CropLife Australia

February 2021

Independent review of the agvet chemical regulatory framework

1. INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both patent holding and generic Australian and international companies and accordingly, CropLife advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect crops against pests, weeds and diseases, key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $20 billion annually to the Australian economy and directly employs thousands of people across the country.[1]

CropLife welcomes the opportunity to provide input to the *Draft report of the Independent Review of the Agvet Chemicals Regulatory System* (the Report). It is essential to ensure the regulatory framework for agricultural chemicals and veterinary medicines is contemporary, fit for purpose and reduces unnecessary red tape, so that Australia's farmers are not disadvantaged compared to those in our major ag trading nation competitors.

The plant science industry

The plant science industry's crop protection products include fungicides, herbicides and insecticides critical to maintaining and improving Australia's agricultural productivity to meet future global food security challenges. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers, the environment and the trade of agricultural produce.

In 1995, it took the assessment of 52,500 compounds to develop one effective crop protection chemical active constituent. It now requires the assessment of more than 140,000 compounds and expenditure of more than $400 million over an 11-year period to bring just one successful crop protection product to the market. More than one-third of this cost directly relates to compliance with regulation and registration requirements. Without access to these tools, farmers could lose as much as 50 per cent of their annual production to pests, weeds and diseases. A Deloitte Access Economics report released in 2018, 'Economic activity attributable to crop protection products', estimates that up to $20.6 billion of Australian agricultural output (or 73 per cent of the total value of crop production) is attributable to the use of crop protection products.[2]

[1] https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

[2] https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among targeted pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be over $4.8 billion each year, or $13 million per day.[3]

Pesticides also play a significant role in protecting Australia's rich biodiversity. In 2006, the then NSW Department of Environment and Conservation listed weeds and pests as second only to habitat loss as a cause of biodiversity decline[4] and cautioned that weeds presented the greatest threat to our National Parks.[5] In 2021, the Invasive Species Council's report 'Glyphosate: A Chemical to Understand' highlighted that herbicides offer the only really effective option for removing invasive weeds from Australia's bushland reserves and that, without them, most of the remaining indigenous vegetation in Australia would decline in both quantity and quality.[6]

The current regulatory system for agricultural chemicals in Australia is scientifically competent, technically proficient and globally recognised. CropLife's only significant concerns with the current system relate to inefficiencies and unnecessary overlaps. The regulation of crop protection products in Australia must be efficient and effective so that Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be productive and internationally competitive, as well as continue to enhance soil health and agricultural sustainability.

A genuine over-the-horizon review and corresponding report on the requirement for a next generation regulator would have been useful. Disappointingly, this report falls well short of that.

Review of the regulatory framework

CropLife commends the Panel for their aspiration to identify where fundamental changes throughout the regulatory system may be possible to boost timely access to innovative and safe agricultural chemicals and veterinary medicines, while delivering on the Government's commitment to reduce unnecessary regulation. It is disappointing, however, that the Draft Report does not outline a cohesive, integrated, strategic principles-based approach to a next generation regulatory framework. Instead, it attempts to insert an a priori "fix" onto specific areas of concern. In doing so, the Panel has at times proposed recommendations that are conflicting and work against stated goals regarding efficient, risk-based regulation and social license.

[3] *https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf*

[4] https://researchprofiles.canberra.edu.au/en/publications/the-impact-of-weeds-on-threatened-biodiversity-in-new-south-wales

[5] https://www.environment.nsw.gov.au/-/media/OEH/Corporate-Site/Documents/Parks-reserves-and-protected-areas/state-of-the-parks-2004-050051.pdf

[6] https://invasives.org.au/wp-content/uploads/2020/11/Glyphosate-A-Chemical-to-Understand.pdf

It is disappointing that the Panel has interpreted their terms of reference of the review in a manner that prevented them from considering the role of some regulatory systems that interact with the APVMA. CropLife disagrees with this interpretation, as the terms of reference clearly state that the Panel will have regard to interactions with other regulatory schemes and arrangements. It is also unclear why some interacting regulatory schemes were considered by the Panel (e.g. the Office of the Gene Technology Regulator (OGTR)) while others were not (e.g. Therapeutic Goods Administration (TGA), Food Standards Australia New Zealand (FSANZ), biosecurity import permits). Many of the inefficiencies associated with the regulation of agricultural and veterinary chemicals lie within these interactions. This review provides a unique opportunity to better understand those interactions and identify areas for potential reform to improve the efficiency of the system. CropLife appreciates that this review has been commissioned by the Honourable David Littleproud, Minister for Agriculture, Drought and Emergency, thus some of the recommendations relating to amending those interactions may not be within that Minister's power (although, that is also the case for the OGTR, which is under the remit of the Minister for Health), but this should not be a barrier to establishing the inefficiencies that exist within this complex regulatory arrangement from a whole of system and whole of government perspective.

The Panel recognises that regulation should not be unnecessarily restrictive and instead be commensurate with the identified risk. This view is supported by CropLife and our members, noting that care must be taken to ensure the delicate balance between adequate regulation and minimising regulatory burden is achieved. The Panel's view that the regulatory system must continue to be risk-based and informed by credible science and evidence is likewise fully supported. The current legislation provides a significant level of protection for farmers regarding the safe and efficacious use of agricultural chemicals and veterinary medicines that should be retained.

The *Australian Government Principles of Best Practice Regulation*[7] and the *Ten Principles for Australian Government Policy Makers*[8] provide the Panel with expert guidance when reviewing the broader regulatory framework for agricultural chemicals and veterinary medicines. Similarly, the *Australian Government Guide to Regulatory Impact Analysis*[9] and Regulation Impact Statement (RIS)[10] process outline the Government's principles for policy-makers to consider and encourages them to consider potential impacts of proposed regulation and ensure that RIS requirements are met. It is therefore disappointing that these guidelines do not appear to have been appropriately considered by the Panel in preparing their draft Report.

[7] *https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation*
[8] *https://www.pmc.gov.au/ria-mooc/agrp/overview/australian-government-10-principles-policy-makers*
[9] *https://www.pmc.gov.au/resource-centre/regulation/australian-government-guide-regulatory-impact-analysis*
[10] *https://www.pmc.gov.au/ria-mooc/extra-detail*

CropLife expects that these best practice management guides for regulation will be considered by the Panel in their Final Report. A detailed proposed implementation plan must be provided, including indications of timeframes and consultation opportunities. Furthermore, an assessment of the current regulatory environment and the anticipated efficiency gains provided by the Panel's recommendations would be beneficial. An analysis of how the proposed regulatory amendments would impact the regulated industries and users of the regulated products over the short, medium and long term would better enable stakeholders to determine their level of support or otherwise of some of the more controversial proposals. Assessment of the benefits and costs associated with proposed policy options and adopting the option that provides the greatest net benefit are recommended in the former Council of Australian Governments (COAG; now National Federation Reform Council, NFRC) Principles of Best Practice Regulation.[11] CropLife recommends the Panel consider these principles and refer to them in their Final Report.

The Panel's recommendation to introduce a Commissioner within the existing policy department responsible for oversight of the APVMA appears to be in response to the identification of a range of failures in the current system. The proposal to introduce a Commissioner to address these failures is misguided but does highlight a range of structural issues and regulatory inefficiencies throughout the system that require further consideration. Given the previous five to ten years of inadequate policy reform options, there is insufficient evidence to suggest a Commissioner would be implemented in a way that provided meaningful improvements to the structure and efficiency of the regulatory system.

Any future operational and legislative reform must provide meaningful gains in the efficiency of the regulatory environment. The Panel does not appear to have considered whether this would be more readily achieved by abolishing the policy area within the Department and instead providing sufficient funding to the APVMA to develop its own agvet regulatory policy reform capability. CropLife believes this structure would be more effective in delivering targeted reform that is fully cognisant of its real operational impact and lead to a greater chance of seamless implementation.

Many of the Panel's recommendations are dependent on establishing the Commissioner role. An indication of how the Panel expects those proposals to progress or be implemented in the event a Commissioner is not established, or during the presumably lengthy timeframe for establishing such a role, would be beneficial for stakeholders. CropLife recommends the Panel rephrase recommendations relating to the proposed Commissioner's responsibilities to recommend the function be performed, but without specific reference to the Commissioner being essential to their implementation.

[11] https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation

Over the last few decades, the cost of successful research and development programs delivering innovative products has increased exponentially. CropLife and our members are pleased that the Panel has attempted to address current barriers for registrants to introduce certain use patterns, likely for minor and specialty crops, into the Australian market. However, the proposed solution to this market failure – in the form of the implementation of an international licensing scheme – is ill-conceived and exposes the crop protection product industry to considerable reputational damage. CropLife and our members do not support any proposal to create a parallel pathway for the introduction of products into the Australian market, which bypasses any regulatory oversight by the national regulator.

An extension to the current patent period of 20 years [12] would significantly benefit commercial investment, as well as investment in research and development, alleviating a significant hurdle to innovation in Australia. The Federal Government's commitment to the agricultural chemical industry following the previous patent reform process to offset the loss of patent period that is created by the lengthy mandatory regulatory system in a pro rata manner must be acted on as a matter of urgency.

The *IP Laws Amendment (Raising the Bar) Act 2012*[13] allows for manufacturers of generic products to obtain regulatory approval for a product containing a chemical under patent, such that regulatory approval for the generic product can be granted as soon as the patent period expires. While this practice, known as "spring-boarding" encourages competition within the marketplace, it creates a disadvantage for the pioneer registrant that has invested considerable resources into developing the patented active constituent. As the registration process for the pioneer product generally takes a number of years, the pioneer registrant's patent period is considerably diminished, as are commercial returns associated with the patent period. This discourages investment in the Australian market.

