of pesticide

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:

- 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
- destroying a plant, and
- when at least one of the following applies:
  - the use of which will expose persons, or ecosystems other than at point of application, to the product or its residues
  - the product is classified 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:

- whole plants
- whole animals
- products declared not to be a PP by legislative instrument.

A PP does include, regardless of hazard classification or exposure, those products with uses declared to be a PP by legislative instrument.

New definition of veterinary medicine

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:

- preventing, diagnosing, curing, or alleviating a disease or condition in the animal or an infestation of the animal by a pest, or
- curing or alleviating an injury suffered by the animal, or
- modifying the physiology of the animal, or
- altering its natural development, productivity, quality, or reproductive capacity, or
- making it more manageable, or
- euthanising an animal (other than through the application of physical force or as a means of pest control); and

- when at least one of the following applies:
  - the use will expose persons or ecosystems, other than at point of application, to the product or its residues, or
  - the product is classified in any of the top 3 categories in any hazard class under the GHS.

A VMP does not include, regardless of representation or use:

- a product that is a PP
- a vitamin, a mineral substance, or a feed additive of same, orally administered to or voluntarily consumed by an animal

A VMP does include, regardless of hazard classification or exposure, those products:

- that are a substance or mixture of substances prepared by, or on the instruction, of a veterinarian.
- with uses declared to be a VMP by legislative instrument.

Instructions of veterinarians must be in writing and precede the creation of the substance or mixture of substances, except where there is no suitable VMP registered

- instructions must include matters as prescribed
- instructions must be carried out by a registered pharmacist in the course of their practice.

Additional Definitions

Active constituent means the substance that is, or one of the substances that together are, primarily responsible for the effectiveness of the product.

Compounded veterinary medicine means 2 or more ingredients (of which at least one is a veterinary medicine product or an active constituent) have been combined or mixed together to create a final product in an appropriate form for dosing. A compounded veterinary medicine can consist of an active constituent or the alteration of the form and strength of commercially available products. It can include reformulation to allow for a novel delivery (e.g., transdermal). A compounded product does not include mixing, reconstituting or any other manipulation that is performed in accordance with the directions for use on the approved label of a veterinary medicine product.

Control includes destroy, repel, and prevent.

Clinical relationship means:

- Other than in emergency circumstance where the life of the animal to be treated would cease without veterinary intervention, the veterinarian has been given responsibility for the health of the animal or group of animals in question by the person responsible for the care of the animal(s) (the client).

- Other than for animals on their first clinical consultation/visit, the veterinarian or veterinary practice has:
  - records of personal contact with the animal(s) for diagnosis, treatment and of assuming responsibility for the diagnosis, treatment, and outcome
  - a detailed knowledge of the current health and treatment status of the animal or group of animals by having:
  - seen the animal(s) for the purpose of diagnosis and establishing a therapeutic need immediately prior to supplying a veterinary medicine; or
  - visited the premises where the animal(s) is kept within the previous 6 months for the purpose of diagnosing, assessing therapeutic need and treating the animal(s) or assessing response to treatment; or
  - consulted remotely with the assistance of digital technology to view contemporary photos or video recordings, and/or assistance from written records including disease control plans, laboratory data and abattoir monitoring data as appropriate, for the purpose of diagnosis of the disease or condition and establishing a therapeutic need, where the veterinarian has visited the property within the previous 12 months and can likewise demonstrate via clinical records an ongoing relationship with the client and a good working knowledge of the client's livestock operation and the disease status of the animals; or
  - examined any clinical records made by other veterinarians within the same practice, where these conditions have been met.

Domestic pest control products mean products:

- acting through a chemical or biological means, and
- used inside, on, or around private dwellings, and
- for the control of terrestrial arthropod pests such as cockroaches, ants, spiders, silverfish, flies, mosquitoes, and fleas, and
- that are not intended for use as a vertebrate poison.

Garden pest control products means products:

- acting through a chemical or biological means, and
- for the control of plant diseases, insect pests, weeds, snails, slugs, and rodents, and
- for use on vegetables and fruit primarily grown for personal consumption (e.g., not grown on a commercial scale or for sale), or
- trees, ornamentals, lawns, and other areas around private dwellings, and
- that are not used for pool and spa sanitisation.

Pool chemical product means a product or products:

- acting through a chemical or biological means, and
- used in pools or spas located in or at a dwelling, and
- used to control fungal or microbial pests or

- used for sanitisation, or
- used to support the effective use of a product to control fungal or microbial pests or sanitisation in pools or spas.

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.

Products Requiring Pre-market Assessment are defined in a legislative instrument as being any of the following, unless exempted by condition (such as a specific use pattern):

- 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
- 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
- a formulation that meets the criteria of carcinogenicity Categories 1A and 1B of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)
- a formulation that meets the criteria of mutagenicity Categories 1A and 1B of the GHS
- a formulation that meets the criteria of reproductive toxicity Categories 1A and 1B of the GHS
- a formulation that is listed in Schedules 4 or 8 of the Poisons Standard
- 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
- pesticide active constituents listed under the Montreal Protocol on Substances that Deplete the Ozone Layer.

Supply to the public means through retail (including online) outlets.

5B: Standards for products exempt from requirement for pre-market assessment (Level B)

Domestic Pest Control and Garden Pest Control Products – Potential Standard

Conditions

A product may be registered by notification to the APVMA if all of the following conditions apply:

1) the Products Requiring Pre-market Assessment instrument does not apply.
2) the product is supplied with a label that complies with the labelling standard.
3) either of the following applies:
   - the product is a domestic pest control product with:
     i) a pack size not exceeding 10 litres or 10 kilograms, and
     ii) a concentration of active constituent not exceeding 100 grams per litre or 100 grams per kilogram, and
     iii) a formulation that does not meet any of the following categories of the GHS:
     - 2 for carcinogenicity, except for petroleum oils, or other hydrocarbons routinely used as fuel, and boron present as boric acid or borax decahydrate
     - 2 for mutagenicity
     - 2 for reproductive toxicity.
   - 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:
     - 2 for carcinogenicity, except for petroleum oils, or other hydrocarbons routinely used as fuel, and boron present as boric acid or borax decahydrate
     - 2 for mutagenicity
     - 2 for reproductive toxicity.
     - 1 for acute or chronic aquatic toxicity.

