

# Issues paper—review of the agvet chemicals regulatory system

## Future reform opportunities

Ken Matthews AO, Dr Mary Corbett, Dr Craig Suann and Dr Anne Astin AM PSM

Independent Review Panel



© Commonwealth of Australia 2020

### Ownership of intellectual property rights

Unless otherwise noted, copyright (and any other intellectual property rights) in this publication is owned by the Commonwealth of Australia (referred to as the Commonwealth).

### Creative Commons licence

All material in this publication is licensed under a [Creative Commons Attribution 4.0 International Licence](https://creativecommons.org/licenses/by/4.0/) except content supplied by third parties, logos and the Commonwealth Coat of Arms.

Inquiries about the licence and any use of this document should be emailed to [copyright@awe.gov.au](mailto:copyright@awe.gov.au).



### Cataloguing data

This publication (and any material sourced from it) should be attributed as: Matthews, K, Corbett, M, Suann, C & Astin, A 2020, *Issues paper—review of the agvet chemicals regulatory system: future reform opportunities*, Department of Agriculture, Water and the Environment, Canberra, March. CC BY 4.0.

ISBN 978-1-76003-257-9

This publication is available at [haveyoursay.agriculture.gov.au/agvet-chemicals-regulatory-reform](https://haveyoursay.agriculture.gov.au/agvet-chemicals-regulatory-reform).

Department of Agriculture, Water and the Environment

GPO Box 858 Canberra ACT 2601

Telephone 1800 900 090

Web [awe.gov.au](https://awe.gov.au)

The Australian Government acting through the Department of Agriculture, Water and the Environment has exercised due care and skill in preparing and compiling the information and data in this publication. Notwithstanding, the Department of Agriculture, Water and the Environment, its employees and advisers disclaim all liability, including liability for negligence and for any loss, damage, injury, expense or cost incurred by any person as a result of accessing, using or relying on any of the information or data in this publication to the maximum extent permitted by law.

### Disclaimer

The proposals in this paper do not represent the final views of the panel or the views of the Australian Government but rather are provided to determine the extent of reform stakeholders are seeking to the agvet chemicals regulatory system.

# Foreword

The independent panel that I chair is reviewing the Australian agvet chemicals regulatory system. The panel has spent the last 6 months analysing and synthesising information and feedback from a range of sources and stakeholders. This issues paper provides the panel's point-in-time snapshot of the strengths and weaknesses of the system. The paper provides an indication of our early thoughts about how to modernise and streamline parts of the regulatory framework in order to achieve its objectives.

To date, the panel has had the benefit of considerable input from a key stakeholder consultative group, a range of regulated entities, and the key national regulator itself. The panel still needs to hear from more participants across the whole system before it can settle on recommended changes to the whole framework. The aim of this paper is to start a further conversation with the wider community about how best to protect their health and safety and that of animals, plants and the environment, through agvet chemicals regulation into the future.

The regulation of agvet chemicals isn't just some abstract process of concern only to specialists; it touches our lives every day. Agvet chemicals are used to grow the food we eat, to keep our playing fields and public spaces useable, our pets and livestock healthy, and our environment free from pests (such as mosquitoes and rats) that threaten our health. Getting regulation right has real and significant implications for the safety of people, animals, plants and the environment—who are only as safe as the riskiest point in a chemical's lifecycle.

This review may be the only opportunity the community will get to contribute to the design, from scratch, of Australia's future system to manage agvet chemicals that meets the needs of stakeholders and the expectations of government. We seek a future regulatory system that is efficient, predictable, adaptive, nationally consistent, open and accountable, and places at its centre the protection of human, animal, plant and environmental health and safety.

The panel and I acknowledge and sincerely appreciate the input we have received so far and we encourage everyone with ideas about how to improve the regulation of agvet chemicals, to seize this chance to shape the laws and practices that affect their everyday lives, and have their say.

Ken Matthews AO  
Chair  
Independent Review Panel  
March 2020

# Contents

<b>Foreword .....</b>	<b>iii</b>
<b>Summary .....</b>	<b>viii</b>
What works well with the current system? .....	viii
What's wrong with the current system? .....	ix
Possible reforms? .....	ix
<b>Have your say.....</b>	<b>xi</b>
Publishing of submissions.....	xi
<b>Introduction.....</b>	<b>1</b>
Economic contribution of the agvet chemicals sector .....	2
Why agvet chemicals need to be regulated .....	3
International context.....	4
A proposed vision for the system .....	4
Discussion questions.....	5
<b>1 Is the National Registration Scheme working as needed? .....</b>	<b>6</b>
1.1 State of the system.....	6
Discussion questions.....	11
1.2 What should be the core objectives of the future system? .....	11
Proposed primary purpose statement .....	12
Discussion questions.....	13
1.3 What principles should underpin design of the system? .....	14
Discussion questions.....	15
1.4 Is a risk-based system better than a hazard-based system?.....	15
Panel's view .....	16
Discussion question .....	16
<b>2 Who should ultimately be responsible for aspects of the system? .....</b>	<b>17</b>
2.1 How should the supply of agvet chemicals be regulated? .....	19
Panel's view .....	19
2.2 Who should lead key responsibilities and reforms for the national system? .....	19
Discussion question .....	23
2.3 Should control of use be nationally consistent? .....	23
Discussion questions.....	29
2.4 Should there be shared responsibilities between industry and government? .....	29
Discussion questions.....	34
2.5 Is compliance and enforcement effective? .....	35

Panel's view .....	37
Discussion questions.....	37
<b>3 What chemicals are currently regulated? .....</b>	<b>39</b>
3.1 Should the system only include chemicals for primary producers, veterinarians and non-urban land managers?.....	40
Panel's view .....	41
Discussion questions.....	42
3.2 Should agricultural and veterinary chemicals be regulated together? .....	42
Discussion questions.....	44
<b>4 Are there gaps in agvet chemicals regulation or management? .....</b>	<b>45</b>
4.1 Can we assess use by region, pest, disease or other instead of state boundaries? .....	45
Discussion questions.....	47
4.2 Should benefits be considered in assessments? .....	48
Discussion questions.....	49
4.3 Should the impact of chemical combinations matter? .....	50
Discussion questions.....	52
4.4 Can data mining drive better targeting of effort? .....	52
Panel's view .....	54
Discussion questions.....	54
4.5 Should there be greater monitoring of chemicals in produce and the environment? .....	55
Discussion questions.....	57
Discussion questions.....	59
<b>5 How can communication and engagement be improved? .....</b>	<b>60</b>
5.1 Is there a need for more community information on regulatory actions? .....	60
Discussion questions.....	62
5.2 Do stakeholders require a formal consultation mechanism with the regulators? .....	62
Panel's view .....	64
Discussion questions.....	64
<b>6 How can we simplify the regulatory system? .....</b>	<b>65</b>
6.1 Does a product that is the same as another need its own assessment? .....	65
Discussion questions.....	67
6.2 Who should be responsible for ensuring products work? .....	67
Discussion questions.....	70
6.3 Should there be greater use of standards? .....	71
Discussion questions.....	73

6.4	Does Australia need to assess products that comparable regulators already agree are acceptable? 73	
	Panel's view .....	74
	Discussion questions.....	77
6.5	Does the existing approach for assessing permits (minor-use and emergency use) meet the needs of users? .....	77
	Discussion questions.....	79
6.6	Should chemical reviews be timelier and more informative? .....	79
	Discussion questions.....	80
6.7	Should greater use of technology be used—smart labelling? .....	80
	Discussion questions.....	83
<b>7</b>	<b>How can Australia build national and international capacity? .....</b>	<b>84</b>
7.1	Are there sufficient international networks of expertise? .....	84
	Discussion questions.....	86
7.2	Is an operational regulatory working group needed? .....	86
	Panel's view .....	87
	Discussion questions.....	87
7.3	Should the private sector be able to perform assessment work? .....	87
	Discussion questions.....	89
7.4	What capabilities may be needed to adapt to future technology? .....	89
	Discussion questions.....	91
<b>8</b>	<b>How will a new regulatory system be sustainably funded? .....</b>	<b>92</b>
8.1	Are all system users paying their fair share of costs? .....	93
8.2	Are fairer cost recovery arrangements needed? .....	93
	Discussion questions.....	96
8.3	Are there 'public goods' government should fund? .....	97
	Discussion questions.....	98
<b>9</b>	<b>Appendix A: Independent review: agvet chemicals national regulatory framework .....</b>	<b>99</b>
	Terms of reference .....	99
	Panel and process .....	99
	<b>Glossary.....</b>	<b>100</b>
	<b>References .....</b>	<b>104</b>
	<b>Annex 1.....</b>	<b>105</b>
	Summary of reform proposals and panel preferences.....	105
	<b>Annex 2.....</b>	<b>111</b>
	Proposal—New Definition of agricultural chemical and veterinary medicine .....	111

## Tables

Table 1 Agvet chemicals regulatory system risks.....	35
------------------------------------------------------	----

## Figures

Figure 1 The panel's proposed hierarchy of objectives.....	13
Figure 2 Roles and responsibilities for agvet chemicals.....	18
Figure 3 Lifecycle stages of an agvet chemical product .....	31

## Case studies

Case study 1 Variation in label instructions between jurisdictions .....	46
Case study 2 Regulating herbicides .....	48
Case study 3 The European Chemicals Agency's (ECHA) approach to data mining .....	54
Case study 4 UK Pesticide Forum .....	63

## Boxes

Box 1 Proposed vision statement.....	5
--------------------------------------	---

# Summary

This issues paper provides the panel's initial thinking on possible reforms that, if implemented as a package of measures, would substantially improve outcomes for Australian agriculture, environment, and the community.

These initial, provisional views are based on the panel's examination of the system to date. In researching the many aspects of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), the panel has drawn on a range of research, information and with targeted stakeholder consultation. The proposals presented in this paper are not exhaustive and the panel is seeking stakeholder feedback on specific questions relating to the panel's potential proposals, concepts and options designed to improve the agvet chemicals regulatory system.

In considering the regulatory system as a whole, an activity not conducted since its inception in the mid 1990s, the panel has identified a wide range of issues throughout the system that may warrant reform. Improvements addressing these issues (identified throughout this paper) could deliver an agvet chemicals regulatory system that is more efficient, adaptable, responsive and effective.

The panel recognises the current system has successfully protected the health and safety of people, animals and the environment in Australia for the last 25 years. However, the panel is concerned that the system is not keeping pace with changes to technology, business structures, and agricultural and veterinary needs. The industry and community it serves has also changed. Primary producers are more technically proficient with a greater use of science and technology to maximise productivity. Farm labour inputs have reduced, but there is a heavier reliance on skilled professionals including agronomists, veterinarians and contract sprayers. The domestic chemical manufacturing industry has developed over time to specialise in market niches, with Australia also reaping the benefits of the advanced, research-based offshore manufacturing available through globalised supply chains. Global connection to abundant information means the community expects to know more about what is in their food, or when there are animal welfare issues.

The panel's aim in proposing an interconnected and comprehensive package of reforms is to ensure the recommendations we finally make to the government will modernise the regulatory framework, and to the extent possible, prepare the system for the inevitable further changes the future will bring. That said, the panel has not yet developed proposals or options for all aspects of the system, further work is continuing, and this will also be guided by the feedback received in response to this issues paper.

The panel is committed to maintaining the protection of the health and safety of people, animals and the environment, while providing increased and faster access to safe chemicals for users. The panel recognises that, whatever changes are eventually made to the regulatory system, it is vital that the public's confidence in agvet chemicals regulation remains strong.

## What works well with the current system?

There are many areas of the current regulatory system that are highly regarded. The panel shares the view of all stakeholders to date, that the regulator must remain independent, with no political interference in its scientific decision making. Stakeholders also support the centralisation of supply



side regulation under the single national regulator, which they see as a substantial improvement over the previous system of separate state-based registration systems. Stakeholders have made clear that the scientific rigour and technical proficiency of the APVMA, leading it to be a world class regulator, is a critically important strength of the current system. Stakeholders have also emphasised the importance of maintaining the current risk-based approach to chemical assessment and continuing to apply the criterion for assessing trade impacts to protect our agricultural exports. The Australian Government's financial support for the minor use grants program is critically important to increase farmers' access to chemical uses and should be continued.

The panel is committed to preserving these positive features of Australia's regulatory arrangements.

## **What's wrong with the current system?**

The panel is concerned that Australian farmers do not currently have access to the same chemicals, in the same timeframes, as their overseas competitors. Many new products are registered overseas well before they are registered in Australia. The panel will be seeking to redress this competitive disadvantage, while maintaining standards of safety.

The panel is concerned that the scope (regulatory coverage) of agvet chemicals in the Australian system is extremely broad. This leaves room for duplication/cross-over with other regulatory schemes particularly with consumer and industrial goods. This has the potential to divert government resources from regulating agvet chemicals used by primary producers, veterinarians and non-urban land managers as well as chemicals posing a high health risk. The panel is committed to refocussing the regulatory system to chemicals of direct relevance to primary producers, veterinarians and non-urban land managers.

Other issues identified by the panel include the regulatory system being obscure and difficult to understand. Many stakeholders see it as complex, costly and slow. Governance and consultation arrangements for the system as a whole are unclear and have been argued by stakeholders to be ineffective. Commonwealth–state relationships has been identified as one of the many challenges.

The Australian regulatory system dedicates a disproportionate share of resources to pre-market assessment of agvet chemicals, rather than post-market compliance (regardless of the risk). This disparity is likely reducing regulatory efficiency. Additionally, despite work on all sides, a major shortcoming continues to be the inconsistencies and inadequacies in implementing the so-called 'control of use' functions across jurisdictions, which directly impacts primary producers' and veterinarians' access to chemicals and the ways they may be used.

There is significant cross-subsidisation among chemical registration holders in respect of fees and levies paid. This will need to be examined.

## **Possible reforms?**

In order to improve the current system, the panel is suggesting many areas for reform which are explored in depth throughout this paper. However, to highlight the most far-reaching reforms, the panel has provisionally identified seven key flagship reform proposals that together could result in significant improvements to the system. These flagship proposals are:

- increasing national consistency of control of use

- removing consumer and non-primary production products from the system
- introducing a benefits test
- changing the way chemical product efficacy is managed
- introducing a registration by reference approach
- introducing smart labelling
- introducing an accredited assessor scheme.

This paper also proposes a new vision for the future system, and suggests key principles to govern the design of the future regulatory system together with a simplified hierarchy of system objectives.

Proposals to enable greater stakeholder engagement are presented, including improved consultative mechanisms for all stakeholders in the system (agricultural producers, agvet chemicals industry, consumers, environmental managers, governments and the broader community). Additionally, options for improving the information flow to the community on regulatory decisions are canvassed in the paper.

The panel also sees an opportunity to improve how the regulatory system operates to assure the community that the regulatory controls in place are effective. This paper proposes a strengthening and expansion of monitoring of chemical residues in produce, water, and the environment and offers options for addressing the possible risks of combinations of chemicals and the synergistic impacts of chemicals. In addition, the paper envisages that chemical approvals could be based on regions, rather than on state boundaries. This could enable regions to identify unique environmental circumstances that would warrant placing restrictions or bans on some agricultural chemical uses.

The panel is also keen to promote greater uptake and use of new and emerging technologies to streamline on-farm chemical application practices and improve regulatory functions. Additionally, the panel supports greater sharing of responsibilities between governments, industry participants and users, to provide more effective management of the lifecycle of agvet chemicals, from laboratory through to disposal of chemical wastes and containers.

The panel is keen to hear stakeholder views on the proposals presented in this paper and any other proposals that could be considered. The panel would welcome suggestions about further issues meriting examination. While the panel will make its final recommendations guided by the evidence and best practice policy, all input is valued and will be carefully considered.

# Have your say

The independent panel is seeking feedback from stakeholders. Your views will help inform the panel's recommendations.

We encourage you to read this issues paper before you submit. It details key issues to consider.

You can provide feedback on some or all of these issues. We also encourage you to suggest any other areas the panel should explore.

You can provide feedback via our online form, or by email or post.

Find out how to have your say. Visit <https://haveyoursay.agriculture.gov.au/agvet-chemicals-regulatory-reform>

The deadline for receipt of all submissions is **5:00 pm (EST) on Friday 26 June 2020**.

Questions about the review or the submission process can be directed to the review secretariat at [reviewsubmissions@agriculture.gov.au](mailto:reviewsubmissions@agriculture.gov.au).

## Publishing of submissions

All submissions will be published on the Department of Agriculture, Water and the Environment's website unless clearly marked as confidential, although the panel may redact parts of submissions. We will not publish confidential material but will record that such information is held. Confidential submissions may be subject to release under the provisions of the *Freedom of Information Act 1982* (FOI Act). Submissions will be published as soon as possible after the end of the public comment period.

If you are making a confidential submission, you may wish to indicate any grounds for withholding information it contains. Reasons could include that the information is commercially sensitive or that you wish personal information, such as names and contact details, to be withheld. An automatic confidentiality disclaimer from your IT system will not be considered as grounds for withholding information if the department receives an FOI request.

We will take your indications into account when determining whether to release information under an FOI request. Any decisions to withhold information requested under the FOI Act may be reviewed by the Commonwealth Ombudsman.

The panel reserves the right not to publish submissions.

## Privacy

The panel will only use the personal information collected about you to enable us to contact you about your submission and may (where the disclosure is consistent with relevant laws, in particular the *Privacy Act 1988*) disclose it to specialists; other Commonwealth government agencies; state and territory government agencies or foreign government departments.

The panel requests that, at a minimum, you provide your name and contact details with your submission. Please indicate if you do not wish to have identifying information published with your submission or disclosed to third parties.

The department will use and store all personal information it collects on behalf of the panel in accordance with the Australian Privacy Principles as outlined in the department's [Privacy Policy](#) available on the department's website.

### **Next steps**

The panel will consider all submissions and use these to assist in developing recommendations to the Minister for a new modern fit for purpose system to manage agvet chemicals into the future to be included in its draft report. The draft report will be released later this year for public consultation. Submissions on the draft report will then feed into the final recommendations to the minister to be included in the panel's final report. The final report will be delivered to the Minister for Agriculture, Drought and Emergency Management by February 2021.

# Introduction

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 is examining the agvet chemicals regulatory framework's aims, structure and operation, and will make recommendations to ensure it is contemporary, fit for purpose and reduces unnecessary red tape.

The review is being conducted by an independent panel of experts in regulation, agricultural production, veterinary medicines and public health. Terms of reference for the review were released with the Minister's announcement ([Appendix A](#)). The panel will deliver its final report to the Minister for Agriculture, Drought and Emergency Management no later than February 2021.

In undertaking the review, the panel has been asked to:

- assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
- consider what the goals of Australian agvet chemicals regulation should be
- consider the current and future requirements of Australia's regulatory framework for agvet chemicals
- provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture and allow Australia to remain competitive in global markets.

This first principles review is an opportunity to make fundamental changes throughout the regulatory system and boost timely access to innovative and safe agvet chemicals. Balancing access to safe chemicals with the broader community objectives of health, safety, and environmental protection is vital for supporting sustainable agriculture—with resulting benefits to primary production, veterinary care, management of the environment, and the broader community.

In addition, the review provides an opportunity to deliver on the Australian Government's commitment to reduce unnecessary regulation to improve Australians' experience interacting with government red tape.

This issues paper presents the panel's current observations on the strengths and weaknesses with the agvet chemicals regulatory system and provides some potential reform proposals on which the panel is keen to receive feedback (a summary of the proposals is at [Annex 1](#)). This includes some possible flagship reforms that the panel considers would be far-reaching changes to the current system. These proposals are not intended to cover the full range of possible reforms that could be canvassed, and the panel encourages stakeholders to suggest amendments or additional proposals for consideration.

**These proposals do not represent the final views of the panel nor the views of the Australian Government but rather demonstrate the scope of reform that could be pursued.**

## Economic contribution of the agvet chemicals sector

Agricultural chemicals and veterinary medicines are a major contributor to Australia's economic and social wellbeing and are critical to its agricultural productivity and competitiveness. Agvet chemicals enable producers to: manage pests and diseases that would otherwise significantly affect agricultural, fishery and forestry production; eradicate pests and diseases in our home environments to keep us safe and healthy; and manage the health and welfare of our pets, livestock and other companion animals.

Agvet chemicals are also a critical instrument for effective management of Australia's environmental assets. Control of weeds and feral animals and disease outbreaks in native flora and fauna will often require the use of agvet chemicals to sustain environmental health.

In the 2017–18 financial year, Australia's total market for agvet chemicals was about \$4.09 billion in annual sales with \$3.03 billion from crop protection products and \$1.06 billion from veterinary medicine products (APVMA 2019). Australia's market is small compared with its trade competitors (typically only 2 to 4% of the global market). There is only a limited manufacturing industry in Australia for agvet chemicals and imports currently account for 59% of the Australian market for agricultural chemicals—up from 33% a decade ago (IBISWorld Australia 2018). With the growth in imports it is likely to result in Australia becoming largely a price-taker for the cost of agvet chemicals.

Since 2000, the number of registered crop protection products in Australia has risen by over 50% (3,091 versus 7,584); whereas growth in registered veterinary medicine products has remained steady, increasing from 3,144 to 3,223.

In 2018, Deloitte Access Economics found that agricultural chemicals applied predominantly to crops contribute around \$2.3 billion and over 9,200 full time equivalent (FTE) jobs to the Australian economy.

Deloitte estimated that \$20.6 billion of Australian agricultural output in 2015–16 could be attributed to crop protection products (Deloitte 2018).

Farm Survey data for 2017, estimates total Australian broadacre farm expenditure on agricultural chemicals at \$1.8 billion. Annual farm expenditure on agricultural chemicals has increased by around 45% (in real terms) since the early 2000s and has risen faster than other farm costs. In 2017, expenditure on crop and pasture chemicals accounted for approximately 9% of non-capital on-farm costs for broadacre farms, up from around 6% in the early 2000s (ABARES 2020).

Australia's veterinary medicines industry is also of significant importance to Australia's livestock industries. ACIL Allen (2018) reported the industry contributed 9,900 FTE jobs and \$2.7 billion to the Australian economy. Broadacre farm expenditure on veterinary medicines in 2017 was \$438 million, however this figure can fluctuate significantly year to year due to changing livestock numbers. Veterinary medicine sales in Australia are dominated by parasiticides which account for 33% of livestock related sales value, followed by animal vaccines at 29%.

Given the economic significance of agvet chemicals and their critical role in agricultural production, human and animal safety, and environmental management, and that chemical input costs are rising faster than other farm input costs, Australia needs an internationally competitive regulatory system enabling speedy and minimum-cost access to these chemicals, whilst also meeting the community's expectations of protecting the environment and human and animal health and welfare.

## Why agvet chemicals need to be regulated

While agricultural chemicals and veterinary medicines are critical to Australia's agricultural competitiveness and land management, their use or misuse can pose a risk to human and animal health and welfare, plant health and the environment. To mitigate these risks, the supply and use of these chemicals is regulated to provide assurance to the community that they are safe to use. In addition, there are responsibilities on the users of chemicals and veterinary medicines to ensure they appropriately use and dispose of these products. Employers are also obliged to ensure their workers have access to the appropriate protective equipment to handle agvet chemicals in undertaking their duties.

Poorly designed regulation damages productivity, deters investment and undermines jobs and growth. For primary producers, poorly designed regulation could delay or prevent the introduction of innovative chemical products and increase costs. The mismanagement of agvet chemicals, including use and disposal could impact on the community's acceptance of such chemicals. Whilst regulatory actions are crucial to deter this, the responsibility for use and disposal of agvet chemicals sits predominantly with the users of these chemicals—they have an obligation to manage this for the safety of others and the environment.

Agvet chemicals used in agricultural systems can also jeopardise international trade and market access, as Australia's trading partners have restrictions on the presence, above established concentrations, of certain chemical residues on agricultural imports. Thus, credible Australian arrangements for the use of agvet chemicals are crucial to provide assurance to our trading partners that appropriate chemicals are available and used properly.

At the same time, Australia's natural environment gains from the appropriate use of agvet chemicals. Thanks to their availability, environmental managers can successfully control invasive weeds, feral animals and disease outbreaks to safeguard native fauna and flora. Thus, agvet chemicals regulation must be well designed not only to minimise the presence of chemicals in the environment but to provide the necessary tools for environmental managers to do their jobs.

For these reasons, agvet chemicals are regulated in Australia, as they are in other comparable markets. In the targeted consultations, the panel has had to date, stakeholders have indicated they support the continuing need for a regulatory system for agvet chemicals. It is also recognised that there are aspects of chemical management that currently sit outside of formal regulation that are equally important (for example, industry quality assurance schemes).

Although the broad case for continuing regulation of agvet chemicals is therefore strong, it is important that the focus of effort is closely aligned with the real level of risk that particular chemicals pose. Many agvet chemical products pose very little risk to humans, animals or the environment whilst others pose significant risks that need to be mitigated through the approval process before they can be used. The regulatory system needs to be able to account for the different risk profiles of agvet chemicals and ensure that chemicals that pose the most significant risks are subject to pre-market assessment, and that regulatory resources are redirected from chemicals with a lower risk profile.

The Australian Government aims to ensure that regulation is not unnecessarily restrictive and therefore only the minimum effective regulation needed to meet regulatory requirements should be

implemented. This is an important consideration to be taken into account in the panel's deliberations on reforms to the agvet chemicals regulatory system.

## **International context**

Many agricultural chemicals and veterinary medicine products used in Australia are imported. Many of the companies registering these products in Australia are transnational companies that operate in numerous international regulatory systems. Most agvet chemicals are used globally, with Australia-specific variations in formulation and use introduced to better fit our unique conditions. Access to global supply chains provides access to economies of scale in manufacturing and exposure to key international innovations in chemistries, technology and management practices.

However, Australia's relative remoteness, highly variable climate, large internal distances and small market size (2 to 4% of the global agvet chemicals market) act as cost barriers that can slow or prevent the availability of agricultural chemical and veterinary medicine products that are more readily available to international competitors.

For example, when the total quantity of pesticide sold in 2016 is compared between the US (449.97 tonnes), the EU (353.81 tonnes) and Australia (63.42 tonnes), the US market is approximately 7 times larger and the EU market is approximately 5.5 times larger than the Australian market (OECD 2017). The small size of the Australian market for these products and the tyranny of distance for distribution are not things that can be easily fixed by governments. That said, the panel recognises the need to explore reforms to the agvet chemicals regulatory system that can reduce the impacts of these barriers.

Lack of access to chemicals that are available to farmers in other countries puts Australian farmers at a costly competitive disadvantage. This is because Australian farmers must sell into the same world markets, at the same world price as their international competitors (OECD 2019). But for every cropping season that passes where Australian farmers do not have access to the same chemical inputs as their competitors, they must absorb higher production costs, lower production per hectare, less flexible production practices, slower time to market and other penalties avoided by their overseas competitors.

Agvet chemicals are the primary way in which agricultural businesses manage pests, weeds and diseases. Bringing more agvet chemical products and uses into Australia when the market is so small requires an open mind to the broadest possible range of options specifically targeted to Australian agriculture to ensure access to a wide range of chemical products. It also requires that we look at reform slightly differently from some of our comparable international regulators as they don't face the same market limitations as Australia. In this regard, the panel considers that it should not shy away from reforms that would put Australia at the forefront of, or set precedents for, regulatory change compared to other regulators.

## **A proposed vision for the system**

The panel has been considering a possible high-level vision for the future agvet chemicals regulatory system. The purpose of this vision is to assist the panel in targeting reforms that will directly support the realisation of the vision. The panel is keen to hear stakeholders' views on this vision.



### Box 1 Proposed vision statement

The proposed 'vision statement' for the system that the panel is inclined towards is:

An Australian regulatory system for agvet chemicals that provides all Australian primary producers and veterinarians with timely access to a similar range of approved agvet chemicals to their overseas competitors, while preserving human, animal, plant, and environmental health.

To achieve this vision in the future:

- The Australian system should be more closely aligned with international agvet chemicals regulators, processes, and timelines.
- The regulatory system should be consistent in its application and implementation across the states and territories.
- The regulatory system should specifically aim to foster innovation in all its forms among chemical companies, veterinary medicine manufacturers, other industry groups, farmers, environmental managers, and the broader Australian science community.
- The system should aim to foster and build national capacity to assess and manage the safe and effective use of agvet chemicals throughout Australia.
- Compared to current arrangements, the future system should be more transparent and accessible to stakeholders and interested members of the public.
- The system should function as an asset rather than a barrier for Australia's primary industries, veterinary industries and environmental managers, while maintaining public respect and confidence.

Throughout this paper the panel is suggesting potential reforms that could assist in achieving aspects of this vision and welcomes any suggestions of additional reforms that would assist.

## Discussion questions

- 1) Do you support the proposed vision for the agvet chemicals regulatory system and is it sufficient to meet the needs of all stakeholders?
  - a) What, if any other considerations should be included in the vision?
  - b) Do you have any suggestions for reforms that could assist in achieving this vision that are not canvassed in this paper?

# 1 Is the National Registration Scheme working as needed?

## 1.1 State of the system

At face value it appears that the current agvet chemicals regulatory system works reasonably effectively and the fundamental principles are sound. That said, there are significant improvements that could be made to ensure the system is more efficient, adaptable, responsive and will continue to provide access to agvet chemicals into the future whilst protecting people, animals, plants and the environment.

Through stakeholder consultation and information available, the panel has identified numerous areas of the system that work well and are supported. However, many areas for potential improvement have been identified and these are explored in depth throughout this paper.

Areas of the current system that are considered worthy of retaining as is, given their importance include:

- the independence of the national regulator with no political interference in its scientific decision making
- the scientific rigour and technical proficiency of the APVMA, leading it to be a world class regulator
- the centralisation of the supply side regulation of agvet chemicals
- the importance of the criterion for assessing trade impacts to protect our agricultural exports
- the use of a risk-based approach to chemical assessment
- the need to maintain or expand the current minor use grants program to increase farmers' access to chemical uses.

The key areas of the system that the panel considers require improvement include the following:

- The scope of agvet chemicals covered by the legislation is extremely broad and leaves room for duplication/cross-over with other regulatory schemes—potentially diverting resources from agvet chemicals used by primary producers, veterinarians and non-urban land managers.
- The current system is complex, costly, slow and lacks transparency in internal work prioritisation within the national regulator and decision making across all aspects of the system.
- The complex and excessively prescriptive nature of the legislation makes it difficult to follow and inaccessible to the general public.
- The unbalanced focus on pre-market assessment versus post-market compliance, may not always be the most efficient approach as it can subject products to the same assessment pathways regardless of risk.
- Many products are registered overseas well before they are registered in Australia, leaving farmers without access to chemicals that are readily available to their international competitors.