While the pharmaceutical industry experiences similar issues associated with patent periods and regulatory requirements, the *IP Laws Amendment (Raising the Bar) Act 2012* allows for an extension of the patent period for up to five years to offset the impact of the registration assessment period. A similar extension associated with agricultural technologies, particularly agricultural chemicals and veterinary medicines, would significantly improve global investment into Australia. It was, in fact, an undertaking of the previous government recognising that it should have been done at the same time when 'spring-boarding' was formalised in the Act and is now a matter that should be pursued with utmost urgency.

[12] https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents
[13] https://www.ipaustralia.gov.au/about-us/legislation/raising-bar-act

While CropLife agrees with and supports addressing many of the problems identified by the Panel, CropLife outright opposes the creation of a Commissioner as a means of addressing these issues. They can be more than effectively addressed more effectively through simpler measures. Many of the recommendations contained within the Report are far-reaching and will have major implications between and across a multitude of current regulatory agencies and pieces of legislation, including those relating to control of use and licensing. While supportive of national harmonisation, CropLife is concerned that the Panel has not given adequate consideration to the complexities of designing and implementing these proposed reforms, or that the outcome of such disruptive reform would provide sufficient benefit to participants in the industry to justify such changes.

The COVID-19 pandemic has identified the vulnerabilities of the agricultural chemical supply chain, which is essential for ensuring growers have access to the tools they require to not only satisfy Australia's domestic food security, but also maintain critical export markets.

While the Panel has made some attempt to consider the vulnerabilities of the supply chain, the draft report and associated recommendations do not include a detailed assessment of current threats to Australia's agvet chemical supply chain. It appears that the Panel's solution to these threats is to create a second, parallel regulatory arrangement under the control of the Department of Agriculture, Water and the Environment (the Department), rather than addressing current failings in the existing framework. The APVMA's considerable efforts to streamline operations to ensure continuity of supply without compromising risk management are to be commended and should be recognised as best practice in future. Consideration should be given to implementing these streamlining initiatives as part of the Regulator's operational processes.

The Australian government recently announced a $107.2 million Supply Chain Resilience Initiative, which aims to identify and address international supply vulnerabilities. CropLife recommends the Panel engage with the Department of Industry, Science, Energy and Resources, to ensure alignment, where appropriate, with this broad government initiative.[14] Similarly, the government recently requested that the Productivity Commission conduct an inquiry to examine the nature and source of vulnerabilities in global supply chains.[15] CropLife recommends that the Panel considers this inquiry in finalising their report to the Minister.

CropLife and our members are supportive of any recommendations to strengthen and support the current regulatory framework, while improving efficiencies and removing unnecessary duplication. In doing so, the scientific and regulatory independence of the APVMA is paramount and any proposals that may seek to undermine or diminish its independence or credibility, or to add additional bureaucratic oversight are wholly rejected.

[14] https://www.industry.gov.au/news/meeting-our-needs-in-times-of-crisis
[15] https://www.pc.gov.au/inquiries/current/supply-chains

Proposed vision statement and underlying objectives and principles

CropLife and our members support the vision statement as proposed by the Panel.

While the importance of the regulatory system supporting primary industries is acknowledged by the proposed objectives, an important objective of the system should be to ensure farmers continue to have appropriate and timely access to safe, efficacious crop protection products and animal medicines. The inclusion of such an objective should be considered by the Panel.

The proposed principles for governing the design and implementation of the regulatory system appropriately acknowledge the importance of a transparent and efficient risk-based, scientific regulatory framework. CropLife commends the inclusion of principles that relate to ensuring that the regulatory system is adaptive to new technologies, practices and knowledge, and supporting a resilient supply chain.

2. THE NATIONAL REGULATION SCHEME

2.1 Nationally consistent control of use

CropLife strongly supports the concept of national harmonisation of agricultural and veterinary chemical control of use regulation. Improved harmonisation of state control of use regulations in Australia will remove duplication and inconsistencies and reduce unnecessary costs to industry. CropLife members find it difficult, confusing and costly to meet the multiple regulatory requirements of all Australian jurisdictions.

CropLife remains concerned that the then COAG 2010 direction to the Primary Industries Ministerial Council (now Agriculture Minister's Forum) to develop a national framework for harmonised agricultural chemical regulation in Australia, has not yet been delivered. While some progress was made in 2013 via an intergovernmental agreement, considerable differences remain between jurisdictions regarding off-label use of agricultural chemical products. Ten years after the initial COAG directive, these differences continue to create confusion among users and increase costs associated with compliance for industry. Substantial reform is urgently required to create a national harmonised framework for agricultural chemical regulation in Australia, to reduce confusion and costs for both industry and farmers.

CropLife is concerned that the recommendations outlined in the Report do not adequately reflect the complexity of the state-based regulatory systems. Careful consideration of this complexity is necessary to ensure the integrity of the jurisdictional control of use functions performed by the states and territories is maintained and improved. The Report does not provide a comprehensive analysis of the various state or territory control of use regulators and the interconnected nature of the regulation of agvet chemicals with that of other chemicals (e.g. state based drugs and poisons legislation, dangerous goods, WHS, waste management, pest management etc.). These various functions are captured by numerous pieces of legislation and are not unique to the regulation of agvet chemicals.

By annexing control of use of agvet chemicals under a single Commonwealth scheme, there is a risk that many of the functions currently performed by the state and territory regulators could be duplicated or may supplement controls that already exist in other parts of the state regulatory frameworks. In creating a separate pathway specifically for the control of use of agvet chemicals, the expertise that currently exists within the state and territory regulatory agencies (including those within the various agricultural/primary industry, health and environment departments etc.) may be lost to the industry, which could consequently weaken the rigour of the system.

Whether control of use functions are performed by the states and territories or the Commonwealth, the success of this aspect of the regulatory framework is dependent on appropriate resourcing and expertise. CropLife is concerned that the current proposal does not adequately appreciate the extent of resourcing that supports the current control of use arrangements, as they span multiple departments.

The final Report would benefit from an assessment of the current status of the various state and territory based regulatory systems alongside parallel assessments of how to implement the proposed alternative scheme vs improving the existing arrangement. This assessment should include a detailed analysis not only of the resourcing required to ensure success, but also the expertise that currently exists within the various state and territory governments that contribute to the control of use regulatory framework that would need to be replicated in the proposed new system. Further consideration regarding the ultimate objectives of the control of use framework and appropriate performance measures would be beneficial to determine the most appropriate path forwards.

Throughout the Report, there seems to be confusion regarding the management of off-label uses. As outlined in our submission to the Issues Paper, CropLife and our members do not support off-label use of agricultural chemical products as these uses are not specifically risk-assessed by a scientifically competent regulator for Australian conditions. It is not reasonable to place the responsibility on farmers to assess the relative risks of using crop protection products in a manner not outlined on registered product labels. Ongoing funding of the Australian Government's access to agricultural and veterinary chemicals grants program will remove the need for off label uses as all necessary minor uses and uses for specialty crops will become APVMA approved label uses. This will deliver the platform in which national harmonisation of control of use can occur. Shifting the administrative responsibility for administering this program from the Department to industry (for example Plant Health Australia or the University of New England) would ensure the highest priority projects were supported and the full value obtained from the Government's investment.

2.2 National leadership of the regulatory system

While CropLife recognises the value in the existence of a central point of responsibility over the broader regulatory framework for agvet chemicals – particularly in regard to providing weight in budget and wider government discussions – any proposal that would introduce an additional layer of bureaucracy over the regulation of agvet chemicals and potentially interrupt the operations of the Regulator is not acceptable.

CropLife and our members have constructively engaged in all previous reform agendas and proposed specific initiatives to improve the system and are growing increasingly frustrated with the slow process and lack of proper implementation of reform. In identifying many of the current failings of the regulatory system for reform, the Report has highlighted the continued failing of the Department to deliver regulatory efficiency.

Defined efficiency gains from legislative reforms introduced in 2014 have not yet been realised. The Australian National Audit Office's 2017 performance audit report on the implementation of pesticide and veterinary medicine regulatory reform highlights the serious failure of the reform processes.[16]

CropLife repeatedly sought the urgent implementation of well-considered regulatory reform to address the expected significant resource and capability loss of experienced regulatory scientists when the APVMA transitioned to Armidale. Despite constructively engaging in several reform consultation processes with the Department, numerous legislative reforms – which would have significant ongoing benefit to industry – are yet to be passed into legislation, 18 months after the Regulator completed its relocation.

Introducing mechanisms which may be used to influence or override the independence of the APVMA, or its science-based regulatory decisions, would be rejected. Without detailed, clearly defined responsibilities and competences, the introduction of a Commissioner is a risk to the integrity of the system and fair competition within the agricultural chemical market in Australia. It is unclear how issues would be resolved efficiently under this complex arrangement involving a proposed Commissioner, a proposed governance board and the APVMA where a difference of opinion existed. Furthermore, as the proposed Commissioner role would be situated within the Department and be accountable to the Minister for Agriculture, it is unclear just how much responsibility or leadership such a Commissioner would have over the entirety of the regulatory framework, which reaches into other departments and portfolios (e.g. Department of Health).

CropLife and our members are fundamentally opposed to any arrangement that effectively creates parallel registration streams. The recommendation for a Commissioner to be responsible for the proposed product licensing and exemption schemes is not supported. CropLife disagrees with the Panel's view that these functions lie in the post-registration space and, as such, lie most appropriately independently of the APVMA. This simplified view does not adequately reflect the level of expertise and consistency that registrants and the community expect when decisions about whether a product should be permitted to be used in Australia in a particular way are made. It is appropriate that the APVMA alone are responsible for determining which products may be used in Australia in a particular manner.