Repacks and Dilution products – Potential Standard

Conditions

A product may be registered by notification to the APVMA if all of the following conditions apply:

1) the *Products Requiring Pre-market Assessment* instrument does not apply.
2) the product is supplied with a label that complies with the labelling standard, and where a use pattern or circumstance of use is drawn from another product (such as dilution of a registered product) the label listed use rates, frequencies and concentrations have been accurately converted to ensure safe use of the product.

3) at least one of the following applies:

- the national supply regulator, by legislative instrument, has stated a class of products, or products with specified use(s), are exempt from the need for pre-market assessment.
- the product is the same as another chemical product in all relevant particulars other than the name of the product, and/or the holder of registration
- the product is a diluted version of another registered chemical product (the primary registered product) and:

  i) the product's pack size not exceeding 100 litres or 100 kilograms, and

  ii) the product's concentration of active constituent not exceeding 400 grams per litre or 400 grams per kilograms, and

  iii) the primary registered chemical product is not listed in schedule 7 of the Poisons Standard or a restricted chemical product.

5C: Standards for products exempt from requirement for registration (Level C)

Pool and Spa Products – potential standard

Conditions

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 for:

1) ingredients
2) pack size
3) user safety statements
4) packaging and
5) labelling.

Ingredients requirements

The *Products Requiring Pre-Market Assessment* instrument does not apply.

Maximum pack size requirements

The product does not exceed 50 litres or 50 kilograms.

User safety statements requirements

The product instructions must not include a need for special precautions or personal protective equipment (other than can reasonably be accessed by a non-commercial entity) in the product's preparation, use, or disposal.

For example, none of the following will is 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.

Packaging requirements

The packaging material must be sufficient to ensure the product's safe handling in terms of storage, transport, and use.

The container must:

- be impervious to, and incapable of chemical reaction with its contents when under conditions of temperature and pressure that are likely to be encountered in normal service, and
- have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions, and
- if it is intended to be opened more than once—be able to be securely and readily closed and reclosed, and
- have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage, and

- enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:
  - harm a person, or
  - have an unintended effect that is harmful to the environment.

Labelling requirements
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.

This standard does not diminish the operation of workplace health and safety legislation where the pool or spa is subject to these obligations.

Compounded veterinary medicines – potential standard

Definitions
Active constituent means the substance that is, or one of the substances that together are, primarily responsible for the effectiveness of the product.

Conditions
A veterinary medicine compounded by a veterinarian or by a pharmacist on the written instruction of a veterinarian is exempt from the requirements for registration where it complies with the requirements for:

1) care of the animal
2) protocol for selecting veterinary medicines
3) quality standard
4) written instructions
5) labelling.

Care of the animal requirements
The veterinarian, or their veterinary practice, has a clinical relationship with the animal(s) to be treated with the compounded veterinary medicine.

Protocol for selecting veterinary medicines requirements
The selection and use of the compounded veterinary medicine are in accordance with either the Protocol for selecting veterinary medicines for use in production animals or the Protocol for selecting veterinary medicines for use in non-production animals, as relevant.

Quality standard requirements
The compounded veterinary medicine was prepared in a facility that complies with a recognised standard for good compounding quality.

Written instruction requirements
Where the veterinarian provides written instruction to a pharmacist to prepare a compounded veterinary medicine, the instruction must include sufficient details to identify the prescribing veterinarian; the animal; the name, address, and phone number of the client; chemical names and quantities of all active constituents in the compounded product.

Where the compounded veterinary medicine will also be dispensed by the pharmacist the instructions must include directions for its safe use, in terms of animal and human health, including the dose, route of administration, frequency and duration of treatment, first aid and safety instructions and actions to be taken in the event of an adverse effect in the animal.

Labelling requirements
In addition to any requirements of the Poisons Standard or related product dispensing legislation, the compounded veterinary medicine must, where use is by a person other than the veterinarian, include directions for its safe use, in terms of animal and human health, including the dose, route of administration, frequency and duration of treatment, first aid and safety instructions and actions to be taken in the event of an adverse effect in the animal.

Pesticide Products containing only Generally Recognised As Safe ingredients – potential standard
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.

Conditions
A pesticide product is exempt from the requirements for registration where it complies with the requirements for:

1) ingredients
2) claims
3) labelling.

Ingredient requirements
The *Products Requiring Pre-Market Assessment* instrument does not apply.

All ingredients, including active constituent(s) are listed in the following lists:

Active constituent(s)

- Organic Acids
  - Acetic acid
  - Citric Acid
  - Malic acid
- Botanical extracts
  - Eugenol
  - Geraniol
- Botanicals and Botanical oils
  - Castor Oil
  - Cedarwood Oil
  - Cinnamon
  - Cinnamon oil
  - Citronella

  - Citronella oil
  - Cloves
  - Clove Oil
  - Corn gluten meal
  - Corn meal
  - Cornmint
  - Cornmint oil
  - Cottonseed oil
  - Garlic
  - Garlic oil
  - Geranium oil
  - Lemongrass oil
  - Linseed oil
  - Pepper
  - Peppermint oil
  - Rosemary
  - Rosemary oil
  - Sesame
  - Sesame oil
  - Soybean oil
  - Spearmint
  - Spearmint oil
  - Thyme
  - Thyme oil
- Other
  - Lauryl sulphate
  - Petroleum distillates
  - Phenylethyl propionate
  - Potassium sorbate
  - Putrescent whole egg solids
  - Sodium Chloride
  - Sodium lauryl sulphate
  - Zinc (metallic)

All other ingredients

- Material that is commonly consumed as food, animal feed, edible fats and oils.
- Listed as inert ingredients eligible for the United States of America Federal Insecticide, Fungicide, and Rodenticide Act section 25(b) Pesticide products (that is inert ingredients that can be used in pesticide products that are exempt from Federal (USA) regulation under the Minimum Risk Exemption regulation in (USA) 40 CFR 152.25(f)).
- Listed in the Australia New Zealand Food Standards Code – Standard 1.3.1 – Food Additives.

Claims requirements

The pesticide product must not make claims in relation to:

- the control of organisms or pests that pose a threat to human health
- the control of termites in pre- or post-constructions of buildings.

The person responsible for the product holds, or has access to within 48 hrs, information to support any claim or representation they have made for or about the product. Where the information is in the form of scientific studies, it must be published in a reputable, refereed scientific journal or be of a standard publishable in such a journal.

Claims must not be false or misleading.

Labelling requirements
In addition to any requirements of the Poisons Standard the label must:

- specify all ingredients
- identify the active constituent(s) and concentration of active constituent(s) in the product
- order all other ingredients by percentage concentration
- state the person responsible for the product in Australia and their contact information
- state directions for the product's safe use, including first aid and safety instructions and actions to be undertaken in the event of an adverse effect.