- The inconsistencies in implementing control of use functions across states and territories affects farmers' access to chemicals. In addition, there are no performance measures or national reporting requirements for the states and territories in compliance, enforcement and monitoring.
- Monitoring of chemical residues in domestic produce is deficient and there are inconsistencies and deficiencies in the surveillance and monitoring of chemical residues in water and the environment.
- The regulatory system lacks national leadership and requires clearer overall governance arrangements.
- Australia's national capacity for scientific assessments, whilst recognised for its expertise, is limited both inside and outside the national regulator.

Over decades, numerous ad hoc changes and piecemeal reform to agvet chemicals legislation have added to its complexity. Industry has indicated to the panel that it is keen for the development of a simpler framework allowing greater regulatory flexibility and efficiency to facilitate improved chemical access as well as measures that enable innovation and increased speed to market. Some industry stakeholders have also indicated a desire for improved certainty in arrangements to support investment decisions, particularly certainty in respect to the timeframes for registration.

As will be discussed in later chapters of this paper, to ensure greater integrity of the system, areas identified for improvement include monitoring of chemical residues in domestic produce and the environment, building national capacity in regulatory science capabilities, and using data and intelligence gathering to assist and guide regulatory functions and focus.

### **1.1.1 Future trends and developments**

The technical sophistication of primary production, veterinary practice and the agvet chemicals industry is continually advancing. At the same time consumer awareness, access to information and scrutiny related to agvet chemicals and provenance and traceability in the food system more generally is leading to a greater level of regulatory accountability.

The panel has identified several key trends that are likely to strongly interact with the agvet chemicals regulatory system in the years ahead. While it is always difficult to predict the future, the panel considers that the future operating environment for agvet chemicals regulation will be very different from the environment of the past. In this changing environment, a high quality, responsive, and flexible national regulatory system for agvet chemicals will be a competitive advantage for Australia.

The panel expects that the following trends could be especially important to inform the design of a more future-proofed agvet chemicals regulatory system:

#### **Consumer market expectations and authenticity**

The provenance of food and fibre will increase in importance in domestic and export markets as consumers increasingly seek to know where their produce comes from and how it has been grown (ABARES 2018). Public perception and awareness of the health and environmental impacts of pesticides are driving a significant shift down the food supply chains towards farming systems operating with reduced reliance on synthetic pesticides, as well as creating new markets for alternative sources of protein e.g. plant-based or lab-grown. Consumer demand for organic, minimally treated, and/or sustainably produced products continues to grow rapidly. For example, the total value of Australia's

domestic organics market is conservatively estimated to be \$2.4 billion with an increase of 88% since 2012 (Australian Organic 2018).

Animal welfare and ensuring animals are treated humanely in food production will continue to grow as a consideration in domestic and export markets (Futureye 2018). The Australian community and our export markets want to be assured that production animals are only treated with medicines necessary to protect their health and ensure their welfare. They also want to be assured that these medicines have no lingering effect that could affect the food supply chain.

Major commercial organisations, such as Coles and Woolworths, implement their own standards and monitoring controls over the produce they sell in order to satisfy consumer expectations. These systems are likely to increasingly drive agricultural production systems more broadly.

Testing equipment and methodologies are rapidly becoming more sensitive, meaning residues at levels not previously identifiable can be tested for. While residues below current limits do not necessarily represent a human health concern, many consumers are concerned about the presence in food of any agvet chemical residues at any level. This will likely drive further reductions in agvet chemicals use.

Increasing participation in 'citizen science', improved access to affordable monitoring and analytical equipment and techniques, and expanded epidemiological data, are enabling more informed and robust community discussion about agriculture's social licence to operate. There is a growing expectation among consumers and markets that the chemical treatment of produce can be traced and accounted for (Futureye 2018). The typical grow, use, dispose cycle of food production is slowly being replaced with a 'circular economy' that favours more use of previously discarded parts of agricultural production (e.g. potato skins, fruit pulp etc.). Consequently, customers and markets are now routinely expecting lifecycle traceability of chemical use as a way of assuring people that the food they are consuming is safe and responsibly produced.

If these trends continue, with agvet chemicals use declining in favour of non-chemical, or reduced chemical pest management solutions, the regulatory system may be expected to consider integrated and non-chemical pest management solutions as part of its approval process.

### **Social licence**

There is an increasing focus on agvet chemicals use and impacts on the community and trading markets such that any failings in the system will be quickly transmitted domestically and globally via social media. This is evidenced by the global reactions to allegations of the impacts of chemicals (such as glyphosate) even though all comparable regulators (USA, Europe, Canada, New Zealand and the WHO and FAO) consider glyphosate safe to use when specific use instructions are followed.

This growing community concern over agvet chemicals requires design of a future regulatory system that acknowledges the concerns of citizens and makes clear that the protection of humans, animals, plants and the environment is a fundamental priority.

Social attitudes to the use of veterinary chemicals in part mirror those seen for pesticides but are complicated by issues such as the development of antimicrobial resistance (AMR) and the role that antibiotic use plays in animals, particularly those used in food production, in contributing to this global challenge. In Europe, efforts to reduce the development of AMR have led to the prohibition of the

prophylactic use of antimicrobial products in food producing animals. This prohibition can result in import restrictions on animals and produce that have been treated with antibiotics.

Community pressure will also likely strengthen around animal welfare concerns. The future regulatory system needs to acknowledge and accommodate the community's changing expectations in relation to responsible animal production.

For all these reasons, the growing community concern over agvet chemicals is likely to impact the use of these chemicals in the future—the panel is interested in what mechanisms are needed to build a regulatory system that responds sensitively to these community concerns, and maintains community trust in the use of agvet chemicals.

### **Industry development**

The rate of development of novel chemistries has significantly decreased in the last few years. This is a global concern due to increasing consumer and regulatory pressures and high product development costs. It typically takes eight to eleven years and approximately US\$286 million to bring a new chemical to market—from idea generation to market launch (McDougal 2018).

High research and development costs, the small size of the Australian market for agvet chemicals, the ongoing availability of older, cheaper chemicals, and declining livestock numbers will continue to act as barriers to the registration of new agvet chemicals in Australia, as companies will increasingly focus their R&D efforts on northern hemisphere problems and opportunities at the expense of Australia.

There is a growing trend in the innovative agricultural chemistry sector towards company consolidation and mergers. Bayer's acquisition of Monsanto the most prominent recent example. This consolidation is reducing the pool of companies registering chemicals and is potentially reducing the competitive pressures to drive innovation. The acquisitions and mergers are optimising corporate portfolios and expanding geographical presence but resulting in a sharpened focus on commodities with high crop protection demands (that is high sales potential, for example grains).

Companies are also diversifying their business with major agrochemical companies acquiring seed companies (identifying and distributing the optimal genetic traits of a commodity). With the reduction in costs and advancement in technology many in the innovative sector are also developing and selling genetically modified products targeted to specific crop protection products or with GM traits to remove the need for chemical crop protection products entirely.

There is a similar growing trend towards mergers among veterinary medicine companies, with large pharmaceutical companies selling off their animal medicine parts of their business. These are then merging with some of the existing large veterinary medicine firms. This is resulting in far fewer players in the veterinary medicine development and manufacturing space.

In the current agvet chemicals market paradigm, as the costs to innovate rise, and market concentration increases, the opportunities for newer, smaller companies to participate as innovators can be expected to shrink (although there should always be opportunities to supply generic chemicals to the price-sensitive purchasers of agvet chemicals). However, contrary market developments can also be expected based on new opportunities for emerging smaller, more agile companies to challenge the established players by using emerging technologies, such as gene editing, to create bespoke pest management solutions that could be targeted to individual farms.

### **Farm practices**

Farm businesses are making better use of data from a wide variety of sources to inform all aspects of their decision-making. The quality and timeliness of data on climate and weather, pest and disease incursions, and real-time commodity and currency fluctuations continues to improve, allowing farmers to maximise their profitability and competitiveness. This is also leading to an increase in the use of chemical alternatives alongside synthetic chemicals. Such integrated pest management (IPM) combines the use of biological, mechanical, genetic and chemical practices to control insect pests. It seeks to use pesticides only when alternative control options are not effective.

New technologies and precision application techniques enable farmers to minimise the use of pesticides while maximising crop protection. Targeted, ultra-low precision application technology has achieved an approximate reduction of 50 to 70% in spray volume in some trials while achieving similar levels of pest control (Durham 2016). Precision application technology, which includes greater use of intelligent robots, is predicted to play major roles on farms. It is possible that previously restricted chemicals may return to use as a result of the reduced exposure risks to workers and the environment, offering growers more options to treat their crops. It should be noted that as a result of reduced application volumes, sales volume also reduces by the same rate. This will further impact, what is already a very small market in Australia for agvet chemicals (low use leads to low sales, which leads to low market value), making it even less attractive to bring new products to the Australian market through the current regulatory system.

Advances in spray technology will also have an impact on the regulatory assessments of products. The greater use of drones, or other autonomous vehicles leads to overlap with applicator licensing and harmonisation of control of use requirements. Effective engagement of chemical pest management policy with existing systems to support development of new technology is necessary to realise the full benefit of these advances.

There are innovations in farm systems for animal management that reduce the need for intensive treatments and interventions. For example, developments in animal genetics and practices such as robotic milking have reduced reported incidents of mastitis.

In the future, the regulatory system may be able to partner with farm businesses, universities, and the private sector to consolidate and leverage the vast quantities of new data being generated on individual farms to develop new tools. For example, intelligence could drive the development of predictive models for microbiological evolution, to enhance preparedness and responses to biosecurity incidents.

### **Electronic (smart) labelling**

The advances in technology can support different ways for users to access and engage with instructions for the safe use of a chemical product. Industry sectors outside of agvet chemicals are increasingly sharing targeted information to users through electronic means, such as quick reference codes. This has the potential in an agvet chemicals context to simplify the printed label and allow a more responsive approach to information sharing. The latter would be an advantage where use instructions change.

Machine readable labels can support the increasing use of robotics and technology on farms. This also has advantages in the regulatory assessment of products by allowing the use of computers to review and compare labels, enabling the professional scientific staff to focus on more complex assessments and other tasks.

Full adoption of smart labelling in Australia could improve the regulator's handling of recalls and communication of changes to use instructions in real time. Chemical users will have access to the latest tools and information about best practice chemical use, and will be able to filter out irrelevant label information that can cause confusion and lead to errors in chemical handling and use.

## Discussion questions

- 2) Do you agree or disagree with the future trends identified and their implications for the agvet chemicals regulatory system?
  - a) Are there additional implications for the regulatory system posed by the trends identified that the panel has not adequately addressed? If yes, please provide details.
  - b) Are there other trends that the panel needs to consider in designing the future system?

## 1.2 What should be the core objectives of the future system?

A clear description of the objectives of the system is important for regulators, stakeholders and the community to understand what the system is supposed to achieve. The current Commonwealth agvet chemicals legislation contains a range of objectives, developed almost 30 years ago that include: protecting the health and safety of humans, animals and the environment; supporting user access to safe and effective chemical products; protection of agricultural trade; supporting domestic chemical manufacturing; and promoting agricultural productivity. In addition, there are a range of objectives relating to efficiency, transparency, consistency and science-based risk assessment.

In its current state, it is difficult for the general public and stakeholders to understand the primary purpose and functions of the agvet chemicals regulatory system. There doesn't appear to be a natural hierarchy to the objectives so the relative importance of each is unclear. The panel is disposed towards a more simplified hierarchy of objectives, which could consist of an overarching primary purpose statement supported by tiered supplementary objectives. This would make the order of objectives for the regulatory system clear.

The primary purpose statement and supplementary objectives need to be simple and understandable, provide clear guidance for decision-makers and stakeholders, and maintain community confidence.

The panel is of the view that the purpose of the agvet chemicals regulatory system is to achieve 2 primary outcomes: to protect the health and safety of people, animals, plants and the environment; and to provide users with access to safe chemicals. The panel considers these two outcomes for the system to be equally important and mutually supportive and should therefore be combined as the system's overarching primary purpose statement.

Ensuring the protection of people, animals, plants and the environment should always be at the heart of the regulatory system. In part, this is to ensure that the use of chemical products at the present time will not impair the prospects of future generations.

Equally however, the community needs access to suitable tools to safely control pests and diseases that threaten the health and safety of people, animals, plants and the environment. Many of these pests and diseases are controlled by agvet chemicals. For example, mosquitoes that can spread Ross River fever or

dengue fever, hydatid tapeworms that can infect us through our pets, rodents that can spread leptospirosis or typhus fever, or weeds and animal pests that can disrupt natural ecosystems in environmentally valuable areas. The panel also recognises that no or poor access to suitable pest management solutions can have significant health and safety consequences.

## **Proposed primary purpose statement**

The panel would welcome feedback on the primary purpose statement of the system being:

The purpose of the agvet chemicals regulatory system is to protect the health and safety of people, animals, plants and the environment and provide safe and timely access to agvet chemicals.

It does this by preventing or managing unintended adverse consequences from exposure to agvet chemicals in food, the environment, and the workplace; and by ensuring that suitable pest management solutions are available to safely control the pests and diseases of plants, animals, and places, that threaten the health and safety of people, animals, plants and the environment.

Some of the system's current objectives, such as those relating to trade, domestic chemical manufacturing and agricultural productivity set Australia apart from other comparable international regulatory systems.

The panel recognises that as the bulk of Australia's primary production is exported and, as participants in a highly trade-exposed sector, Australia's primary producers value the regulator's consideration of trade impacts (such as residues) of a chemical when it is assessing an application. Given Australia's export focus, the panel is inclined to keep trade as a core objective of the scheme (like New Zealand).

The panel therefore considers that protecting trade should be the first supplementary objective in the new hierarchy.

The panel is also of the view that the objective of fostering domestic chemical manufacturing may no longer be as relevant as was originally the case. Both the industry structure and market circumstances have changed significantly since it was originally drafted into the legislation. There have never been any specific measures in the legislation to give practical effect to this objective—it appears to have acted as little more than an aspirational statement, with particular relevance to past circumstances. Given the change in the manufacturing environment and supply chain and the fact that 59% of agricultural chemicals are now imported with this expected to continue to rise, the panel is inclined to consider that this specific objective is no longer required in a modern regulatory system (IBISWorld Australia 2018).

Increasing the viability and competitiveness of agricultural production remains an ever-important priority for Australia. The panel supports the retention of a specific objective relating to primary industry and considers that this supports the overarching primary purpose statement relating to timely access to safe chemicals, especially in respect of primary producers and environmental managers.

The panel therefore considers that supporting Australia's primary production sector should be the second objective in the hierarchy.



Animal welfare has always been an important concern for farmers, veterinarians and the community and is almost certain to increase in importance in the years ahead, yet it is not a specific objective in the current system. The panel is therefore of the view that protecting animal welfare into the future should be a key focus of the agvet chemicals regulatory system. Considering this, the panel is proposing that protecting animal welfare should be the third and final objective in the hierarchy.

Therefore, the simplified hierarchy of objectives that the panel is proposing for the future agvet chemicals regulatory system contains an overarching primary purpose statement on safety and access and three supplementary objectives (trade, primary production and animal welfare) in that order (Figure 1).

**Figure 1 The panel's proposed hierarchy of objectives.**



The other current scheme objectives referred to in relation to efficiency, transparency, consistency and science-based risk assessment are considered by the panel to be more appropriately applied as key principles governing the design of the regulatory system and are incorporated in section 1.3.

## Discussion questions

- 3) Do you support the proposed overarching primary purpose statement for the agvet chemicals regulatory system being safety and access?
  - a) Do you agree that the proposed hierarchy of simplified objectives provides greater clarity of their relative importance and is this supported? If not, why?
  - b) Are there objections to removing the domestic chemical manufacturing objective? If so, what are the objections?
  - c) Do you agree that the current objectives for efficiency, transparency and risk-based science are more appropriately expressed as principles governing design of the system? If not, why?
  - d) Are there other objectives that should be considered?

## 1.3 What principles should underpin design of the system?

The effectiveness and success of any regulatory system rests on its design. It is therefore important that the design of the system is based on clearly defined principles.

The current agvet chemicals regulatory system is a complex and multi-layered network of primary legislation, legislative and administrative instruments and policies, with responsibility shared across multiple agencies and jurisdictions. Although the system rests on and benefits from the valuable oversight provided by a long-term regulatory partnership between the Commonwealth, states and territories, its overly intricate design has led to unnecessarily complex processes, making it difficult and costly for all parties to navigate, interpret and implement.

The panel acknowledges the national whole-of-government agenda—already underway—to reduce regulatory burdens on business and the community. The review supplements this existing work and aims to further reduce unnecessary regulatory burdens by examining the underlying policies and processes embodied in current agvet chemicals regulation.

The panel has been considering the range of principles that should govern its design of the regulatory system. At a high level, the principles the panel considers important include consistency, efficiency, certainty, transparency, objectivity, independence, simplicity, shared responsibility and accountability. In addition, the panel considers that the principles guiding reform need to be able to deliver on the proposed overarching objective of the system—safety (people, animals, plants and the environment) and timely access (to safe chemicals).

The panel is considering the following principles to guide proposed reforms to the agvet chemicals regulatory system:

- **performance** of the system
  - **objectivity**—the system should be based on sound science, and be evidence and risk-based in its decision making
  - **independence**—decisions of the national regulator overseeing approval of agvet chemicals should continue to be independent from government
  - **efficiency**—promote use of the most efficient regulation required to achieve the objective—by making use of more streamlined and fit for purpose pathways, plus considering how the market can drive registration holders to make optimal choices about their chemical products
  - **consistency**—there should be one coherent national system, with consistency in control of use and any differences amongst jurisdictions should be required to be justified publicly
- **access**—the system should be harmonised as much as possible with international regulatory systems, processes and timeframes
  - **simplicity**—replace the current suite of legislation with one that is modern, outcomes focused, free from unnecessary prescription and is simpler and easier to understand and implement
  - **certainty**—provide confidence about regulatory processes and timeframes
- **shared responsibility**—the system should facilitate the sharing of responsibility among governments, agvet chemicals suppliers and users

- **transparency and accountability**—provide a clear and transparent policy and regulatory framework that provides for regular engagement and input from the regulated industry, users and the community.

The system should be designed to build public confidence and maintain the social licence to use agvet chemicals.

Any reforms to the system that the panel recommends to the government should not reduce the overall level of protection of human, animal or plant health and the environment, nor jeopardise overseas trade.

## Discussion questions

- 4) Do you support the principles proposed to guide design and reforms to the future agvet chemicals regulatory system? If not, why?
  - a) How could these principles be enshrined to ensure they are met?
  - b) Do you have suggestions for additional principles that should be considered by the panel?

### 1.4 Is a risk-based system better than a hazard-based system?

At the heart of responsible agvet chemicals management are two concepts—hazard and risk. In basic terms, hazard is the potential of something causing harm, while risk is the likelihood of harm occurring.

The intrinsic hazard of a specific chemical ingredient in a product does not itself determine whether the product is safe. The risk to human health, for example, associated with a hazardous chemical product will depend not only on the presence of the chemical but also on the nature and extent of any potential human exposure to that chemical from the use of that product.

Hazard and risk are not mutually exclusive. In order to assess risk, you must first understand and assess the hazards. Hazard-based regulation assumes that the only way to manage risks is to remove the hazard. This ignores the ability to manage the risk of exposure to an acceptable level through specific conditions on use. For chemical substances, the risk to human health depends on the toxicological potency of the substance and the frequency and duration of exposure; only risk-based assessments offer information on these aspects.

Hazard-based assessments can be cheaper than risk-based assessments as less assessment effort is required. Risk assessments are more comprehensive and time consuming, however these types of assessments provide for more specific regulatory decision making because of the consideration of potential exposure and options to mitigate harm.

The first step in a risk-based approach is a hazard assessment, thus hazard is an intrinsic part of the process. A risk-based approach means that hazardous chemicals that can be effectively managed to reduce the harm can be available to deliver beneficial outcomes to agricultural production. Quantitative approaches, such as risk-based assessments, can give insights into the magnitude of risks and can be used as a basis for deriving safe levels of exposure. Where there are sufficient data, risk-based assessments provide practical information concerning the likely or probable risk to the exposed population, rather than a hypothetical indicator which may never be realised.

If a hazard-based approach was adopted in Australia, many products would be lost from the market that do not pose a risk to human health, animal health or the environment if used correctly. This would have wide-ranging negative implications for Australia's food security, farm productivity, animal welfare and environmental management, as the most appropriate chemical tools would no longer be available. Additionally, hazard-based assessments can divert economic and scientific resources into further investigation of chemicals/products for which risk assessments show there is reasonable certainty of no harm during normal handling and use.

Decisions made on hazard alone can have negative consequences such as loss of safer beneficial products, substitution with less safe chemicals, higher costs for consumers and disincentives to innovate safer products. This is because some chemicals, that on a hazard-based assessment alone would appear to be safer, in fact can be more harmful due to the way or circumstances in which they are used. For example, a hazard assessment would find, in respect of personal insect repellents, that products containing DEET (are more hazardous) versus non-DEET products (less hazardous but also less effective). If the less hazardous product was then used in a malaria/dengue/Ross River fever endemic area it would be the less safe option due to the difference in efficacy and the likely consequence of contracting one of these diseases.

## **Panel's view**

The panel is of the view that it is critically important that Australia's future regulatory system is based on risk, not hazard alone. Such an approach provides for a more scientifically robust and comprehensive regulatory system, and incorporates hazard assessments along with exposure and use, to determine chemicals suitable for use and the safest way of using them. This approach also ensures that users and the community have access to the broadest suite possible of safe chemicals to manage pests and diseases.

## **Discussion question**

- 5) Do you agree that the regulatory system needs to have a risk-based focus to provide for a more scientifically robust and comprehensive system? If not, why?

## 2 Who should ultimately be responsible for aspects of the system?

The current system splits responsibility across numerous bodies, the Minister, Department of Agriculture, Water and the Environment, the APVMA, states and territories, other Commonwealth agencies, the regulated industry and others involved in agvet chemicals regulation and management. This means that there is no single person or agency with ultimate authoritative responsibility for agvet chemicals regulation. The complex deployment of responsibilities among many parties is illustrated in Figure 2.

The Agvet Admin Act and Agvet Code Act establish the APVMA as an independent regulator that assesses and approves the supply of agvet chemicals. The states and territories are responsible for the control of use of agvet chemicals, including compliance and enforcement of use.

The Department of Agriculture, Water and the Environment provides advice to the Commonwealth Minister in relation to the legislative and policy settings of the system and is responsible for proposing reforms to amend the legislation and regulations. The department also facilitates the Council of Australian Governments (COAG) endorsed efforts to harmonise control of use among the states and territories. In addition, the department implements decisions relating to international treaties on chemical use and engages with international regulators and governments on chemical access.

The department's National Residue Survey monitors residues in exported produce and provides information to the states and territories on breaches that require compliance action.

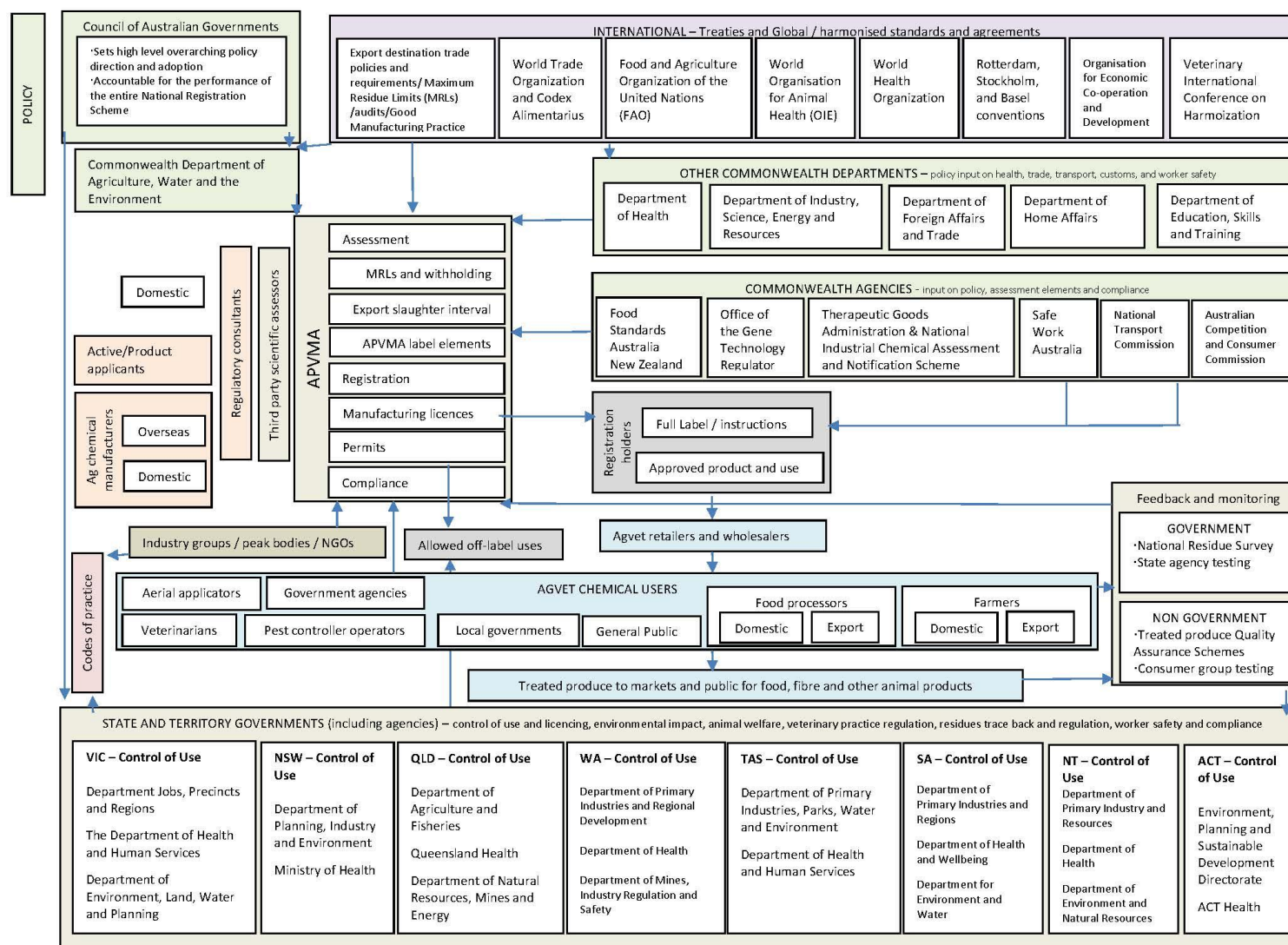
The Minister relies on the power under the Agvet Admin Act to provide directions to the regulator on the performance of its functions or exercise of its powers. This direction power does not extend to decisions the regulator makes on specific chemicals, but rather the broader operations of the regulator.

Chemical suppliers have a range of stewardship programs in place that guide the use and disposal of agvet chemicals. There are also a range of industry residue monitoring programs that are designed to provide some quality assurance on chemical use.

The panel has been tasked with reviewing the current intergovernmental agreement (IGA) between the Commonwealth and the states and territories. Decisions on the overall design of the agvet chemicals regulatory system will largely determine what needs to be addressed in the IGA.

The panel is inclined to seek a governance arrangement that: provides clearer leadership for the regulatory system overall; identifies the different roles of Commonwealth and state and territory governments; and, consistent with the concept of shared responsibility (section 2.4), gives more weight to industry and user responsibilities in the future.

**Figure 2 Roles and responsibilities for agvet chemicals**



## **2.1 How should the supply of agvet chemicals be regulated?**

The current Agvet Code provides a successful model for a nationally unified approach to the supply of agvet chemicals that has lasted for nearly 30 years. Prior to this, states and territories each undertook supply side approvals of agvet chemicals, but in creating the national system they ceded these powers to the national independent regulator, through an applied law scheme. In the current system, assessment, labelling and controls up to the point of retail supply are unified under the single national regulator. The result is that these aspects of the system are nationally consistent and this is strongly supported by industry stakeholders who engage with the system.

Labelling and the application of the Agvet Code by each jurisdiction also ensures that the base rules for managing a chemical or product conform to one standard across all jurisdictions.

### **Panel's view**

The panel has a strong view that there is little justification for considering any changes to the current approach of a single national regulator for the supply of agvet chemicals.

## **2.2 Who should lead key responsibilities and reforms for the national system?**

Many parties play a role in the whole national agvet chemicals regulatory system. These include governments at all levels, regulators of many descriptions, manufacturers, the research community, users of chemicals and chemical waste disposal entities. This complex and inter-dependant web of arrangements risks obscuring accountability, where everyone is accountable, but as a result, no-one is accountable. This is supported by stakeholders reporting a lack of clarity about where leadership responsibility and accountability for the whole system lies.

The strengths, weaknesses and opportunities for improvement to create a future system need to be kept under review and reform initiatives sponsored when required. Progress and performance improvement must be assured. There needs to be machinery for the many players involved to liaise with each other and reinforce each other's initiatives. Such arrangements are not currently in place.

Governments need strong systems and stakeholder relationships if they are to lead on the new policy questions and reforms needed to navigate a path that maximises the benefits of agvet chemicals access and use for Australia. Governance structures that support responsiveness and responsibility at multiple levels are important for meeting the needs of the national regulatory system, food producers and community expectations.

The Australian Government has both national policy and regulatory roles. It has chosen to keep these roles structurally separated in a Commonwealth department and an independent statutory authority (APVMA) respectively. As a consequence, the APVMA is:

- a 'one stop shop' in relation to registrations with hazard identification, risk assessment, risk management and risk communication capability to span its full range of functions

- accountable to the community through the Parliament of Australia and its committees, although the minister may give written directions to the APVMA concerning its functions or powers [s.10 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*]
- a small authority with responsibility for all of its own corporate functions.

The APVMA, as the current registration authority has complex regulatory responsibilities, including weighty decisions that have direct impact on public/human health, animal welfare, the environment, export trade and agricultural productivity. The CEO alone is responsible for strategic leadership, governance and day-to-day operations of the APVMA including setting, implementing, monitoring, reporting on and reviewing all significant APVMA policies. Ministers have over time provided the CEO of the day with letters of expectation and directions that have identified opportunities for both legislative and operational improvement. While past reviews have praised the APVMA's scientific rigor, they have noted the lack of progress or implementation of certain reform recommendations.

To progress system-wide reforms, the Department of Agriculture, Water and the Environment provides support for a committee consisting of all signatories to the NRS, the Harmonised Agvet Chemicals Control of Use Task Group (HACCUT). The role of this group is to deliver the agenda endorsed by COAG for a single national regulatory framework. However, this group does not have the remit to consider broader NRS policy issues or the operations of the APVMA.