Considering the broad and varied responsibilities proposed by the Panel for the Commissioner to undertake, it is difficult to see how adequate resources, both in terms of expertise and funding, would be available to ensure this function operated efficiently and delivered demonstrable benefit to the industry. The Panel's view that the majority of the proposed Commissioner's initial resources would be met through existing appropriation for pesticides and veterinary medicine functions by the Department seems extremely

[16] *Pesticide and Veterinary Medicine Regulatory Reform, Australian National Audit Office website, sourced 29 June 2017, https://www.anao.gov.au/work/performance-audit/pesticide-and-veterinary-medicine-regulatory-reform*

unlikely. Any increase to the overall cost of regulation in Australia could diminish the attractiveness of the Australian market for international crop protection product manufacturers and compound current inequalities between product access for Australian farmers in comparison with their international counterparts.

Having recently been subject to the staggering disruption to the registration process experienced due to the relocation of the Regulator to Armidale and subsequent loss of experienced staff, CropLife and our members are extremely wary of any major overhaul to the regulatory system that may result in similar disruption and loss of efficiency. After the APVMA's timeframe performance for pesticide applications within statutory timeframes plummeted to just 24 per cent in the June 2017 quarter, it took years for timeframe performance to return to those prior to the announcement of the Regulator's relocation. Since then, the APVMA has implemented various operational improvements that have significantly improved statutory timeframe performance, particularly for major assessments requiring more than two technical assessments. Any further disruption to the Regulator's operations that does not provide significant long-term benefits in efficiency would not be supported.

2.3 APVMA Governance

As outlined in our response to the Issues paper, CropLife has been vocal in not supporting the introduction of a governance board for the APVMA in the form proposed by the Panel. The APVMA's previous board was abolished in 2007, following recommendations made in the independent Review of Corporate Governance of Statutory Authorities and Office Holders (the Uhrig Review).[17] This review recommended that statutory authorities only implement governance boards where they can be given the full power to act. Considering the APVMA's function as a globally respected, scientifically and technically sound independent regulator of agricultural chemicals and veterinary medicines, it would be wholly inappropriate for any board to make or influence normal regulatory and registration decisions. This sentiment is shared by the Panel, thus it is unclear why the Panel considers that reinstating the APVMA board is appropriate. The Report does not provide any clarification or assurance that the introduction of a governance board will deliver any improvement to the operations of the APVMA.

The argument that the majority of other corporate Commonwealth entities have governance boards is not a compelling argument for re-instating such a board for the APVMA. The Panel argues that as other Commonwealth regulatory entities, including Food Standards Australia New Zealand, have boards, a board would be an appropriate governance mechanism for the APVMA. CropLife refutes this position, as the FSANZ board has the power to influence regulatory decisions, by reviewing scientific assessments and

[17] *https://www.finance.gov.au/sites/default/files/Uhrig-Report.pdf*

technical discussions and critically analysing and challenging assessment reports.[18] Therefore, its function supports the value of a governance Board in a manner that the proposed APVMA governance board does not.

CropLife and our members do not, in principle, oppose governance structures like boards. What we do oppose is unnecessary initiatives that impose significant costs on the farming sector without corresponding improvement. The APVMA currently has a functioning governance structure, including an audit committee with external appointees and changes should only be implemented after proper and comprehensive assessment and consideration.

The approximately $600,000 a year cost attributed to the governance board, as referenced in Senate Estimates[19] in May 2018, is an exorbitant and unnecessary cost to what is already one of the world's most expensive agricultural chemical regulators for industry. It is unclear why the Panel considers that the costs of an APVMA board should be borne in their entirety by the regulated industry, while other regulators that have governance boards receive varying degrees of government funding.

It is clear the Panel has chosen not to seriously review whether a board is the most appropriate governance structure for the APVMA but has simply proposed it for no greater reason than that the government has sought to reintroduce a board.

If a board were to be introduced, appropriate analysis and genuine industry and farmer consultation must be conducted so that it adds genuine value to the APVMA, rather than just adding an additional layer of costly administration and management. Additionally, the direct and associated costs should be fully funded by the Federal Government as an appropriate contribution to the effective operations of the Regulator. Without government funding, the cost of a board would be an additional direct cost to the farming sector.

2.4 Engagement with industry and the community

In principle, CropLife recognises the benefits of implementing a formal consultative forum for stakeholders. For it to positively contribute to the regulatory process and be sustainable, it needs a clear purpose with well-defined objectives. We do note, however, that the current Chief Executive Officer of the APVMA has recently started taking a number of actions in terms of stakeholder engagement.

[18] https://www.foodstandards.gov.au/about/board/Documents/FSANZ%20Board%20Charter%202019%20-%20FINAL.pdf

[19] Rural and Regional Affairs and Transport Legislation Committee Senate Estimates Hansard, Wednesday, 23 May 2018, page 95

Care should be taken regarding any stakeholder forum's representation. Under the proposal, the Forum would be influential in developing and reviewing health risk indicators and annual monitoring and surveillance plans, as well as making recommendations to the proposed Commissioner for further consideration. This Forum must not simply provide a voice for activist organisations fundamentally opposed to the use of agricultural chemicals aiming to disrupt the regulatory process.

The APVMA currently undertakes public consultation on various regulatory matters, as required by legislation and additionally at their discretion, including during the product registration process. CropLife is opposed to any additional formal consultation during the registration process, as this would likely involve considerable resources by the Regulator to implement and significantly increase registration timeframes, without adding to the scientific validity of the APVMA's assessment. Such a process could easily be hijacked by activist organisations with anti-pesticide, anti-agriculture agendas.

The Government has a responsibility for ensuring confidence in the Regulator. As such, any consultative forum for public engagement that provides specific public benefit functions should be funded by government.

The Panel's view that an operational group of regulators across jurisdictions focused on addressing regulatory issues has merit. This Forum would be ideally be placed to provide a supporting framework for the proposed ad hoc Expert Advisory Committees to assist in the development of technical information to inform regulatory operations and guidance.

CropLife supports the Panel's view that the proposed stakeholder forum and advisory panels are public good functions, and the proposed operational forum is a function of government. As such, all forums should be funded by government.

2.5 Whole of system performance measures

CropLife agrees with the Panel that performance measures are a critical part of the regulatory system and that transparency of the regulatory system and maintaining and improving community confidence in the system is crucial. The proposal to expand the current timeframe performance reporting to include an indication of days from target is supported as it would encourage efficiency and provide more clarity regarding the timeliness of regulatory decisions.

The proposal to expand performance measures to include whole-of-system performance measures, however, undermines the foundations of a technically proficient, competent regulatory system. The regulatory process must be independent and free from undue political, activist or registrant pressure. There is a risk that the proposed whole-of-system performance measures would provide an avenue for individuals and organisations who do not support the use of agvet chemicals to undermine the regulatory system and would not, as the Panel intends, provide them with any reassurance that the system is robust.

CropLife rejects any proposal to adopt monitoring programs based on the hazard-based, politically vulnerable and compromised European Union regulatory processes. On every front, the EU regulatory model is flawed and open to political and activist influence. The EU model has not increased public confidence in the regulatory system and the use of crucial, safe crop protection products. Instead, it has increased community misunderstanding of what is a scientifically complex process.

3. PROTECTING THE HEALTH AND SAFETY OF PEOPLE, ANIMALS AND THE ENVIRONMENT

3.1 System surveillance and data mining and analysis

In general, CropLife supports the utilisation of appropriate data mining to improve efficiencies throughout the regulatory system, providing intellectual property, confidentiality and privacy are protected and maintained. Consideration would have to be given to ensuring data is generated or collated appropriately and could not be subject to misuse. International data mining is already widely used by registrants to support Australian registration applications.

Prior to any such data mining and surveillance programs being implemented, however, the strategic goal of the program must be clearly determined, to ensure the program is run efficiently and is fit for purpose.

The source and quality of data must be determined and evaluated prior to use. Any data that was used, for example to justify a reconsideration of a particular chemical, must adhere to the same stringent requirements applied to data generated by registrants during the registration process.

Similarly, greater clarity regarding testing regimes, data security and data release is required. In particular, it is critical that the differences between the setting and enforcement of water quality parameters by other government bodies and those considered acceptable by the APVMA during the registration process must be recognised and reconciled.

For instance, the Report is factually incorrect in stating that the APVMA fails to use Species Sensitivity Distributions when conducting aquatic risk assessments. The APVMA readily uses this approach when proposed by applicants or as part of a chemical reconsideration when data of sufficient scientific quality is available for a sufficient range of species. The assessment factor method (a more conservative approach) is only used to address data gaps. This flexibility to utilise more than one approach should be utilised for all risk assessment processes. Factual inaccuracies such as this contained in the draft Report are concerning and demonstrate a lack of understanding on the behalf of the Panel regarding the complex regulatory environment.

CropLife appreciates there could be regulatory benefits associated with governments improving their data holdings and sharing data among jurisdictions to improve the management of agvet chemicals. Sufficient resourcing would be required for regulators to undertake this work, as it would add a significant additional layer of complexity to the Regulator's responsibilities.

CropLife supports all genuine measures that assist farmers achieve best practice when using crop protection tools but considers that government must recognise their responsibility in assisting and supporting farmers in achieving best practice. A scientifically sound, risk-based approach to monitoring residues of crop protection products in produce and the environment will provide realistic protection goals for human and environmental health. An appropriately funded and administered minor use and specialty use program that provides growers with registered products and uses is urgently required before national surveillance programs are introduced.