5D: 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, produced, or do not exist in Australia, or
- uses that the Department has determined may harm humans, animals or ecosystems in Australia or may prejudice trade between Australia and places outside of Australia, and for which the licensor has been notified 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 associated with the supply and use of 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 internationally 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 internationally 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 internationally registered products; and
- publishing the risk management plan on the licence holder's website (excluding any commercial-in-confidential information)
- making records, and providing these records to the licensor on request, about:

- all dealings with any internationally registered products in Australia
- the procedures and controls employed for internationally registered products
- any stability studies that validate the recommended shelf life and appropriate storage conditions of any internationally registered products
- any complaint or product failure in relation to any internationally registered product, and the investigations and actions undertaken in relation to the complaint or product failure
- details of all internationally registered products dealt with by, or on behalf of the holder of the licence during the previous 12 months.

5E: Supplemental label criteria

Safety criteria

A product meets the safety criteria if use (other than a use set out in a supplemental label) of the product, in accordance with any instructions approved, or to be approved, by the APVMA for the constituent or product or contained in an established standard:

- is not, or would not be, an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
- is not, or would not be, likely to have an effect that is harmful to human beings; and
- is not, or would not be, likely to have an unintended effect that is harmful to animals, plants or things or to the environment.

Efficacy criteria

A product meets the efficacy criteria if use (other than a use set out in a supplemental label) of the product, in accordance with instructions approved, or to be approved, by the APVMA for the product or contained in an established standard, is, or would be, effective according to criteria determined by the APVMA by legislative instrument.

Trade criteria

A product meets the trade criteria if use (other than a use set out in a supplemental label) of the product, in accordance with instructions approved, or to be approved, by the APVMA or contained in an established standard, does not, or would not, unduly prejudice trade or commerce between Australia and places outside Australia.

Label criteria

A label (other than a supplemental label) for containers for a product meets the labelling criteria if the label contains adequate instructions relating to such of the following as are appropriate.

- APVMA must have regard to how supplemental labels are referenced from the label on the container for the product.

Use (supplemental label) criteria

The APVMA may issue a supplemental label where all of the following apply:

- The use relates to a pest/disease and commodity pairing set as a user determined priority [as set specified in a separate legislative instrument]
- The APVMA is satisfied that the use of the product in accordance with the instructions to be approved:
  - would not be likely to:
    - be harmful to humans or animals, or
    - have an unintended effect to the environment
    - give rise to residues that pose a threat to humans, animals or the environment
    - unduly prejudice trade between Australia and places outside of Australia.
  - would be likely to be effective according to criteria determined by the APVMA by legislative instrument.

- The APVMA has determined that for use in the pest/disease and commodity pairing trial data is required for confirming or refining the decision to issue the supplemental label relating to:
  - efficacy,
  - target safety and/or
  - residues.
- Conditions of label approval are set that require the establishment of a workplan for the completion of submission of findings from the APVMA determined trials. The workplan is to detail specific trials and milestones, failure to comply with milestones is grounds for label suspension/cancellation.
- The supplemental label approval does not exceed 5 years.
- The supplemental label includes, at a minimum, all of the following:
  - the name of the product
  - details of the person responsible for the product in Australia
  - instructions for use (crop, target, rates, critical use comments, WHP etc.)
  - any special precautions or other instructions unique for that use
  - a statement referring the user to the approved label for complete directions and precautions
  - dates of its enforcement (i.e., commencement and expiration date).

Annex 6: Summary of label elements for pesticide and veterinary medicine products

The label elements in this Annex are illustrative only. The Panel accepts that they may need to be refined and amended as reforms are implemented.

The elements assessed and approved by the APVMA are referred to as 'Regulatory Assessed Elements' (RAE).

Other components of the label will be set as 'Condition Required Elements' (CRE). CREs would not be reviewed at the time of registration (that is initial market entry) but would constitute a key feature of post market compliance. Failure to comply with a condition would constitute grounds for regulatory action, including product market withdrawal, product suspension, penalty infringement notices, or criminal prosecution.

Table A9 Pesticide products

Label element	Future state
Signal word heading	CRE – not a label element reviewed by the APVMA at time of registration. Labels would be required to include the relevant heading required by poisons scheduling, or in the absence of such a heading, the WHS legislation.
Product name	CRE – not a label element reviewed by the APVMA at time of registration.
Constituent statements, including active constituents and solvents	CRE – not a label element reviewed by the APVMA at time of registration.
Net contents	CRE – not a label element reviewed by the APVMA at time of registration. CRE will reference National Measurement legislation.
Anticholinesterase statement	CRE – not a label element reviewed by the APVMA at time of registration. Conditions would require the inclusion of standard statement as needed.
Mode of action	CRE – not a label element reviewed by the APVMA at time of registration. The conditions may, as needed, make reference to industry standards.
Statement of claims (simplified description of product purpose)	RAE – the APVMA would continue to assess the claims for the product against the directions for use of the product.
Restricted Chemical Product (RCP)	CRE – not a label element reviewed by the APVMA at time of registration. Conditions would require the inclusion of standard statement as needed.
Person responsible for the product	CRE – not a label element reviewed by the APVMA at time of registration. The condition would require sufficient information is included on the label to identify the person responsible for the product in Australia. This element would be expanded from the current consideration of the party responsible for the marketing of the product.
Directions for use	RAE – the APVMA would continue to assess the proposed use of the product and identify any restraints necessary for safe use. 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.