In the absence of a designated forum to discuss concerns about the scope, role, performance and outcomes of agvet chemicals regulation, some stakeholders identify the APVMA as the responsible agency. However, as a Commonwealth independent statutory authority, with legislatively defined regulatory tasks, the national regulator is not properly empowered legally or constitutionally to provide direction to other areas of Commonwealth and state governments, nor non-government players in Australia's national agvet chemicals regulatory system.

In recent times much of the reform agenda has needed to be driven by the Australian Government due to the states and territories having resource constraints to propose reform measures. This may be because the states and territories have been fully supportive of the national reform agenda. However, there may be other reasons for their inability to fully engage in the reform initiatives that should be explored.

Similarly, non-government stakeholders have felt disenfranchised and have identified few channels for suggesting systemic reforms, other than conventional political advocacy processes. Improved arrangements for consultation are addressed elsewhere in this paper, but whatever arrangements are adopted in the future, it will be important that stakeholder consultative arrangements, and government to government liaison at all levels is more effectively linked.

The panel is therefore interested in exploring governance mechanisms that could improve the effectiveness of the system and further build and maintain community trust and consumer confidence in the control and use of agvet chemicals (this is explored in chapter 5). The panel has identified the following potential operational models for the national regulator:

- 1) retain existing APVMA statutory authority arrangements (no change)
- 2) introduce an APVMA statutory Board to govern the work of the regulator



- 3) transfer compliance and enforcement functions to a centralised government department
- 4) convert the current regulator (APVMA) to a statutory office holder within the department
- 5) appoint the APVMA as a risk assessment agency, with the department as regulator
- 6) introduce an overarching, temporary steering committee to oversee implementation of reform.

### **Option 1 Existing statutory authority**

The APVMA would remain a structurally separate statutory authority operating in partnership with the states and territories. The statutory authority structure provides the APVMA and its CEO with the legal and operational autonomy to decide how it can be best run.

However, policy authority for regulatory changes rests with the minister and department. The panel suggests that the APVMA should be routinely required to report on actions taken in response to letters of expectation or directions from the minister to further improve transparency and accountability.

Under this option, the APVMA would:

- retain its scientific and regulatory roles
- perform its functions with minimal influence from government and informed by the community as it chooses (outside of mandatory public submission requirements)
- pursue regulatory and cost efficiency on its own terms.

### **Option 2 Statutory authority with Board**

The national regulator would remain a structurally separate statutory authority with its focus and strategic direction established by a board of directors in line with the minister's statement of expectations. A governing board can make a valuable contribution when diverse expertise and leadership experience is required, to support and augment the management capability of the CEO. Parliament is currently considering a Bill that seeks to reinstate a governance board for the APVMA to replace the CEO as the accountable authority. Subject to the passage of legislation, the CEO will be an ex officio member of the (five person, skills-based) board.

Under this option, the APVMA would:

- retain its scientific and regulatory roles. The board would not be involved in management and operational activities of the regulator, nor would it impact or influence the scientific integrity of regulatory risk assessment
- perform its functions under the strategic direction of the board to ensure the authority is held accountable to the government and reflects community expectations
- pursue regulatory and cost efficiency on its own terms, but with a board responsible for organisational performance and accountability, regulatory compliance and enforcement, statutory objectives and the organisation's fiduciary sustainability.

### **Option 3 Statutory authority with the department responsible for compliance and enforcement**

The APVMA, as the current national regulatory authority, would remain a structurally separate statutory authority responsible for registration decisions. However, Commonwealth compliance and enforcement responsibility for controls up to the point of supply would become the responsibility of the department.

Under this option, the APVMA would:

- retain its scientific, registration and labelling regulatory roles
- perform its functions with minimal influence from government. The department would undertake compliance and enforcement activities, likely in conjunction with its existing approach to biosecurity, imported food and illegal logging legislation
- pursue regulatory and cost efficiency in assessment and registration on its own terms. Consolidating compliance and enforcement activity with the department's existing regulatory responsibilities could represent a major cost efficiency and simplification of the regulatory landscape for industry.

### **Option 4 Statutory officeholder within the department**

A statutory officeholder would be appointed with independent responsibility to make decisions on agvet chemicals under the scheme including approval, registration and chemical reconsiderations. The functions of the APVMA would be absorbed into the department (e.g. as a division of the department).

Under this option, the statutory officeholder (and supporting 'APVMA office') would:

- retain its scientific and regulatory roles, including continuing to provide independent and objective scientific risk assessments
- perform its functions in line with departmental processes, but with minimal direct influence from the department. Provisions surrounding the appointment of officeholders generally provide for direct accountability, and a significant degree of legal and operational autonomy for the officeholder in exercising their regulatory functions
- be supported by the department to pursue regulatory and cost efficiency. The department could provide access to a large and diverse body of governance, implementation and efficiency practices.

### **Option 5 Independent scientific advisor with department as regulator**

The APVMA would become an independent scientific assessment agency. The department would be responsible for all regulatory functions. Applications for registration and approval would be submitted to the department and scientific advice requested from the APVMA. The decision maker would be obliged as a matter of law to have regard to the advice provided.

Under this option, the APVMA would:

- retain its scientific risk assessment capability and role; the independence and objectivity of the APVMA scientific risk assessment activity would be unaffected

- perform its functions with minimal influence from government. A departmental decision maker would be accountable to the Secretary or Minister, who may have power to intervene in regulatory decisions
- pursue cost efficiency in scientific assessment on its own terms. The APVMA would retain corporate functionality appropriate to its reduced size. Consolidating regulatory functions with the department's existing regulatory responsibilities could offer major cost savings and simplification of the regulatory landscape for industry.

### **Option 6 Reform oversight steering committee**

A representative steering committee would be established, e.g. under a COAG body, for a period to oversight the delivery of the reforms across the system that may flow from the panel's recommendations. All parties contributing to the reform agenda, including the APVMA, states and territories, and the formal consultative forum proposed in [Chapter 5](#), would have a responsibility to report to this body on implementation of reforms they are responsible for or have oversight of.

This could be combined with any other option, but if the APVMA remained a structurally separate statutory authority under options 1 or 2, then the APVMA would:

- retain its scientific and regulatory roles. The steering committee would not be involved in the day to day activities of the APVMA or affect the independence of APVMA risk assessment
- perform its functions with minimal influence from government and be informed by the community as it chooses (outside of mandatory public submission requirements)
- pursue regulatory reforms under the strategic direction of the steering committee to ensure the APVMA is held accountable for their implementation and reflects community expectations.

## **Discussion question**

- 6) What governance structure might be best for delivering the Australian Government's responsibilities in the national regulatory system?
- 7) Do you see merit in a time-limited High-Level Steering Committee to drive implementation action on the regulatory reform agenda?

## **2.3 Should control of use be nationally consistent?**

Controlling the use of chemicals after supply is currently the responsibility of each of the states and territories, this includes activities such as ensuring that label instructions are followed, aerial sprayers are licensed, spray drift occurrences and adverse events are reported and investigated, veterinarians and compounding pharmacists are registered and follow appropriate standards of professional conduct, chemicals are properly disposed of, and off-label use only occurs as permitted.

The panel recognises that efforts to nationally harmonise control of use across all states and territories has been an ongoing challenge for the agvet chemicals regulatory system since it became national. National harmonisation is about access to appropriate chemicals, consistent rules on chemical use and a consistent compliance and enforcement regime for all users and regulators.

In 2010, in response to a request from COAG, the Agriculture Ministers' Forum (AGMIN) agreed to develop a single national framework to harmonise the regulation of agvet chemicals. The panel

acknowledges the efforts of governments, and the contributions of industry, in developing nationally harmonised post-supply regulation to date.

However, the current processes seeking harmonisation are based on negotiation and consensus. As a consequence, the panel notes that these efforts have had very limited success and, in most cases, have achieved, at best, in-principle support for a common goal or minimum consistency in implementation, thus diluting the benefits of harmonisation.

Three measures have been agreed by AGMIN in the ten years to date, with full implementation by all states and territories not expected until 2022:

- 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 panel is also aware that three major areas of the harmonisation agenda, with the most potential for benefit to Australian growers and animal owners, remain unresolved:

- off-label use of agvet chemicals
- veterinary prescribing and compounding rights
- national coordination of domestic produce residue monitoring.

The differences between jurisdictions deny growers in one jurisdiction equivalent access to chemical tools that are allowed in another, which can encourage illegal use to maintain farm viability. For example, Victorian growers have greater access to agricultural chemicals than those in other jurisdictions, as is the case for Victorian and South Australian producers in relation to veterinary chemicals. Access in the other jurisdictions routinely requires a permit issued by the national regulator, with the resulting cost and delays for data generation, application compilation and assessment.

User and chemical industry stakeholders are highly critical of the slow pace and lack of progress in establishing a harmonised approach for control of use. This criticism has been raised by stakeholders over many years, in past reviews and repeatedly with the panel. Stakeholders report that the lack of harmonisation in control of use is making the system inefficient, ineffective and costly. Stakeholders have also criticised inconsistent interpretation and enforcement of legislation between jurisdictions and the declining resources provided to the regulation, including compliance and enforcement, of control of chemical use in most jurisdictions. The panel notes that regulatory resources in jurisdictions have declined over the years to the point where in many cases they have fallen below the critical mass required to effectively undertake their control of use functions.

A serious risk of loss of community confidence exists while control of use arrangements are inadequate or inconsistent across the states.

Consolidating regulatory requirements for agvet chemicals use would address the current cross-border fragmentation, duplication and inconsistency. Benefits from harmonised use arrangements would accrue to:

- agvet chemical companies (registration holders/manufacturers/importers) for whom the lack of harmonisation leads to concern about unclear exposure to liability—achieving harmonisation may give them confidence to register additional chemicals, products and uses
- the regulator, by providing it with greater insight into product use and thus more certainty about real levels of risk when making decisions about risk management
- state and territory governments by enabling sharing or centralisation across jurisdictions that can help keep critical areas resourced at the levels needed to maintain confidence in the system
- exporters of treated produce who could more effectively describe Australia's agvet chemicals control of use arrangements to trading partners
- users by providing them with the same access to chemicals and products, especially for those that operate across state boundaries, including contract sprayers.

These benefits should be supported by a comprehensive domestic produce monitoring and surveillance program to assure our trading partners of the robustness of our regulatory arrangements, identify and respond to issues of chemical misuse quickly, and assure our community that chemicals used to treat produce are appropriate and remain safe for consumption. The last point, the social licence to apply chemicals to food, is a key risk to Australian agriculture and if unaddressed could increasingly compromise agricultural production, including valuable exports. The concept of residue monitoring, both in produce and the environment, is discussed further in chapter 4. The panel believes residue monitoring could potentially provide an important opportunity for cooperation and collaboration between all jurisdictions and the Australian Government.

Looking at history, the panel is not confident that consensus on the incomplete harmonisation reforms will occur in the near future, despite the best intentions of all players. The resources available in jurisdictions appear to be insufficient to support both reform and ensure integrity of the system. Nor is the panel assured that the completed harmonisation efforts will not see the introduction of additional jurisdiction specific requirements in the future, leading to inconsistencies once again.

The lack of progress in, and effectiveness of harmonisation needs to be addressed. It appears to the panel that the competing demands of governments and parliamentary systems in each jurisdiction and the Commonwealth is unlikely to ever efficiently achieve national consistency in control of use. Given that each jurisdiction will act, understandably, in the interests of their own state or territory, the current process is fraught with difficulty and may only ever deliver small incremental reforms.

Therefore, the panel believes alternative approaches need to be considered. These approaches must recognise and build on the strengths within current arrangements and be focused on efficient and responsive regulation across the lifecycle of a chemical product.

As part of the panel's flagship reforms, three potential approaches are currently being considered.

## **Flagship reform proposals**

### **Option 1 Expanded applied law model**

The success of the supply side of the regulatory system is based on a single legislative scheme that has seen the states and territories effectively apply Commonwealth legislation as a single national law.

Establishing a single comprehensive suite of legislation spanning the lifecycle of agvet chemicals (from manufacture/import to supply, use and ultimate disposal) would allow a single clear view of the regulatory arrangements and how they are to be delivered. This would provide certainty, efficiency and reduce regulatory costs for chemical registration holders, Australian farmers and other chemical users.

The current applied law scheme (covering import, manufacture, supply and related matters) would be expanded to comprehensively cover control of use activities. This could be conveyed in the legislation as a series of chapters, each addressing a specific aspect of a product's lifecycle or regulatory requirements.

A model of these chapters for the future applied law scheme could be:

- 1) control of registration and supply
- 2) licensing
- 3) control of use (including access controls, record keeping and disposal)
- 4) residues (both environmental and treated commodities)
- 5) regulatory powers (compliance and enforcement)
- 6) consultative processes

The inclusion in legislation of residues reflects the panel's considerations in chapter 4. The panel considers there are advantages to public and consumer confidence in the regulatory system establishing national domestic residue monitoring.

The panel considers there would be significant advantage in formal and transparent consultative machinery that engages the diverse stakeholders of the agvet chemicals system (grower, governments, manufacturers and community). These consultative processes are explored further in [Chapter 5](#).

The applied law arrangement should be underpinned by an IGA. The panel believes that it would be appropriate for this to incorporate similar inter-government consultation arrangements to those in place for changes to the current applied law. Jurisdictions are currently provided a minimum of three months to review changes to primary law, and three months' notice of changes to subordinate legislation.

Harmonisation of control of use could be achieved by the states and territories applying the Commonwealth legislation as a law of their respective jurisdiction. This is how the current arrangements work for the supply-side of regulation, which effectively works as a single national law. The additional chapters would become part of the national law and the jurisdictions would apply (adopt) this just as they do now but with expanded scope. If any jurisdiction chose not to adopt all chapters of the national law, it would need to justify its position in a publicly available notice to COAG. Once jurisdictions adopted the expanded national law, they would need to repeal their existing control of use legislation.

Ultimately however, it would be up to each jurisdiction to decide whether to apply the legislation. If only some states applied this model, there would still be inconsistencies across jurisdictions. Should

any jurisdiction choose not to apply the Commonwealth law it would need to account to its constituency to provide valid justification for not doing so.

In terms of operation the Commonwealth regulator would continue to register agvet chemical products for supply consistent with those chapters of the expanded legislation. States and territories would continue to resource and enforce the control of use chapters. Some cost savings and regulatory efficiency for jurisdictions would be achieved through the Commonwealth having control of the legislation that covers the whole system.

The comprehensive suite would also need to be supported with agreed compliance and enforcement arrangements that ideally standardise initial response options.

Cost savings and operational efficiency would be achieved for growers through a single national harmonised agvet framework.

### **Option 2 Commonwealth exercising its full constitutional reach**

An alternative approach to the expanded applied law model would be for the Commonwealth to assume the regulation of agvet chemicals relying on some of its own constitutional powers, with the states then applying the national law in the 'gaps' left by the Commonwealth Act.

This, for example, is how national maritime safety legislation works, with most states applying the national law through their own legislation. Relevantly, it is also essentially the approach used to regulate therapeutic goods and poisons.

The panel believes the Commonwealth has significant legislative power, under section 51 of the Australian Constitution, to implement laws for regulating agvet chemicals. The panel notes that in recent years, the scope of Commonwealth responsibility has increased consistent with constitutional interpretations.

In particular, the panel takes the view that the Commonwealth may be able to regulate the use of agvet chemicals by constitutional corporations and other entities, including individuals that:

- are selling produce or goods to a constitutional corporation where misuse of the chemical could result in loss or damage to those corporations
- have entered a contract with an upstream or downstream corporation requiring it to comply with label conditions.

In addition, there are several international treaties that may trigger the external affairs power, including those covering biological diversity and human health. For example, the Commonwealth may be able to regulate agvet chemicals to the extent necessary to prevent significant adverse effects to (native) biological diversity.

While the full spectrum of agvet chemicals suppliers and users may not be within Commonwealth responsibility, the states and territories could either apply the national law to these to continue to regulate in the gaps or could formally refer power to the Commonwealth to ensure that the Commonwealth could legislate comprehensively.

The panel is interested in exploring stakeholder views on how this could be most appropriately funded and how to balance the considerations of costs for pre-market assessment, with the costs of



ongoing registration and the control of use compliance and enforcement. The panel believes it is appropriate to include guidance for government on possible funding models.

**Option 3 Re-invigorating the existing Intergovernmental Agreement on control of use**

The current IGA could be re-negotiated to provide for a specific model of control of use that would be applied consistently in each jurisdiction (including off-label use and compliance and enforcement activities). The IGA could be revised to:

- list streamlined policy goals of agvet chemicals regulation
- state division of responsibilities between jurisdictions, and as an attachment (updateable and separate to the IGA) listing the regulatory agencies in each jurisdiction including a point of contact
- establish a formal inter-government consultative group, to inform policy development and set national standards for, amongst other things, environmental and residue outcomes, compliance and enforcement and off-label chemical use
- provide that where consensus on a common approach cannot be reached, a two thirds majority of jurisdictions will be employed
- mandate minimum resource levels (as a proportion of jurisdiction domestic production value)
- require biannual publication of a work plan for agvet chemicals reform, and reporting against the previous plan including
  - any activities not covered by the plan
  - all compliance and enforcement activities
  - outcomes and findings of residue monitoring
- require any jurisdiction choosing not to fully implement the IGA to provide a publicly available justification to COAG for its departure from the common national approach.

The IGA would not include details affecting the national regulator's operations.

The panel considers the lack of performance measures within the regulatory system, and particularly for control of use, a key failing of the current IGA.

The panel considers that providing clarity and specified resources for regulating agvet chemicals use will significantly contribute to community confidence in the regulatory process.

This model has the lowest legislative resource implications, but may, depending on current jurisdictional resources, result in operational increases. The panel considers this could support, for example, increased activities through residue monitoring. The overall responsibilities for supply and control of use remain as they are currently.

This approach would be like what has been attempted for well over a decade in trying to negotiate an agreed model with the states and territories. The panel is aware that compromise has been difficult to find in some areas, although the proposed inclusion of a two-third majority would be a critical innovation to overcome this barrier to effective national regulation.



The panel considers that some of the options for re-invigoration presented under this approach could also be relevant to the other reform options discussed.

## Discussion questions

- 7) Which of the three reform options outlined do you support and why?
  - a) Which option is likely to deliver the best chance of consistency in control of use and the greatest likelihood of success and why?
  - b) What risks do you foresee in implementing any of the options proposed?

## 2.4 Should there be shared responsibilities between industry and government?

The purpose of managing agvet chemicals is to ensure the use of these products does not pose a risk to the safety of human, plant and animal health and welfare, the environment or Australia's international trade, thereby retaining public confidence in chemical use.

In the current arrangement much of the responsibility and effort for ensuring compliance rests with government (either the Commonwealth or the states and territories). The panel is aware that in recent years other safety regulatory systems (such as work health and safety and consumer products) have established formal mechanisms to expand the range of actors with formal responsibility for safety. These approaches do not reduce the safety nets within the systems, but rather seek to identify the most appropriate parties for specific components. While still retaining ultimate responsibility for safety, this has allowed governments, to target resources to higher risk areas, and ultimately provide better outcomes for Australia.

In the nearly 30 years since the inception of the NRS, industry (manufacturing, supply and user) has changed significantly, with increased levels of professionalism and global standardisation. The panel believes, in general, Australian industry is committed to the manufacture and supply of safe and appropriate agricultural chemicals, and their responsible use ('as little as possible, as often as needed'). The panel sees an opportunity, as is the case in other safety regimes, to take advantage of these higher standards and active interest in maintaining community confidence by formally assigning industry responsibility for managing safety, where appropriate.

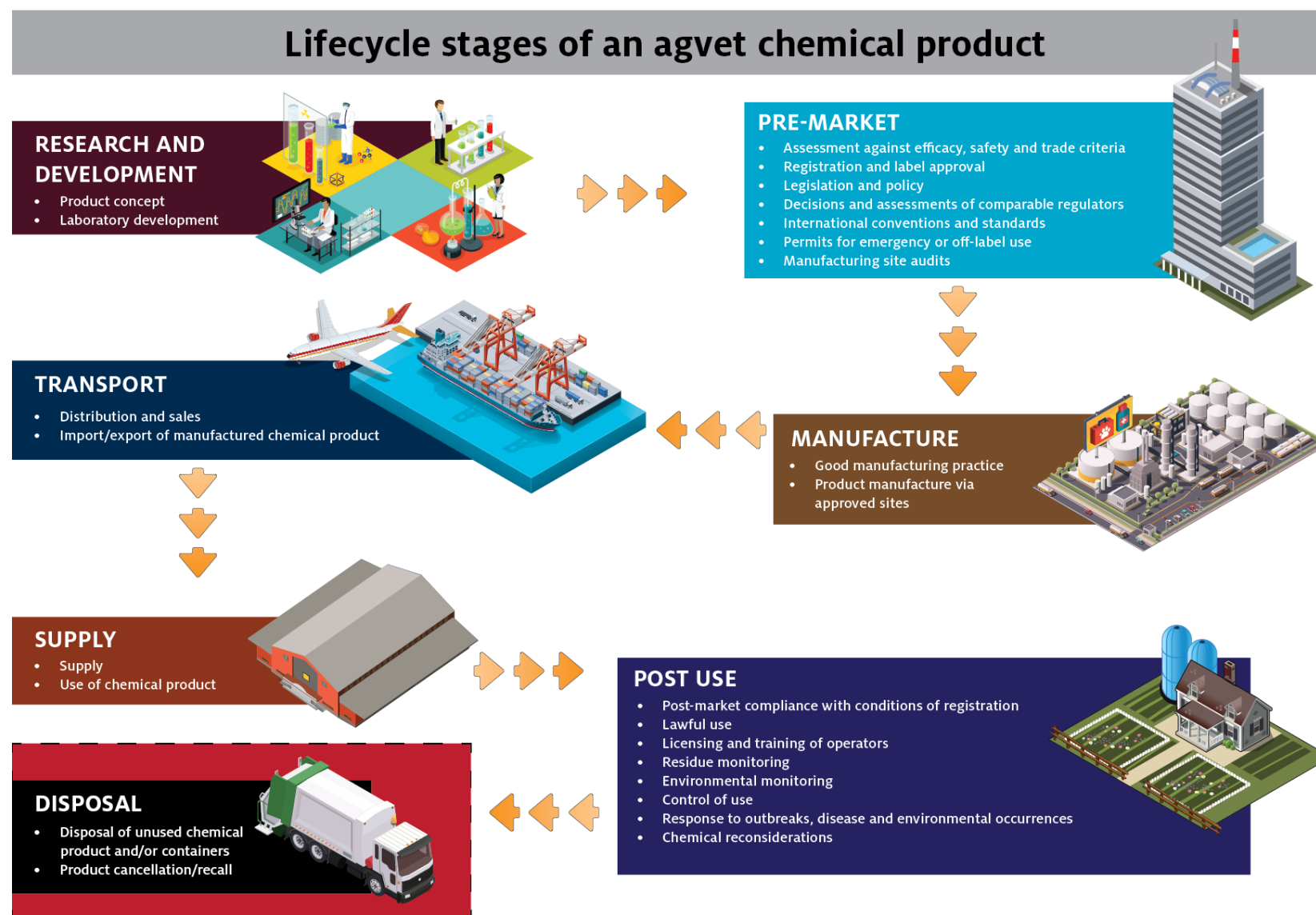
In this system, regulatory responsibilities would be shared and rest with those most able to deliver efficient and effective compliance.

The benefits that can be delivered for Australian growers and the agvet chemicals industry through sharing of responsibility are significant in terms of opportunity for innovation, increased speed of product to market, reduced regulatory, compliance and administrative costs, increased flexibility and earned autonomy, and harnessing industry knowledge and expertise to directly address industry specific issues.

The panel is of the view that strong regulation, along with co- and self-regulatory approaches to agvet chemicals management (across all levels of a product lifecycle) can deliver better outcomes. The challenge is finding points of commonality and defined boundaries between government and industry responsibilities (Figure 3). Changing consumer expectations and supply chains are driving

industry to develop industry specific quality and safety systems. It is good contemporary public administration practice for governments to be open to opportunities to recognise this system maturity by formalising these industry efforts in co-regulatory approaches. Areas where a co-regulatory approach has already delivered, or is likely to deliver, positive outcomes include waste disposal and management, quality assurance schemes for good agricultural practice, accreditation for permit and registration holders, and training and licensing requirements for the supply and use of agvet chemicals.

Figure 3 Lifecycle stages of an agvet chemical product



### **2.4.1 Waste disposal and management**

The panel notes the success that has been achieved through the industry and government co-regulatory approach set out in the Australian Packaging Covenant. The Covenant applies to businesses in a supply chain that produce packaging or packaged products and have an annual turnover of \$5 million or more. While some large agvet chemicals manufacturers are already participating in the Covenant, the panel believes the majority of agvet chemical companies, regardless of their size, could take part in this co-regulatory framework through a condition of product registration. The condition would require the packaging material for all products (exceeding a certain volume or mass, for example 5 litres or kilograms) to be recyclable or reusable through an industry recognised scheme.

The panel commends the work of stewardship programs such as ChemClear and drumMUSTER for their role in the collection and environmentally friendly disposal of agvet chemicals and empty chemical containers. The services provided by these programs, which are funded by a levy collected under the Industry Waste Reduction Scheme, benefit chemical users, industry, the environment and the wider community by providing reliable and cost-effective solutions for chemical waste management.

### **2.4.2 Industry-led quality assurance schemes**

Greater use of recognised industry-led quality assurance schemes could lead to significant benefits for the regulator, users and industry by freeing up regulatory assessment resources, expediting product assessment timeframes and speeding up market access of chemical products.

For example, the panel has heard from the veterinary manufacturing industry of the potential for expanding the regulatory role of the current Good Manufacturing Practice (GMP) requirements for veterinary medicines. GMP is not technically an industry-led scheme but rather a legislated system designed to ensure that products are consistently produced according to set quality standards during all stages of the manufacturing process by requiring high level and documented quality control steps. However, it is a scheme that the entire industry must adhere to that provides assurance that veterinary medicines are manufactured consistently.

By taking advantage of the fact that manufacturing quality assurance obligations are already mandated under the GMP arrangements, it may be possible to eliminate the need for separate approvals of manufacturing sites for active constituents, leading to reduced assessment timeframes for veterinary medicine products.

### **2.4.3 Accreditation schemes for permit and registration holders**

Regulatory efforts could be more efficiently shared through the establishment of a holder accreditation scheme. Under this model only accredited entities could seek, and ultimately hold, a registration, permit or label approval. The panel believes it would be appropriate to establish a minimum standard for accreditation, and levels of accreditation where the minimum standard is exceeded. This approach is conceptually similar to the issuing of drivers licences for different kinds of vehicles, with requirements increasing for larger vehicles (where risk to the public is increased).

For example, the minimum standard might be a requirement for an applicant to be a registered business in Australia and be of good character (i.e. no convictions or civil findings relating to safety or chemical activities, by entity, directors or key personnel). Additional levels of accreditation could be

attained through independent audits of manufacturing processes, adverse experience and recall programs, comprehensive quality assurance and product stewardship protocols, and a history of regulatory compliance.

The accreditation number(s) would be the reference supplied to the regulator in seeking a product registration and act as the single source of information about the holder, simplifying many administrative processes. Those holders with the highest level of accreditation (i.e. certified/reviewed quality assurance and product stewardship programs, history of compliance) would be subject to reduced regulatory scrutiny in pre-market assessment. The reduced costs and application processing times would be a strong incentive for industry to participate in the accreditation scheme.

The panel considers that specific accreditation level restrictions could be dependent on the role a company has in the manufacturing/supply process. For example, a company that supplies a re-labelled product from a toll manufacturer with limited involvement in or knowledge of the manufacturing process may only be able to hold approvals of that nature. It would not be necessary or desirable for this company to have complex manufacturing quality assurance systems in place. However, if the company chooses to expand its business into manufacture, additional protocols will need to be established and additional accreditation sought.

A condition of registration would be applied to all products that the holder of the registration is accredited. This would provide an additional incentive for industry compliance, as the potential for non-compliance in one product could result in the suspension of an accreditation and impact the supply of an entire product range.

#### **2.4.4 Training and licensing requirements for the supply of agvet chemicals**

Another area that would benefit from a co-regulatory approach includes training and licensing requirements for the supply of agvet chemicals like those existing for users of these chemicals. The panel understands many growers are completing industry-led training and accreditation programs (such as ChemCert) to, in part, meet their obligations under work health and safety regulation. The panel is interested in exploring whether similar programs could be developed for the purchase of agricultural chemicals above a certain volume. These programs could:

- simplify the instructions for use of a chemical product, and related assessment effort
- support residue management
- deliver improved outcomes for environmental and human safety
- contribute to the community confidence in the supply and use of these products.

#### **2.4.5 Statutory duty of care for the chemical industry and chemical users**

Currently the regulator utilises significant resources to assess product quality, efficacy and safety. The costs of these resources to a large extent flow through to industry who, generally, passes them on to either the producer and/or the consumer. The responsibility of industry is to supply products that are consistent with the details assessed and recorded by the regulator.

This is subtly, but importantly, different from a responsibility to provide a product that is safe and appropriate. The former approach is passive in terms of product supply. It encourages a 'tick the box' mindset with risk assigned to the regulator. The latter requires a more active involvement and consideration by manufacturers and suppliers for each product supplied. It encourages a mindset of prudent initiative on the producer's part. The panel sees this active engagement as both desirable and reflective of the current best practices of Australian industry.

Another arrangement for sharing regulatory responsibility involves the possible introduction of a statutory duty of care on the chemical industry and chemical users. A duty of care sets outcomes and responsibilities that entities are required to meet and penalties for failure to meet these. The duty would apply to each entity that deals with a product from manufacturers through to users.

All agvet chemicals manufacturers, importers and suppliers would have a duty of care to ensure they only import, manufacture or supply products that are safe and appropriate. The panel believes greater clarity in the expected behaviour of these entities could provide soundly based justification to reduce pre-market assessment by the regulator in some circumstances, for example for the registration of many generics (such as repacks explored further in [Chapter 6](#)), thereby decreasing the timeframe for a product to enter the market.

The panel also recognises the role users have in effective risk management for agricultural chemical products and the potential negative impacts where this role is undertaken poorly. Therefore, it could be argued that there would be value in introducing a similar duty of care on users of agvet chemicals to minimise the risks of harm to human health and the environment. This could simplify control of use management efforts as well as provide a comprehensive linkage between chemical use, record-keeping and health, safety and environmental outcomes.

Users of agvet chemicals products that cause damage when using a product in accordance with the label, should be provided with a mechanism to seek recourse/redress through this duty. This would empower users in responding to adverse events and delineate civil damage from criminal behaviour.