Greater domestic produce and environmental monitoring must be connected with better reporting. The Panel is rightly concerned with the agvet chemical industry's social license to operate and ongoing community concerns. Simply increasing monitoring and reporting of residues in produce and the environment will not satisfy those in the community that are concerned about the presence of trace pesticide residues in their food or the environment. There is a common misconception among the community that the mere presence of a crop protection product equates to damage to the environment or human health. The risks to the reputational damage of the agvet chemical industry from poorly communicated or contextualised results, due to inadequate monitoring and reporting schemes, cannot be understated.

Similarly, in order to fulfil a meaningful purpose, monitoring programs must be associated with adequate trace-back processes. The National Residue Survey (NRS) utilises such a trace-back process, to ensure that any maximum residue limit (MRL) exceedances can be investigated to identify the source and cause of the exceedance. Simply identifying residues in produce or the environment without the ability to identify and address the cause of those residue detections will not serve to allay community concerns and may actually exacerbate them.

The Panel's view that such data mining and surveillance activities would be considered public good activities and should, therefore, be funded by government is supported. CropLife does, however, contend that this function should be performed by the Department, as the overarching policy department for the primary regulator.

3.2 Domestic produce monitoring

CropLife agrees it is inevitable that domestic residue data will become publicly available eventually and that, depending on its source, the quality and integrity of the data may be uncertain. The Panel is correct in its view that the risks to social license and confidence in the regulatory system in export markets could be compromised if this data is unsound or presented to the community incorrectly or irresponsibly.

As outlined in our response to the Issues Paper, it is a long-held CropLife position that any produce and environment monitoring should be managed and appropriately funded by the Commonwealth. CropLife notes, however, that domestic produce monitoring is currently performed by state and territory health agencies and that the sale of commodities where

it is known or suspected that the commodity exceeds an MRL is an offence under the model food act implemented in all jurisdictions. The design and implementation of a Commonwealth-led domestic produce residue monitoring program must not duplicate or compromise these current legislative arrangements. Clarity regarding the strategic goals of such a program and how the data would be used and reported is, therefore, required in the Final Report. A domestic produce residue program that monitors adherence to product labels via MRL exceedances (performed by the Department) would differ in its strategic goal and objectives from one that aims to ensure human health by assessing residue detections against health-based guidance values and may be more appropriately performed by FSANZ.

Any monitoring programs must be carefully designed and managed, with clear purpose and governance to ensure the outcomes achieved actually reflect the intended purpose of the programs – ensuring public confidence in the Regulator. This will require a coordinated, risk-based and targeted approach that utilises independently validated methodologies for measurement and interpretation.

The evidence to date, as reported by the NRS, is that compliance among growers is good and the risk to consumers from pesticide residues is low. The NRS monitors the presence or absence of agricultural chemicals and veterinary medicines, or other contaminants, in produce, according to MRLs. As outlined by the Panel, detection of a residue does not infer that a human health risk is present. MRLs are set by the APVMA at levels that are not likely to be exceeded when used in accordance with the directions on the label and are set well below the level that could pose a risk to human health. In 2018-19, more than 99 per cent of samples indicated compliance with registered label directions.[20]

CropLife supports the Panel's proposal to build on and expand the current NRA infrastructure and leverage existing processes for sample collections, laboratory analysis and reporting. The proposal, however, to create a parallel domestic produce monitoring program under the jurisdiction of the proposed Commissioner is not supported.

It is also essential that the produce monitoring program allows for appropriate traceback where residue detections are identified. Consideration should be given to using existing Quality Assurance schemes that capture data relating to residue monitoring programs to conduct traceback activities. Some consideration of alternative funding arrangements, in which the relevant grower industries are involved, should also be considered. This would ensure equity against the current export produce NRS program, which is funded by industry levies.

[20] *https://www.agriculture.gov.au/ag-farm-food/food/nrs/nrs-results-publications/industry-brochures/summary*

3.3 Environmental monitoring

Any environmental surveillance program should be targeted and risk-based, with clearly defined objectives and reporting requirements. The need for environmental monitoring programs to be implemented on a national level, rather than by state and territory governments, is highlighted by the Senate Inquiry into Identification of leading practices in ensuring evidence-based regulation of farm practices that impact water quality outcomes in the Great Barrier Reef.21 This Inquiry examined the validity of the scientific methodology being employed by the Queensland Government to develop regulations regarding the use of agricultural inputs in the Great Barrier Reef catchment. The Inquiry was initiated in response to concerns raised by the agricultural industry in Queensland regarding the validity and transparency of the scientific method underpinning the Queensland Government's regulation of farm inputs, including pesticides. In our submission[22] to that Inquiry, CropLife highlighted that the key methodology used to monitor potential impacts of crop protection products on the Great Barrier Reef catchment areas was not yet published, rendering any meaningful peer review of that methodology impossible. In contrast, the APVMA utilises methodology that has been peer reviewed by the scientific community both domestically and internationally and has undergone extensive public consultation. Inexplicably, it has not even been considered by the Queensland Government. CropLife is pleased, however, to see that the methodology underpinning the Queensland Government's pesticide monitoring program has recently been published[23] and looks forward to peer reviewing that document.

It is essential that the scientific method behind the approach to produce or environmental monitoring is sound, transparent and appropriately validated. Environmental modelling methodologies must work in synergy with the environmental risk assessment processes conducted by the APVMA during product registration, to ensure that monitoring is aligned with the registered label directions for use. The Panel acknowledges (albeit incorrectly at times, as noted previously in this submission) the different approaches taken by the APVMA and the National Water Quality Management Strategy (NWQMS) regarding risk assessment but does not propose any solutions other than to suggest that water guidelines with the same status as MRLs be introduced.

[21] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport/GreatBarrierReef/Report

[22] https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Rural_and_Regional_Affairs_and_Transport/GreatBarrierReef/Submissions

[23] https://www.publications.qld.gov.au/dataset/method-development-pesticide-risk-metric-baseline-condition-of-waterways-to-gbr/resource/c65858f9-d7ba-4aef-aa4f-e148f950220f

The recommendation to establish potable and non-potable water guidelines with the same status as MRLs that are enforceable demonstrates a lack of understanding of current water quality guidelines and testing. It is not clear how the Panel proposes that water monitoring could be used to determine whether a product has been used responsibly and according to the label directions or, how any residue detections could be reliably traced to a source.

Similarly, the draft Report appears to lack the fundamental understanding that residues in water and soil are a function of use pattern and degradation. A monitoring program that assesses random samples from multiple sources is not appropriate for determining whether products are being used safely and responsibly, in accordance with label directions.

CropLife does not share the Panel's belief that monitoring of environmental locations will improve community confidence in the regulatory system. The presence of background concentrations of chemicals in the environment will likely create unnecessary concern among the community.

3.4 Identifying product related concerns

The Panel's recommendations regarding adverse experience reporting demonstrate a concerning lack of understanding of the current arrangements and perpetrates misinformation regarding the ongoing monitoring of the safety and efficacy of registered agvet products in Australia. The Panel recommends providing a legislated obligation for holders of approvals and registrations to notify the proposed Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product. There is already a legislative requirement for approval holders and registrants to notify the APMVA when they become aware of any information that may impact conditions under which an active constituent was approved or product registered. In order to ensure swift regulatory action is taken under these circumstances, it is appropriate for this function to remain with the Regulator.

Similarly, shifting the responsibility to collating and assessing adverse experience reports to the proposed Commissioner is not supported. The APVMA, as the technical regulator, is best placed to perform this function and to ensure any necessary regulatory action is taken in response to adverse experiences. In the past, the APVMA has not been required by legislation to undertake this function, nor has it been appropriately funded to do so. CropLife recommends that the APVMA be required and appropriately funded to perform this duty, rather than recreating an adverse experience reporting program within the Commissioner's office and duplicating the expertise required to assess such reports.

The proposal to establish a system wide 'pharmacovigilance' approach to managing adverse experience reporting may have the unintended outcome of distracting from areas of genuine concern by increasing the requirements for reporting where a demonstrated issue has not been identified. The Final Report would benefit from further detail regarding how such a program would operate and the benefits it would provide beyond an appropriately resourced adverse experience reporting program.

3.5 Transparency

It is crucial the Australian public has confidence in the APVMA as an independent, science- and evidence-based regulator of agricultural and veterinary chemical products.

The government should play a greater role in educating and reassuring the community regarding the Regulator's purpose, processes and decisions. Consideration should be given to greater collaboration with organisations and experts that specialise in science communication, to determine the most effective way of engaging with the community regarding the regulatory system, while reinforcing trust in the system.

The inadvertent perpetration of misunderstanding and misinformation by media and other commentators regarding the safety and regulation of agricultural and veterinary chemicals unnecessarily escalates community concern and erodes community confidence in Australia's world-leading science- and evidence-based regulatory system. More proactive and effective engagement with the community will assist in minimising the role that sensationalist, misinformed commentary is permitted to play in the public discussion regarding the safe use and regulation of agvet chemicals.

Care should be taken regarding the presentation of surveillance data to ensure it does not simply provide a voice for activist organisations fundamentally opposed to the use of agricultural chemicals, aiming to disrupt the regulatory process. The objective of providing a pathway for educating the general public regarding the regulatory system in Australia must not be compromised.

As outlined previously in this submission, simply increasing monitoring and reporting of residues in produce and the environment will not satisfy those in the community that are concerned about the presence of pesticide residues in their food or the environment.