Label element	Future state
	Information to be presented in a table of Host/Circumstance, Pest, Application rate. The table to be included in publication of RAE and within the APVMA's publicly available register, PubCRIS. CRE – The label attached to the container must at a minimum present information for crop groups, and representative crops. Uses in all other commodities assessed as RAE must then be accessible through smart technology. CRE – any restraint imposed by the manufacturer beyond the RAE must be clearly identified. Compliance with these restraints (intended to limit liability) would not form part of the regulatory system.
Circumstances where product 'not to be used'	RAE – the APVMA would continue to assess circumstances where the product is not be used to support the safe use of the product.
Other limitations	RAE – combined into single restraint element under 'Directions for use'.
Withholding periods, Re-entry Periods, Non-Grazing Intervals	RAE – the APVMA would continue to assess the withholding periods to ensure risks from the exposure to residues in treated produce are managed.
General instructions	RAE – the APVMA would continue to assess the proposed use of the product and identify any restraints necessary for safe use.
Resistance statement	CRE – not a label element reviewed by the APVMA at time of registration. This will be information to support users and manufacturers GPO for responsible stewardship.
Compatibility statements	Omit from the APVMA's assessment for RAE as this is currently not a mandatory element.
Precaution statements	RAE – combined into single restraint element under 'Directions for use'.
Vulnerable area statements	RAE – the APVMA would continue to assess the proposed use of the product in terms of environmental safety.
Storage and Disposal	RAE – the APVMA would continue to assess the proposed storage and disposal arrangements for the product.
Safety statements	RAE – the APVMA would continue to assess the statements proposed that would ensure the safe use of the product, including in terms of worker, non-target species (such as pollinators) and environmental safety. The statements may be drawn from the first aid and safety directions, Poison's scheduling, GHS, or any other recognised source and must be considered by the APVMA in terms of the outcome achieved. CRE – where the manufacturer includes additional safety statements these must be clearly distinguished from the RAE element. Compliance with these restraints would not form part of the regulatory system.
First aid statements	RAE – the APVMA would continue to assess the statements proposed that would ensure the safe use of the product, including in terms of worker and environmental safety.
Batch number/Date of manufacture/APVMA registration number	CRE – not a label element reviewed by the APVMA at time of registration. Each element would be required to be included on labels of products released to the market.
Work Health and Safety and Australian Dangerous Goods (ADG) Code content	Content required by other legislative schemes to be included on the label will not form part of either RAE or CRE. Noting the potential exists for RAE and CRE content to meet obligations of other schemes and vice versa. For the latter the content would be considered only in terms of RAE and CRE, not against obligations of the other regulatory system.

Table A10 Veterinary medicine products

Label element	Future state
Signal word heading	CRE – not a label element reviewed by the APVMA at time of registration. Labels would be required to include the relevant heading required by poisons scheduling, or in the absence of such a heading, the WHS legislation.

Label element	Future state
Product name	CRE – not a label element reviewed by the APVMA at time of registration.
Constituent statements, including active constituent and solvents	CRE – not a label element reviewed by the APVMA at time of registration.
Net contents	CRE – not a label element reviewed by the APVMA at time of registration. CRE will reference National Measurement legislation.
Statement of claims (simplified description of product purpose)	RAE – the APVMA would continue to assess the claims for the product against the directions for use of the product.
Person responsible for marketing the product	CRE – not a label element reviewed by the APVMA at time of registration. The condition would require sufficient information is included on the label to identify the person responsible for the product in Australia. This element would be expanded from the current consideration of the party responsible for the marketing of the product.
Contraindications	RAE – the APVMA would continue to assess the contraindications from a product's proposed use and set restraints accordingly.
Dosage and administration	RAE – the APVMA would continue to assess the proposed use of the product and identify any restraints necessary for safe use. 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. Information to be presented in a table of Host/Circumstance, Pest/Disease, Dose rate. The table to be included in publication of RAE and within the APVMA's publicly available register. CRE – any restraint imposed by the manufacturer beyond the RAE must be clearly identified. Compliance with these restraints (intended to limit liability) would not form part of the regulatory system.
Circumstances where product 'not to be used'	RAE – the APVMA would continue to assess circumstances where the product is not be used to support the safe use of the product.
Other limitations	RAE – combined into single restraint element under 'Directions for use'.
Withholding periods/Export Slaughter Intervals/Trade Advice	RAE – the APVMA would continue to assess the withholding periods to ensure risks from the exposure to residues in treated produce are managed.
Side effects	RAE – the APVMA would continue to assess the identified side effects from the use of the product.
General instructions/Precaution statements	RAE – the APVMA would continue to assess the proposed use of the product and identify any restraints necessary for safe use.
Safety statements/Environmental protection statements	RAE – the APVMA would continue to assess the statements proposed that would ensure the safe use of the product, including in terms of worker, non-target species (such as pollinators) and environmental safety. The statements may be drawn from the first aid and safety directions, Poison's scheduling, GHS, or any other recognised source (to the extent practicable) and must be considered by the APVMA in terms of the outcome achieved. CRE – where the manufacturer includes additional safety statements these must be clearly distinguished from the RAE element. Compliance with these restraints would not form part of the regulatory system.
Storage and disposal	RAE – the APVMA would continue to assess the proposed storage and disposal arrangements for the product.
First aid statements	RAE – the APVMA would continue to assess the statements proposed that would ensure the safe use of the product, including in terms of worker and environmental safety.

Label element	Future state
Batch number/Date of manufacture/APVMA registration number	CRE – not a label element reviewed by the APVMA at time of registration. Each element would be required to be included on labels of products released to the market.
Work Health and Safety and Australian Dangerous Goods (ADG) Code content	Content required by other legislative schemes to be included on the label will not form part of either RAE or CRE. Noting the potential exists for RAE and CRE content to meet obligations of other schemes and vice versa. For the latter the content would be considered only in terms of RAE and CRE, not against obligations of the other regulatory systems.

Annex 7: General product obligations

The obligations in this Annex are illustrative only. The Panel accepts they may need to be refined and amended as reforms are implemented.

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 described in the remainder of this annex.

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.

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).

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 veterinarian. 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.

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, veterinarian 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 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 national rule set out in this Annex is illustrative only. The Panel accepts that it may need to be refined and amended as reforms are implemented.

The following rules apply to all users of pesticides.

- A user must only use a pesticide in one or more of the following ways:
  a) according to its label or permit instructions
  b) on the same commodity or situation as stated for use by the label or permit
     - at a lower rate than stated on the label or permit
     - at a lower frequency than stated on the label or permit
     - at a lower concentration than stated on the label or permit
     - to treat a different pest than stated on the label or permit
     - by a different application method
     - in a different jurisdiction if already permitted in 2 jurisdictions.
  c) on any non-food crop not stated on the label or permit
     - at a lower rate than stated on the label or permit
     - at a lower frequency than stated on the label or permit
     - at a lower concentration than stated on the label or permit
     - to treat a different pest than stated on the label or permit
     - by a different application method.
  d) Uses listed in b) or c) do not apply to pesticides that are either a restricted chemical product or listed in schedule 7 of the Poisons Standard.
  e) User relying on uses listed in b) or c) must demonstrate regard to resistance management in that use.
- A user of a pesticide, other than a user in a domestic or garden situation, 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

- A user of a pesticide must, within 48 hours of its use, cause a record to be made containing the following:
  – product name
  – sufficient details to identify the commodity or situation receiving treatment
  – dosage or rate of application
  – date of use
  – location

  - contact details of the user
  - contact details of the crop owner (if different to the applicator)
  - start and finish time of the application
  - equipment used for application (including aircraft in case of aerial application)
  - weather conditions at the time of application.
- 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 commodity or situation means:

- its location within the property
- common or scientific name (if a commodity).