The panel is well aware that introducing a formal duty of care requirement could be contentious and would therefore welcome stakeholder views on its advantages and disadvantages.

## Discussion questions

- 8) Do you support the addition of co-and-self regulatory approaches to agvet chemicals management (across all levels of a product lifecycle like the Australian Packaging Covenant) to deliver more effective and efficient outcomes than direct regulation alone?
  - a) Do you support the panel's proposal for a holder accreditation scheme? Would the proposed levels of accreditation provide greater incentives for industry compliance?
  - b) Is there additional value in limiting the scope for a holder based on the nature of the registration?
  - c) Do you agree with the panel's proposal for formal training requirements for users to access (purchase) agricultural chemicals above a certain volume?
  - d) Do you have suggestions for how existing assurance schemes such as GMP could be used to streamline assessment processes?

- e) Is there value in a statutory duty of care on industry and/or users to strengthen incentives for responsible use of chemical products to minimise risks to human health, animals and the environment?
- f) Can you think of any alternative or additional measures the government could implement to strengthen the responsibilities of regulated entities and users?

## 2.5 Is compliance and enforcement effective?

The regulatory system cannot adequately manage the risks posed by agricultural chemicals and veterinary medicines without a well-designed and appropriately resourced compliance and enforcement regime. The panel is keen to explore approaches to compliance and enforcement that provide the public with the assurance it needs that the chemicals used to grow their food and fibre, treat their pets and livestock, and maintain their public spaces are safe.

The agvet chemicals regulatory system manages three main types of risk, all of which the national regulator has a role in (

Table 1). States and territories only directly manage the risks related to misuse of products.

**Table 1 Agvet chemicals regulatory system risks**

Risk type	Regulator	Tools
Product risks—those risks inherent to the product and active constituent	National	Pre-market assessment of proposals for registrations and approvals Maintaining the product register Adverse Experience Reporting Program Chemical review (reconsideration)
Pre-market compliance risk—risks from the (intentional or unintentional) failure of a manufacturer or supplier to comply with legal requirements.	National	Education services Information and communication products Product surveillance <ul style="list-style-type: none"> <li>Follow up tip-offs</li> <li>Random and targeted audits</li> </ul> GMP licensing Approve sites of manufacture of active constituents Investigations, enforcement, and imposition of sanctions
User compliance risks—risks from accidental or deliberate product misuse.	National	Approves instructions for use Approves product labels Sets packaging requirements May declare a product to be a restricted chemical product Recommends access restrictions via Scheduling

Risk type	Regulator	Tools
	States and territories	Education services Licensing of users Other access restrictions—e.g. declaring restricted or buffer zones under environmental laws Surveillance Environmental and water monitoring Follow up complaints Random and targeted audits Crisis response (e.g. crop damage) Investigations, enforcement, and imposition of sanctions

### 2.5.1 Compliance and enforcement

Manufacturers, suppliers, and users of agricultural chemicals and veterinary medicines who do not comply with the regulations can cause serious harm to the health and safety of humans; animals; plants; and the environment. They can undermine consumer confidence in the safety of food and fibre, damaging agriculture's social licence. They can also tarnish Australia's reputation with our trading partners, threatening market access and potentially costing billions in lost export revenue. The way that regulators facilitate compliance from the regulated entities is therefore essential to preserve the integrity of the agvet chemicals regulatory framework.

The panel takes the view that Commonwealth and state and territory agvet chemicals regulators' regulatory posture towards regulated entities should be based on how likely a supplier or user is to fail (accidentally or deliberately) to comply with legal requirements. This will allow the regulators to focus their regulatory activities proportionately on the people and businesses that pose the greatest risks to the integrity of the system. They need sufficient resources, and an appetite and incentives, to use appropriate detection, investigation, and enforcement tools to deter regulated entities from engaging in careless or deliberate non-compliant conduct. It is also important that they have an appropriate range of sanctions (criminal, civil and administrative) to respond to non-compliance.

Prima facie, pre-market assessment of chemical applications is the most resource intensive of the controls available to treat product risk. Chapter 6 of this issues paper advances reform options that, if adopted, would reduce or remove the detailed pre-market assessments of certain products and make greater use of notifications as a means of maintaining the product register. The panel is inclined to recommend that some of these resources be redirected to detection and investigation activities. Increasing these activities should manage the possibility of increased compliance risks from reducing pre-market scrutiny (where appropriate), as well as strengthening the existing controls on pre-market compliance risks.

The panel is also favourably disposed towards the establishment of incentives, or other mechanisms, to ensure that regulators maintain sufficient resourcing and make appropriate use of their detection, investigation, and enforcement powers and tools. The panel notes that other regulators, such as the Therapeutic Goods Administration (TGA), have designed their compliance and enforcement regimes to incentivise participation from applicants with the requisite expertise, capacity, and integrity to comply with the regulations, and deter negligent or wilfully non-compliant participants. The TGA requirement that all manufacturers of therapeutic goods hold GMP clearance is an effective means of ensuring their ability to supply a compliant product. The sponsor (equivalent to an agvet chemicals registration holder) must reside, be part of a company, or conduct business in Australia; and where



they are sponsoring a product that is manufactured overseas, they must have a formal relationship with the manufacturer because they undertake responsibilities on its behalf.

The TGA maximises voluntary compliance from regulated entities by providing high quality communication and education materials. It deters non-compliance by identifying the level of compliance for different regulated entities via its pharmacovigilance audit and product testing, and it takes appropriate corrective action using administrative actions and civil and criminal penalties.

The option of accrediting all pre-market participants is explored elsewhere in this paper, but the panel is keen to hear from stakeholders about other ideas to adopt a regulatory posture that could assure the public that only reputable entities can market agvet chemicals in Australia.

## Panel's view

The panel notes that state and territory regulatory powers to control agricultural chemical and veterinary medicine use differ from jurisdiction to jurisdiction, as does the approach to compliance by the various regulators. The panel is inclined to recommend a national approach to compliance and enforcement of agvet chemicals use that employs a consistent set of compliance and enforcement tools. For example, there could be a more consistent approach to: licensing of chemical users; monitoring and investigative powers; record-keeping requirements; and the full suite of administrative actions, plus civil and criminal penalty provisions with a consistent range of available sanctions.

### 2.5.2 Sanctions for breaches

Ideally the regulation will include sufficient incentives to encourage compliance from the majority of participants. However, the panel would also like to consider the current suite of sanctions for breaches, including their scope, proportionality, and application by regulators. The panel is also considering the merits of adopting the provisions of the *Regulatory Powers (Standard Provisions) Act 2014* to simplify and standardise with other Commonwealth coercive and enforcement provisions.

Of possible interest is the difference in the magnitude of penalties available to the national agvet chemicals regulator compared to the TGA. The maximum civil penalty that can be imposed on a body corporate is 7,500 penalty units, compared to 50,000 for the TGA and the maximum (non-custodial) criminal penalties available are 1,500 penalty units, compared to 4,000 for the TGA. However, it is not clear if the sanctions available to the national regulator are insufficient, given the difficulty in establishing equivalent breaches between the two systems.

The panel would also like to know if stakeholders consider that regulators make appropriate use of the powers they have to detect and respond to non-compliance, or if they consider they should use them more or less frequently than they currently do.

The panel notes that some other kinds of sanctions for breaches that are not used in agvet chemicals regulation, such as publishing details of breaches in the media, can be a more effective deterrent than financial penalties for larger and better resourced entities. The panel considers that this kind of sanction could be a useful addition to the sanctions available to regulators.

## Discussion questions

- 9) Should detection and investigation measures be augmented to better treat the risks posed by agvet chemicals?
  - a) Do agvet chemicals regulators need more effective and nationally consistent tools and sanctions than they already possess to manage the risks for which they are responsible?
  - b) Do agvet chemicals regulators have appropriate resources, appetite and/or incentive to use the detection and enforcement tools they have? If not, how could this be addressed?
  - c) Are you confident that regulators will detect non-compliance (in particular, that which poses the greatest threats to human and animal health and the environment) and respond appropriately? If not, what should/could be done differently?
  - d) Should agvet chemicals registration-holders be screened in some way to ensure they are reputable? Why, why not?

### 3 What chemicals are currently regulated?

The scope of regulation for agvet chemicals (products and active constituents) is currently determined based on definitions within the Agvet Code. The definitions operate on how a product is used, represented for use or manufactured for use. When considering what chemicals are covered by the agvet chemicals regulatory system, most people would assume that it refers to products used solely in agricultural production and the treatment of animals. However, the current definitions of an agvet chemical is considerably broad and not only captures chemicals used in agriculture, fisheries and forestry production and by veterinarians, but also chemicals used by consumers in households and public places (to manage pests and diseases), pool and spas and anti-fouling paints for boats.

Many of the products captured under the current definition are also subject to other regulatory systems. For example, consumer products (e.g. household fly sprays, household garden pesticides, and flea collars) are all covered by Australian Consumer Law (ACL) and the ACCC, yet they are also regulated under the Agvet Code. This represents duplication of effort and does not appear to provide any real advantages. The ACL requires that consumer products are fit for purpose and this includes appropriate safety instructions. In addition, under the ACL a standards model sets out requirements for ingredients and uses for consumer products. As there is no pre-market assessment of these products, responsibility is placed on the company to comply with the obligations.

The rationale for having agvet chemicals consumer products regulated in addition to the regulation provided by the ACL is not strong.

The agvet chemicals regulatory system regulates pool and spa chemicals used for sanitisation whereas the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulates the introduction to Australia of pool and spa chemicals for purposes other than sanitisation. There appears to be no clear reason for the split of regulation of pool and spa chemicals, other than that they fall within the current definition of an agvet chemical product, as many of the same materials are used in industrial chemicals just with different uses.

An anti-fouling paint is a film-forming coating that releases biocides (contained within the film) in a controlled manner. They are designed to prevent the settlement and growth of fouling marine organisms and algae on the hulls of boats. They currently fall within the definition of an agvet chemical whereas NICNAS regulates the introduction of industrial chemicals into Australia used for boat surface cleaning.

Determining which chemicals should be regulated under the agvet system is about considering who the most appropriate regulator is—given some products are currently subject to multiple regulators.

### **3.1 Should the system only include chemicals for primary producers, veterinarians and non-urban land managers?**

The NRS has regulatory responsibility for products based on their intended or represented use. This is provided for through the current legislated definition of agricultural and veterinary chemical products. In practical terms this means:

- current definitions for agvet chemicals do not consider the inherent risks posed by the product or its use in determining the need for regulation
- certain products outside of the agricultural sector, the perceived focus of the NRS, being captured by the NRS.

The panel believes that it is appropriate to introduce a specific consideration of risk (hazard and likely exposure from use) in determining the scope of products considered within the NRS. This will allow a more appropriate allocation of regulatory effort and resources on those products that pose a measurable risk to Australian health or trade.

While it is perceived that the NRS is focused on the agricultural sector other products with pesticidal action are currently equally relevant. However, in some instances, these products are subject to other regulatory arrangements that can or do provide more appropriate regulatory controls commensurate with the level of risk. Numerous reviews of both chemical regulation in Australia generally, and agvet chemicals regulation specifically, have identified the unnecessarily broad scope of regulation in terms of agvet chemicals to be an issue. These reviews have also highlighted the need to better align the regulatory effort of government and industry to the risks posed by the product.

The products identified earlier (consumer products, pool and spa chemicals and anti-fouling paints) are products of low regulatory concern which do not warrant being subject to multiple regulatory systems. The low regulatory concern nature of consumer products makes them ideal for the post-market focused regulation of the ACL. Pool and spa chemicals and anti-fouling paints would appear to sit more logically with similar industrial chemicals under NICNAS.

Removing these low regulatory concern non-agricultural products from the definition of the agvet chemicals regulatory system would provide for its regulatory focus to be on products of higher regulatory concern that have a greater impact on people, animals and the environment. It would also provide for the focus to be on products used in primary production and by veterinarians which is what the panel considers the system should be focused on. The panel acknowledges the additional factor of animal welfare that exists with veterinary chemicals, and the strong positive outcomes delivered for animal health and the veterinary sector through pre-market assessment in the majority of products. To that extent the panel accepts that the approach to products for plants may rightly differ from that of products for animals.

The panel considers this rationalisation of regulatory effort will establish equivalent regulatory controls for agvet chemicals products with other equivalently low regulatory concern consumer accessible chemicals. As is the case for oven cleaners, household paints and detergents, access to the

market would not involve pre-market assessment, with post-market response only occurring after an identifiable adverse event that warrants intervention. Such arrangements have worked well for many years under Australian consumer law. The panel also recognises that this approach – clarifying the responsibility for these products within single regulatory agencies (ACCC and NICNAS), could imply an increase in workload for these agencies. However, the panel considers this is not likely to be significant.

The panel acknowledges there are provisions within existing legislation to exclude products or product classes from regulation as an agvet chemical. These provisions have been used infrequently despite the findings of previous reviews. This may in part reflect the complexity of process, an alternative that is more responsive to risk and advancements in science would increase the flexibility of regulation.

The panel has also identified that the current process for restricting chemicals to veterinarians was not intended to cover animal toxicity, being solely focused on human toxicity of a product. To that end the panel believes opportunity exists to recognize the necessary role of veterinary expertise in some products, separate to the requirements of scheduling through the Poisons Standard.

## Panel's view

The panel is disposed to removing from the scope of the agvet chemicals regulatory system products with limited relevance to primary production or animal welfare. As examples this would include most consumer goods, pool and spa chemicals, antifouling paints and some veterinary products.

The panel considers that this would give a clearer 'identity' to the agvet chemicals regulatory system: it supports Australian primary production, veterinarians, and non-urban land management.

The panel is also disposed towards the introduction of restrictions of 'veterinary use only', where warranted for animal welfare, along similar lines to that adopted for agricultural chemicals currently under the auspices of Restricted Chemical Products. The panel considers that at the minimum, and to the extent not already addressed through scheduling, injectable veterinary products should require the direct involvement (either in administration or under their instruction) of a veterinarian.

## Flagship reform proposal

The panel's proposed approach of having new definitions for what constitutes agricultural chemicals and veterinary medicines (detailed in [Annex 2](#)) operates on several levels to improve the focus of regulatory effort by:

- establishing simplified and intuitive titles for an agricultural chemical product and a veterinary chemical product—plant protection product and veterinary medicine respectively
- focusing NRS activities on products with direct action on, or against, an animal (in all settings) or a plant in primary production and non-urban land settings
- introducing the risk of using the product (through specific reference to the product's hazard and likely exposure) as a specific consideration for the need for regulation
- providing that products supplied for use in small quantities, without intention for use on food for public consumption, and by consumers generally are subject to equivalent controls as other chemical consumer goods (such as oven cleaners, detergents and household paints)

- establishing a list of chemicals, and products made containing only those chemicals, that may be excluded from the operation of agvet chemicals legislation
- providing a mechanism for proposing additions to the list
- aligning with relevant existing national legislative definitions and practices thus increasing the connectivity between agvet chemicals legislation and the wider chemical controls of Australia.

The approach would exclude from consideration by the agvet chemicals regulator:

- products supplied to the home garden and domestic market
- anti-fouling paints
- pool and spa chemicals
- insect pheromone attractants
- products modifying the effect of another product such as wetters, spray adjuvants and spray markers
- many over-the-counter companion animal products, in particular impregnated material (such as flea collars)
- most products based on essential oils or other herbal extracts
- products containing only substances generally recognised as safe (GRAS), set out in regulation
- all products currently excluded from the scope of agvet chemicals regulation.

To ensure that chemicals removed from the agricultural sector, as the result of an adverse finding by the regulator, could not appear in the domestic market the panel believes it is necessary to also establish a prohibited substances list. Inclusion of any of these substances would make the resulting product subject to the regulatory controls of a plant protection product or veterinary medicine.

## Discussion questions

- 10) Do you support the proposal to remove consumer products and pool and spa chemicals, anti-fouling paints and certain over-the-counter companion animal products from the agvet chemicals regulatory system? If not, why?
- a) Do the benefits of the proposed removal of these products outweigh the risks? If not, why?
  - b) Are the new definitions of a plant protection product and veterinary medicine supported? If not, why?
  - c) Do you agree that certain product uses, such as those administered by injection, warrant the direct involvement of veterinarians, separate to the controls under the poisons scheduling?

## 3.2 Should agricultural and veterinary chemicals be regulated together?

Australia and New Zealand are the only regulators that combine the regulation of agricultural chemicals and veterinary medicines within one single regulatory system, with common legislative requirements and obligations. Other international regulatory schemes place veterinary medicines

under the health portfolio with agricultural chemicals in the agriculture portfolio, each product type having distinct legislative requirements. Canada is significant in that while agricultural chemicals and veterinary medicines are regulated within the same portfolio (health) the assessments and legislative requirements are separate.

The panel acknowledges that previous reviews of the agvet chemicals regulatory system have considered whether agricultural chemicals and veterinary medicines should be regulated by different agencies. However, there doesn't appear to have been a consistent position expressed in these previous reviews of the benefits or efficiencies of such a separation and therefore no change was ever implemented.

The panel has heard from the veterinary chemicals manufacturing sector who strongly support the retention of veterinary medicines within the current agvet chemicals regulatory system. Representatives of the sector indicated that they see no benefit in moving veterinary medicines into the human medicines regulatory system under the TGA in the health portfolio. Nor was there support for the establishment of a 'stand-alone' entity with responsibility for veterinary medicines only.

The panel notes that control of use for veterinary medicines varies from that of agricultural products in that a veterinarian can prescribe a registered product as they see fit, to address a therapeutic need for a single animal. However, in general, for users of veterinary medicines other than veterinarians or those operating under their direction, the arrangements for control of use are like those for agricultural chemicals. The arrangements are routinely detailed within the same jurisdictional legislative suite.

The panel has not heard any compelling reasons to date to suggest there would be benefit in separating the regulation of agricultural chemicals and veterinary medicines from the one regulator. That said, it is possible to articulate separate provisions within legislation that relate specifically to veterinary medicines or agricultural chemicals (as is done to some extent now) which could be expanded, whilst remaining under the one regulator.

The panel's desired overall reform is for a stronger identity for the system as a support for primary producers and veterinarians. The panel understands that many Australian farm businesses are a mixture of cropping and animal production. To the extent that many currently regulated agricultural chemicals and veterinary medicines are farm inputs, a consistent regulatory approach to both could improve the experience of growers and producers.

The greatest risks posed by veterinary medicines (safety to humans either at application or through consumption of animal produce, safety to the environment, threats to Australia's international trade) are also common to agricultural chemicals. To that extent, the panel considers there to be value in retention of expertise in assessments within one body.

Within the assessment of any application the panel understands there is usually a range of distinct areas of work, notwithstanding the obligation of the regulator to be satisfied the product is safe, efficacious, not a hazard to trade and complies with labelling requirements. The panel has been informed by veterinary manufacturing stakeholders of the value specific veterinary technical knowledge in some areas can have in efficient and effective application assessment. They expressed

a desire to see separate assessment teams, so that veterinary medicine applications were generally only assessed by skilled veterinary chemical assessors. The panel acknowledges that specific technical knowledge is critical and should be retained.

However, the panel also acknowledges the opportunity for learnings and cross-pollination of ideas that are possible through assessment staff working on a range of both agricultural chemicals and veterinary medicine products. The panel notes the high potential for 'silos' to develop if a rigid delineation is created.

The panel appreciates there are also risks that differ between agricultural chemical and veterinary medicine products, specifically animal safety and welfare. These risks are appropriately managed at the supply side at the time of registration which sets use instructions. To that extent the panel sees value in there being a distinction in the criteria for registration. This is seen in part in the proposal outlined earlier for the definition of a veterinary medicine (specific inclusion of products administered by injection) and the efficacy proposal at chapter 6 for considering the potential for a product to increase or prolong an animal's suffering as part of the safety assessment.

The panel acknowledges there are aspects of current regulation that are separated in this way (licensing of manufacturers and the need to comply with manufacturing standards—which in practice applies only to veterinary medicines).

## Discussion questions

- 11) Are there areas where the approach to agricultural chemicals and veterinary medicines should be different?
  - a) Should there be separate requirements specified in the legislation for veterinary medicines and agricultural chemicals? If so, what should these requirements be?



## 4 Are there gaps in agvet chemicals regulation or management?

International regulators of agvet chemicals all approach their task slightly differently. For example, the New Zealand and Canadian regulators weigh the benefits of a proposed chemical or use against the risks that it poses when they make their decision. In Europe and the US regulators are trying to consider the cumulative and synergistic effects of chemicals in modern diets as part of their regulatory assessments.

Some regulators have quite comprehensive monitoring programs for chemical residues in food, water and the environment, whilst others do this in an ad hoc fashion. The use of data, intelligence and analytics are also being increasingly utilised by regulators to improve regulatory decisions, identify trends and for predictive purposes.

In this chapter the panel considers some potential enhancements to the way Australia regulates agvet chemicals that could more comprehensively and effectively manage the risks that they pose. The panel invites stakeholders to comment on these or propose their own suggestions about important things that might be missing from the regulatory system, or that regulators are not undertaking as effectively or comprehensively as they should.

### 4.1 Can we assess use by region, pest, disease or other instead of state boundaries?

While the supply of an agricultural chemical product is authorised nationally through the registration approval, the instructions for use have routinely included state specific use patterns. The panel understands some of this reflects historical approaches preceding the establishment of the national scheme. The panel also accepts that, as a result of environmental, climatic or soil conditions, a use pattern for a product may differ or be prohibited in a specific location, regardless of the commodity/pest combination.

The panel considers that state boundaries could represent an arbitrary distinction that may be ineffective for assessing the variable risks of agricultural chemical use. The panel acknowledges and commends the national regulator's efforts in recent years to avoid, where possible, the approval of state-specific uses for new registrations, and to provide more detailed geographical or climatic context for restrictions on a product's use.

The panel is concerned by the number of available chemical products that still include state specific instructions for use that may, at a minimum, cause confusion for growers—it is unclear how the risks of using a product in accordance with the instructions in one state are different from those one metre inside a neighbouring state with different use instructions (Case study 1). More worryingly, growers may be liable for prosecution where the use is not expressly included on the label for their jurisdiction, but it is for another.

## Case study 1 Variation in label instructions between jurisdictions

The historical consideration of use patterns and instructions being set based on state boundaries can create unnecessary confusion for growers treating the same pests in the same commodities. It may also be unclear from the label directions why such a variation exists, or needs to be maintained. The latter is particularly relevant where the production location spans a border between boundaries, or where the production site increases post label approval.

### Example 1 Insecticide

A product registered for use in macadamia and pawpaw to treat banana spotting bug (BSB) in Queensland and the Northern Territory, is not approved to treat BSB in New South Wales. The same product has a label use in those same commodities for Fruit Spotting Bug in QLD, NT and NSW.

The product will also control numerous worms and caterpillars in safflower, small grains and sorghum but is approved for those uses in QLD and NT only. Uses against these pests in other states would, in general, be illegal and would require a permit.

These issues also extend beyond agricultural production, with the product having label uses for lawn grub and lawn army worm in QLD, NSW, NT and Western Australia. But not for South Australia, Tasmania or the Australian Capital Territory.

In all cases, the label limits uses when accompanied by the word 'only', providing a potential user in another state with a reasonable belief they have reduced access to treat the same pests.

### Example 2 Herbicide

A broadacre product registered for multiple uses in many regions of Australia is approved for different application rates and uses across the states. In addition, there are inconsistencies in regional definitions.

In Tasmania the product may be used for the treatment of perennial weeds at a rate of up to 2.4 L/ha, whereas in other southern Australian states (defined as WA, SA, VIC, NSW and TAS) the application rate may only be 1.2L/ha.

In addition to the previously mentioned inconsistency, the product may be used in NSW to treat skeleton weed (fully emerged rosettes), while this use pattern is not permitted in other listed southern states, including VIC and SA, both of which share borders with NSW. There is also ambiguity as to whether this use pattern is permitted in TAS due to the wording of the label.

Further still, the label restricts the products use in treating annual ryegrass, barley grass and other weeds in direct drilling rice production to NSW, despite this cropping technique being used in multiple other Australian states.

The panel welcomes AGMIN's decision of 2019 to allow, subject to some restrictions, chemicals that are registered for use in two or more jurisdictions to be used in all jurisdictions for all uses included on the approved label. The panel would like to see jurisdictions give full effect to this change as a matter of urgency, and also recommends wider publicity for this reform.

Consistent with the broad view in [Chapter 2](#) that the agvet chemicals industry could assume a greater responsibility for self-regulation, the panel is inclined towards options, including potential for legal obligation, for registration-holders to review their product label at least once every five years to ensure it contains correct and current information. This would apply to both agricultural and veterinary products. To support holders making changes, the panel would suggest the removal of state references, to the extent it aligns with the AGMIN approach, and that it be a notifiable change

(having the lowest impact possible). The review timing would align with the holder's responsibility to review safety data sheets at least five-yearly.

Despite the panel's general inclination for nationally standardised use controls, it acknowledges that there may too be merit in formally designating some environments that warrant different restrictions on the use of chemicals than those that would apply nationally. This could include identifying areas where agricultural chemicals should not be used at all. The panel considers that there may already be ways to divide the nation into distinct zones, for example [National Landcare Management Units](#), or catchment management boundaries, that could assist with the identification of particularly sensitive or otherwise unusual regions. Alternatively, other environmental or climatic factors, such as average annual rainfall, rainfall reliability, elevation, etc, could provide context that is relevant to the use of agvet chemicals.

In considering possible means to improve clarity for products addressing pest/commodity needs, the panel recognises the significant benefit crop grouping provides, and notes the efforts of the regulator and agricultural chemical industry in establishing an Australian system. The panel is interested to learn if there is potential for establishing 'pest groups' either formally on the label, or as a reference tool for growers to make decisions based on label stated pest controls. The panel notes this happens to a limited extent for some plant pests (such as broad-leaf weeds and annual grasses).

Most jurisdictions currently, and all ultimately will, allow the use of an agricultural chemical product against any pest in a label stated commodity (where the maximum rate of application, frequency, or concentration is not exceeded for that commodity). However, the panel considers growers would be helped by information on the full spectrum of pests the product could be reasonably effective against. The panel notes some products already list collections of plant pests (broad-leaf weeds, woody weeds and annual grasses). The panel would welcome comment on the viability of establishing representative pests for a pest type (mites, scale, larval stages), similar to the current [crop grouping model](#). Establishing such a list would require significant academic and industry effort (supported by government and the regulator), but would deliver practical benefit to Australian growers. Alternatively a greater focus on using a non species-specific description on the label would deliver similar outcomes.

The panel understands that pest groupings may not cover as many species as is the case for some crop groups. However, crop grouping has provided advantages for groups with a small set of commodities. The reduction or removal of the regulator's consideration of a product's efficacy (outside of safety), discussed in chapter 6, would allow industry a greater latitude in making representations about their product (where sufficient evidence exists to satisfy the company of efficacy).

## Discussion questions

- 12) What are the merits of considering boundaries (other than state) that might be relevant to the use patterns of agvet chemicals use?
  - a) What are the merits of considering regions of significant environmental interest, such as those adjacent to the Great Barrier Reef, or unique environmental values, for restrictions or bans on some agvet chemicals uses?

- b) What are the merits of mandating five yearly label reviews (by the holder) to remove where appropriate state references and aligning with the review of safety data sheets?
- c) Is it possible to establish pest groupings?

## 4.2 Should benefits be considered in assessments?

Some international regulators of agvet chemicals, including in Canada, New Zealand, the United States of America (USA) and the USA state of California, have incorporated benefit or value considerations into their chemical assessment systems. In these systems benefits can cover such things as: agronomic; economic; social; health; environmental; contribution to resistance management; likely consequences of the public not having access; and whether the new pesticide fulfils an unmet need (Case study 2).

Other than in relation to product efficacy or impact on trade, the Australian regulator does not currently consider a chemical's benefit or value (hereafter referred to as benefits). The panel is keen to explore the merits of allowing the regulator to evaluate a product's social or economic benefit if they are relevant to the registration process and could be defined and applied to improve the achievement of the regulation's objectives.

In those countries applying a benefits test, chemicals/products can be approved where the overall benefits outweigh the risks posed by their use. For example, a chemical/product that poses some minor risks to non-target species but offers significant benefits to the broader agricultural sector may be approved. However, the regulator would still have to refuse to register a product or use that poses an unmanageable risk to non-target species. This approach would provide the regulator with an ability to apply a 'relative risk' assessment in these cases and avoid the legislative constraint of absolute risk. This would not undermine the scientific assessment process but rather add another dimension to the assessment.

A risk/benefit or cost/benefit consideration is a well-established principle of good regulation in wider government regulatory decisions. It enables national interest or the balance of interests to be taken into account in rational decision making. Such considerations are routinely employed by governments as a basis for regulatory decisions, as it enhances the evidence base to inform decisions and ensures all practical options have been considered for addressing a problem. Despite the additional work for the regulator and increased cost for industry it would appear from international experiences that a benefits test could deliver access to more chemical uses and improved safety outcomes.

### Case study 2 Regulating herbicides

The regulator is currently reviewing the use of the herbicide hexazinone in sugar cane to treat annual and perennial broad leaf weeds, grasses, woody weeds, small trees and vines. The product uses are also relevant to the forestry sector for hard-to-kill weeds.

Where herbicide resistance is a problem, and against such a wide variety of plant types, the most common alternatives would be paraquat or diquat (or a combination of both) or some formulations of glyphosate salts. Paraquat and diquat are highly toxic to all plant species, and likely glyphosate candidates may be highly toxic to aquatic environments. While instructions for the use of alternatives may reduce the risks, the likelihood of negative environmental impacts may be greater than for the current solution, as a result of run-off or

uncommon use patterns. In this case, the ability for the regulator to consider the benefit of retaining the chemistry may provide, if for a short period, better outcomes for the environment.

## Flagship reform proposal

### Benefits Test

The panel is inclined towards adding a benefits test to the agvet chemicals regulatory system for two purposes. Firstly, the benefits consideration would form part of the assessment and final regulatory decision for registration or reconsideration for all applications. It would become a standard part of the assessment process, requiring the applicant to demonstrate any relevant benefits. The regulator would then make a weight of evidence assessment of risks versus benefits prior to registration.

Secondly, where an applicant could demonstrate up front that the product would have national benefits it could be prioritised in the assessment workflow process. If Australia adopted a model like that used in Canada applicants would have to outline why their assessment should be prioritised as part of their application dossier. For transparency this part of the submission, and the regulator's response to it, would be publicly available. On the available information the panel considers it likely that only a small number of applications per year will be able to demonstrate national significance, therefore the test wouldn't result in a continual re-prioritisation of applications.