3.6 Chemical reviews

The Panel's proposal to establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA regarding chemical reviews demonstrates another example of a concerning lack of understanding regarding the current trigger process. Under the current arrangements, anyone can, at any time, nominate an active/product for review. Thus, an international regulatory decision is already a potential trigger. The APVMA already scan the international regulatory environment and literature to determine whether a review is required. Similarly, under the current arrangement, the recommendation that the proposed Commissioner may refer substances to the APVMA for review would already be possible.

The proposed requirement for the APVMA to publish a statement of reasons whenever a decision was made not to commence a review would introduce a massive administrative burden on the Regulator, without any meaningful improvement in their operations or reduction in risk.

The Panel intends that a review would only be conducted on the basis of a 'science-based' regulatory decision but does not comment further on the distinction between a hazard-based and risk-based decision, both of which could be claimed to be based on science. CropLife does not support any proposal whereby the APVMA would be obligated to conduct a risk-based regulatory review based on the decision of a hazard-based regulatory system such as the European Union. Equally, the APVMA should not be obligated to conduct a risk-based regulatory review based on a risk-based decision by another regulator where that risk is irrelevant to the registered Australian use pattern.

The Panel does not provide any guidance regarding whether the APVMA's decision (either to review or not review a chemical) would be challengeable under law. If so, this could result in considerable additional administrative burden for the Regulator being required to defend its decision (e.g., where a hazard-based regulatory decision resulted in the withdrawal of a product in the European Union but the APVMA's risk-based assessment determined no regulatory action was required).

Any scenario under which the APVMA would be compelled to undertake a review of a substance separate to its own determination is bad policy and undermines best regulatory practice. In all cases, the final decision regarding whether a substance should be placed under review must lie with the Regulator to ensure that the system is free from any undue influence.

3.7 Humaneness assessment for vertebrate pest control products

Within Australia, the main classes of chemistry that are registered for rodent control, include first- and second-generation anticoagulants, as well as more recently introduced non-anticoagulants baits. These technologies broadly function in the same manner to cause organ failure following bait consumption. As such, under the proposed scheme, all currently available rodent baits are likely to receive the same or very similar humaneness classification.

Consequently, CropLife is unconvinced that the recommendation to introduce a humaneness score on product labels would alleviate public concerns or introduce an additional mechanism for consumer choice regarding humaneness, as argued by the Panel. This recommendation is likely to be a costly exercise that would provide little value in allowing the consumer to differentiate between individual bait products. Furthermore, the additional layer of administrative burden involved may detrimentally impact the attractiveness of the Australian market to registrants, potentially reducing the number of new technologies introduced to the market over time.

Similar considerations of humaneness scores for vertebrate pest control have been rejected in other jurisdictions for the reasons outlined previously in this submission.[24]

[24] https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/humane-vertebrate-pest-control-summary.html

4. ENSURING RESPONSIBLE USE

4.1 General product obligations

CropLife agrees that all participants in the agvet regulatory system must accept and respect their responsibility to ensure agricultural and veterinary products are used safely and responsibly throughout their lifecycle. CropLife is also supportive of the concept of shared responsibility and co-regulation where appropriate.

Product registrants are already obligated to meet the stringent requirements of the Regulator in order to access the market in Australia. It is unclear from the Report how the recommended general product obligations would improve on these world-class, science- and risk-based requirements.

The Panel has recommended an additional obligation for product manufacturers that they would be required to ensure, so far as is reasonably practicable, that the product is effective. This would include an obligation to carry out, or arrange the carrying out of, any calculations, analysis, testing or examination that may be necessary for demonstrating the product is effective. This obligation is performed at the time of registration and is redundant. CropLife does not support the introduction of duplicative processes, which are potentially costly and burdensome, in the regulatory system.

CropLife members recognise they have an ongoing responsibility to ensure the safe and sustainable use of their products. For this reason, CropLife and our members support and adhere to the *International Code of Conduct on Pesticide Management* of the Food and Agriculture Organization and the World Health Organization of the United Nations. This Code specifies obligations about the stewardship of agricultural chemicals throughout their lifecycle, from innovation, discovery and development, through to ultimate disposal of waste. In addition, CropLife members are required to adhere to our mandatory code of conduct and a suite of world-leading industry stewardship initiatives and programs, to ensure the responsible production and use of their products. Therefore, the introduction of general product obligations for registrants is duplicative and unnecessary for CropLife member companies.

CropLife and our members have proven themselves to be world leaders in stewardship. Recognition of industry stewardship programs, via an alternative mechanism, is strongly supported.

4.2 National licensing

In principle, CropLife supports the concept of nationally harmonised licensing arrangements (excluding the supply of internationally registered products). As detailed previously in this submission, however, CropLife is not supportive of implementing a Commissioner role. Without an alternative option put forward by the Panel for implementing a nationally harmonised licensing scheme that is not reliant on a Commissioner being instated, CropLife is unable to support the recommendation as proposed.

As described previously in this submission, significant consideration of current arrangements, their complexity within various state and territory departments and resourcing, alongside a comparison of the benefits associated with implementing a Commonwealth-led licensing scheme would assist in determining the most appropriate approach to managing licensing. Similar to concerns described earlier in this submission regarding the proposed model for nationally harmonised control of use arrangements, the proposal to absorb dealings with agricultural and veterinary medicine substances listed under the Stockholm Convention would create duplication and discord with the regulation of substances listed under the Stockholm Convention that are not used primarily as agricultural or veterinary chemicals. Similarly, the regulation of restricted chemical products, including Schedule 7 poisons is not limited to agricultural and veterinary products. Creating a parallel approach for managing only agvet products would be inefficient and unnecessarily duplicative.

The government must be cognisant that there are already a multitude of competing pressures on farmers. Any change to the current licensing schemes must deliver more efficient, less burdensome requirements for Australia's agricultural sector, while continuing to ensure safe and responsible use.

The Panel's recommendation appears to be a reinvigoration of the proposed National Occupational Licensing Scheme that was abandoned because concerns raised by the various jurisdictions regarding the proposed model and associated costs were not resolved.

The Mutual Recognition Amendment Bill 2020, which proposes to introduce automatic mutual recognition into the Mutual Recognition Act 1992 in all jurisdictions is expected to be introduced to parliament in mid-2021. It is therefore likely that a framework for nationally consistent licensing requirements will be in place before the end of 2021. Automatic mutual recognition may provide a more efficient, timely and non-disruptive approach to achieving nationally harmonised licensing requirements.

As outlined in our submission to the Issues paper, the APVMA currently assess applications against the 'worst case' on a label and apply restrictions on use accordingly. While this approach ensures risks are effectively managed, the outcome is that lower risk use patterns on labels are unable to be fully realised or utilised by growers. For example, it is not uncommon for a wide range of application rates to be presented on labels for different pests, diseases or weeds. The withholding periods, personal protective equipment requirements and environmental restrictions, however, are based on the highest label rate. Ergo, when the lowest rate is used, no flexibility is provided to reduce these restrictions.

A local risk assessment tool would provide for a more accurate, scenario-based determination of appropriate risk mitigation restrictions. Growers would be able to log onto the APVMA website and enter their actual use details to determine whether reduced restrictions are supported. The Panel recommend a special use license to enable holders to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone as presented on the label. This license may allow for safe and responsible use of a product without restricting users to working to the worse-case scenario. Care must be taken, however, to ensure that such a license does not have unintentional negative impacts on either public health or the availability of products and their registered uses in Australia, as raised by state and territory control of use representatives.

A chronic dietary risk assessment considers potential residues in the diet from the consumption of all treated commodities, to ensure that there is no risk to public health when products are used responsibly according to label directions. As more commodities are treated with the same chemical or their potential residues increase as a result of less conservative withholding periods etc. there is a risk that no additional registered uses of that chemical are allowed.

As discussed in Section 5.2, CropLife and our members reject the Panel's recommendation to implement a licensing scheme for agricultural and veterinary medicines registered by international regulators, without any oversight by the APVMA.

It is also noted that the list provided in Recommendation 50 of the Report fails to identify the need for a licensing scheme to manage import or manufacture for products destined to be supplied for export markets. In particular, the process of down-packing products bound for New Zealand and the Pacific Islands from a bulk formulation registered for use in Australia triggers the requirement for a specific APVMA permit (as any product not bearing the APVMA approved relevant label particulars is deemed unregistered under the legislation).

4.3 Nationally consistent training and competency system

In principle, CropLife supports the concept of a nationally consistent training and competency scheme. However, without an alternative option put forward by the Panel for implementing a nationally consistent training scheme that is not reliant on a Commissioner being appointed, CropLife is unable to support the recommendation as proposed. The Report does not provide any convincing argument that current inadequacies and inefficiencies related to training and competency schemes would be substantially improved by oversight of the proposed Commissioner. Agsafe training and professional services were implemented by CropLife and our members ahead of any regulatory requirements, as were other industry-led stewardship programs, including the Aerial Application Association of Australia's Aerial Improvement Management System.

A more thorough assessment of reported inadequacies relating to the development and delivery of accredited training courses and units of competencies under the regulatory remit of the Australian Skills Quality Agency (ASQA) would better highlight areas for improvement. This may provide insight regarding more efficient, practical pathways for addressing these inequalities than removing responsibility for the management of national training programs from ASQA and recreating new training and competencies specific to the agvet sector under the proposed Commissioner role.

As mentioned previously in this submission, the government must be cognizant that there are already a multitude of competing pressures on farmers. Any change to the current training schemes must deliver more efficient, tailored and practical training programs and requirements for Australia's agricultural sector.

4.4 Labelling

CropLife and our members fully support the development and implementation of smart labels that are machine-readable, to accommodate advances in application technology. The Panel's view that information relating to safety, first aid, disposal or use restrictions continue to remain affixed to the container, with consideration given to how it could be enhanced through more comprehensive smart-label content is supported. As the adoption of smart labelling will require considerable investment and collaboration on an international level, the ability for growers to use products safely and responsibly must not be compromised during development.