Animal(s) means:

- any identifying markers (e.g., marking, ear tags, microchips)
- intended use of the animal(s) (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

Definitions for the national rule for veterinary medicines

The national rule set out in this Annex is illustrative only. The Panel accepts that it may need to be refined and amended as reforms are implemented.

- Contact details mean:
  - 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 (e.g., ear tags, RFIDs)
    - intended use of the animal(s) (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 registered veterinarian means that the veterinary practice must have been given responsibility for the health of the animal(s) by the owner or person responsible for the care of the animal(s), and that:
  - there are records of a veterinarian within the practice of personally having contact with the animal(s) for 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 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.

Requirements for the selection and use of veterinary medicines

- The requirements for the use of a veterinary medicine set out in the national rule, do not extinguish other legislative requirements that may apply to the dealings with a veterinary medicine (such as dealings with a scheduled substance).
- A registered veterinarian must select a veterinary medicine for use, either directly or to provide written instruction to another person to use the veterinary medicine, according to the *Protocols for selecting veterinary medicines*.
- A user of a veterinary medicine, other than a registered veterinarian, must use the veterinary medicine according to the instructions detailed on the veterinary medicine's label or a relevant permit, or as directed by a veterinarian.
  - This does not apply to users operating in accordance with the written or electronic instructions of a registered veterinarian with direct responsibility for the care of the animal(s) the veterinary medicine is used on.
- For production animals, a user must record the veterinary medicine, or other substance, used to treat the disease or condition, according to the national record keeping rules for veterinary medicines.

For non-production animals, a user, other than a registered veterinarian, is not required to keep a record of the use the veterinary medicine, or other substance, used to treat the disease or condition, in the animals, unless such record is required by the codes or rules of an animal sporting or exhibition organisation.

Protocol for selecting veterinary medicines for use in production animals

A registered veterinarian must select the first suitable veterinary medicine, to treat (for their own use or under their instruction to another person, i.e., a prescription) production animals under their care, that is available from the following ordered list:

- A veterinary medicine for use in the species requiring treatment that is one of the following:
  - registered by the APVMA
  - subject of a permit from the APVMA for use in that species, or
  - an internationally registered product available in Australia under licence for use in that species.
- A veterinary medicine for use in a different major production animal species (e.g., cattle, sheep, pigs, and chickens for animals), that is one of the following:
  - registered by the APVMA
  - subject of a permit from the APVMA for use in the different major animal species, or
  - an internationally registered product available in Australia under licence for use in the different major animal species;

and is subject to the following restrictions,

  - 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, or
  - 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.

- A veterinary medicine for use in any species, where the product contains the same active ingredient(s) as a veterinary medicine that is one of the following:
  - registered by the APVMA
  - subject of a permit from the APVMA for use in any animal species, or
  - an internationally registered product available in Australia under licence for use in any animal species;

and is subject to the following restrictions,

  - 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, or
  - 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.

- If, in the professional opinion of the veterinarian, the lack of treatment would result in death or significantly poor welfare, the veterinarian may use or prescribe any product of their choosing (such as a compounded or human pharmaceutical product) subject to the following restrictions:
  - the product must not contain
    - an antimicrobial of high importance to human health, unless that antimicrobial is registered for use in a major production species
    - any other prohibited substance(s) for veterinary preparations
  - 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 so that use of the product would not result in detectable residue levels.

Protocol for selecting veterinary medicines for use in non-production animals

A registered veterinarian must select the first suitable veterinary medicine, to treat (for their own use or under their instruction to another person, i.e., a prescription) non-production animals under their care, that is available from the following ordered list:

- A veterinary medicine for use in the species requiring treatment that is one of the following:
  - registered by the APVMA
  - subject of a permit from the APVMA for use in that species, or
  - an internationally registered product available in Australia under licence for use in that species.

- A veterinary medicine for use in any animal species that is one of the following:
  - registered by the APVMA
  - subject of a permit from the APVMA for use in any animal species, or
  - an internationally registered product available in Australia under licence.
- A veterinary medicine of their choosing (such as a compounded or human pharmaceutical product) if:
  - the veterinarian has discussed the risks and benefits of the selected medicine with the person responsible for the care of the animal; and
  - The person responsible for care of the animal has consented to the use of the selected product.

Requirements for record keeping of veterinary medicines use

Production animal veterinary medicine use record requirements

- A registered veterinarian using a veterinary medicine, or other substance to treat a disease or condition in the animal, must cause a record to be made containing the following:
  - product name
  - sufficient details to identify the animal(s) receiving treatment
  - condition or reasons for treatment
  - dosage regimen (route, dose rate, frequency, and duration of treatment) or rate of application
  - date of use/prescription
  - location of animal(s) to be treated
  - contact details of the user/prescriber
  - active constituent(s) and concentration
  - dosage form (for compounded products)
  - if prescribing or applying off-label
    - the manner in which the use is different from label instructions
    - an appropriate withholding period/export slaughter interval
  - total quantity of veterinary medicine prescribed or dispensed
  - frequency of dosage and length of treatment
  - any other directions for use the veterinarian believes necessary
  - the date instructions are issued
  - the date the instructions are valid till (not more than 12 months from issuing).
- A user, other than a registered veterinarian must cause a record to be made containing the following:
  - product name
  - sufficient details to identify the animal(s) receiving treatment
  - dosage or rate of application
  - date of use/prescription
  - location of the animal(s) to be treated

  - contact details of the user
  - route of administration
  - condition or reasons for treatment
  - if more than one animal is treated, the number of animals being treated
  - withholding period/export slaughter interval
  - if the veterinary medicine is prescribed by a veterinarian, the contact details of the person prescribed the veterinary chemical (if different to the user).
- The records must be made within 48 hours of use.
- Records must be kept for a minimum of 2 years, or longer if required by other legislative schemes. Records can be written or electronic, and do not need to be stored in a single location.

Annex 10: Stakeholder Forum

All terms of reference, and other details in this Annex are illustrative only. The Panel accepts that they may need to be refined and amended as reforms are implemented.