Factors that the panel is disposed towards including in a benefit assessment are:

- introduction of a new active constituent or inclusion of a new use on existing crops
- the value of benefit to agricultural production, animal welfare, environmental outcomes or increased public health and safety
- positive social or economic impacts (could be localised, regional or national)
- a crop group or two or more priorities for access (e.g. listed as a chemical under review, or listed as a weed of national significance)
- controlling a pest of national significance (e.g. rabbits)
- replacing a use that is subject to reconsideration
- impacts to the community or users of not having access to the product.

The benefits test could also be considered for reconsiderations (chemical reviews) by the regulator whereby, the regulator would consider the environmental impacts of the alternative options (chemical or otherwise), before finalising its decision. The panel considers this should only apply where the grounds for reconsideration were environmental. If the risks of approval or continued use of an agvet chemical are relatively high, then the panel's view is that the projected benefits must be compelling. In this instance benefit could be considered at either a national or local level.

## Discussion questions

- 13) Would a benefits test as proposed be a useful addition to the agvet chemicals regulatory system?
  - a) Are the benefits outlined appropriate?
  - b) Are there additional benefits that should be considered?

- c) Should the benefits test have the two purposes proposed?

### **4.3 Should the impact of chemical combinations matter?**

Chemicals are often not used alone, but in combination or soon after another. This creates a possibility of interactions between chemicals. Two (or more) chemicals that are individually not toxic at recommended dosages and likely dietary exposures, could theoretically combine in an unexpected manner to produce additional effects (synergistic impacts). This interaction could be of concern if it creates or increases animal, human, plant or environmental health risks. Alternatively, a chemical combination might be beneficial by reducing or cancelling out each other's risks in some way.

Chemicals might be combined for a variety of reasons, but particularly to meet the increasing challenge across the agricultural sector of pest, disease and weed resistance. Effective resistance management is complex. Mixing and rotating chemicals with different chemical modes of action is one important practice for slowing the spread of resistance and preserving chemical efficacy.

In the past, interactions between chemicals have been identified via retrospective analyses of epidemiological data—e.g. unanticipated drug interactions with common foods like grapefruit, or the amplifying effect on the risk of developing cardiovascular disease from the combination of smoking and taking an oral contraceptive.

The potential for interactions with some veterinary medicines is already managed through the professional skill and knowledge of veterinarians. Increasing scientific knowledge and technological advances could make it possible to also consider the impacts of agricultural and veterinary chemical combinations earlier, at the point of regulatory assessment. However, it will never be possible to consider every potential combination of chemicals, uses and potential health and environmental impacts.

The regulator is not currently required to consider the impacts of chemical combinations beyond those in the specific product formulation. However, there are international regulators that are required to consider cumulative effects at the point of assessment. For instance, EU regulations on pesticides in food and feed stipulate that cumulative and synergistic effects of pesticides should be considered for dietary risk assessment when the appropriate methodologies are available. They also state that residues of pesticides should not have any harmful effects on human health, considering known cumulative and synergistic effects.

The US Environmental Protection Agency (EPA) has had a published policy and guidelines for evaluating data on the health risks from exposures to chemical mixtures since 1986. The EPA's supplementary guidance from 2000 also provides evaluators with procedures for different ways of conducting an assessment depending on the nature and quality of the available data, and the risk under consideration—e.g. carcinogenic risk vs non carcinogenic toxicity. There are no clear circumstances triggering use of the EPA guidelines and no single approach is recommended.

Despite these international moves in the EU and US, it appears that no regulatory system is currently able to systematically look at the synergistic impact of chemical combinations. The EU and US do not have published methodologies for considering synergistic risks of chemical mixes, although it is possible that these may be under development.

Instead, when making a new regulatory decision about a chemical, the consideration of risks from chemical combinations in the EU and US appears to focus mainly on the less difficult proposition of assessments of cumulative or aggregate risk. For instance, considering multiple chemical exposures according to the kind of risk to human health that a chemical poses—for example, carcinogenicity, reprotoxicity, mutagenicity.

The panel considers that understanding impacts from chemical combinations is important for maintaining confidence in the system but acknowledges that assessing synergistic risk is quite complex to undertake and other regulators have not made significant progress in this area.

The European Food Safety Authority (EFSA) is developing methodologies to carry out cumulative risk assessment of pesticide residues in food, starting with a procedure for establishing cumulative assessment groups of pesticides, based on their known common toxicological effects. To date EFSA has carried out two pilot cumulative risk assessments: one considering chronic effects on the thyroid system; and another looking at acute effects on the nervous system. The overall conclusion of those assessments (considering uncertainties) is that consumer risk from cumulative dietary exposure is below the threshold that triggers regulatory action defined by risk managers at the European Commission and in EU member states.

The options the panel is considering include:

- 1) Recommend consideration of impacts for only common and well-known combinations of agvet chemicals. Limiting consideration to a small group of well understood chemicals may reduce the complexity sufficiently so the task becomes achievable. This could be supported by the panel's approaches for greater use of data mining ([Chapter 4](#)).
- 2) Prepare the framework for the future by stipulating that synergistic effects should be considered when the appropriate methodologies are available (the same approach as the EU). This would allow Australia to act on, and possibly work to support, the progress of other international regulators.
- 3) Require applicants for registration, and holders of registration, to provide to the regulator any information they possess in relation to chemical combinations relating to their product.
- 4) Establish a process for the regulator to consider synergistic effects (e.g. through the chemical review process) when credible evidence (for example through multiple reputable scientific journals) of plausible synergistic impacts exists, or when a comparable international regulator commences a review activity themselves on synergistic effects.

In terms of the latter the Australian reconsideration would be concurrent with the international regulator(s) with a view to working cooperatively together.

The panel is inclined towards options 1 or 2 as they should position Australia to take advantage of scientific advances and the progress of international regulators. They also provide a good starting point for the regulator to work with Australian experts and international counterparts to develop the necessary skills, tools and methodologies to undertake more complex work in the future. However, the panel notes that options 3 and 4 provide a direct means to establish a bank of evidence to draw upon and support Australia's involvement in the development of methodologies for assessment of chemical combinations and synergistic effects.

## Discussion questions

14) Is the area of chemical combinations highlighted worth exploring?

- a) How might consideration of the impacts of chemicals (cumulative and synergistic) be feasibly considered in the Australian system, given the limited progress in this area internationally?
- b) Should Australia wait until international methodologies for assessing impacts of chemical combinations have been developed? Or should Australia have a role in assisting in their development?
- c) What skills and tools are needed in Australia to allow consideration of the impacts of synergistic impacts of chemicals?

### 4.4 Can data mining drive better targeting of effort?

The panel is aware that governments (at both the state/territory and national levels) have access to vast volumes of agvet chemicals data that is often underutilised and not analysed to its full potential. The panel believes there is significant opportunity to improve the practical operation of agvet chemicals regulation by leveraging these data holdings to optimise business processes and enable innovation.

Data mining or intelligence gathering is the process of analysing large data sets for hidden patterns and relationships to identify useful information and drive informed decision making. It is routinely used in financial data analysis, retail industry and scientific research. Chemical regulators worldwide, including the US Food and Drugs Administration and the European Chemicals Agency (ECHA), are increasingly using data mining tools to improve their business operations (Case study 3). The panel believes Australia can take similar advantage of the opportunities comprehensive and extensive government data holdings present.

The panel sees potential benefits of data mining for agvet chemicals regulation as deep and wide ranging. Data mining could improve policy and regulatory (registration, compliance and enforcement) decisions and in addition:

- reduce costs by driving efficiency and quality as analyses are conducted much faster than through traditional computerised systems and produce more accurate, objective and reproducible outputs
- improve internal operations, for example in the area of (manual) completeness checks
- enable more powerful, dynamic and science-driven discussion with stakeholders
- provide competitive advantage to the agricultural sector and support innovation.

Data mining improves decision-making by allowing the identification of patterns and relationships within datasets based on historical information. This provides the ability for predictive analysis in decision making which could facilitate both registration and compliance actions. For example, the use of sophisticated algorithms can lead to the identification of substances of potential concern and the prioritisation of safety reviews, changes in product labels, product recalls and allocation of resources towards specific compliance and enforcement activities.



It could also play an important role in a post-market safety surveillance program for veterinary products. For instance, data mining algorithms have been developed to improve the detection of products of concern in Adverse Event Reporting (AER) databases. The panel sees this as a significant potential benefit for animal welfare.

The panel also understands that the potential benefits of data mining increase with the size of the available data, as trends become more evident, and more subtle factors can be identified. The panel therefore believes that, to achieve the maximum benefit, it is essential that data is shared with trusted national and international parties such as regulators, academia, NGOs and industry.

A national surveillance program could be one way of achieving the benefits of dataset scale and linkage. Rather than a monitoring program that focuses on specific items of interest, a surveillance program looks across whole systems. By uniting multiple datasets including those on volumes of product sales, pest outbreaks, spray drift occurrence, adverse events, annual cropping and forestation data, etc. trends can be identified. While this can support targeting of compliance, it can also support better horizon scanning for policy response and formulation. Better supporting horizon scanning through earlier and more accurate identification of trends could allow governments to see what is emerging in the system and talk to the relevant sector or sub-sector e.g. forestry, broadacre, horticulture, citrus or southern winter wheat growers, etc.

The panel is mindful that while data mining creates new opportunities it also brings new challenges in data development, implementation and maintenance. For data mining tools to run efficiently, the data standards must be of high-quality with minimum errors and duplications. Also, data sharing platforms must be supported by robust infrastructure ensuring data security such as integrity, confidentiality and accountability.

The acquisition of data about chemical use can be challenging because of the potential sensitivities associated with this information. Currently growers, and many other users of agvet chemicals, are required to keep records relating to use. The panel sees value, where a suitably efficient robust platform can be established, for government to mandate the reporting of these records. This could allow a more 'real time' understanding of Australian chemical use and support region specific pest management approaches.

The panel understands that some stakeholders could be concerned about how government would use data, in particular information relating to the use of chemical products. There is potential for this to identify misuse or illegal use, and therefore decrease a willingness to provide the data. The panel considers the identification of misuse or illegal use of chemical products to be essential for the development of informed regulatory and policy initiatives and for maintaining confidence in the system. Collecting data on chemical use could also assist in verifying the effectiveness of the regulatory controls for these chemicals. Another challenge facing government relates to the need to protect industry's ownership of data and citizens' privacy, while enabling access and collaboration with authorities and other stakeholders.

### Case study 3 The European Chemicals Agency's (ECHA) approach to data mining

The ECHA is a decentralised agency of the EU, managing EU internal market regulations for industrial chemicals and biocides. ECHA holds a wealth of scientific and regulatory data on chemicals and has a reputation as pioneer e-Agency.

By law and design ECHA is a largely IT-based entity, seeing IT as a key enabler of the regulatory activities and an indispensable instrument to elaborate and disseminate knowledge on chemicals. The Agency provides a range of IT tools free of charge to industry, the European Commission and Member States. Secure connections with the Commission and Member States allow efficient information exchange and workflows.

ECHA uses algorithms to support the submission process, for example through automated completeness check and fee calculation, and is also able to apply text mining by extracting plausible information from Chemical Safety Reports and free text documents. Data is aggregated and enriched with other public data including from EU agencies, the United States of America and Canada. The success rate of ECHA's advanced algorithms is very high with over 80% of substances identified as a concern, later selected for regulatory action by Member States.

ECHA, in cooperation with the Organisation for Economic Cooperation and Development (OECD), has developed data formats to facilitate worldwide data exchange. The backbone for this is the International Uniform Chemical Information Database (IUCLID), that records, stores, maintains and exchanges data on intrinsic and hazard properties of chemical substances. IUCLID is increasingly recognised as the international platform to store/share chemical data between regulators.

ECHA has also developed tools, freely available, that enable third parties to manage their data on chemicals, giving them access to state-of-the-art risk assessment methodologies. Finally, ECHA makes non-confidential information on substances accessible to the public through a dissemination portal. Information on 120 000 chemicals is publicly available, aggregated by chemical substance and summarised in info cards and brief profiles. The portal supports industry (e.g. for Safety Data Sheet preparation and research), NGOs and the public in getting a view on the chemicals they are exposed to in their daily lives.

### Panel's view

The panel acknowledges these issues would need to be addressed in the implementation of any relevant initiative. If governments are to achieve the benefits that data mining offers it will be essential for them to find a way of enabling access while protecting intellectual property and privacy. Nevertheless, the panel sees considerable potential in more effective data mining arrangements in the regulatory scheme of the future.

### Discussion questions

- 15) What role could data mining and intelligence use play in the regulatory system?
- a) Should governments improve their data holdings and share this data among the jurisdictions to improve the management of agvet chemicals?
  - b) Should agvet chemical users be required to mandatorily report chemical use data to the regulator? On what basis, If not, why?
  - c) How could data mining and analytics drive better targeting of regulatory effort?
  - d) What standards should operate to ensure data integrity, confidentiality and use?

## **4.5 Should there be greater monitoring of chemicals in produce and the environment?**

In its deliberations to date, the panel has been considering whether there is a need for increased monitoring of the presence of chemicals in the food we consume and, in the environment, including in waterways.

It could be argued that the presence or absence of residues is a critical factor in determining whether the regulatory system governing agvet chemicals is effective. The lack of comprehensive monitoring systems that document how the regulatory system is working to protect consumers and the environment risks undermining the legitimacy of the system.

Collecting monitoring data over a prolonged period allows robust useful datasets to be established and maintained. This data can also be entered into specialised modelling software, allowing compliance and enforcement officers to undertake predictive monitoring actions. Big data offers a chance for an increased understanding of on-the-ground activities and allows long-term strategies and management plans to be accurately developed.

There is a growing awareness amongst the community about the potential for chemical residues to be found in food, the environment and water but what is unclear is whether the level of detection is worthy of concern. The presence of residues, in and of themselves, does not necessarily pose a risk to human, animal or environmental health but this is poorly communicated to the community. Sound monitoring systems would provide information to assist with better communication activities to reassure the community.

There is some monitoring that currently occurs for residues in produce, however this is mostly for export produce with some limited domestic produce monitoring undertaken. The states and territories are responsible for monitoring chemical residues, however, there is no consistent methodology applied across jurisdictions and currently only three states (QLD, VIC and WA) undertake monitoring. Some states leave it to industry to monitor residues, but these schemes don't necessarily lead to or result in compliance and enforcement activity by the states. These industry schemes include Freshcare (a QA scheme) which provides assurance to supermarkets through an annual residues test and Freshtest which tests at major vegetable markets (such as Sydney, Melbourne and Adelaide).

Monitoring in waterways and the environment is also undertaken to some extent, however this is not exhaustive and is subject to different requirements depending on the jurisdiction in which the monitoring is done. The most comprehensive water monitoring program including pesticides is undertaken by the Queensland Department of Environment and Science, through the Great Barrier Reef Catchment Loads Monitoring Program. This is separate to the monitoring done by the Great Barrier Reef Marine Park Authority (GBRMPA).

GBRMPA has developed Water Quality Guidelines for the Great Barrier Reef Marine Park (2010) with set levels for specific pollutants, which, when exceeded, prompt managers to act. The guidelines focus on levels of sediments, nutrients and pesticides. The states and territories currently undertake some monitoring of residues in the environment; however, this is neither comprehensive nor consistent. The panel notes a national guideline review process is underway for levels of pesticides in

waterways. The panel recognises the value of levels set by contemporary science but believes this should be complemented by an effective national monitoring program.

Although such formal, structured monitoring arrangements across Australia are patchy, the availability of monitoring and surveying technology to third-party groups is improving constantly, and the cost is decreasing. It can therefore be expected that, in the absence of formal national monitoring arrangements, unofficial monitoring arrangements will emerge in the years to come and various interest groups will begin publishing their findings about residue exposures.

While conscious of keeping the costs of activities proportionate to the risks they are managing, the panel is inclined towards an expanded focus, and a nationally consistent approach, to the monitoring of agvet chemicals residues in water, the environment and produce. Data from these activities would allow regulators to determine the real level of risk posed by these residues, and it would improve their ability to target efforts to detect and respond to non-compliance. Publishing data on a regular basis would provide the community with confidence that the system's regulatory controls are effective.

In the first instance, it is worth exploring whether existing programs can be easily expanded, possibly via an annual monitoring priority-setting exercise, targeting areas such as chemical sales, outbreaks or levels of risk, to which jurisdictions could sign up to. Alternatively, the Commonwealth and the states and territories could jointly develop national standards for monitoring programs to meet. Either option would improve national consistency overall and strengthen regulators' compliance and enforcement actions.

#### **4.5.1 Is there a need for domestic produce monitoring?**

Australia has a comprehensive and nationally consistent agvet chemicals residue monitoring system for major agricultural export commodities such as meat, grains and some horticultural commodities (National Residue Survey) and domestically for animal products (meat, eggs, honey), pome fruit and grains. However, there is no equivalent comprehensive and nationally consistent government led system for monitoring other domestic produce.

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

Although chemical residues in food do not necessarily equate to a human health risk, the increasing community focus on the safety of agvet chemicals is bringing greater attention to the presence of residues in food. The panel has considered information that indicates that, across a range of commodities, there are consistent detections that exceed residue limits, acknowledging that this does not indicate a risk to human health, it may indicate deviations from good agricultural practice (the basis of registration in Australia) in particular the off-label use of chemicals.

The lack of a comprehensive government led system for monitoring chemical residues in domestic produce could:

- undermine the legitimacy of the domestic agvet chemicals regulatory system

- erode public trust in the agriculture and food industries
- lead to the stigmatisation of agvet chemicals and their use
- mean that agvet chemicals users in different jurisdictions are subject to unequal treatment
- have a negative impact on Australia's clean and green image overseas and damage Australian export performance
- restrict the evidence available to regulators to make comprehensive and sound decisions potentially leading to disproportionate actions, such as the deregistration of chemicals.

There is a real risk to Australia's export trade from residue breaches in domestic produce, which could lead to markets losing faith in our ability to effectively manage chemical use. There is also the risk that some domestic produce, not produced for export, finds its way into an export consignment, causing a trade incident.

The panel acknowledges that there is work underway between the Commonwealth, states and territories to develop a national domestic produce monitoring system modelled on the current National Residue Survey. This is likely to provide the most effective option for a nationally harmonised domestic monitoring and traceback system. The panel considers that consideration should be given to utilising the existing National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise and traceback arrangements with jurisdictions for non-compliant residues.

The panel fully endorses the need for a government-led national domestic produce monitoring system and considers that it is imperative that governments progress this as soon as possible.

## Discussion questions

- 16) Do you support the need for a national domestic produce monitoring system and should it be modelled on the National Residue Survey?
- a) Should data on residues in domestic produce be publicly available?
  - b) What should core design principles of such a system encompass?

### 4.5.2 Agricultural chemical testing in Australian waterways

The national regulator considers the risks of pesticides entering waterways at harmful levels as part of its authorisation process and determines label instructions that, when followed, should minimise pesticide contamination of waterways.

In Australia, water quality is managed through strategies, plans, laws and regulations established by state, territory or local governments.

Relevant water authorities monitor a range of microbiological and chemical substances that can enter water supplies and impact human health to verify compliance with the Australian Drinking Water Guidelines (ADWG). These guidelines address a range of uses for different purposes and water users (drinking water, recycled water, groundwater, urban stormwater, effluent management etc.), setting out good practice for managing water quality in each context. Values, targets and actions in these guidelines are neither mandatory nor legally enforceable. The guidelines contain 'health-based guideline' values for over 200 pesticides.

Some water authorities monitor pesticide residues. However, the range of pesticides tested and the frequency of the tests depend on the resources and policies of each particular water authority.

Monitoring by the GBRMPA shows detections of a range of herbicides (especially high mobility herbicides) and insecticides (especially the neonicotinoid imidacloprid). Water contamination can occur via spray drift, drainage discharge, unlawful acts or accidental spills.

Generally, water authorities publish annual quality reports. Victoria's legislation requires water suppliers to disclose to the public, information relating to the quality of drinking water and to report known or suspected contamination of drinking water to the Victorian Department of Human Services. In NSW regular monitoring of water supplies for pesticides is undertaken, and there is periodic monitoring of water discharges from some irrigation districts. However, it is unclear how water authorities in other jurisdictions consider results of pesticide exceedance in terms of control of use, or as part of ongoing safety considerations of agricultural practice by the national regulator. It is also unclear what actions, if any, are taken by water or environmental regulators as a result of exceedance.

It is unlikely that community expectations are being met with the ad hoc testing regimes currently in place. As in the case of a possible residue exceedance in the domestic food market, a breach in water standards and the lack of a systematic testing regime for water can impact public acceptance of chemical use and cause the community to lose faith in the regulator's ability to manage the risks posed by agvet chemicals use.

The panel considers one option to better align with community expectations would be to use a risk-based approach to identify agvet chemicals of high risk to waterways or human health and testing for their presence. These chemicals could either be of national or regional interest, with jurisdictions given the ability to nominate chemicals.

#### **4.5.3 Agricultural chemical testing in the environment**

As is the case for monitoring of residues in water, there does not appear to be comprehensive or consistent monitoring of agricultural chemicals in the environment nationally. In some jurisdictions relevant information on pesticide levels is collected in the course of undertaking other environmental activities. It also appears that most of the environmental monitoring undertaken is associated with chemicals in water systems (discussed in the preceding section).

The panel understands environmental monitoring (other than water) can be complex and covers multiple components such as soil (and leaching from soil into groundwater), turf and other vegetation and air and that each of these would require different testing regimes. It is unlikely to be economically feasible to undertake environmental monitoring across large parts of Australia and in fact may not be desirable. However, there could be specific areas, where pesticide application is more concentrated and could lead to potential environmental impacts that would warrant the need for ongoing monitoring to ensure the management of these chemicals is effective.

In New South Wales the government undertakes targeted studies on the behaviour of pesticides in specific situations and environments. In addition, they also undertake targeted investigations as part of specific incidents known or suspected to be the result of pesticide pollution.

The Victorian Environment Protection Agency is currently undertaking an ambient monitoring program for emerging chemical contaminants, including some agricultural chemicals.

The panel acknowledges the efforts of jurisdictions in environmental monitoring, including the historical activities. The panel notes the efforts in specific locations such as the Great Barrier Reef, and is interested if some of the concepts could be applied elsewhere in Australia.

The panel is keen to explore with stakeholders the benefits that may arise for public confidence in the safe use of agvet chemicals through a nationally consistent and coordinated approach. It may be viable for the program to operate nationally through the jurisdictions, rather than at the Australian Government level.

## Discussion questions

- 17) How could consistency in water and environmental monitoring across jurisdictions be achieved?
- a) Would monitoring systems (for both water and the environment) based on risk priorities be effective?
  - b) Are there specific environments that should be a priority for monitoring?
  - c) Should monitoring results be published and how often?

## 5 How can communication and engagement be improved?

The credibility and responsiveness of the agvet chemicals regulatory system depends on effective identification of, and communication with, its stakeholders—the national and state governments and their regulatory agencies; the regulated industry; and the broader community, for whose benefit the system largely exists.

While the regulatory system exists to ensure any risks are appropriately managed, and user and chemical industries have a direct interest in ensuring this outcome, there is a healthy (but in some cases, unwarranted) scepticism among parts of the community about whether the short-term commercial interests of chemical companies outweighs sound risk-management decisions. This scepticism can extend to decisions made by government.

In the absence of open dialogue based on factual information from a credible source, false information and public misconceptions can proliferate. This, in turn, can influence the media (social and traditional), policy makers and political positions in a way that leads to perverse outcomes.

Failure to manage stakeholder relationships, particularly failing to engage effectively with the broader community, could result in an unnecessary loss of confidence in the continued use of agvet chemicals—with flow-on impacts to agricultural productivity, animal welfare and the environment. This is being seen in a growing number of overseas markets, where misunderstanding and politicisation of the risks of agvet chemicals threatens their continued use and availability.

With Australia's dependence on agricultural outputs—and a growing (and increasingly affluent) global population to feed and supply with fibre—Australia cannot afford to lose access to safe and effective chemical pest management options. It is important therefore, that industry and government work to effectively communicate and engage with all interested parties.

### 5.1 Is there a need for more community information on regulatory actions?

The sheer volume of information—including misinformation—about agvet chemical use, combined with a degree of inherent scepticism, makes it extremely difficult for the public to form a fair and balanced view about chemical use and management.

There are many players in the regulation of agvet chemicals in Australia, all with different roles. It would be legitimate to consider that it is the regulated industry's responsibility to combat misinformation and influence public perceptions that affect a market (in this case, both primary producers and the chemicals industry).

However, the panel believes that government also has a vital part to play as an 'honest broker' in disseminating information about the agvet chemicals that it regulates. There are several reasons for this, including government's unique role in providing independent and science-based assessments; the importance of agvet chemicals to food and fibre production (and the associated social and



economic benefits); and the importance of the industry to trade and to public health and safety. Further underlying the importance of the government in providing honest and balanced information is that many members of the public may also consider information provided by industry to be 'tainted' by commercial self-interest.

The panel believes that a well-informed market will lead to better outcomes for the community—including optimised food and fibre production, the social and economic benefits of agricultural production and companion animal ownership, and environmental outcomes (both through effective weed and pest management and by minimising environmental exposure to hazardous chemicals). Perversely, an unwarranted lack of confidence in the chemical industry could increase market uncertainty, and so impede the development of new, safer chemistries.

Accordingly, it is important that government regulators clearly and transparently communicate how they do their jobs, why they make the decisions they do, and how those decisions directly contribute to the protection of public (and worker) health and safety and the environment.

An equally important role for government is transparently demonstrating whether the regulatory system is achieving its objectives. This includes communicating (through data where appropriate) the outcomes of monitoring, detection, and enforcement activities. In general, public confidence in the regulator—and in legitimate industry players—will be enhanced by the knowledge that strong action is taken against breaches of the regulations and that chemical residues are being actively monitored.

Effective engagement requires clear, transparent, accessible and regular contact. The government currently has few, if any, regular channels in place for effective communication about agvet chemicals issues. In addition, the APVMA produces little information that is accessible to a non-technical audience. This is in contrast to other regulators—for instance, Food Standards Australia and New Zealand (FSANZ) is prolific in the information it publishes online to inform consumers about food safety, while the United States Environmental Protection Agency (US EPA) produces information on a variety of pesticide topics of community and user interest such as how individuals can help with protecting pollinators, managing pests in schools, integrated pest management activities for kids, as well as more technical guides and manuals.

In part, this may reflect the fragmentation of the regulatory system, which comprises eight state/territory regulators in addition to the national regulator. Despite this, the national regulator is generally the main focus of the public's attention and it would seem appropriate that the agency acts as the primary conduit for information about the aspects of the regulatory system that are within its purview.

For example, it appears that in many cases the significant work the APVMA has undertaken to reach its decisions is not well communicated. For example, community concerns with chemical reconsiderations often touch on the long timelines for their completion. However, typically there are several interim actions taken during the process as a precaution to manage the risks that are being reconsidered.

The panel is inclined towards having the national regulator identify, in consultation with governments, community and agvet chemicals industry and users, the information needed to support the agvet chemicals sector and the public. The regulator would then have targets to work to,

to improve the availability and quality of this information over time. This would include the quality, accuracy and usability of registration information and conditions of use, agvet chemicals availability and sector trends and statistics. The dissemination of this information should be in the spirit of 'open data'. The aim should be for information to be readily accessible for all, up-to-date and as interactive as possible, accounting for data protection and other confidentiality limitations on information.

The regulator could report to the minister through its annual work program on its efforts to improve and maintain the range, availability and quality of information on its regulatory activities.

## Discussion questions

- 18) What information would consumers like to see more of from the national and state agvet chemicals regulators?
- a) How would consumers prefer to receive information?
  - b) What should be the role of regulators in communicating decisions to the wider community?

## 5.2 Do stakeholders require a formal consultation mechanism with the regulators?

The NRS has no standing consultation forum for the public to engage with its regulators or policymakers. As a result, the most common opportunities for the community—and others—to engage with the government typically arise during consultation for legislative amendments, or through an inquiry by the Parliament, the Auditor General, or the Productivity Commission. None of these generally involve direct responses back to the community.

As part of the 2018 Senate inquiry into the independence of regulatory decisions made by the APVMA, stakeholders from the chemical and user industries and community advocates noted the need for greater consultation about APVMA regulatory actions. However, stakeholders' concerns extended beyond the operational matters of the APVMA to the policy aspects of the NRS, suggesting a need for greater involvement in policy setting.

The APVMA undertakes public consultation on relevant matters as needed. For example, there are legislated requirements for public comment periods in relation to the registration of new chemicals. The Department of Agriculture, Water and the Environment also undertakes public consultation on relevant legislation amendment processes. Like the regulator, public consultation most commonly takes the form of a website release with requests for comment and key stakeholders given the opportunity to provide comments and discuss the issues directly with departmental officers.

Prior to 2015, the APVMA maintained several committees that sought both technical and regulation-related input from a selection of the regulated industry and wider community. This included the Community Consultative Committee—a forum established to provide a two-way communication vehicle with chemical users and community members interested in, or concerned about, agvet chemicals.

Two long-standing examples from overseas suggest that formal mechanisms that allow exchange of ideas between governments, the public and industry stakeholders can be beneficial for all parties. For example, the United Kingdom operates a pesticide forum to ensure that regulatory systems are

accessible and responsive to the needs of the public (Case study 4). A similar mechanism is used by the US Pesticide Program Dialogue Committee. Both the UK Forum and the US EPA Committee are seen by stakeholders as important ways to ensure their direct involvement in scientific and regulatory policy.

One of the strengths of the UK Forum that has led to its longevity and success, appears to be its clearly identified functions, goals and accountabilities, and the panel suggests a similar approach to any future Australian forum is desirable.

The panel sees value in establishing a formal consultative mechanism that brings together and facilitates communication between governments (regulators and policymakers), agvet chemicals suppliers, users and community groups. This could be modelled on the former APVMA Community Consultative Committee and/or the UK pesticide forum. Like the UK model, the panel believes the body should have active functions (deliverables), to give it momentum and improve its chances of survival.

The success of regulatory schemes has always relied on more than just government actions. The knowledge and contribution of all players can have a strong influence on the success or failure of regulation.

Options for improving stakeholder consultation are to:

- Reconstitute and reinvigorate the existing Community Consultative Committee.
- Establish a new formal consultative forum that reports to government, similar to the UK model.
- Require formal public consultation during the registration and approval assessment process. This will add time to these processes, but this may be offset by other proposals in this issues paper.

#### **Case study 4 UK Pesticide Forum**

The UK Pesticide Forum established in 1996 brings together organisations (26 currently) with interest in pesticides uses and impacts, including conventional and organic farming, environmental and consumer groups, trade unions and relevant government departments. The Forum's decisions generally reflect agreement of all members, thereby providing a comprehensive view of the range of positions relevant to pesticide use.