As outlined in our submission to the Issues paper, it is important to recognise the range of production and global supply chain issues associated with labelling that must be seriously considered, so as not to significantly interrupt the supply of agricultural chemicals in Australia.

Ideally, a complete phase-out of physical label leaflets will be possible over time. As identified by the Panel, the information contained on the physical label can be out of date and users may not immediately be aware of chemical review decisions, recalls and label variations. Providing this information via a QR code on a smart label would enable the product user to access real-time information regarding the use requirements for the product. Further consideration of the information required on the smart label is necessary to ensure growers have sufficient information to understand the full context of the label. Currently, the relevant label particulars text, as required by the APVMA, is generally inadequate to understand the full context of the label.

In order for the development of smart labels for agvet products to succeed, considerable international and industry collaboration will be required. CropLife understands that the APVMA is already involved in the development of international standards and requirements for developing this technology.

The Panel's recommendation that product reviews must be conducted by the registrant at least every five years has merit in addressing current concerns regarding outdated label directions. However, any arbitrary time-based requirement is an intellectually weak and simplistic bureaucratic solution which would also be unnecessarily costly and administratively burdensome for both registrants and the Regulator. A more detailed assessment of the current situation regarding outdated labels and the risk posed by them, alongside an assessment of the burden and benefits that would be realised in performing five-yearly label reviews would be beneficial.

It may be more efficient to simply resource the APVMA's review program to conduct label reviews as required. For example, when significant amendments are made to their assessment of such parameters as spray drift. A five-yearly review process, whereby labels for similar products would be updated gradually over that time period, may generate considerable confusion. This confusion could be significantly reduced by a coordinated label review program supported by appropriate communications, underpinning an effective and efficient chemical review program. Once a full smart labelling concept with the ability to conduct localised risk assessments has been realised, this would largely become a redundant process as the updated label instructions would be instantaneously rolled out across all products after the chemical review process is followed.

CropLife wholly rejects any proposal to replace risk-based labelling instructions and precautions relating to worker health and safety with the hazard-based Globally Harmonized System of Classification and Labelling of Chemicals (GHS) labelling system, as recommended by the Panel. Replacing information generated by Australia's world-class, risk-based regulator with generic information generated under a hazard-based system is nonsensical and would serve only to decrease the credibility of Australia's internationally respected regulatory system. GHS is appropriate only for unregulated hazardous chemicals in their concentrate form and for all hazardous chemicals in developing countries that do not have an appropriately funded, independent and technically proficient agricultural chemical regulator.

The GHS system was never intended to account for exposure to a product diluted in water, as almost always occurs when using crop protection products. Perversely, if the unsupported licensing scheme for internationally registered products was implemented along with this recommendation, the same formulation registered with the APVMA would have significantly more stringent and onerous personal protective equipment (PPE) requirements during application of the product than if the formulation were introduced through the licensing scheme. This is because all globally recognised regulators of agricultural chemicals conduct risk assessments using exposure modelling and/or specific product studies.

As outlined in our response to the Issues paper, CropLife through its international affiliate, CropLife International, has been actively involved in the development of the GHS from its inception. It is from this basis that CropLife can attest that the supplier assessed hazard-based GHS was never designed to be imposed in an already effectively regulated environment.

CropLife recommends instead that any requirement for hazard-based labelling be removed from crop protection products, as they are unnecessary and confusing and, in fact, undermine our modern, sophisticated labelling system.

Moving further away from a risk-based regulatory approach towards a hazard-based, precautionary system would serve neither the interest of the nation's agricultural sector nor that of the broader Australian community. While hazard identification is the crucial first step of any risk assessment, a more quantitative approach that allows for determination of the likelihood and extent of exposure – and whether the hazard can be appropriately mitigated – provides for a regulatory decision that more accurately reflects the probable risk associated with the use of a product.

Hazard-based regulation ignores the ability to manage any risks associated with exposure to a particular substance or scenario to an acceptable level. CropLife supports the Panel's view that risk-based regulatory assessment provides for a more scientific robust and comprehensive regulatory system to ensure users and the community have access to the broadest suite possible of safe chemicals to manage pests and diseases.

Rather than implementing unnecessary and confusing duplication of agvet chemical labels, confidence should be shown in the APVMA regulatory system. Currently, a partial exemption has been provided for agvet chemicals in recognition of the APVMA's labelling requirements. Agricultural chemicals should be fully exempted from GHS in recognition that their existing regulatory system meets WHS requirements.

This is not without precedence. The TGA approved labels for pharmaceutical chemicals continue to be exempt from GHS labelling and, consequently, receive the same recognition previously received by APVMA approved labels. Agricultural and pharmaceutical chemicals are both tightly regulated by dedicated agencies with hazards identified, risks assessed and approved uses prescribed on the label. The only difference is that the Department of Health proactively secured this ongoing recognition when consultation about changes to WHS regulations began before 2009, whereas the then Department did not. The Department has since made its strong objections known to Safe Work Australia.

Compliance with two separate sets of fundamentally conflicting regulations is not only costly for manufacturers, it is likely to confuse users and subsequently threaten worker health and safety. Safe Work Australia admits there has not been one occurrence where the lack of GHS hazard and precautionary statements on APVMA approved labels directly led to a WHS incident[25]. The additional GHS hazard and precautionary statements are available in the Safety Data Sheets (SDS). SDSs are legally required to be accessible for all workers involved in using, handling or storing the chemical, emergency service workers and anyone else who may be exposed to the chemical. Duplicating this information on agricultural chemical labels is unnecessary and risks undermining worker health and safety.

Furthermore, this proposal creates an inconsistency between the regulation of chemical products used on farms or in the workplace and those used primarily in the home and garden. The GHS system applied only to chemicals used in the workplace, not home and garden products and it would be inappropriate for this hazard-based system for worker health and safety to be applied to home and garden products.

All state governments except for Victoria, Western Australia and the Australian Capital Territory have mandated compliance with Safe Work Australia's Model Regulations since 1 January 2017. Agricultural chemical products, however, are supplied nationally and can be in the market for over 12 months after production. We now have a situation where agricultural chemical products with nationally registered and approved labels can be legally sold in one jurisdiction, but not others, highlighting the urgent requirement for nationally consistent control of use requirements.

4.5 Stewardship

CropLife is pleased that the Panel acknowledges the success of ***drum****MUSTER* and ChemClear® for their roles in ensuring the sustainability of the plant science industry. To date, these programs have collected and disposed of more than 36.6 million chemical containers and 750,635 litres of obsolete or unwanted chemical nationally. As a result, more than 40,000 tonnes of metal and plastic have been diverted from landfill and recycled into re-usable products and 98 per cent of the collected chemical subsequently used as an alternative fuel source.

The 2017-18 Australian Plastics Recycling Survey reported that just seven per cent of agricultural plastics are being recycled. While this figure is concerningly low, the ***drum****MUSTER* program accounts for almost half of all agricultural plastics being recycled in Australia.[26]

[25] *Senate Education and Employment Legislation Committee estimates, Hansard reference: 22 Oct 2015 pg. 49-50*

[26] *https://www.environment.gov.au/protection/waste-resource-recovery/publications/australian-plastics-recycling-survey-report-2017-18*

It is important to recognise that these programs are undertaken voluntarily by industry (although they are enforced for CropLife member companies through our membership requirements and code of conduct), not through any regulation. This reinforces how the issues of environmental sustainability are culturally entrenched both in the Australian and global plant science industry. The voluntary, industry-led approach to the stewardship of waste management facilitates a proactive and dynamic environment in which the programs can be updated and improved without requiring costly or slow government oversight. Currently, CropLife Australia's mandatory code of conduct is being amended to require member companies to ensure that all Intermediate Bulk Containers (IBCs) supplied with products are part of a returnable scheme. Already more than 90 per cent of products supplied in IBCs by CropLife member companies are eligible. This amendment is being made ahead of an audit being conducted by the Australian Packaging Covenant Organisation (APCO) to assess adherence to the National Environmental Protection Measure (Used Packaging Materials) Measure 2011.

Although ***drum****MUSTER* and ChemClear® are now funded by an industry levy, the programs were initially established with significant upfront investment by CropLife and our member companies. Imposition of the levy is authorised by the Australian Competition and Consumer Commission (ACCC), which ensures there is a net benefit to the community. This authorisation is regularly reviewed to ensure the benefits of these schemes remain and the projected anti-competitive impact remains acceptable.

Any potential increase relating to the costs of regulatory compliance for product stewardship schemes will ultimately be borne by farmers and will have one of two consequences. As resources are directed to complying with rigid, bureaucratic monitoring and reporting provisions, resources that could be deployed to collecting, recycling and disposing of empty containers and unwanted chemicals will be reduced. If excessive, the ultimate sustainability of the program may be threatened. Alternatively, should existing levies be increased to reflect the increased regulatory compliance costs, the relative benefits to the community may be outweighed by the anti-competitive cost, requiring the ACCC to withdraw its authorisation of the levy.

The recommendation for the publication of a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent is redundant. A list of participating companies is publicly available via the ***drum****MUSTER* website.[27] Instead, CropLife recommends consideration of mandating participation in Agsafe's ***drum****MUSTER* and ChemClear® programs.

[27] https://www.drummuster.org.au/whos-involved/manufacturers/

Similarly, CropLife supports the recommendation for industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations, if those are implemented.