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 pesticides and veterinary medicines 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

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.

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
- pesticides and veterinary medicines 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.

Members of the Stakeholder Forum will be selected by the independent Chair through an expression of interest process.

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 system, 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 the 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 system 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 the 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 pesticides and veterinary medicines.
- To conduct data analytics for data management, mining, and analysis relating to the pesticides and veterinary medicines reporting and monitoring systems.

Annex 11: Whole of System Forum

All terms of reference, and other details in this Annex are illustrative only. The Panel accepts that they may need to be refined and amended as reforms are implemented.

Overall aims

To provide a cross-portfolio, interjurisdictional forum to discuss operational policies and practices, and administer 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 and a number of Australian Government agencies.
- 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 and 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 the public annually on the deliberations, and actions, of the Forum.

Annex 12: Expert Advisory Panels

All terms of reference, and other details in this Annex are illustrative only. The Panel accepts that they may need to be refined and amended as reforms are implemented.

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

Expert Advisory Panels 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.

The Commissioner will select Expert Advisory Panel members.

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 inquiry.

Expert Advisory Panels 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 an 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 finding's 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

Findings of Expert Advisory Panels, 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 commercially confidential 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.

Annex 13: Summaries of the Panel's reforms and their benefits

What do the proposed changes mean for… CHEMICAL COMPANIES?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The recommended changes will improve the way you manufacture and supply pesticides and veterinary medicines in Australia.

The recommended changes will help you to:

- **Be more competitive in the Australian market**. The introduction of a licensing scheme for internationally registered products will provide an alternative pathway to allow you to introduce chemical products currently registered in certain overseas markets without seeking full Australian registration. (Recommendation 36).
- **Access more sources of active constituents**. Active constituents will be approved at the substance level, independent of the site of manufacture. This will make it easier to source active constituents, providing your business with resilience and flexibility (Recommendation 48).
- **Add uses to labels more easily**. Filling the gap between permits and registrations, supplemental labels will allow new and minor uses to be added to registered products, increasing your market access (Recommendation 41).
- **Get your products on the market faster**. The introduction of lower regulatory pathways for lower risk products, and fast-tracked generic/priority applications will reduce the time taken to register these chemical products (Recommendation 42).
- **Access a national sales market**. The introduction of a national licensing scheme for applicators, and consistent rules for using and supplying pesticides and veterinary medicines will make it easier for you to supply products in different states and territories (Recommendation 19).
- **Simplify your product labels**. When designing or updating your product labels, you will have more flexibility on wording and presentation and be able to provide information electronically (Recommendation 24).

Other benefits that will improve the system and the chemical manufacturing industry include:

- **Changes to data protection periods**. Data provided for veterinary medicine applications to the APVMA will now have the same period of protection as data for pesticide product applications, providing consistency across the system (Recommendation 46).
- **Allowing assessments by accredited assessors**. Introducing a pool of accredited assessors will allow you to have more control over your assessment timeframes (Recommendation 49).

- **Providing consistent advice to your users**. Under the single national law reform, rules for using pesticides and veterinary medicines will become consistent across Australia, making it easier for you to provide advice to users (Recommendation 43).
- **Simplify adverse experience reporting**. The process for reporting adverse experiences associated with your products will be streamlined, reducing the time taken to submit reports (Recommendation 13).

What do the proposed changes mean for… COMMUNITY GROUPS?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The recommended changes strengthen and maintain a resilient and effective regulatory system for Australia.

The Panel recognises the importance of protecting the health of humans, animals, plants, and ecosystems. To ensure this underpins all future work in the regulatory system, the Panel has proposed a new vision and objectives that reflect these priorities.

The recommendations include many changes that will help protect humans, animals, plants, and ecosystems, including:

- **The opportunity for you to have a national voice**. The establishment of stakeholder forums will allow for your views and ideas on chemical use in Australia to be heard (Recommendation 10).
- **Increased monitoring and surveillance**. Nation-wide environmental monitoring will examine pesticides in our soil and waterways, while a domestic produce monitoring program will test for pesticide and veterinary medicine residue in produce destined for human and animal consumption (Recommendation 12).
- **Regular public reporting**. The new Commissioner for Pesticides and Veterinary Medicines will undertake whole-of-system reporting every 2 years, increasing transparency of trends, statistics, and regulatory decisions (Recommendation 8).
- **A humaneness score on product labels**. This score will help consumers make informed decisions by telling them how humane a vertebrate pest control product is when compared to other products available for the same use (Recommendation 17).
- **Increased transparency of chemical reviews**. A new legislated trigger will improve the effectiveness and transparency of the review process. The trigger will require the APVMA to undertake a review if a comparable international regulator has made a final, science-based regulatory decision as a result of a review within the last 3 years. The APVMA would be required to publish the reasons for not commencing its own review under this trigger (Recommendation 14).
- **Streamlined adverse experience reporting**. If a person, animal, or crop experiences an unintended adverse reaction to a pesticide or veterinary medicine, there will be one central place to lodge a report and view subsequent outcomes (Recommendation 13).

Other recommended changes to improve the system include:

- **Improved access to label information**. The introduction of a smart labelling system allows label and use information to be updated instantaneously and in multiple languages. This ensures that users have the most up to date information, meaning risk to humans, animals and the environment is better managed (Recommendation 24).
- **National leadership**. The new Commissioner for Pesticides and Veterinary Medicines will provide national leadership, increased transparency and will keep you informed on issues you want to know about (Recommendation 7).

What do the proposed changes mean for… CONSUMERS?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The recommended changes will improve the way you interact with pesticides and veterinary medicines in your everyday life.

Pesticides that you might use day-to-day include bait for vermin, cockroaches, ants, and snails; weed killer; and fly spray. Veterinary medicines might include medicine for your pet's illnesses and health conditions; products such as wormers; or for flea and tick protection.

Pesticides and veterinary medicines are also used in the agricultural industry to protect crops and livestock from pests and diseases. The regulatory system ensures farmers and growers know how to use products safely, so the produce you eat is safe for consumption.

The recommended changes include:

- **Increased monitoring and surveillance**. Nationwide environmental monitoring will monitor pesticides in our soil and waterways, while a domestic produce monitoring program will test for pesticide and veterinary medicine residues in produce destined for human and animal consumption (Recommendation 12).
- **A humaneness score on product labels**. This score will help you make an informed decision by telling you how humane a vertebrate pest control product is when compared to other products available for the same purpose (Recommendation 17).
- **Wider access to specialist veterinary medicines**. Your veterinarian will have access to more medicinal options to respond to your pets' individual health needs (Recommendation 36).
- **Electronic access to product labels and leaflets**. Product labels and leaflets will be made available online to help you stay up to date, understand what the product does, and how to use it safely (Recommendation 24).
- **Streamlined adverse experience reporting**. If you observe an adverse reaction on a person, animal or in your garden, from use of a pesticide or veterinary medicine, there will be one central place for you to lodge a report (Recommendation 13).