The Forum has oversight of the UK Pesticides National Action Plan and provides advice to the government on its progress and future opportunities. The Forum also assists with the effective dissemination of best practice for pesticide use, advances in technology, and advises government on the development, promotion and implementation of its policy relating to the responsible use of pesticides. Sub-groups of the forum have addressed specific issues including:

- identifying, evaluating and advising on research/information that could promote more sustainable pesticide use
- identifying key messages relevant to the operators in the sector and recommending how to promote changes in agricultural practice and uptake of legal requirements
- recommending and monitoring measures and indicators for the Action Plan
- promoting integrated farm management.

The Forum meets twice a year and releases the minutes of each meeting on its website.

It publishes an annual report summarising the various activities undertaken by members during the year and details key objectives of, and progress in delivering, the National Action Plan. The annual report also includes a full update of indicators adopted by the Forum to measure the progress made by farmers and growers to minimise their use of pesticides. A key Forum priority is to ensure that the public has access to accurate and balanced information on pesticide use and its impact, the annual report is one mechanism for doing this.

## Panel's view

The panel is disposed towards a consultative mechanism, like the UK model, with active functions that give it momentum and a greater likelihood of being sustained over time.

## Discussion questions

- 19) Do you support the establishment of a formal consultative forum in Australia, similar to the UK model? If not, why?
  - a) Do you have suggestions on the possible membership and scope for a formal consultative forum in Australia?
  - b) If this model is adopted would there be benefits in forum meetings being open to the public?

## 6 How can we simplify the regulatory system?

The panel is aware that there have been ongoing criticisms about the complexity and time-consuming nature of the current regulatory system. Considering this, the panel is keen to explore what opportunities are available to reduce assessment processes and provide efficiencies in the system.

Whilst there have been several different (low regulatory concern) pathways available to the national regulator for assessing chemicals, they have, for various reasons, been seldom used. It is unclear whether the reasons for the lack of adoption of these pathways is due to a lack of understanding on how to utilise these measures or a reluctance to assess products differently. The former suggests that the legislation needs to be clearer on how measures are implemented, whereas the latter suggests that the risk appetite and culture in the regulator to approach registration differently may need adjusting.

As has been discussed earlier in this paper, the small size of the Australian market for agvet chemicals requires Australia to think beyond the norm if it is to encourage more new chemicals and uses to be registered in Australia.

The panel in no way wants to reduce the protections afforded by regulatory oversight, but it does consider that there may be potentially more efficient and effective ways of administering the assessment process of applications in Australia, whilst still protecting people, animals and the environment. The panel is keen to receive feedback on the proposals and options set out in this chapter.

### 6.1 Does a product that is the same as another need its own assessment?

There are currently a multitude of application types that are assessed. One of these application types gives an applicant the ability to copy another product (with consent from the manufacturer/owner). As an exact copy of an already registered product (the pioneer product), except for the product name and registration holder, there is no need to reassess the product against the safety, efficacy and trade criteria.

These applications are commonly referred to as a 'repack' (item 8). Repacked products encourage competition in the marketplace for smaller or generic companies, as well as providing choice and competitive pricing for chemical users.

Some repack applications are eligible for a fast-track process, which has a significantly shorter processing time (3 weeks versus 3 months). However, this process is only available to applicants who repack their own product, which does not act to encourage competition in the marketplace.

The regulator processes a considerable number of repack applications. The last two financial years of the regulator's performance statistics indicate 164 and 173 repack applications assessed respectively.

These applications currently have a timeframe of three months and a cost of \$1,655.00 each. Under the APVMA's draft cost recovery implementation statement, there is a proposal to increase the cost of processing these applications by as much as \$977.00.

The panel has identified three possible proposals for consideration.

### **Option 1 Repack applications become a declaration/notification process**

This option would still allow applicants to reference or copy another product. The notification system could require that the details of the formulation owner of the pioneer product are provided as part of the notification. An automated notification could be sent to the formulation owner seeking confirmation, within seven days, that they supported the referencing (if they didn't, the notification would be rejected). Following the seven days if confirmation is received the applicant would be issued with a notice of registration acceptance.

This approach would still allow for a 'product registration' which continues to entitle the regulator to collect fees and levies. It would also prevent issues for international trade as the products are still registered and would be included on the inventory of registered products.

This approach significantly reduces the administration burden for the regulator and the applicant and completely removes the need for any assessment by the regulator.

### **Option 2 Link the registration status of repacked products to the pioneer product**

This option provides that, regardless of the method via which a repacked product is registered (i.e. notification or the current approach), in the event that the pioneer product ceases to be registered, all products whose registration relies on the pioneer product would also cease to be registered.

The regulator needs to be confident that at least one responsible entity holds data to support the safety and efficacy of the product. Generally speaking, this would only be held by the owner of the pioneer product.

Registration holders of the repacked products could be given a grace period in which they could attempt to continue the registration either by:

- providing proof of ownership of the formulation
- providing the formulation and manufacturing process to the regulator.

This would not apply in circumstances where a product is removed from the marketplace because of health and safety concerns.

### **Option 3 Continue to assess repack applications as per the current approach**

Under this approach there would be no changes and the registration of repack applications would continue as they currently do. It would then be up to the regulator to find any efficiencies that could be implemented to try and streamline the process.

The panel is currently disposed towards option 1 due to its practicality and efficiency. Given that an assessment of the exact same product has already occurred, the panel considers that there appears to be little justification for maintaining a process that is administratively burdensome and costly. In

addition, given the known level of risk due to existing assessments of the safety, efficacy and trade criteria, the panel considers option 1 provides the best streamlined approach to support continued chemical access and choice in the marketplace.

## Discussion questions

20) Which of the three repack application options presented do you prefer and why?

- a) Are there likely to be any increased risks with a product if option 1 is adopted?
- b) In option 2, is it reasonable to cancel the registration of all repacks following cancellation of the pioneer product (except in circumstances where the registration holder is in possession of appropriate data and product information)?
- c) Are there alternative options for dealing with repack applications?

## 6.2 Who should be responsible for ensuring products work?

Australian agvet legislation requires the regulator to register a chemical product if it is satisfied that it meets the prescribed safety, trade, and efficacy criteria (this applies to both agricultural chemicals and veterinary medicines).

All comparable international regulators perform some level of efficacy assessment for veterinary medicines. However, for agricultural chemicals, international approaches range between full regulatory assessments, including efficacy, that are comparable to those of Australia (European Union), through to a waiver of the assessment requirements entirely (USA where most suppliers or manufacturers must hold but not submit efficacy data). In New Zealand, applicants can put forward a case why efficacy data need not be considered.

Under current legislation the regulator must have regard to efficacy when assessing applications. If efficacy has been assessed for an innovator product, then all products with the same active constituent and use pattern are taken to be efficacious without the need for an additional efficacy assessment. This extrapolative method applies to most domestic and home garden products, and some products used by Australian farmers.

In practice while the regulator is satisfied with the efficacy of all registered chemical products, the majority of these have not been assessed by the regulator for efficacy specifically (noting it is expected in many instances the supplier or manufacturer hold this data). The regulator routinely only performs an assessment against the criteria, including efficacy, if it has not established its satisfaction during an earlier assessment of that product or a reference product with comparable claims.

In 2018–19 the regulator finalised 303 applications (out of a total of 2,959) that required an efficacy assessment. A further 261 applications in categories where the assessment may have included efficacy were also finalised in this period.

The regulator currently outsources many efficacy assessments to external providers, in part due to the specialist nature of the work and the tight timeframes allowed for in the legislation (3 to 6 months, running concurrently with other assessments). These assessments add between \$580 and \$2,370 to the application fee.

Unlike safety and trade, the consideration of which is central to the regulation of agvet chemicals, the case for the regulator to verify the efficacy of all or some agvet chemicals products is less obvious.

Agvet chemicals are one of the few tools used by Australian farmers that are 'signed off' by government—there is no similar assessment carried out for other farm inputs such as machinery or fertilisers. The panel questions whether it should be the role of the regulator to provide assurance, through its assessment process, that agvet chemicals are efficacious.

The panel is keen to explore the benefits or ramifications of changing the way efficacy is considered in the agvet chemicals regulatory system and whether it needs to be considered at all for some products. The regulator would still continue to assess safety of the product.

Most products used by consumers and commercial entities don't have efficacy confirmed by a regulator.

Since the inception of the NRS, strong consumer protection laws have been introduced through Australian Consumer Law. This provides that products supplied to consumers are fit for purpose and operate (are efficacious) consistent with the claims made about the product. This provision is independent from any assessment conducted by the regulator and may constitute a duplication of regulatory controls.

For products used in production systems by corporate entities, avenues for redress for a lack of efficacy, again independent of the regulatory assessment, have existed from the initiation of the national scheme.

The panel has heard that some stakeholders consider efficacy an important assessment criterion required to ensure that people/animals are not being unnecessarily exposed to ineffective chemicals. The reasons stated for maintaining efficacy as an assessment criterion include the need to avoid production losses and animal welfare concerns. Even for human therapeutics efficacy is not always considered by the regulator. The TGA has a 'listed medicines' approach where the regulator considers the quality and safety of the product but not its efficacy prior to the product entering the market. Listed medicines are usually considered to be relatively benign, with well-known low-risk ingredients, usually with a long history of safe use.

Alternatively, other stakeholders have indicated that the risks of not assessing product efficacy are low, especially given the considerable costs associated with developing new chemistries and bringing them to market, its unlikely companies would invest in chemistries that are not efficacious. Consideration of efficacy by the regulator does provide applicants with efficacy related data protection that can support investment in innovation. Should the efficacy requirement be removed the panel would be interested to explore other options for data protection to incentivise innovation.

The vast majority of new chemicals are brought to market by multinational innovator companies. As part of their product development process these companies have in place robust assurance systems ensuring the effectiveness of their products. These companies are unlikely to risk their reputation by introducing a new product without testing it thoroughly, including (where necessary) by generating data that is specific to Australian uses.



Farmers are capable business operators, often supported by their industry bodies and well connected in their industry. Some commodity industry bodies play a role in trialling new products, testing efficacy and advising growers on pest management approaches. New products may not be widely used in production systems until the industry body has completed these trials. This is an approach like the support growers get from their industry bodies with other major new farm input decisions such as seed trials etc.

It is possible that the current legislative requirements for efficacy assessments could prevent the regulator from approving alternative chemicals (for example to glyphosate) if they are not as effective as those currently in the marketplace. This would obviously be an undesirable outcome.

The panel has also recognised that there are certain circumstances where efficacy considerations go beyond the effect in controlling a pest or disease and extend to product safety or the consequences to human, animal, plant or environmental health. For example, controls for mosquitoes, in parts of Australia an ineffectual product could expose a human (who believed they were protected) to blood borne disease. In the animal sector an ineffectual pain relief product would result in unnecessary (albeit unintended) animal suffering. Given these are safety issues, if efficacy assessment is removed these issues need to be factored into the safety assessment.

Options for retaining (for specific products), reducing, or removing product efficacy assessments from the agvet chemicals regulatory system are proposed.

## **Flagship reform proposals**

### **Option 1 Removing efficacy from the scope of agvet chemicals regulation**

The legislation would be amended to remove efficacy entirely from the scope of regulation as a distinct criterion for registration for either some or all product types. The efficacy of a product, or the consequences of a product being ineffectual, would for some products still be considered as a safety factor. Efficacy would be relevant to human safety where the product is intended to manage the risks to public health by treating/controlling human health vectors (mosquitoes, rats or mice). Efficacy would also be relevant to human safety for veterinary products whose use may contribute to the development of antimicrobial resistance to products significant for human health. Efficacy would be relevant to animal safety where ineffectual would prolong the suffering of an animal or result in future suffering through insufficient protection (such as vaccine products).

This means that applicants would not be required to provide efficacy data as part of registration or variation applications, unless required for safety considerations as outlined. There would also be no separate requirement on the registration holder to produce or hold efficacy data.

Under this option there would be no action the regulator would take in relation to products found not to be efficacious, but not unsafe, after registration. The remedies available to users for ineffective products would be provided through existing consumer laws for consumer products, and through litigation for products used for industrial or commercial purposes (including the majority of uses by farmers).

This option has similarities to the TGA 'listed medicines' approach, in that the regulator would consider the quality and safety of the product but not the products efficacy prior to the product

entering the market. However, it is a requirement under the TGA Act that sponsors hold information to substantiate all their product claims.

### **Option 2 Removing the requirement for efficacy data assessment**

The legislation would be amended to remove the requirement for the regulator to assess efficacy data as part of the registration process. Applicants would be required to make a declaration that the product is efficacious and that they hold sufficient data to support that declaration.

The regulator could request supporting data at any time post registration if there were concerns about the products efficacy. This is a similar approach to that adopted by the US EPA. A statutory duty would exist for the holder of the registration to make that information available to the regulator within a period (five working days). Failure to do so or failure to hold appropriate information would constitute an offence and could include a criminal penalty for making a false declaration. The potential for judicial sanction would be separate from the ability of the regulator to take administrative action against the product or holder, by requiring a product recall, or suspending or cancelling the product.

Requiring the applicant to provide a declaration of efficacy places the onus on the applicant to be satisfied. The legislation would provide for appropriate sanctions to be imposed on anyone who is found to be making a false or misleading declaration.

### **Option 3 Maintaining the criterion and amending requirements and streamlining assessments**

There would be no changes to the current efficacy criterion but the circumstances where evidence of product efficacy must be provided could be further reduced, perhaps in line with the safety concepts explored in option 1.

There would also be scope to consider streamlining the assessment process through:

- accrediting efficacy assessors to allow the assessment to be completed prior to applications being submitted to the regulator
- mandating use of overseas regulatory decisions (and/or assessments) as sufficient to address efficacy requirements for an equivalent product use in Australia
- where available, establishing arrangements where the past behaviours and current stewardship practices of an applicant warrant reduced pre-market scrutiny of a product's efficacy.

The panel is disposed towards option 1 for all crop protection products and non-scheduled veterinary medicines and is inclined towards option 2 for scheduled veterinary medicines. If one of the earlier proposals that the panel is inclined towards, removing consumer products from the agvet chemicals regulatory system is progressed then there would be no need to consider what option would apply to those products.

## **Discussion questions**

- 21) Which of the three options presented for retaining (for specific products), reducing or removing efficacy from the current agvet chemicals regulatory system do you prefer and why?
- a) Do you support applying option 1 to all crop protection products and non-scheduled veterinary medicines? If not, why?
  - b) Do you support applying option 2 to scheduled veterinary medicines? If not, why?

- c) Are there unmanageable risks or costs if the efficacy criterion was removed or reduced from the regulatory system? If so, could you provide details?

## 6.3 Should there be greater use of standards?

Groups of substances that are of a similar nature, type or use may have clearly established or low risks. The substances within such a group should be able to be covered by a standardised set of conditions for use, avoiding the need to consider each product individually.

Stakeholders and previous reviews have suggested that the current level of regulatory effort is not well aligned with the level of risk. With limited exceptions, a registration process is conducted by individual application and can be lengthy, expensive and complicated. Greater use of a standards approach would allow industry to self-assess products as compliant with a standard and consequently remove the need to prepare an application for registration. It would also remove the cost and risks of delayed market entry associated with the assessment timeframe. This would provide cost savings for industry that should flow on to chemical users.

Removing the need for the regulator to assess a considerable number of like applications will free up the regulator's assessment resources to focus on higher risk and innovative applications.

Publicly available standards would provide transparency and assurance to chemical users and the community that the products they are using, whilst not so tightly regulated, are still safe to use. Any adoption of a standards-based approach would need to be supported by a rigorous compliance and monitoring scheme. Applicants would still be required to hold data to support their product's compliance with the standard and make that data available to the regulator on request.

The New Zealand Environmental Protection Agency (NZ EPA) uses a 'Group Standards' approach for approvals of a group of low-risk substances that are of a similar nature, type or use, as opposed to approving them as individual products. Different types of products can be approved together under a single group standard on the basis of the risks they pose and the controls prescribed to manage those risks. All these standards are limited to the hazards listed in the specific group standard. In addition, they cover restrictions relating to labelling, advertising, packaging and supply.

The group standards approach relies on applicants making their own determination of whether or not their substance or product accurately sits within a group standard. If an applicant determines that the hazardous substance meets the conditions of an existing group standard, it is automatically deemed to be approved. If it does not meet the conditions, an application for approval to import or manufacture is required.

Group standards are typically made by referring to the characteristics and functions of substances in the group, rather than stating specific constituents and formulations. They therefore act as a template for a certain product type, for example, tablet-based products must include a stabiliser, lubricant, carrier etc; but do not stipulate the identity of the constituents. The group standards can prohibit particular constituents, such as those known for their hazard, volatility or incompatibility in certain situations.

New Zealand currently has over 200 group standards in force. At this stage, the New Zealand group standards do not yet apply to any crop protection products, but they are used for many veterinary medicines as well as other chemicals. Example veterinary medicine group standards include:

- Veterinary medicines (limited pack size, finished dose)—this standard allows importation of a veterinary substance with packaged weight 500 g/500 ml or less.
- Veterinary medicines (non-dispersive open system application)—this standard applies to specific substances imported or manufactured for use as a veterinary medicine using a non-dispersive open system application method. The substance must be a liquid administered as a liquid or a gas.
- Veterinary medicines (non-dispersive closed system application)—this standard applies to specific substances imported or manufactured for use as a veterinary medicine using a non-dispersive closed system application. The substance must be a liquid administered as a liquid or a gas.

Currently Australia's national regulator has broad powers to develop standards that simplify and streamline the registration process. Under either the listed product or reserved chemical product model, the regulator prepares a standard for a specific group of products. Compliance with the standard ensures the product meets the safety, efficacy, trade and labelling criteria. Regulatory assessments of applications for the registration of a listed product are significantly reduced in complexity. Reserved chemical products do not require review by the regulator.

The APVMA's use of standards is currently significantly under-utilised. The APVMA has established only two listed product standards, home swimming pool and spa products and joint health products for dogs and horses; and one reserved product standard for some hard surface disinfectants. Both mechanisms require direct implementation through changes to the regulations, by contrast the NZ EPA Group Standards only need to be published in the Gazette.

Sectors of the chemical manufacturing industry groups have previously indicated their support for standardised assessment models that build on, but are different from, the current regulatory approach for listed products.

The panel considers that maximising the use of standards could lead to significant efficiencies for both the regulator and industry.

The panel is interested in industry views on the potential to extend the reach of standards to other products or formulation types. An approach that is more flexible than either the current listed or reserved product processes is likely to be more desirable and better facilitate market innovation and access i.e. development should be industry not regulator driven, specification of constituents and formulations should be as broad and less prescriptive to the extent reasonable, and the publishing of standards should be quick and simple.

The panel would like feedback from industry on its willingness to contribute to the development of such standards.

The panel is aware this approach may have similarities to the finished product monographs adopted in some international pharmacopoeias. The panel is keen to know if adoption of these monographs may provide an effective alternative or starting point.

## Discussion questions

- 22) Would the ability to make greater use of standards be beneficial for applicants? If not, why?
- a) Should the use of standards be limited to products of low regulatory concern? Why/why not?
  - b) Are there any unforeseen risks with adopting a standards approach like New Zealand that wouldn't require regulation changes each time a standard is created?
  - c) Should the development of standards be driven by industry or the regulator?
  - d) Are there any other types of standards, or approaches to self-assessment the panel should consider?

### 6.4 Does Australia need to assess products that comparable regulators already agree are acceptable?

The Australian Government's position (outlined in its Industry Innovation and Competitiveness agenda: Plan for a stronger Australia 2014) is that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements, unless there is a good and demonstrable reason to do so.

The panel is keen to apply this policy to the agvet chemicals regulatory system where possible. Australia presents commercial barriers of small market size and long distances, so it is important that the additional barrier of the regulatory system is only what is necessary. This suggests that the Australian regulatory system needs to be innovative and open to new approaches that counter this barrier. Being able to accept international decisions on approved agvet chemicals products would allow Australia to become an immediate joint launch market alongside the international reference country, significantly speeding up entry of products into the Australian market, thus providing Australian users with timely access to the same chemical products their competitors have access to.

Like Australia, many international regulatory systems rely on robust objective scientific evidence to make decisions about allowing products to enter the market. Using registration decisions from comparable regulatory systems in the Australian decision-making process is one way to maintain scientific robustness, whilst increasing and expediting access to safe uses of agvet chemicals and significantly reducing the time and cost of regulatory checks. Faster access to chemicals would be another benefit. The challenge is how best to handle unique Australian circumstances, which would not have been considered by an international regulator.

The panel considered analysis comparing regulatory approvals for the major markets of the US, Canada and EU with Australia. For the 22 actives approved by the Australian regulator from 2013 to 2019, 16 have also been approved in at least two of these comparable regulatory systems. The median time to approval in two markets was 16 months sooner than the Australian approval for 12 of the actives. The largest difference was for Metofluthrin, which was approved (just over 7 years sooner in Canada and the US (2011–12 versus 2019 in Australia). The approach of using overseas decisions would still result in 7 out of 10 actives refused/rejected over the last 10 years, being rejected.

One reason for not being able to consider an international assessment is that it may not have given consideration to all the elements needed to satisfy each of the statutory criteria in a manner relevant for Australia. For instance, other than New Zealand, we are the only regulatory system that considers a trade criterion. However, combining the decisions from one or more regulatory systems is likely to increase the chance that a matter has been assessed.

The panel has heard concerns from some stakeholders, that accepting registration decisions from other international regulatory systems would impact Australia's sovereignty and may adversely affect the regulators international standing and its scientific credibility.

In addition, there is concern that if Australia accepted international regulatory decisions on registrations, this would also bind Australia in adopting future decisions from the same regulatory system such as banning a previously approved chemical. The panel is not convinced that this is an automatic assumption that holds. A regulator's decision to ban a specific chemical and its follow-on impacts to Australia would depend on the circumstances relating to the decision to ban the chemical. If those circumstances were not relevant to Australia, for example the decision was political rather than scientific, the panel considers this would have no bearing on Australia's regulatory decisions. For example, in the case of a ban, an Australian regulator would need to satisfy itself that the legislative criteria were no longer satisfied. To support such post registration decisions, it would be a condition of registration that the APVMA has access on request to the full data package for the international regulatory decision.

The panel agrees that the major reason why an overseas assessment could be considered insufficient is that it does not address risks associated with our unique environments and practices. However, if guidance was provided to potential applicants on what the 'unique' Australian conditions were that needed to be considered, this could be factored into their application to the reference regulatory system thereby providing an immediate additional 'launch market' for their product on registration.

The uniqueness of Australia's fauna and flora; some environmental differences such as streamflow and soil types and profiles; the effect of different strains and growing conditions on pest susceptibility and target plant/animal toxicity; and the Australian diet are all issues that could require specific assessment by the regulator.

The panel is interested in understanding exactly how unique Australia is considering that all other international regulators must also consider a diverse range of climates, environments and practices. For example, the USA covers a wide range of latitudes, climates and ecosystems. The EU is similarly diverse, with a wide range of dietary differences and great variations in national and regional agricultural practices.

## **Panel's view**

The Australian regulatory system needs to take full advantage of the work of comparable regulators, so that Australian effort is only focused on the issues that are unique to Australia.

## Flagship reform proposal

### Registration by reference

A registration by reference approach would introduce a mechanism deeming the regulator to be satisfied about the appropriateness of a chemical product or use based on the decision to accept it by one or more comparable international regulatory systems.

The regulator would be required to register the product based on the decisions of the comparable international regulatory systems. The only grounds to decline or defer registration would be where there are specific circumstances unique to Australia that need to be considered (such as use patterns, environmental conditions, host animal and plant toxicity, trade and dietary differences).

This means that no assessment or peer review by the regulator would be undertaken on those aspects of the application that are not unique to Australia—providing substantial savings in cost and time to the regulator and industry.

Basing the requirement for accepting a registered product, on the grounds it has been assessed and approved by one or more comparable regulatory systems would provide assurance that the assessment quality is equivalent to that of Australia.

### What decisions could it apply to?

The aim is primarily to facilitate faster access to market. Therefore, a *registration by reference* approach should, where possible, consider products, active constituents and labels as one complete registration. This would be a change from current pre-market assessment in Australia, which involves separate steps of approval for an active constituent, registration of a chemical product and approval of a label. This would offer a significant benefit for the regulator and industry in removing the need for separate approvals for the active, product and label.

Consideration could also be given to expanding the registration by reference approach to variations and chemical reconsiderations.

### When could a product be considered under a registration by reference approach?

The ability for an approval or registration to be granted on the strength of one or more international regulatory decisions will depend on:

- equivalency of comparable regulatory system outcomes—the extent their decisions can satisfy Australian criteria and provide outputs for other essential regulatory steps (labelling, scheduling and MRLs)
- equivalency of the product in the overseas and Australian markets
- the formulation and sites of manufacture will need to be the same
- the instructions for use in Australia will need to be equivalent to the use patterns of the approved product
- transparency of the assessment—the applicant would need to provide sufficient information, in English, from the assessment decision of their registration by reference application. This would need to confirm the elements satisfied by the comparable regulatory decision, identify areas requiring unique assessment for Australia, and support the full range of post-registration activities including variations, reconsiderations, compliance, monitoring and enforcement.

### **Who should determine the comparability of another regulatory system?**

Either the Minister, Secretary (Department of Agriculture, Water and the Environment) or the national regulator could be given the power to set through legislation, the criteria for what constitutes a decision of a comparable regulatory system. The need to balance policy and operational considerations suggests that the Secretary may be the appropriate decision maker to set the criteria in consultation with the regulator. As the criteria would be set under legislation, stakeholders and the general public would also be consulted.

### **What makes for a comparable regulatory system?**

To be considered sufficiently comparable to support a registration by reference approach an international regulatory system would need to provide a similar outcome in terms of regulatory decisions to the Australian regulator. The panel considers at minimum, their decision would need to:

- be a full de novo assessment of all relevant matters i.e. not based on assessment/decision of another regulator
- involve similar inspections programs where relevant (e.g. Good Manufacturing Practice for veterinary chemicals) but also any other practices required in future e.g. Agricultural Practices, etc.
- apply similar pharmacopeial standards and international guidelines for scientific assessment. Differences in how these international standards are adopted will need to be well understood and accepted as not detracting from equivalency.

### **How to manage considerations unique to the Australian regulatory system?**

As outlined earlier, the regulator would retain a specific discretion to consider unique circumstances or decisions where the risk profile appears to be well outside what is considered appropriate in Australia.

Applicants would be supported by regulatory guidelines on how to address unique Australian matters e.g. appropriate choice of indicator species, shelf stability parameters and addressing issues that were/were not raised at approval of the active constituents. Clear guidance on what is considered unique is necessary to ensure the concept of 'uniqueness' is not used as a barrier to accepting international decisions. This enables the applicant to include all of the relevant material in the original application, thereby streamlining the Australian national regulator's consideration of the uniquely Australian aspects of the application.

The regulator is also likely to still need to approve labels for containers of products. There may be an unavoidable need to consider any appropriate signal words required by the Poisons Standard and instructions related to the 'prevention of undue prejudice to Australian trade'.

Approval of the product label through regulatory assessment could be accelerated by statutory conditions for content and format or compliance with international standards. Label digitisation and digitalisation of label generation and confirmation are other avenues for reducing the delay associated with label approval.



## Discussion questions

- 23) Should the regulator utilise prior assessment decisions from comparable regulators to fast track registration where appropriate? If not, why?
- a) Do you support a registration by reference approach as outlined? If not, why?
  - b) Is basing the approach on decisions from one or more comparable international regulatory systems sufficient?
  - c) Should the approach make it one registration for product, active constituent and label?
  - d) Should the approach be used for variations and reconsiderations?
  - e) Are the criteria for what constitutes a decision of a comparable regulatory system a policy decision appropriate for the minister, departmental secretary or the national regulator?
  - f) What should be the requirements when considering regulatory comparability?
  - g) Are there uniquely Australian issues that need to be assessed that have no international equivalence?
  - h) How might the assessment of any unique Australian matters be easily managed?

### 6.5 Does the existing approach for assessing permits (minor-use and emergency use) meet the needs of users?

One of the most effective tools available to the Australian agricultural and veterinary industries to respond to circumstances outside of uses set on labels or to effectively address specific circumstances of non-compliance, is the ability for the regulator to permit an activity that would otherwise be unlawful. The current permit system is an important feature of the agvet chemicals regulatory system and one that is unique to Australia.

As described in [Chapter 2](#), there is a separation between control of supply and control of use of agvet chemicals, the national regulator has primary operational responsibility for the former and the states and territories the latter. The exception to this separation is the ability for the regulator to authorise the use of a product in a manner that would otherwise constitute an offence under state or territory law. The costs of permit assessments vary with the nature of the permit, however consistent with the wider cost recovery arrangements of the regulator, none recover the full costs of assessment from the applicant. Emergency permits are free, research permits are approximately 40% of the cost of assessment and permits for off-label use and most others are \$350. The significantly lower fees for permits (compared to registrations) are considered justified as it significantly increases growers' access to chemical uses.

Permits are the primary means by which Australian growers can access a use where there is no commercial incentive for agricultural chemical product manufacturers to include the use on the label. Chemical access issues are most keenly felt in new and emerging industries where economic returns are insufficient to justify corporate investment. Chemical access issues also exist in major commodities often as the result of an increase in pest resistance or smaller/infrequent pest emergence. Together these access issues are called the 'minor use' issue.

In assessing a minor use permit the regulator considers a range of information and has a history of utilising data extrapolation and scientific argument. The panel commends the regulator on this approach and would welcome comments on how the regulator might expand this within registration decisions.

While minor use permit applications have a reduced timeframe for application assessment (relative to comparable registration applications) the regulator can, where the circumstances warrant it, focus resources on specific permit decisions. Where an emergency exists (plague event or biosecurity incursion) the regulator can and does consider emergency permits in a very shortened timeframe, and without cost to the applicant. The panel fully supports this approach and would like to see this continue.

The panel supports the government's actions to address minor use and support Australian growers' access to safe and appropriate chemical products. The panel highlights the success of the Improved Access to Agvet Chemicals Initiative (the initiative). A recent economic analysis (ABARES 2020) of the grants program has shown an average return to industry of \$117 per government grant dollar (or \$17 million per project over 20 years). These returns are comparable to those achieved for similar international minor use programs. The panel considers this clear evidence of the value in equipping industries with the necessary tools for pest and disease management.

Stakeholders across the agvet chemicals spectrum have indicated to the panel their strong support for the grants program specifically and government leadership on minor use generally. Minor use is a global issue that spans agricultural and veterinary sectors. The panel supports greater alignment with international approaches on minor use to identify where international decisions have relevance to Australian growers or expanding export markets.