It is important to recognise, however, that stewardship goes well beyond those world-class waste management programs, instead demonstrating a commitment to whole-of-lifecycle responsibility. CropLife's stewardship approach both in Australia and globally embodies this whole-of-lifecycle commitment to the responsible handling, use and disposal of crop protection products.

This is why CropLife established our StewardshipFirst program, a comprehensive suite of stewardship and best practice initiatives and programs that ensure human health and safety, and the responsible and sustainable management of the environment and trade issues associated with agricultural chemical use in Australia. Collectively, these controls help maintain the sustainability of Australian agriculture by responsibly and efficiently managing farm inputs. As well as Agsafe's ***drum****MUSTER* and ChemClear® programs, StewardshipFirst includes CropLife's mandatory code of conduct for members, resistance management strategies for herbicides, insecticides and fungicides, the spray drift and best practice management initiatives SprayBest and MyAgCHEMuse, and the Pollinator Protection Initiative, which includes BeeConnected and the Seed Treatment Stewardship Strategy. In addition, CropLife member companies have their own product stewardship initiatives to ensure the responsible use and longevity of their products.

4.6 Managing risks from compounded products

CropLife recognises that Animal Medicines Australia and the Veterinary Manufacturers and Distributors Association have expertise in this area and defers to their assessments on these recommendations.

4.7 National rules

While acknowledging the requirement for greater national harmonisation regarding all aspects of the agvet regulatory framework, CropLife and our members do not support off label use of agricultural chemical products. Off label uses are not specifically risk assessed by a scientifically competent regulator for Australian conditions. It is not reasonable for farmers to have responsibility for assessing the relative risks of using crop protection products in a manner that is not outlined on registered product labels.

CropLife encourages the Panel to further consider mechanisms that would incentivise registrants to expand the labels of registered agricultural chemical products to include minor uses and specialty crops. Increasing the number of registered use patterns on product labels would ensure that Australian farmers have improved access to important crop protection tools via a legal, regulated pathway.

Ongoing funding of the Australian Government's access to agricultural and veterinary chemicals grants program, and self-administration by industry, will remove the need for off label uses as all necessary minor uses and uses for specialty crops will become APVMA approved label uses. This will deliver the platform in which national harmonisation of control of use can occur.

Additionally, the APVMA published its final crop groupings guidance in 2019 to encourage a broader range of crops to be registered within a group compared to only the major crops. This commendable initiative by the APVMA has already contributed to the inclusion of additional minor use patterns on registered labels and will increasingly incentivise registrants in the future as awareness of this registration option is adopted during the dossier development stage.

CropLife also notes that the Department made a commitment to industry in 2018 to allow additional periods of data protection to incentivise registrants to bring additional use patterns to Australian registrations. Unfortunately, this has not been delivered as the required legislative amendment has yet to be passed by the Australian Parliament. When this has finally been resolved, it will act as an immediate incentive for both overseas and Australian innovators.

Together, these initiatives will lead to significant improvements in access to use patterns for growers without jeopardising the integrity of the Australian registration scheme.

5. IMPROVING ACCESS

5.1 Refocusing the scope of the regulatory system

As outlined in our submission to the Issues paper, CropLife has long advocated for the scope of the Agvet Code to be narrowed to remove chemicals with limited relevance to primary production or animal welfare, such as pool and spa chemicals, anti-fouling paints, dairy sanitisers, etc. Removing such products from the APVMA's regulatory scope will allow it to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

CropLife commends the Panel for recognising that sound regulatory practice demands that the level of regulatory intervention directed towards a product that falls within the scope of the APVMA be commensurate with the risks that require management. This approach would allow the APVMA to focus on products of higher regulatory concern. Previous attempts by the APVMA to develop pathways of lighter regulatory touch for low-risk products have not been successful. The APVMA already has strict requirements for the registration of a product for home garden use, which could be used to develop a simplified pathway to market for these products, without compromising the integrity of the regulatory system or community confidence in it.

CropLife does not support any proposal to remove home and garden and non-urban land management pesticides from the scope of the APVMA. As these products are identical to the crop protection products registered by the APVMA and proper use remains important, it is appropriate that they remain in the regulatory system. Excluding pesticide products intended for use in home gardens and non-urban land management from the regulatory scope of the APVMA is unlikely to improve or maintain the trust of the wider community in this matter.

Further consultation with the APVMA and industry is required before finalising the criteria for the proposed exemptions for products that pose lower risk to ensure that risks are appropriately managed.

As described previously in this submission, CropLife does not support the use of the hazard-based GHS classification and labelling system for the regulation of agricultural and veterinary chemicals. The Panel's recommendation to utilise the GHS classification system to inform a Potentially Hazardous of Injurious Substance list is, therefore, rejected. Introducing a hazard-based system for listing chemicals that are subsequently registered using a risk-based regulatory system will cause unnecessary confusion for the wider community, who may consider that any product included on the list should be prohibited from use entirely and may not be reassured that risk mitigation measures would be sufficient for ensuring the product could be used safely and responsibly in Australia. If this list were to be made publicly available, it could be used by activist organisations fundamentally opposed to the use of agricultural chemicals and veterinary medicines aiming to disrupt the regulatory process.

The Panel has recommended refining the definition of what is considered a pesticide. CropLife recommends caution regarding any proposal to amend the definition of a pesticide, which is currently technology-agnostic and accommodates all current and future technologies. Any amendment of the definition of a pesticide that compromises this and moves towards technology-specific definitions is wholly rejected. Amending the definition of what is considered a pesticide within the Australian regulatory system could have significant implications for Australia's major trading partners. A comparison of how international regulators define the word pesticide and how the proposed definition aligns or differs from international standards would be beneficial in the Final Report. In particular, the recommendation to exclude plant growth regulators or any active that does not trigger a certain GHS classification is not appropriate. This approach would fail to manage trade issues given these actives would almost certainly require registration (and therefore MRL setting) by our trading partners. Furthermore, unacceptable risks to the environment may result from this recommendation, as the GHS system is entirely inadequate regarding environmental considerations.

Removing the regulatory duplication of whole viable seeds is urgently required, as proposed by CropLife previously. Whole viable seeds that are genetically modified with incorporated pest and/or disease control are regulated by the OGTR, FSANZ and the APVMA. Exclusion of whole viable seeds from APVMA regulation as an agvet chemical allows significant efficiency gains without compromising human health or environmental safety.

CropLife's submission for Phase 1 of the National Gene Technology Scheme review sets out in detail its concerns regarding duplication of regulation between the OGTR, FSANZ and the APVMA for products regulated as genetically modified organisms (GMOs). CropLife views removal of such duplication as high priority, as it imposes heavy regulatory burden, time delays and costs on applicants, with no associated benefits. To improve this situation, CropLife recommends that the APVMA accepts the risk assessments of the OGTR and FSANZ, or that APVMA regulatory responsibility for GM products with incorporated pest and/or disease control is removed. This regulatory responsibility is an outdated remnant of the pre-OGTR system and these changes would be consistent with the Australian Government's commitment to reducing the cost of unnecessary or inefficient regulation imposed on individuals, businesses and community organisations.

5.2 Innovation and alternative products

CropLife recognises the need to address the inherent failures in the current regulatory environment that disincentivise the introduction of new innovative products or product uses being registered in Australia.

CropLife and our members reject the Panel's recommendation as outlined in the Report to implement a licensing scheme for agricultural and veterinary medicines registered by international regulators, without any oversight by the APVMA or conducted separately from the APVMA.

This proposal seems to entirely contradict the Panel's determination that community confidence in the regulatory framework must be considered when developing broad regulatory reform options. It is difficult to see how community confidence would be improved by creating a parallel regulatory system that bypasses any form of consideration or assessment by Australia's independent regulator, the APVMA.

In order to implement such a recommendation, the proposed Commissioner would be required to replicate expertise currently contained within the APVMA. This is neither efficient nor feasible.

CropLife and our members are concerned that the international licensing scheme would allow non-efficacious products to enter the market, bypassing the current rigorous regulatory system. Currently, products must adhere to stringent rules regarding the nature of the claims regarding efficacy that can be included on products. By enabling products to enter the Australian market that have been registered in international jurisdictions with less stringent efficacy requirements could result in the market being flooded with products making spurious efficacy claims that would not be permissible via the APVMA's registration pathway. Resulting reputational damage to the entire agricultural and veterinary product industry could be substantial.

To assist in developing meaningful legislative amendments that enable the APVMA to meet its legislative requirements and conduct its core business during the transition of the Regulator to Armidale, CropLife provided the Department with a range of urgent regulatory and legislative reform proposals for consideration in July 2017. The proposal to implement a pathway for conditional registration and variation would streamline regulatory processes for specific application types, while remaining within the APVMA's regulatory oversight and without reducing human health and environmental protections.

Introducing a legitimate pathway for introducing agricultural and vet products into Australia from international jurisdictions may also inadvertently increase the risk for illegal or counterfeit products to enter the market.

CropLife is disappointed that the Report does not contain a detailed assessment of the multiple factors that contribute to the known market failures for introducing products and, more commonly, product use patterns for minor and specialty crops in Australia. Such a detailed assessment would have highlighted the aspects of the regulatory system that contribute to this failure and provided pathways for improvement of the current system, rather than simply creating a new, parallel system.

This recommendation, if adopted, would significantly impact a registrant's ability to justify development for Australian-specific data to support registered use patterns in Australia. The recommendation would pose a significant risk of an overseas registered product being introduced into the market without any requirement to demonstrate its suitability under Australian conditions.