Other recommended changes that will give you peace of mind that the system is working as intended include:

- **Uniform training standards**. Consistent training standards will give you confidence that chemical applicators, including pest controllers are always applying, handling and disposing of products in a safe manner, regardless of where in Australia they are working (Recommendations 19-21).
- **Consistent rules for using pesticides and veterinary medicines**. The same standards and usage patterns for pesticides and veterinary medicines will apply across Australia, regardless of which state or territory the produce is grown in (Recommendation 43).
- **Emergency preparedness**. Products will be available to respond to pest and disease outbreaks to ensure the health and safety of people, animals, our crops, and the environment (Recommendation 39).

- **Formal recognition of industry quality assurance schemes**. These schemes ensure Australian produce meets consistently high standards, giving you confidence that the food you eat is safe and has been produced with consideration given to safety, the environment and sustainability (Recommendation 19).
- **Streamlined chemical reviews**. Formal triggers will mean that chemical reviews are undertaken and completed more quickly, meaning that the safety and necessity of chemical products is regularly considered (Recommendation 14).
- **Consultation forums**. The establishment of a stakeholder forum between government and a range of key stakeholders will mean that your views are represented (Recommendation 10).

What do the proposed changes mean for… FARM BUSINESSES, GROWER GROUPS AND LAND MANAGERS?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The changes will improve the accessibility and safe use of pesticides and veterinary medicines.

As part of your agricultural practices, you might use pesticides and veterinary medicines to protect crops from pests and weeds, protect livestock and companion animals from disease and illness, and control vermin.

The recommended changes aim to help you conduct your business by:

- **Giving you more choice in the products you use**. A new licensing scheme for internationally registered products will allow overseas pesticides and veterinary medicines that meet robust criteria to be introduced into Australia in a timely manner. This will give you access to product and use choices currently only available to your overseas competitors and allow your agricultural operations to respond to climatic, economic and market drivers without jeopardising trade or social licence (Recommendation 36).
- **Improving access to fast tracked products**. Fast tracked product registration will give you more timely access to the products you need such as those that provide effective pest and disease management, enhance farm viability, and protect ecosystems (Recommendation 42).
- **Improving Australia's emergency preparedness**. Streamlining systems to prepare for, and react to, emergency events (such as exotic animal or plant diseases) will help protect your livelihood, protect ecosystems and aid in Australia's recovery from such events (Recommendation 39).
- **Supporting your use of cross-border contractors**. Increasing workforce access and mobility through new nationally consistent licensing, education, training, and competency requirements can help to improve your business's efficiency and competitiveness through an increase in available contractors (Recommendation 20).
- **Providing consistent national access to products and uses**. How and where you use pesticides and veterinary medicines currently varies across Australian borders. Under the proposed new system, approved uses will vary across different geographic and climatic regions, while a product's directions for use will be consistent nationwide (Recommendation 43).
- **Recognising good agricultural practices**. Formal recognition of industry and farmer's quality assurance schemes will give consumers confidence in your produce and will reduce duplication in record keeping (Recommendation 19).
- **Providing up-to-date labelling information**. The introduction of a smart labelling system allows label information to be updated instantaneously and in multiple languages so you're aware if you need to change how you use a particular product (Recommendation 24).
- **Simplified mechanism for adding uses to labels**. Filling the gap between permits and registrations, supplemental labels will allow you to access new and minor uses that have been added to registered products, increasing your market access (Recommendation 41).

Other benefits that will improve the system and support the agricultural industry include:

- **Securing Australia's international trade reputation**. Establishing a comprehensive system that aligns quality assurance schemes and monitoring and surveillance will help strengthen Australia's international trade reputation (Recommendations 11, 12 and 19).
- **Increasing consumer confidence**. Domestic produce and environmental monitoring will give consumers confidence in your produce and agricultural production processes and provide a competitive advantage for high quality products (Recommendation 12).
- **Giving you a national voice**. The establishment of a stakeholder forum between government and national industry member groups, including peak farming bodies, will allow you to contribute to discussions that impact on farm practices and your farm business (Recommendation 10).

What do the proposed changes mean for… PROFESSIONAL PESTICIDE APPLICATORS?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The recommended changes will improve the way you interact with pesticides as part of your work.

As a professional pesticide applicator, your duties may solely relate to applying pesticides (for example, a pest control technician), or it might only be one part of your job (for example, a ranger who undertakes seasonal weed management). Pesticides can be applied by professionals in many settings, including:

- agricultural
- domestic/industrial buildings
- national parks
- urban areas.

The recommended changes aim to help you conduct your work by giving you:

- **Nationally consistent licensing, education, training, and competency**. National licensing for pesticide applicators, coupled with consistent training requirements will reduce administrative burdens and duplication in costs, allowing you to conduct activities safely and easily across state and territory borders (Recommendation 20).
- **More choice in the products you use**. A new licensing scheme for internationally registered products will allow pesticides registered overseas that meet robust criteria into Australia in a timely manner, giving you access to product and use choices currently only available in overseas markets (Recommendation 36).
- **Consistent national access to products and uses**. Approved uses of pesticides currently vary between states and territories. Under the proposed new system, approved uses will be consistent across Australia making it easier for you to operate across borders (Recommendation 43).

Other benefits that will improve the system and support professional applicators include:

- **Up-to-date safety and use information**. The introduction of a smart labelling system over time, will allow label information to be updated instantaneously and in multiple languages so you can see any updates and ensure you are using products safely and effectively (Recommendation 24).
- **A humaneness score on product labels**. This score will help you make an informed decision and answer questions from clients by detailing how humane a vertebrate pest control product is when compared to other products available for the same purpose (Recommendation 17).

What do the proposed changes mean for… VETERINARIANS?

The Panel has reviewed the Australian pesticides and veterinary medicines regulatory system. The recommended changes will improve the way you access, use, compound and prescribe veterinary medicines.