The ability for the regulator to authorise the use of a product, or the supply of an unregistered chemical product, to respond to growers' needs is considered by the panel to be a strong positive outcome within the current arrangements. The panel notes that in issuing a permit the regulator must be satisfied to the same degree of the use of the product in terms of safety, efficacy and trade risks as if the product use was being registered.

However, the support of the manufacturer is not required providing an avenue for growers (or their representative bodies such as rural research and development corporations) to respond to their own needs. The panel acknowledges the growing interest of manufacturers in the permit scheme, and the support to date provided by some manufacturers for growers seeking permits.

There are currently over 1,000 permits in operation relating to minor uses. These cover a diverse range of commodities, pests, and chemical combinations. For example, there are permits:

- to allow annual grass weed control in barley
- allowing a range of herbicides and insecticides in hemp production
- addressing electric ants in sugar cane
- to allow the use of plant growth regulators in potatoes
- for autogenous vaccines to treat diseases and conditions in pigs, horses, cattle, sheep, poultry and dogs

- for vaccine treatments of salmonid fish.

The regulator can also issue permits, amongst other things, to:

- support industry research
- address short-term issues in GMP facilities
- possess material for the purposes of export
- supply product material with differing labels
- supply material that differs from the details assessed at registration.

The issuance of permits by the regulator is one of the most beneficial activities the regulator undertakes in terms of actions that can most benefit users, especially farmers. The panel considers that Australian growers are well served by the regulatory permit system, and it is important that:

- the government continues, with increased ongoing funding, the current minor use grants program to support chemical access
- the permit issuing capacity is retained in any future regulatory system (in terms of minor use, research, emergency and general scope for unlawful activities).

## Discussion questions

24) Is enough being done to address minor use permit applications, if not what more could be done?

- a) Are there any improvements or changes to the permit system that would be beneficial?
- b) Should permits be expanded beyond the activities they currently cover? If so, what activities would you suggest?

## 6.6 Should chemical reviews be timelier and more informative?

The regulator, as required by legislation, is responsible for undertaking formal chemical reconsiderations of active constituents and registered agvet chemical products. New scientific information can emerge after the approval/registration, which can suggest a change in the risks to human health, the environment, animal or crop safety or trade which can warrant the need for a chemical reconsideration.

Whilst the legislation refers to chemical reconsiderations, given that industry and the general public know these as chemical reviews, this is the term that will be used in this paper.

All other international regulators undertake similar chemical reviews. Some regulators, such as the US, Canada and the EU have rolling reviews of chemicals, every 10 or 15 years. The panel notes that in countries where they have a rolling review, this is generally supported by significant dedicated resources to undertake the activity, acknowledging the resource intensiveness of such reviews. The panel noted that the Australian regulator does not receive such dedicated funding.

Under the legislation the regulator can initiate a chemical review based on concerns they have about a specific chemical or a chemical can be nominated by anyone for potential review. The seven

nominations received over the last four years for chemical reviews had come from other government agencies (e.g. Office of Chemical Safety), six of these were accepted.

The regulator lists all the chemical reviews they are undertaking on their website. The decision documents relating to a chemical review are made public, as well as the gazette containing the legally required detail about why the regulator was or was not satisfied and the actions to be taken.

The panel is inclined to think that chemical reviews should be risk-based and triggered by new information (that questions its safety—human or animal health and environment) and not calendar driven and therefore does not support the notion of rolling reviews based on specific timeframes. The resources involved in rolling reviews does not appear, from international experience, to provide better outcomes in terms of human, animal or environmental safety.

The panel has heard that the current legislation is too prescriptive in respect of the components (all statutory criteria) that need to be considered in undertaking a chemical review. It has been suggested that if the regulator was able to be more targeted in what was needed to review a specific chemical (e.g. the only issue was safety related), this could significantly streamline the process resulting in more timely decisions. The panel supports this suggestion and considers it appropriate to focus chemical reviews solely on the specific issues that warrant review rather than requiring the regulator to reassess all aspects of the original approval.

It is acknowledged that during a chemical review, many interim decisions can be made at various times throughout the process, but the overall timeframe for completion needs to be explored. Many of the current chemical reviews have been underway for more than 20 years. These lengthy timeframes reduce the confidence of the general public in the effectiveness of chemical reviews.

The panel also notes that there are a variety of legislative measures available to the regulator to withdraw, cancel or limit registrations based on new information about safety at any time. It could be argued that these legislative measures perform the same purpose as a chemical review thus potentially making chemical reviews somewhat redundant. That said the panel is inclined to keep a specific chemical review process in the legislation.

## Discussion questions

- 25) Are there changes that need to be made to the chemical review process to accelerate timeframes for completion? If so, what would these changes be?
- a) Should reviews have flexibility to consider specific issues that warrant review rather than a comprehensive reassessment of all aspects of the original approval?
  - b) Should chemical reviews be risk-based rather than driven by rolling specified timeframes?

## 6.7 Should greater use of technology be used—smart labelling?

Advances in technology can support different ways for users to access and engage with instructions for the safe use of a chemical product.

Industry sectors outside of agvet chemicals are increasingly sharing targeted information to 'users' through electronic means, such as quick reference (QR) codes. This has the potential in an agvet

chemicals context to allow a more responsive approach to information sharing and simplify the printed label.

It is not uncommon for the instructions for a product to change from time-to-time. As a result, different labels for the same product can sometimes be found in the supply chain, or more importantly, within users' chemical stores. Should this occur, some users would not have access to the most current information on how the product can be used safely.

Many labels include instructions that cover a range of commodities and pests, across a diverse range of circumstances. This can lead to excessively long, detailed labels, in which most information is not relevant to individual users. Users have told the panel that the ability to access the specific content relevant to a commodity would be advantageous.

Industry has encouraged the panel to explore the currently unrealised opportunities offered by electronic labelling (e-labels or smart labels). Industry argues that the benefits include simplified assessment processes, easier user access to use instructions relevant to a given situation (e.g. crop) and the ability to provide updated information when label particulars change.

Currently, agvet chemicals legislation requires that a label is attached to (or provided with) all registered chemical products. Labels must contain adequate instructions about:

- the circumstances in which the product can be used and how it should be used
- the times when the product can be used and the frequency of use
- withholding and re-entry period after use of the product
- disposal of unused product and containers
- safe handling and first aid
- any other matters prescribed in the regulations
- any matters specified as a condition of registration or approval
- any matter specified in a standard made for the label
- any matters determined by the regulator's CEO.

Historically, the regulator would request copies of the final market product label. This would be assessed for content, as well as font size, colours and proposed imagery. Changes to these requirements in 2010 meant the regulator now only needs to assess label content (approved label wording). The changes also provided for the development of a labelling standard (font size, information location etc.). Matters relating to artwork and imagery are, largely, no longer within the regulator's purview.

The regulator has implemented a model electronic labelling template, which allows holders to make label content available in electronic form. However, uptake of the template has been 'patchy' at best. Also, it is not aimed at enabling 'smart content' to show the specific content relevant to the user and situation. As such, the benefits of electronic labelling have not been fully realised under the current arrangements.

The Canadian Pesticide Management Regulatory Agency electronic labelling approach incorporates a comprehensive 'instruction for use database'. This presents the majority of (if not all) product labels in a single consistent format. While the Australian regulator does have a database that effectively records the commodity and pests a product may be used against, its publicly-available label database is separate from this. The panel is interested in stakeholder views about whether Australia should adopt a comprehensive use database similar to that employed in Canada and/or whether users should be able to access an exact copy of the label (including artwork, layout etc.) as affixed to the product.

Separate to the issue of electronic labels, the panel has heard that the current labelling process is arduous and complex. For example, there are separate labelling codes for agricultural and veterinary products, which outline differing legislative requirements for each, but no labelling standard. The panel is interested in stakeholders' views as to whether removing the requirement for separate label approvals and relying more on specifying label content as a condition of registration, could relieve some unnecessary regulatory burden. This could be combined with a statutory duty (as discussed in [Chapter 2](#)) to ensure holders provide labels that are legible and have an appropriate format.

## Flagship reform proposal

### Smart labelling

Smart-labels would be used in different ways to provide:

- smart content on labels affixed to a container, such as a quick response (QR) code (or similar) that would allow companies to update label information in real time and allow users to access updated or commodity-specific instructions etc.
- an electronic means for editing label content, allowing applicants to update their label following authorisation from the regulator (following a variation)
- labels that are machine readable, to support increased on-farm automation.

Smart-labels could enable easy dissemination of information such as:

- changes to authorised product uses
- notices of product recall or cancellation
- changes to scheduling, storage or disposal instructions.

The panel considers that the legislation should provide for smart-labelling, to capture the benefits outlined. Smart-labels would include 'smart content' to take full benefit of technology. This approach has already been adopted in Australia as part of reforms to excluded nutritional and digestive products.

Primary producers, veterinarians and non-urban land managers would be able to receive up-to-date content targeted to their pest/commodity/situation. Chemical users will have access to the latest tools and information about best practice chemical use, and will be able to filter out competing label information that can cause confusion and lead to errors in chemical handling and use. Information that relates to safety, first aid, disposal, transport or use restrictions would remain affixed to the container, but could be enhanced through additional smart-label content. The result should be safer use and an improved user experience.

Targeted, on demand delivery of searchable label content should significantly reduce labelling (and relabelling) cost to industry, and avoid delays in disseminating information (currently, a label variation may not reach the market until stocks of old labels are expended).

With the potential for increased automation and machine support to Australian agriculture the necessity for machine readable labels is clear. It would be possible, recognising that agricultural producers frequently purchase chemicals in large volumes, to mandate that all labels for containers above a certain volume (for example 10 litres or kilograms) be machine readable.

The panel welcomes stakeholder views on the viability of using smart information on a label to improve user experience and whether this would enhance the safe use of chemicals. The panel would like to understand if a similar approach has been adopted in other industries. The panel is also interested in learning about any potential limitations to this approach arising from control of use legislation.

## Discussion questions

- 26) Should smart-labels be used, what smart content should they contain and should they be machine readable?
- a) Does control of use legislation limit this approach in any way?
  - b) Is mandating labels for containers above a certain volume to be machine readable supported?
  - c) Should Australia adopt a comprehensive use database and/or provide access to an exact copy of the label?
  - d) Should separate label approvals be removed and instead have label content specified as a condition of registration? Are current labelling requirements excessively prescriptive? Could they be made more outcomes oriented?

## 7 How can Australia build national and international capacity?

Australia's continuing economic and social development is increasingly dependent on a sensible balance of scientific, technological, and regulatory capability. A lack of scientists will stifle innovation; insufficient technological capability will send our best minds overseas to transition their ideas from concept to reality; and inefficient, or ineffective regulation can both drive away investment, and damage the public's willingness to embrace the future.

The panel notes that Australia is facing significant disruption to its regulatory capability, as the current cohort of regulatory scientists, (who predominantly work for the Commonwealth) approaches retirement. The next generation of workers has a declining interest in science, technology, engineering, and math (STEM) careers, is increasingly seeking varied, location-independent work, and is less attracted to careers in the public sector than their predecessors. Our agvet chemicals regulators may therefore need to look beyond traditional approaches to attracting and retaining workers with the appropriate skills and engage with the people and institutions with those capabilities, flexibly, and on their terms.

The panel further acknowledges the desirability of non-government activity in the effort to strengthen Australia's national capacity. The future system needs to develop a depth and breadth of capability beyond that which can be provided by government. For example, research and development organisations, universities, private sector start-ups, industry bodies, consultants, not-for-profit groups and philanthropists can all contribute expertise if provided with sufficient access to the system, and system information including its annual work priorities, emerging policy challenges and identified research needs. One area where universities and private sector start-ups could fill a current gap in capacity is in the area of research trials for applications for minor use permits—there is a limited field of research expertise currently available to undertake this work within Australia.

### 7.1 Are there sufficient international networks of expertise?

As agvet chemical markets become increasingly globalised, drawing on international expertise will be important for making policy and regulatory decisions and improving local practices.

There are currently several programs in place aimed at improving collaboration between our regulators and governments internationally. Further communication and increased familiarity with how other regulatory systems operate may be the best starting place from which to achieve improvements in Australia.

Joint reviews provide the opportunity for regulators to collaborate on the assessments of agvet chemicals. This harmonised approach theoretically allows regulators to lead certain assessments (e.g. toxicology, chemistry, etc.) with other regulators peer reviewing the work. Regulators can then use these assessments as the basis of their country's decision while considering regional data and use patterns. Possible benefits of a joint review include:



- greater consistency and predictability in decision-making across regions
- harmonised approaches to assessment
- single dossier preparation
- coordinated access to new markets.

In practice, in joint reviews, each regulator has largely undertaken each assessment separately rather than adopting other regulators' assessments. Despite this, the enhanced understanding of international practice for Australian staff has delivered benefits, and the regulator is willing to continue their involvement and seek opportunities to improve the program. One way to improve the program may be to have a joint registration approach (rather than only joint assessments) as the end goal. While this appears an attractive way to foster collaboration, it is unlikely regulators would agree to participate if they lost their sole decision-making power.

Increasing the transfer (temporary or permanent) of staff between regulatory authorities offers the benefit of strengthening the global expertise of agvet chemical assessors. An example where this would be beneficial is the panel's third-party assessor proposal. As the current pool of assessors in Australia is minimal and decreasing, using international assessors (accredited by the regulator) will likely be necessary to meet demand. This could be expanded to other regulatory functions such as chemical reconsiderations.

The APVMA and the Department of Agriculture, Water and the Environment are currently involved in a range of international agvet chemical relevant committees and projects, where they have developed strong international standings.

The APVMA currently chairs the Expert Group on Minor Use and the Residues Chemistry Expert Group under the OECD Working Group on Pesticides. They have also been involved in global joint reviews of agricultural pesticides, participated in collaborative regulatory assessments of veterinary medicines and undertaken international work sharing arrangements with other regulators.

Similarly, the department is involved in multiple international committees including:

- the Codex Committee on Pesticide Residues that provides recommendations about maximum limits for pesticide residues for specific food items or groups of food
- the Codex Committee on Residues of Veterinary Drugs in Foods that determines priorities for the consideration of residues of veterinary drugs in foods and recommends MRLs for veterinary medicines
- the Joint FAO/WHO Meeting on Pesticide Residues that is an expert ad hoc body working to harmonise the requirements and risk assessments of pesticides residues.

An existing large area of international collaboration is in minor use, due to it being a global issue. Australia is currently involved in the Minor Use Foundation Inc., which is a non-profit organisation that funds research globally into minor use agricultural chemicals. The goal is to use this research as part of an application seeking the legal use of a chemical and improving access for farmers to safe and effective agvet chemicals. Additionally, the regulator and the department have attended minor use forums in other countries and have hosted their international counterparts to attend Australia's minor use forum. These forums award research grants to industry to conduct research into minor

uses. Continuation and expansion of these programs will be an important method of boosting our international networks.

## Discussion questions

- 27) How could the regulator and the Department of Agriculture, Water and the Environment best engage and strengthen international networks?
- a) How can parties outside of government become involved in existing international networks?
  - b) How can the regulator best expand and use its existing network of international assessors?

## 7.2 Is an operational regulatory working group needed?

The importance of agvet chemicals to continued agricultural productivity and animal health makes it essential that all players in the national effort to manage agvet chemicals are engaged in decisions affecting the regulatory system.

In a cooperative regulatory system like the NRS communication between each jurisdiction's regulators is critical for its smooth and consistent functioning. Stakeholder engagement on regulatory operations can also have beneficial impacts on enabling the regulated community to better understand and have confidence in the regulatory system as a whole. These activities are also important for increasing both the regulators and the regulated community's understanding about appropriate chemical use. The panel is disposed towards discussions with the regulated community on technical and operational matters taking place through the new consultative forum proposed in Chapter 5.

The regulator has previously maintained several committees that sought both technical and regulatory input from a selection of the regulated industry and regulators.

These committees included:

- The Registration Liaison Committee (RLC)—a forum consisting of representatives of states and territories signatory to the NRS and relevant Australian Government departments. The RLC was aimed at providing a setting for discussions on operational policies, guidelines and protocols of the regulator and signatory jurisdictions. It sought to allow the effective alignment of agvet chemicals control objectives of the regulator and the states and territories.
- The Manufacturers' Licensing Scheme Industry Liaison Committee (MLSILC)—a forum for veterinary chemical manufacturers and auditors, established to discuss strategic and operational issues related to the Manufacturers' Licensing Scheme and Good Manufacturing Practice.
- The Industry Liaison Committee (ILC)—the main consultative forum between the APVMA and peak agvet chemical organisations representing registration holders. The forum sought to engage these stakeholders in the APVMA's strategic planning (i.e. the operational issues and reforms developed by the regulator).
- The Industry Technical Committee (ITC)—a forum developed to engage peak agvet chemicals industry groups in the APVMA's technical considerations and processes.

With the exception of MLSILC, these committees have essentially ceased to operate.

In 2010, independent of both the regulator and the department, a National Working Party on Pesticide Application was established to assist stakeholders in adapting to policy changes and spray drift reviews being undertaken by the regulator. This group consists of grower groups, chemical companies, spray applicators, and research and development corporations. The regulator and the department participate in the Working Party as relevant. Many of the activities undertaken by the Working Party overlapped with roles of the ITC and ILC. The Working Party is continuing with an increased focus on spray drift, training standards for pesticide applications, best management practices and support to stakeholders in understanding regulatory policy.

The panel is aware that the committees have been effective in the past. The panel has heard the RLC in its early days was very effective in working through issues and collaboratively finding ways to address obstacles to effective regulation. It sought to allow the effective alignment of agvet chemicals control objectives of the regulator and the states and territories. The panel understands that this committee no longer operates in the way it was intended but rather now focuses on the operational aspects of regulation rather than problem solving. The reasons for this are unclear but it appears to be a less effective forum than it was.

## Panel's view

The panel sees benefit in an operational group of regulators across jurisdictions focused on addressing and working through issues that need solving. This would assist in building capacity among regulators as they share information, intelligence and skills to progress their regulatory responsibilities. The panel is interested in feedback on whether there would be merit in reinvigorating the Registration Liaison Committee to focus on its original intent.

## Discussion questions

- 28) Do you support the reinvigoration of the Registration Liaison Committee to focus on its original intent? If not, why?
- a) Do you support the proposed new formal consultative forum (chapter 5) in Australia including work on regulatory operations and technical working committees?

## 7.3 Should the private sector be able to perform assessment work?

Currently the regulator outsources some of its internal assessment work to third party assessors who are experts in the fields of human health, environment, efficacy and target animal and crop safety risk assessments (these assessors are used to assess applications lodged with the regulator). While the regulator outsources some assessment work this does not extend to applicants directly engaging assessors to undertake assessments of their applications prior to submission to the regulator.

The NZ Ministry of Primary Industry has in place a third-party assessor scheme that applicants use to assess their applications prior to submission to the regulator. Under this model the regulator accredits a list of assessors that applicants can approach to undertake their application assessments. Assessments are essentially a peer review that assesses design, adequacy, sampling, interpretation of data and compliance with guidelines.

This system has apparently been quite successful in New Zealand and the panel is interested in the benefits of introducing such a model in Australia. Evidence from New Zealand indicates that this approach has reduced both timeframes and costs for applicants in undertaking assessments. Assessors charge NZD \$150 to \$250 per hour and generally deliver their assessment (with opportunity for applicant feedback) within one month. It is not uncommon for more than one assessor to be involved in an assessment—as assessors are usually experts in a specific field.

The panel considers that the use of third-party assessors may contribute to building national capacity (outside of the regulator) for regulatory science skills and expertise. This has the potential in the long term of providing the regulator with a greater pool of expertise to draw upon in the future.

The panel is inclined to support the accredited assessor scheme that was outlined in the lapsed Streamlining Regulations Bill in 2019 and would be keen to revive this proposal. The panel considers it has the potential to improve national capacity in this area.

The panel notes that some stakeholders have expressed the view that applications could be 'shopped around' to multiple assessors until the application was approved. According to the New Zealand regulator this has never been a problem. They have stringent requirements for dealing with conflicts of interest and this would be something that any Australian model would also include. Alternatively, there could be a panel of assessors that are allocated to applicants by the regulator to further address any issues of conflict of interest.

## **Flagship reform proposal**

### **Accredited assessor scheme**

The legislation would provide for an accreditation scheme for third party assessors. The regulator would be able to establish a framework for assessors in the future which could, for example, specify the requirements for professional experience, insurance, conflict of interest measures and data handling protocols. The regulator would be responsible for monitoring and overseeing these arrangements to ensure the outsourced assessment functions were performed effectively. The regulator would be able to withdraw accreditations for certain reasons, for example, breaches of conditions or requirements.

The proposed accreditation scheme would include requirements for an audit and compliance program to be overseen by the regulator to help ensure quality and consistency and safeguard the integrity of the third-party assessment process.

The scheme would also provide the regulator with the ability to charge for performing accreditation functions, consistent with cost-recovery principles. The specific charges would be developed following consultation on the details of the accreditation scheme and would be set out in a legislative instrument.

The scheme is intended to have broad application to support the regulator and potentially used to accredit persons for a range of purposes in the future, such as:

- roles that accredited assessors might undertake directly on behalf of industry, including preparing assessment reports for applicants that would then be included in applications made to the regulator (like the approach used in New Zealand)

- roles that the regulator currently undertakes but could potentially be undertaken by accredited assessors, such as conducting assessments of information in applications made to the regulator (regulator-initiated assessments by accredited external assessors).

Recognising the technical nature of an accreditation scheme and the expertise required to establish and oversee it, it is proposed that the regulator develop the accreditation scheme through a legislative instrument. This would provide a suitable legislative basis for the scheme (and would be disallowable in parliament and hence subject to parliamentary oversight), while ensuring the scheme was sufficiently responsive to the needs of the regulator.

Furthermore, persons overseas who wished to become accredited assessors would be subject to the offences for non-compliance with conditions of accreditation.

Moving the function of conducting or commissioning data assessments from the regulator to third-party providers has the potential to:

- provide applicants with greater flexibility over data assessment timeframes and costs
- simplify administration processes within the regulator
- increase efficiency of application processing
- open data assessment to greater competition.

These measures will allow the regulator to accredit persons for assessments of information the regulator receives. The regulator's legislative instrument will provide community confidence in the assessors of agvet chemical products as it could, for example, specify requirements for experience, insurance, conflict of interest measures and data handling protocols. The instrument could also include requirements for an audit and compliance program. This would help ensure quality and consistency and safeguard the integrity of the third-party assessment process.

It is anticipated that there would be sanctions for contravening conditions of accreditation to ensure that accredited persons comply with such conditions. Criminal and civil sanctions may be prescribed in regulations.

## Discussion questions

29) Do you support a third-party accredited assessor scheme? If not, why?

- a) Do you support the scheme being based on the model in the lapsed Streamlining Regulations Bill 2019?
- b) Should applicants be able to choose their accredited assessor, or should there be a panel of assessors allocated by the regulator?
- c) Should persons overseas be able to work as accredited assessors?

## 7.4 What capabilities may be needed to adapt to future technology?

In the agvet chemicals space, new technologies and practices are rapidly being developed that offer many benefits, including reductions in pesticide use and therefore human and environmental exposure. Regulators globally face challenges to assess these technologies. This is possibly due to a

lack of understanding of these technologies and not having appropriate risk assessment methodologies and management policies in place to determine whether a new technology reduces risk or causes additional problems. While it is clear regulators should not impede the development and commercialisation of technologies through slow assessments, they must continue to ensure they are applied in a safe and appropriate manner.

Some examples of new technologies include targeted ultra-low application equipment, autonomous drones and other farming machinery, digital platforms and the increased development and use of new biological agricultural products.

Biological agricultural products are pesticides where the active constituent comprises or is derived from a living organism (i.e. plant, animal or microorganism). They are emerging in the market with an annual growth rate of 10 to 15% and the current global value is approximately \$3 billion (Damalas & Koutroubas 2018). In comparison to synthetic chemicals, biological products generally have lower toxicity (to non-target species), are far more target specific and have reduced impacts on mammal health. Regulation of biological products differs considerably between countries. In Australia they are currently regulated on a case-by-case basis by first assessing if the chemical falls within the relevant definition of an agvet chemical. Data requirements are similarly determined. There are multiple biological products registered by the regulator and on the market. Considering this, the regulator appears sufficiently capable of assessing and regulating these emerging products.

Precision application technology, which includes greater use of intelligent robots, is predicted to fulfil a major role on farms in the near future. These technologies are enabling farmers to minimise pesticide use and associated costs while maintaining crop protection. Trials have shown that targeted, low dose application technologies achieved a spray volume reduction of 50-70% while maintaining comparable levels of pest control (Durham 2016).

Additionally, autonomous drones currently exist (though not widely commercialised) that are capable of sensing and treating only the pests or weeds that need targeting. This preserves the crop itself from exposure to pesticides. There is an overlap with this and existing applicator licencing and control of use requirements which is currently being investigated jointly by Commonwealth and state and territory governments. It will also be necessary for the regulator to consider what changes are needed to existing label instructions, toxicology assessments (due to there being smaller site-specific applications) to ensure the safe use of products when applied using these new technologies.

There is a need to draw on lessons from the introduction of new technologies in other countries and identify whether there are any potential unintended consequences. The need for a considered approach may create tensions in an environment of fast-moving technological development, and it may be unrealistic to expect regulators to review all new technologies.

To reduce this risk, one approach regulators could take to increase their ability to adapt and assess emerging technologies is to undertake horizon-scanning activities and more stakeholder consultation. This would allow for a greater level of information exchange between all parties, benefitting the speed and accuracy of assessments. It is unclear whether Australian agvet chemicals regulators undertake enough of these activities and are therefore likely to find it difficult adapting to the challenges posed by new technologies in the area.

## Discussion questions

- 30) What additional capabilities may be needed by agvet chemical regulators to assess new technology?
- a) Which stakeholders should agvet chemicals regulators consult with to stay abreast of current and emerging technologies?
  - b) What horizon scanning activities should be undertaken by agvet chemicals regulators?

## 8 How will a new regulatory system be sustainably funded?

The national regulator is a fully cost recovered agency which means it is funded through industry fees and levies. This is consistent with the Australian Government's charging framework which requires that regulatory services are cost recovered.

This charging framework requires that those that benefit from the system should pay for the services provided to facilitate those benefits. In line with the government's cost recovery guidelines, the applicants registering chemicals are the ones most likely to benefit from the system and therefore, they are the ones that should be subject to the systems' costs.

It is critically important that the regulator tasked with the responsibility of ensuring agvet chemicals entering the market in Australia are safe to humans, animals, plants and the environment, is adequately funded to undertake this role.

In 2017, PricewaterhouseCoopers (PwC) reviewed the regulator's cost recovery arrangements. The review found that the prices set were no longer consistent or reflective of the true costs of undertaking the agency's operations. The review also found that under these current costing arrangements, the regulator could not sustain its financial position in the long-term, and that the costing framework was no longer fit for purpose. This is evident in the operating losses that the agency has had for the past several years.

That this non-viable situation persists is of serious concern to the panel.

The last full Cost Recovery Implementation Statement (CRIS) review was in 2012 and as such, the current charging framework no longer reflects the costs of delivering regulatory services. The current CRIS does not allow for the annual indexation of charges to consider wages growth and CPI movements. As a result, there has been no increase to any charges since 2014. The average annual operating loss (excluding appropriation) since the CRIS' implementation has been over \$2 million. This is clearly unsustainable and impacts the ability of the regulator to undertake its regulatory functions effectively.

The regulator is currently reviewing its cost recovery model including a revised CRIS as a basis for updating its schedule of fees and levies. However, the panel understands that this is likely to only achieve immediate financial stability, rather than considering fundamental reform.

The panel notes that industry has been advocating for comprehensive reform of the regulator's cost recovery arrangements for many years in order to ensure it reflects a user pays system.

The panel notes that most comparable international regulators recover part, or all, of the cost of regulation from the regulated industries. Information the panel has considered indicates that the regulatory charges in Australia are comparable to international regulators, and in many cases are much cheaper.



The majority of the states and territories control of use activities are government funded, however some jurisdictions implement cost recovery for specific activities (for example licensing), this equates to a small component of the total control of use costs (15% or below). It is worth noting that the reliance on government funding for control of use functions has led to decreases in resources over time due to budgetary constraints.

## **8.1 Are all system users paying their fair share of costs?**

The current cost-recovery arrangements allow the regulator to recover around 40% of the average cost of assessing applications, with the remainder of costs funded via a tiered levy on sales and the annual registration renewal levy. The decision to set fees at 40% of the cost, with the remaining revenue to come from levies, was initially intended to reduce the barrier to market entry for products and avoid excessive burden on applicants—including those bringing innovative products to market and applications for generics.

The approach to the regulator's charges (which was agreed between the signatories to the NRS IGA) is inconsistent with the Australian Government's charging framework—which aims to remove cross-subsidisation. Charging only 40% of the cost of assessing applications means that the shortfall is recovered from the wider industry via the levies—approximately 50% of the sales levy revenue comes from around 20 companies. This amounts to significant cross-subsidisation.

The regulator also recovers some costs from its non-registration activities including its manufacturing and licensing scheme, and hormonal growth promotant licensing program.

In addition, for some services—particularly permits—the regulator charges only a minimal fee, or no fee at all. Others, such as the costs associated with manufacturing licences are recovered in full.

The significant reliance on levies can create financial instability. The revenue collected from the sales levy can fluctuate by up to 30%, based on historical observations, as it tends to rise and fall with climate and economic events. In drought years, product sales tend to be lower, meaning that in the following year levies revenue is lower.

Each year approximately one third of registered products make no sales and therefore do not contribute to cost-recovery through levy payments. These may be 'shelf' registration products, where there is no intention to market the product. These product holders receive the benefit of a subsidised registration fee and yet the regulator does not recoup this via sales levies arising from that product—that is, other levy payers end up covering their costs.

The regulator also has a compliance function in relation to products excluded from regulation as agvet chemicals (for example, monitoring that such substances meet the criteria for exclusion) for which it does not recover costs from industry.

## **8.2 Are fairer cost recovery arrangements needed?**

The panel considers that any future changes to cost recovery arrangements should be consistent with the Australian Government's Charging Framework, that is, those receiving the services should be paying for them.

Any changes to the existing cost recovery arrangements will need to be considered in a holistic way and consider changes in regulatory practices. This would include, for example, increased post market compliance if there was a change to the way in which products are registered.

### **8.2.1 Alternatives to the current APVMA cost recovery framework**

The regulator can achieve 100% cost recovery with any permutation of the percentage of application fees charged upfront, if its charging structure is set accordingly. Additionally, whatever the target percentage, there is room to consider that some specific evaluation work may be suitable for 100% upfront recovery while other work (emergency permits etc.) may better suit being fully or substantially recovered by a levy.

There are a number of options that could be considered (some of which could be implemented together) and the panel is keen to receive feedback on which options stakeholders prefer.

### **8.2.2 Status quo—40% (or similar) to most applications**

This option maintains the current upfront application fee at no more than 40% imposed on a broad range of application types, with the balance of revenue collected via statutory levies. This would continue the current cross-subsidisation and remain inconsistent with the Australian Government's charging framework. This would also continue the regulator's reliance on its most variable revenue source, the sales levy.

### **8.2.3 Only subsidise upfront application fees for particular types of applications**

As the original intent of applying a 40% recovery rate was to incentivise product registrations, it may be reasonable to restrict the discount to certain 'categories' of applications to target desired policy outcomes (where subsidisation is considered necessary). For example, applications for product registrations only (as opposed to variations or approvals for active constituents or labels); applications for novel chemistries and new uses; or applications for generic products.

A special case may be that of minor use and emergency permits, for which there is arguably a strong need to maintain a substantial level of subsidisation.

Such an approach, focused on prioritising types of applications, would reduce the value of levy revenue required, but would not eliminate the need for such funding.

### **8.2.4 Apply the Australian Government charging framework settings—no or limited subsidisation**

This approach would align the regulator's cost recovery arrangements with broader whole of government cost recovery policy. It would also create the least amount of market distortion but would significantly increase upfront costs for applicants.

As setting fees at full cost-recovery levels may create an economic barrier for some potential applicants (particularly smaller ones), mitigation strategies may be appropriate. For example, allowing the deferral of a portion of a fee to allow payment over several instalments could ease up-front cash-flow requirements and allow applicants to realise the revenue from sales of the product before being exposed to the full cost of assessment.

However, this may expose the regulator to additional financial risk (from potential non-payment of services; for example, if companies become insolvent after receiving the services) it would also add additional administrative complexity and some fee adjustment might be required to cover these additional costs.

### **8.2.5 Capping the sales levy**

Given that levy liability grows with increasing product sales whereas the regulator's costs of regulating a product may not, capping the sales levy at some upper limit would reduce inequity among levy payers. This, or applying a flat levy (rather than one based on percentage of sales), may more closely align with whole-of-government charging policy.

Given the broad levy base (over 12,000 registered products, around 8,000 of which have sufficient sales to attract a levy liability) it is possible that the associated increase in levy charges for lower selling products associated with a levy cap or flat rate may not be excessive.

There was previously a cap on levy payments (this was removed in the 2005 CRIS). The arguments in favour of a cap are, in brief:

- there is a point beyond which the cost of regulation does not increase and therefore a cap on the sales levy is a tool to manage this finite cost
- an open-ended cost recovery mechanism, such as an uncapped sales levy, will not drive cost efficiencies or productivity gains within the regulator
- the absence of a cap introduces an open-ended wholesale tax on agvet chemicals sales
- there is no correlation between the total amount of levies payable to the regulator in respect of a product and the regulatory cost incurred by the regulator in relation to that product.

### **8.2.6 Apply a fully modular approach**

Presently, the regulator categorises application types according to the average amount of work (hence the average cost) of assessing the application. For example, an application for a novel chemistry requiring full assessment (novel active constituent, new product and new label) attracts a \$96,135 fee. Conversely, assessing an application for a generic product that is closely similar to another registered product has a \$1,755 fee.

The regulator also has a modular application system available, where the cost and effort of individual assessment components can be more closely tailored to the requirements of an individual application. For example, the module for a detailed chemistry assessment has a 13-month timeframe and \$9,220 fee, whereas the module for a simple chemistry assessment has a six-month timeframe and \$1,580 fee. Different categories of module apply to different aspects of an assessment (such as chemistry, efficacy, toxicology, residues, work health and safety and environment).

As is the case with non-modular applications, the fees for modules are calculated based on the estimated average costs of the associated work. Accordingly, while the granularity of modular applications allows fees to be more reflective of the regulator's costs of assessment, an element of imprecision in the pricing will remain.

In the recent past, the regulator has argued for replacing the current system of prescriptive types of applications with an entirely modular system. A 2015 analysis by the University of Melbourne

concluded that the existing application types are not very flexible, particularly given the range of new technologies coming into Australia and the many ways an applicant can structure a scientific argument to support registration of their product. A fully modular approach would go some way to addressing these problems by allowing the regulator to look at each application and determine what type and level of assessment is required.

The regulator applied a fully modular system prior to 1 July 2005. The non-modular application categories were introduced at this time, at least in part to simplify the application process for those unfamiliar with it.

### **8.2.7 Charging an hourly rate**

Charging an hourly rate for assessment (and other) services is an alternative approach to cost recovery that would, by its nature, more accurately tailor the cost of each individual assessment to the amount of work involved in assessing the application. Provided that the hourly rate is priced appropriately, this approach would ensure that the fees charged would recover the minimum efficient cost of the regulatory effort of fee-for-service activities as required under the charging framework.

Different types of assessment (and different regulatory services), may involve different types of work; for example, expert scientific analysis and assessment versus administrative checks of applications. Accordingly, it may be appropriate to introduce different hourly rates according to the work involved. Doing so would add some complexity but need not be overly complicated. Hourly based charging has been used effectively in the Department of Agriculture, Water and the Environment's cost recovered activities.

Applying an hourly rate model would introduce an element of uncertainty, as the total cost to the applicant could not be known until the work was completed. This could be mitigated, however, if the regulator were to provide a price estimate prior to commencing the work.

Assessor performance could vary from individual to individual, as such the price an applicant pays per application could have some inherent variability.

The NZ Ministry of Primary Industries (MPI) applies an hourly rate approach to all its work (including meeting and talking with stakeholders at the stakeholder's request). MPI has advised that variability among assessors has not led to complaints from applicants and that the approach of providing a cost estimate before commencing work has been successful.

The transparency associated with hourly charging may incentivise the regulator and individual assessors to be efficient and to avoid unnecessary work.

The panel has a disposition towards a combination of full cost recovery for fee for service activities, applying a fully modular system and hourly charging.

## **Discussion questions**

31) Which proposed cost recovery options presented do you support and why?

a) Which combinations of the proposed options work best together and why?

- b) Are there other options that the panel should consider?

### **8.3 Are there 'public goods' government should fund?**

The panel notes that public appropriations in agvet chemicals regulation are currently for specific projects, such as the national regulator's recent relocation, its digital strategy and some work relating to minor use permits and compliance activities.

Government appropriation is only warranted when the regulatory activities undertaken are in the interest of the Australian public, rather than an individual or company—anything else would essentially represent a subsidy for the chemical industry.

It can be argued that chemical reviews undertaken by the regulator provide a public good by ensuring that currently registered chemicals posing a high risk to people, animals or the environment are reassessed and withdrawn from the marketplace if necessary. Chemical reviews typically take place because new information becomes available on an approved chemical that indicates potentially unacceptable risks.

Many international regulators have government funding available for this activity, acknowledging that it is a complex and resource intensive process. The panel is inclined towards possibly treating these chemical reviews as a public good that justifies consideration of government funding. Chemical reviews are not in the interest of those who registered the chemicals as it could lead to loss of products and associated revenue. In undertaking a chemical review, the regulator is clearly acting in the interests of the public.

The panel has also heard that some stakeholders believe other compliance activities by the regulator should be government funded. The Australian Government's Charging Framework states that compliance activities should be cost recovered since these tend to be focused on ensuring specific companies and individuals continue to meet their registration conditions.

Other activities that stakeholders have suggested could be treated as public goods include international engagement by the regulator and support and advice to the minister and the Department of Agriculture, Water and the Environment. International engagement assists in enhancing the capability and capacity of the regulator including skill building and learning from international experience, cooperating with other regulators to respond to new policy developments, facilitating international standards setting (eg. GMP harmonisation with PIC/S) and promoting consistent approaches in analysing risk. However, it could also be argued that these activities benefit regulated entities especially those operating across countries due to consistencies and standardisation of approaches that facilitates market access.

Although prior to 2005, the Department of Health implemented cost recovery of NICNAS activities, a small appropriation was received from the government to subsidise the compliance program and the cost of services to government relating to industrial chemicals regulation. However, this ceased in June 2005, with the full costs of administering NICNAS now recovered through fees and charges paid by industrial chemical importers and manufacturers.

Similarly, the Department of Agriculture, Water and the Environment currently has a number of biosecurity cost recovery arrangements to cover compliance activities (such as risk mitigation,

analysis and biosecurity assurance) but receives a government appropriation to cover policy and response activities which include ministerial and parliamentary support.

It is the panel's view that regulatory activities (i.e. chemical reviews), provide an obvious public good, whereas compliance and international engagement activities are more closely related to the regulated entities. The panel also thinks there is a case for activities associated with advising and supporting the minister and parliament (senate estimates briefing etc.) being funded by government. These activities are in the interests of the Australian public (accountability and transparency) rather than regulated entities.

## Discussion questions

32) Which regulatory activities outlined do you think represent a public good and why?

- a) Are there other activities not mentioned that could represent a public good? If so, what are they?

## 9 Appendix A: Independent review: agvet chemicals national regulatory framework

### Terms of reference

On 5 September 2019 Senator the Hon. Bridget McKenzie, Minister for Agriculture, appointed an independent panel to undertake a first principles review of the regulatory framework underpinning the National Registration Scheme for Agricultural Chemicals and Veterinary Chemicals (agvet chemicals). The review will examine the framework's aims, structure and operation, and make recommendations to ensure it is contemporary, fit for purpose and reduces unnecessary red tape.

In undertaking the review, the panel will:

- 1) assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
- 2) consider what the goals of Australian agvet chemicals regulation should be
- 3) consider the current and future requirements of Australia's regulatory framework for agvet chemicals
- 4) provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture.

The panel will have regard to regulatory roles and responsibilities at the national, state and territory level; interactions with other regulatory schemes and arrangements; any relevant domestic or international issues; any recent changes to the current framework, including reforms agreed by the Council of Australian Governments; and the government's agenda to reduce red tape wherever possible.

The process will also review the Intergovernmental Agreement (2013) underpinning the National Registration Scheme, which was due to be reviewed in 2018.

### Panel and process

The independent review panel comprises: Mr Ken Matthews (Chair), Dr Mary Corbett, Dr Craig Suann and Dr Anne Astin.

The panel will:

- consult widely with stakeholders throughout the review process
- consider findings and recommendations from other relevant reviews
- provide regular progress reports to the Minister for Agriculture.

The panel will deliver its final report to the Minister for Agriculture no later than February 2021.

The Department of Agriculture will provide secretariat services.

# Glossary

Term	Definition
AAT	Administrative Appeals Tribunal
ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law
Active or active constituent	Active constituents are the substance(s) in an agricultural chemical 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.
AERP	Adverse Experience Reporting Program AERP is a post-registration quality assurance program established by the APVMA to help facilitate the management of agvet chemicals.
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 cross-jurisdictional cooperative and coordinated 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 chemical	Agricultural chemical and veterinary chemical (medicine)
Agvet Code	<i>Agricultural and Veterinary Chemicals Code</i> as set out in the schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i> The Agvet Code makes provision for the evaluation, registration and control of agricultural and veterinary chemical products and for related matters.
Agvet legislation	Refers to the following group of legislation: <ul style="list-style-type: none"> <li>• <i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i></li> <li>• Agricultural and Veterinary Chemicals (Administration) Regulations 1995</li> <li>• <i>Agricultural and Veterinary Chemicals Act 1994</i></li> <li>• Agricultural and Veterinary Chemicals Regulations 1999</li> <li>• <i>Agricultural and Veterinary Chemicals Code Act 1994</i></li> <li>• Agricultural and Veterinary Chemicals Code Regulations 1995</li> <li>• <i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i></li> <li>• Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995</li> </ul>
AICS	Australian Inventory of Chemical Substances The AICS is a list of industrial chemicals that are available for use in Australia and is administered by NICNAS.
Antimicrobial resistance	The ability of a microbe to resist the effects of medication.
Application item	The type (or category) of application made to the APVMA
Approved active	An approved active is an active constituent approved for use in Australia.
Approved label	The particulars listed on the label of an agvet chemicals product that are approved by the APVMA.



Term	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority (the Australian agvet chemicals regulator)
Carcinogenicity	The tendency of a substance to cause cancer
CCI	Confidential Commercial Information
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
Control of Use	The states and territories have responsibility for controlling the use of chemicals after supply. This is commonly referred to as 'control of use'.
CRIS	Cost Recovery Implementation Statement that sets the fees and charges to be paid by industry for regulatory activities.
Crop grouping	A grouping of crops according to similarities relevant to pesticide use.
Cumulative effects	The effects of multiple exposures to the same chemical across different commodities over time.
Data protection	The colloquial term for protecting information including 'limits on use of information' and 'protected information'
Department (the)	The Department of Agriculture, Water and the Environment (secretariat to the review panel)
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
Epidemiological	The branch of medicine dealing with the incidence distribution and control of diseases.
ESI	Export Slaughter Interval
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
GHS	A globally harmonised system of classification of labelling of chemicals.
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practice
Good agricultural practice	The environmental and operational conditions necessary for the production of safe, wholesome food.
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.
HACCUT	Harmonised Agvet Chemicals Control of Use Task Group
Hazard assessment	A hazard assessment considers only the inherent harm something can cause. It does not consider the likely exposure or chance of the harm occurring.
HGP	Hormonal growth promotant
IGA	Intergovernmental agreement on agricultural and veterinary chemicals
IPM	Integrated pest management
IUCLID	International Uniform Chemical Information Database
Label particulars	Legally defined components of an approved label

<b>Term</b>	<b>Definition</b>
Levies	Levies paid by registration holders based on volume of chemical product sales
Limits on use of information	These provisions limit the APVMA's ability to use confidential information in connection to an application approval, registration or variation when making certain regulatory decisions. Commonly referred to as data protection.
Listed chemical product	A listed chemical product is an agvet chemicals 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
NRA	National Registration Authority for agricultural and veterinary chemical products (former name of the APVMA)
NRS	National Registration System The National Registration Scheme for Agricultural and Veterinary Chemicals (National Registration Scheme (NRS)) was established under Commonwealth and state and territory legislation.
NZEPA	New Zealand Environmental Protection Agency
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator
Panel	The group of individuals appointed by the former Minister for Agriculture to undertake the review of the agvet chemicals framework.
Permit	The APVMA may issue a permit which allows for the legal use of chemicals in certain ways, or certain circumstances that would otherwise be unlawful and allows for the limited use of an unregistered chemical product.
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.
Produce Monitoring	Produce monitoring is the testing of agvet chemicals residues in food commodities.
Prophylactic	Intended to prevent disease
Protected information	Limitation on use of trial or laboratory experiment information provided to the APVMA for an approved active constituent or registered product.
PubCRIS	Public Chemical Registration Information System PubCRIS is a publically 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)
Quick reference codes	A machine readable optical label that contains information about the item to which it is attached.
Reconsideration	The reconsideration process involves reviewing a chemical and issuing a final regulatory decision of whether to support the ongoing registration of an agvet chemical. Commonly referred to as chemical reviews.
Record (the)	The record of approved active constituents as held by the APVMA

Term	Definition
Reference product	A reference product is a registered chemical product nominated by an applicant (with agreement from the authorising party) to support their application and satisfy the APVMA of one or more statutory criteria.
Register (the)	The register of registered agvet chemicals products as held by the APVMA
Registered product	A registered product is an agvet product registered for use in Australia.
Repack	A 'repack' occurs when an application is made to copy a registered product. Only the product name and owner can vary from the original product registration in a repack.
Reprotoxicity	The tendency of a substance to interfere with normal reproduction.
Reserved chemical product	A reserved chemical product is an agvet chemicals product or class of products that is reserved from registration, subject to conditions. The active constituent in the product or product class must be specified in Schedule 3C—Reserved Schedule of the Agvet Code Regulations.
RIS	Regulatory Impact Statement A RIS is a mandated process intended to improve the quality of policy-making.
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.
Scheduling	The process by which medicines and poisons are made available to the public.
Statutory criteria	The list of criteria that the APVMA must be satisfied is met before approving an application. The statutory criteria include: <ul style="list-style-type: none"> <li>• safety criteria</li> <li>• trade criteria</li> <li>• efficacy criteria</li> <li>• labelling criteria</li> </ul>
Synergistic effects	The effects that two or more chemicals can have on each other that are different from the effects caused by the individual substances.
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	Timeframe performance is the proportion of applications finalised on time within the reporting period divided by the total number of applications finalised by the APVMA within that reporting period.
WHS	Workplace health and safety

# References

- ABARES 2018, [Food demand in Australia: trends and issues 2018](#), Australian Bureau of Agricultural and Research Economics, Canberra
- ABARES 2020, [AGSURF Data](#), Australian Bureau of Agricultural and Research Economics, accessed 24 January 2020.
- ACIL Allen 2018, [Economic Contribution of Animal Health Products to Australia's Livestock Industries, 2015–16](#), ACIL Allen, Canberra.
- APVMA 2019, Commonwealth of Australia Gazette: [APVMA No.6, 26 March 2019](#), Australian Pesticides and Veterinary Medicines Authority.
- Australian Organic 2018, [Australian Organic Market Report 2018](#), Australian Organic, QLD
- C. A. Damalas and S. D. Koutroubas. '[Current Status and Recent Developments in Biopesticides Use](#)', *Molecular Diversity Preservation International*, vol. 8, no. 13, 2018, accessed 24 January 2020.
- Deloitte 2018, [Economic Activity Attributable to Crop Protection Products](#), Deloitte Access Economics.
- Durham, Sharon 2016, [Laser-Guided Crop Sprayer](#), *United States Department of Agriculture AgResearch Magazine*, February 2016, accessed 24 January 2020.
- IBISWorld Australia 2018, *Pesticides Manufacturing in Australia*, Industry Report C1832.
- Futureye 2018, [Australia's Shifting Mindset on Farm Animal Welfare](#), Futureye, Victoria
- McDougall 2018, [Evolution of the Crop Protection Industry since 1960](#), Phillips McDougall, United Kingdom.
- OECD 2017, [Environmental Indicators for Agriculture](#), OECD.
- OECD 2019, [Agricultural Policy Monitoring and Evaluation 2019](#), OECD Publishing, Paris.
- PWC 2017, [Australian Pesticides and Veterinary Medicines Authority — Review of Cost Recovery Arrangements](#), PricewaterhouseCoopers, Canberra.

# Annex 1

## Summary of reform proposals and panel preferences

### Future system vision (Introduction)

The panel is inclined to propose a new vision statement for the system:

An Australian regulatory system for agvet chemicals that provides all Australian primary producers and veterinarians with timely access to a similar range of approved agvet chemicals to their overseas competitors, while preserving human, animal, plant, and environmental health.

To achieve this vision in the future the system:

- should be aligned with international regulators and processes
- should be consistent in application and implementation across states and territories
- foster innovation in all its forms
- foster and build national capacity to assess and manage agvet chemicals
- should be more transparent and accessible to all stakeholders
- should be considered an asset rather than a barrier.

### Future system objectives (1.2)

- Have a simplified hierarchy of objectives, with an overarching primary purpose statement to 'protect the health and safety of people, animals, plants and the environment while providing safe and timely access to agvet chemicals and products'.
- Three supporting objectives, in descending order under the primary purpose statement, being to protect trade, promote primary industry and protect animal welfare.

### Principles underpinning future system design (1.3)

The panel is considering the following principles to guide proposed reforms to the agvet chemicals regulatory system:

- Performance of the system
  - objectivity—the system should be based on sound science, and be evidence and risk-based in its decision making
  - independence—the regulator overseeing approval of agvet chemicals should continue to be independent from government
  - efficiency—promote use of the most efficient regulation required to achieve the objective—by making use of more streamlined and fit for purpose pathways, plus considering how the market can drive registration holders to make optimal choices about their chemical products
  - consistency—there should be one coherent national system, with consistency in control of use and any differences amongst jurisdictions should be required to be justified publicly

- Access—the system should be harmonised as much as possible with international regulatory systems and processes
  - Simplicity—replace the current suite of legislation with one that is modern, outcomes focused, removes unnecessary prescription and is simpler and easier to understand and implement
  - certainty—provide confidence about regulatory processes and timeframes
- Shared responsibility—the system should facilitate the sharing of responsibility among governments, agvet chemicals suppliers and users
  - transparency and accountability—provide a clear and transparent policy and regulatory framework that provides for regular engagement and input from industry, users and the community.

## **Nationally consistent agvet chemicals control of use (2.2)**

The panel is considering three proposals to improve control of use for agvet chemicals, these include:

- expanding the current national applied law model for supply to comprehensively regulate the use, transport, and disposal of agvet chemicals that are currently regulated in various state and territory acts
- the Commonwealth exercising its full constitutional reach using the applied law model which would cover most (but not all) control of use activities
- re-invigorating the existing Intergovernmental agreement to provide for a specific model of control to be applied consistently by jurisdictions by agreement.

## **Imposing greater responsibilities on industry participants and users (2.3)**

The panel is exploring several ways to increase the accountability and responsibility of the chemical industry for the safety and use of its products including:

- consideration of more co- and self-regulatory approaches to chemical management across all stages of a products lifecycle, e.g. greater recognition and reliance on industry QA schemes
- establishing a holder accreditation scheme (with mandatory training requirements) that restricts the ability to seek and hold a registration, permit, or label approval to suitably qualified entities
- formalising active risk management responsibility on chemical industry participants and chemical users via statutory duties of care.

## **Compliance and enforcement (2.4)**

The panel is considering the merits of:

- the establishment of incentives, or other mechanisms, to ensure that regulators maintain sufficient resourcing and make appropriate use of their detection, investigation, and enforcement powers and tools
- a national approach to compliance and enforcement using a consistent set of tools
- adopting the *Regulatory Powers (Standard Provisions) Act 2014* to simplify and standardise with other Commonwealth coercive and enforcement provisions.

### **Sharpening the focus onto primary producers, veterinarians and non-urban land managers (3.1)**

The panel is proposing:

- adopting more intuitive nomenclature to distinguish agricultural and veterinary chemical products—'plant protection product' and 'veterinary medicine'
- removing consumer products, pool and spa chemicals and antifouling paints from the agvet chemicals regulatory system
- establishing a list of chemicals, and products made containing only those chemicals, to exclude from the operation of agvet chemicals legislation with provision for industry to propose additions to the list.

### **Assessing use by region, pest/disease rather than state boundaries (4.1)**

The panel is exploring the benefits of:

- assessing uses based on regions (not state boundaries) as this appears to be a less arbitrary approach
- imposing a legal obligation on registration-holders to review their product label at least once every five years to ensure it is correct and current
- identifying specific environments that warrant different restrictions (or prohibitions) on chemical use
- the establishment of pest groupings (similar to crop groupings).

### **Benefits test (4.2)**

The panel is inclined to include a benefits test to inform registration, reconsideration, and workflow prioritisation decisions that gives weight to:

- the introduction of new active constituents or new uses
- the value of the benefits to agricultural production, animal welfare, environmental outcomes or increased public health and safety
- positive social or economic impacts (could be localised, regional or national)
- a crop group or two or more priorities for access (e.g. listed as a chemical under review, or listed as a weed of national significance)
- controlling a pest of national significance (e.g. rabbits)
- replacing a use that is subject to reconsideration
- impacts to the community or users of not having access to the product.

### **Chemical combinations (4.3)**

The panel is inclined towards two options that would position Australia to take advantage of scientific advances in assessing chemical combinations and synergistic impacts:

- Consider impacts of common and well-known combinations of agvet chemicals.

- Prepare the framework for the future by stipulating that synergistic effects must be considered when the appropriate methodologies are available (the same approach as the EU).

#### **Making better use of data (4.4)**

The panel is considering the opportunities to improve policy and regulatory decisions made possible by mandating reporting of agvet chemicals use and is seeking feedback on the appetite for such a move, as well as ideas for improvements that the data could drive.

#### **Monitoring chemical residues in produce, water and the environment (4.5)**

The panel considers that monitoring of agvet chemicals needs to be expanded and consistent across jurisdictions.

- The panel fully endorses the need for a national domestic produce monitoring system for agvet chemical residues and supports the work of the Commonwealth and states and territories to expand the National Residue Survey's focus to include produce intended for domestic consumption.
- The panel recommends the adoption of a national approach to agvet chemical testing in waterways and the environment based on risk priorities.

#### **Communication and engagement (5)**

The panel is inclined towards:

- having the national regulator identify, in consultation with governments, the community and regulated entities, information that should be publicly available and reporting annually on the quantum and quality of information released
- the establishment of a formal public consultative forum (similar to that which operates in the United Kingdom).

#### **Repacks (Item 8) (6.1)**

The panel provides three options (notification, linking repack products to the pioneer product and maintaining the status quo). The panel is disposed towards making repack applications a declaration/notification process that doesn't require any assessment by the regulator.

#### **Efficacy (6.2)**

The panel proposes three options; removing efficacy from the scope of regulation (except where its failure to perform as stated could create a human safety or animal welfare issue) (option 1); removing the requirement for efficacy assessment (option 2); maintaining the requirement but streamlining assessment (option 3). The panel is inclined to:

- support option 1 for all crop protection products and non-scheduled veterinary medicines
- support option 2 for scheduled veterinary medicines.

#### **Standards (6.3)**

The panel is considering a greater use of standards that would remove the need for assessment by the national regulator.

- initially for products of low regulatory concern



- a preference for standard development to be driven by industry
- possibly modelled on the New Zealand group standards approach.

### **Registration by reference (6.4)**

The panel is proposing adoption of registration by reference that has the following key features:

- products registered by one of more comparable international regulatory system would be accepted for registration in Australia with no assessment required, only aspects unique to Australia would require assessment
- what is unique to Australia would be defined (e.g. streamflow, different strains and growing conditions on pest susceptibility and target plant/animal toxicity, Australian diet)
- clearly defined parameters around when products could be considered under this approach
- defining who and how comparability of another regulatory system is defined.

### **Chemical reviews (6.6)**

The panel has considered how the handling of chemical reviews could be adjusted and is inclined to having chemical reviews remain as risk-based and not calendar driven (rolling reviews). The panel is also inclined to provide flexibility so chemical reviews can be limited to specific aspects (e.g. safety) that warrant review rather than having to review all aspects of the original approval/registration.

### **Smart labels (6.7)**

The panel proposes introducing smart labels (e-labels) that contain smart content and are machine readable. The panel is also proposing that containers above a certain volume would have to be machine readable.

### **Operational regulatory working group (7.2)**

The panel is inclined to re-invigorate the Registration Liaison Committee to focus on its original intent, to share regulatory knowledge and solve problems within the system.

### **Accredited assessor scheme (7.3)**

The panel is inclined to recommend the establishment of an accreditation scheme for third party assessors, like that which operates in New Zealand, based on the model proposed in the lapsed Streamlining Regulations Bill of 2019. The scheme would:

- be legislated
- specify minimum requirements for professional experience; insurance; conflict of interest protections; and data handling protocols
- include oversight of audit and compliance by the regulator
- include provisions for the regulator to cost recover its accreditation functions
- include the accreditation of international assessors
- include penalty provisions (administrative, civil, and criminal), and sanctions for non-compliance.

### **Cost recovery (8)**

In considering the ideal cost recovery arrangements, the panel is proposing several options for reform to make the arrangements fairer and financially sustainable. The panel is inclined towards:

- making the arrangements consistent with the Australian Government Charging Framework
- imposing fees for service at 100% of the costs of providing them
- structuring fees for assessment services in a fully modular approach
- imposing hourly charging
- suggesting government funding for chemical reviews and activities the national regulator undertakes to support the minister or parliament.

## Annex 2

### **Proposal—New Definition of agricultural chemical and veterinary medicine**

Amend the agvet chemicals legislation to provide that:

- 1) A plant protection product (PPP) 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
    - destroying a plant, and
  - the use will expose persons, or the environment other than at point of application, to the product or its residues, and
  - the product is hazardous under the GHS
    - hazardous means the product is classified as in any of the top 3 categories in any hazard class

A PPP does not include, regardless of representation or use:

- products incorporating solely ingredients on a GRAS list
- products that are consistent with the definition of a consumer good as detailed in the ACL, but not products including any constituent prohibited by the regulations
- products used in pre-construction insect protection
- whole plants
- whole animals
- products for vertebrate pest control
- products declared not to be a PPP by regulation.

A PPP does include, regardless of hazard classification or exposure, those products:

- with uses declared to be a PPP by regulation
- with uses intended to control, in relation to a place, thing or person, a pest expected to transmit a disease or condition of concern to human public health.

Note a consumer product under ACL is:

- valued at less than \$40,000 at time of purchase
- supplied to a person for their use
- not used in the course of process of production (such as food or fibre) or manufacture

- represented only as suitable for use in a manner ordinarily considered personal, domestic or household.
- 2) A veterinary medicine (VM) is defined as 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
  - curing or alleviating an injury suffered by the animal
  - modifying the physiology of the animal
  - to alter its natural development, productivity, quality or reproductive capacity
  - to make it more manageable
  - euthanizing an animal (other than through the application of physical force), and
  - the use will expose persons or the environment, other than at point of application, to the product or its residues, and
  - the product is hazardous under the GHS
    - hazardous means the product is classified as in any of the top 3 categories in hazard class.

A VM does not include, regardless of representation or use:

- a product that is a PPP
- a vitamin, a mineral substance, or a feed additive of same, orally administered to or voluntarily consumed by an animal
- a substance or mixture of substances prepared by, or on the instruction, of a veterinary surgeon
  - instructions of veterinary surgeons must be in writing and precede the creation of the substance or mixture of substances, except where there is no suitable VM registered
  - instructions must comply with the relevant order for included information
  - instructions must be carried out by a pharmacist suitably licensed by a jurisdiction
- products incorporating solely ingredients on a GRAS list
- a product that is listed in Appendix B of the Poisons Standard and represented, or intended for use on a single companion animal (including an equine)
- products that are consistent with the definition of a consumer good as detailed in the ACL, but not products including any constituent prohibited by the regulations
- products declared not to be a VM by regulation.

A VM does include, regardless of hazard classification or exposure, those products:

- with uses declared to be a VM by regulation
- products intended or represented as vertebrate pest control

- administered to an animal by injection, other than a product for administration by injection prepared by, or on the instruction, of a veterinary surgeon (subject to conditions outlined previously).
- 3) Provide that entities may seek inclusion, for a fee, of chemicals on the GRAS list(s). Criteria for inclusion on the list would include that the ingredients do not present an obvious threat to human or environmental health. The GRAS list to accept by reference, inclusions of equivalent international lists (e.g. US EPA).