The recommended changes will help you conduct your business by:

- **Providing consistent national access to products and uses**. Approved uses of veterinary medicines and prescribing rights currently vary between states and territories. Under the proposed new system, approved uses will be consistent across Australia, making it easier for you to operate across borders (Recommendation 43).
- **Giving you access to international medicines**. A new licensing scheme for internationally registered products will provide access to veterinary medicines not currently registered in Australia (including niche products), including for high value and exotic animal species. A greater access to products and uses will help you better manage animal welfare (Recommendation 36).
- **Providing formal recognition of the role of compounded medicines**. The important role compounded veterinary medicines play in a veterinarian's toolkit is formally recognised under the recommended changes (Recommendation 31).
- **Providing clear guidance on which medicines can be used and when**. A protocol has been developed to guide you on choosing suitable types of products for use, including how and when compounded products can be used (Recommendation 31).
- **Giving you up-to-date labelling information**. Live updates to product labels will allow you to quickly inform animal owners about responsible use and will mean that consumers using products under your direction will have better access to safety information (Recommendation 24).
- **Improving the system for adverse experience reporting**. A more user-friendly system for reporting of adverse experiences relating to the use of veterinary medicines, and the establishment of a system wide 'pharmacovigilance' approach will allow you to better report adverse experiences and determine if there are issues with products you are considering prescribing or dispensing (Recommendation 13).

Other recommended changes that will support the veterinary industry include:

- **Giving you a national voice**. The establishment of a stakeholder forum will allow you to contribute to discussions that concern and impact you and the animals you treat (Recommendation 10).
- **Improving Australia's emergency preparedness**. Streamlining systems to prepare for, and react to, emergency events (such as exotic animal diseases) by approving permits in advance of an anticipated outbreak, will ensure Australia's veterinary industry is ready to respond promptly (Recommendation 39).
- **New national leadership**. The new Commissioner for Pesticides and Veterinary Medicines will provide greater accountability throughout the entire system (Recommendation 7).

Glossary

Term	Definition
AAAA	Aerial Application Association of Australia
AAT	Administrative Appeals Tribunal.
AAWS	Australian Animal Welfare Strategy.
ACCC	Australian Competition and Consumer Commission.
ACL	Australian Consumer Law.
Active/active constituent	The substance(s) in a pesticide or veterinary medicine product that are primarily responsible for a product's biological or other effects.
Acute effect	Adverse effects that develop rapidly from exposure to a toxic substance.
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.
AER	Adverse Experience Report.
AERP	Adverse Experience Reporting Program. AERP is a post-registration quality assurance program established by the APVMA to help facilitate the 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.
AICIS	Australian Industrial Chemicals Introduction Scheme.

Term	Definition
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.
Applied law	A cooperative legislative scheme in which one jurisdiction enacts a 'model' law which is then 'picked up' or 'applied' by another jurisdiction or group of jurisdictions.
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).
APVMA Board and Other Improvements Bill	Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019.
ASQA	Australian Skills Quality Agency.
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.
cGMP	Code of Good Manufacturing Practice.
Chemical review	See 'Reconsideration'.
Chronic effect	Adverse effects that develop slowly from long, continuous exposures of a hazardous substance.
Citizen science	Scientific research conducted, in whole or part, by non-professional scientists.
COAG	Council of Australian Governments.
Codex	Codex Alimentarius. A collection of internationally recognised standards, codes of practice, guidelines, and other recommendations relating to food, food production, food labelling, and food safety.
Companion animal	An animal kept as a pet and is not used for production of food, fibre or hide.
Compounding/ 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).
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.
CRE	Condition Required Elements.
CRIS	Cost Recovery Implementation Statement.

Term	Definition
	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.
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.
Efficacy	The ability of a product to produce its claimed effects.
EFSA	European Food Safety Authority.
EPA	Environmental Protection Agency.
Epidemiological	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.
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	A situation or ting that has the potential 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 agricultural and veterinary (agvet) chemicals.
IPM	Integrated Pest Management (IPM).

Term	Definition
	The practice of preventing or suppressing damaging pest populations by coordinated application of multiple control methods. Control methods are broadly categorised as biological, chemical, cultural and physical.
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.
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.
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 agricultural and veterinary chemicals. (Former name of the APVMA).
NRS	The National Registration Scheme for Agricultural and Veterinary Chemicals (National Registration Scheme).
NRVR	National Recognition of Veterinary Registration.
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.
Owner	Person responsible for the care of an animal(s), also referred to as the client.
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.
Pest	An animal plant or other biological entity that injuriously affects the physical condition, worth or utility of another animal, plant, or thing, or the use or enjoyment of a place.
Pesticide	See Annex 5.

Term	Definition
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.
Poisons schedule	Poison schedules provide a means of classifying poisons to identify the degree of control to exercise over their availability to the public. Scheduling is undertaken by 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	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.
Regenerative farming	A holistic system of principles and practices that seeks to rehabilitate and enhance farming ecosystems.
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.
Registrant	The person or entity listed as having legal responsibility for a product registration issued by either the APVMA or a comparable overseas regulator.
Repack	A product, or application for a product, that is the same as a registered pesticide or veterinary medicine product but registered with a different name and/or owner.
Representative crop	A crop in a crop group from which extrapolations of data may be made to one or more crops in the group for the purposes of an application to the APVMA.

Term	Definition
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.
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	Regulation Impact Statement. A RIS assesses the costs and benefits to the Australian community of a policy or regulatory proposal.
Risk	The possibility that harm (including death, injury or illness) might occur due to exposure to a hazard.
Risk assessment	A risk assessment considers both the hazards posed by a product and the likely exposure of humans, animals and the environment to these hazards.
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.
Spray drift	The movement of spray droplets of a pesticide outside of the application site during, or shortly after, application. It does not encompass off-target movement of a pesticide caused by run-off, volatilisation, erosion, or any other mechanism that occurs after spray droplets reach their intended target.
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 from the effects caused by the individual substances.
Tank mixing	The preparation of a pesticide solution by mixing one or more solutes with a solvent (usually water) in a spray tank, generally done close to or immediately prior to application.
TGA	Therapeutic Goods Administration. The TGA is the regulatory body for 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.
Use pattern	The combination of all factors involved in the use of a formulated agvet chemical product.
VET	Vocational Education and Training.
Veterinarian	A person qualified to treat diseased or injured animals.

Term	Definition
Veterinary medicines	See Annex 5.
VPCP	Vertebrate Pest Control Product.
VPRU	Vertebrate Pest Research Unit (New South Wales Department of Primary Industries)
WHO	World Health Organization.
WHS	Work health and safety.

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