The significance of various pest and weed species differs internationally, depending on various environmental conditions and selection pressures. Many of Australia's greatest weed and pest risks, including annual ryegrass, wild radish and fruit spotting bug, are not present at commercially significant levels in other countries. Developing solutions for these issues in Australia's unique environment can take up to five years or more in research and development and subsequent applications for registration. The threat of an innovative registrant's pipeline product being undermined by an overseas competitor product claimed to have effectiveness on what are minor, or non-existent, weeds or pests in that country may render the investment in data development and registration unprofitable and too risky to pursue. This is of specific concern when a different use pattern is required to control a problem pest or weed in Australia compared to other pests or weeds which are also an issue in the originating country, or if the product has the potential to be used in different crops in Australia due to different production practices. As a result, this proposal may result in the unintended and perverse outcome whereby grower access to products targeting their most significant weed and pest control issues is compromised.

Similarly, this recommendation also has the potential to reduce farmer access to generic products or to formulation or use pattern development by alternative suppliers to the original innovator. The Report fails to recognise that the APVMA will be unable to grant a generic registration for actives that have been allowed to enter the Australian market through the proposed international registration licensing scheme. The only option proposed is through the international licensing scheme itself, but a lack of fundamental understanding of how these international regulatory schemes operate make this unlikely. For example, when a generic product is registered in the United States, it is done so via a data compensation scheme enshrined in legislation. Any supplier attempting to access the Australian market with a generic registered under the United States scheme could be in breach of their data compensation agreement (which exclusively permits access in the United States).

As outlined in the Report, there are a suite of regulatory controls that apply to agricultural and veterinary products in Australia beyond those of registration, including an OGTR licence, biosecurity import permit or amending the Poisons Standard or Food Standards Code to establish a maximum residue limit. The Panel does not seem to be cognisant, however, that these processes may not achieve the purported goal of providing Australian growers more timely access to products registered overseas. For example, the license holder would be required to seek approvals for poisons scheduling and establishing MRLs because they are not seeking registration via the APVMA.

It is likely that responsible licensees would not attempt to be bring a product to Australia until a Codex MRL is established, due to the potential for unmanageable trade risks. Therefore, there is considerable doubt that that the recommended licensing approach would significantly influence the timing of products registered in Australia. A Codex MRL cannot be set until there is registration in at least one country. This process is notoriously slow because the lack of a Codex MRL can benefit trade for some countries. Consequently, it can be years after the product is registered in the first country before a Codex MRL is set.

Some of the proposed conditions for obtaining a license, particularly those relating to residues in human and animal feed do not appear to have been appropriately considered and appear to exclude many products from being eligible from utilising the proposed pathway. For example, there is no pathway proposed to establish a Table 4 entry for animal feed commodities in the APVMA MRL Standard, yet licensees are proposed to ensure they will guarantee compliance with Table 4. CropLife defers to the positions of the APVMA and state and territory-based regulators regarding the technical assessment of these recommendations. Nevertheless, these oversights diminish confidence in the ability of such a program to be adequately implemented and managed without significant involvement by Australia's expert regulators.

Further consideration by the Panel regarding the current inefficiencies in setting MRLs and scheduling poisons would be extremely valuable in terms of identifying areas of meaningful reform and efficiency improvements. The Panel's interpretation of the Terms of Reference for the review process that interactions between the APVMA's legislation and those of other regulatory bodies is untenable. The Terms of Reference clearly state that the Panel will have regard to, among other items, "interactions with other regulatory schemes and arrangements" and the Panel has made recommendations regarding functions currently performed by the OGTR and the biosecurity division of the Department.

5.3 Prioritised assessments

CropLife recognises the value in providing a pathway by which the APVMA can better prioritise and manage their workload. The proposed criteria for implementing a prioritisation process would incentivise registrants to seek registration of new active constituents and alternative chemistries to replace older chemistries, as well as include additional use patterns on registered labels via crop groups or for the control of exotic pests and weeds of national significance. This will assist in ensuring Australian farmers have more rapid access to new technologies and potentially provide them with access to products for minor crops and specialty crops in a more timely manner. Further consultation with industry and the APVMA would be required to finalise the criteria for inclusion in a prioritisation pathway. For example, these criteria would also need to include prioritisation for new use patterns for existing active constituents and innovative formulations that reduce risk. Criteria for de-prioritisation is also necessary, to avoid a pathway that simply increases the workload of the Regulator unsustainably.

As outlined in our response to the Issues paper, the current inability for the APVMA to prioritise applications frequently prevents it from being able to participate in Global Joint Reviews. Enabling the APVMA to implement a prioritisation process will allow the Regulator to take advantage of international expertise and resources to streamline the assessment process, build collaborative relationships and source additional regulatory capability from overseas.

CropLife does not, however, support the recommendation for the prioritisation criteria to be determined by the Minister following advice from the Stakeholder Forum. Nor does CropLife support the Minister to provide direction to the APVMA in any matter regarding the registration process. The membership proposed by the Panel for inclusion in the Stakeholder meeting would include representatives that do not participate in or have a solid understanding of the registration process and would not be equipped to best determine which application types would be suitable for prioritisation. Allowing this forum to influence the criteria for prioritising the registration process would leave it open to political influence, as well as the influence of those without genuine interest in the operations of the Regulator, but whose primary goal is to disrupt the regulatory process. The final decision regarding the prioritisation criteria must lie with the APVMA as the expert regulator that determines the risk profile of certain product types, in consultation with the regulated industry, control of use regulators and farming organisations.

Overall, a more efficient system with appropriate resourcing for the assessment of new, innovative products that are associated with more technical applications would deliver a better outcome.

5.4 Regionally targeted controls and reduced reliance on jurisdictional borders

As outlined in our response to the Issues paper, CropLife and our members consider there to be merit in assessing crop protection products by boundaries other than state borders, where there are genuine biological reasons, such as soil type. The APVMA currently assess stream flow, stream depth and rainfall events as part of their environment assessments, which is not restricted by state or territory boundaries.

For such a system to be successful, it must be restricted to long-term label arrangements to ensure the integrity of the labelling system and not overly burdening the Regulator. The existing permit system addresses many of the issues arising from geographical restrictions in the short-term and could be improved by an ongoing permit-to-label process. Under such arrangements, the APVMA would advise registrants of uses that are eligible for conversion from permit to label on the basis that the Regulator has received sufficient information to support such a registration.

Care must be taken to ensure any approaches to regulating crop protection products by alternative boundaries do not result in excessively complex product labels. Similarly, consideration should be given to the administrative burden imposed by any operational change, for both the Regulator and product registrants.

5.5 Improving access for emergency, research and minor uses

CropLife has long advocated for additional funding and expansion of the current minor use initiative and permit-to-label processes. The Improved Access to Agvet Chemicals Initiative has demonstrated a comparable return on investment to international minor use programs, at an average return to industry of $117 per government grant dollar or $17 million per project over 20 years. CropLife commends the Panel for its recommendation to expand the support provided by government to this critical initiative.

The economic gains achieved by the Initiative so far could be exponentially more. Structural change and sustainable funding are required to alleviate the existing economic and regulatory market failure, deliver more sustainable pest management practices, and increase Australian GDP.

Similar programs in the United States have demonstrated that every dollar invested in the minor use program generates a net return to the economy of US$500. The minor use and specialty crops program in the US, known as IR-4 or Interregional Research Project number 4, began over 50 years ago and receives government funding of approximately US$14 million a year. The success of the IR-4 Project, with additional U.S. Department of Agriculture funding, is proven and can be measured in its development of data to support nearly 20,000 food use and ornamental horticulture label approvals.

IR-4 is managed by Rutgers, the state university of New Jersey. Part of its success is due to the program leveraging a network of university researchers. With appropriate funding from government, the University of New England could accomplish similar feats in Australia.

In 2002, the Ministers of Health Canada and Agriculture and Agri-Food Canada announced funding of CAD$61.8 million to address problems in the minor use system. These included slow access to pesticides, loss of uses due to reliance on older chemistry, international competitiveness and the high cost of data generation to support minor uses.

As outlined in our submission to the Issues paper, CropLife and our members support the APVMA's minor use and emergency use permit application process, as well as the Regulator's permit-to-label initiative. While the regulatory barriers to introducing new products or expanding access to existing products to niche and emerging agricultural industries remain, the APVMA's permit issuing capacity must be retained. The success of the permit-to-label initiative is dependent on adequate resourcing within the Regulator.

The Panel recommends replacing the current permit application process with greater use of exemptions, contending that the exemption process would effectively replicate the current permit system while allowing for a more timely, streamlined and flexible process. CropLife agrees with the Panel that careful definition of the exemption and targeted application of exemption conditions would be necessary to ensure any associated risks (including those relating to MRLs and trade) were appropriately managed.

CropLife is wary of the use of the term 'exemption' as this could imply that no regulatory oversight is being applied and consequently reduce community confidence in the regulatory system. While it is acknowledged that this is a standardised terminology, its use in the regulation of agricultural and veterinary chemicals is not common and could inadvertently undermine the credibility and rigour of the system.

5.6 Biologically-based pest and disease management products

CropLife supports the Panel's view that the regulatory system should be "technology agnostic." A regulatory framework that can adapt nimbly to emerging technologies is fundamental to modern, future-proof regulation that facilitates rapid adoption of agricultural innovation. A more coordinated and collaborative approach to addressing rapid technological and scientific advances in the future is necessary to ensure the APVMA maintains its status as a world-class regulator. It is imperative that the process for appropriately determining how to assess and manage potential risks associated with these technological and scientific advances is efficient and flexible and does not impede their development and adoption.

As such, CropLife and our members support the continued investment in expertise and experience in the regulation of all crop protection products. The Regulator should not be encouraged or seen to be promoting the use of one particular type of crop protection product. This pertains to the previously discussed proposal to amend the definition of a pesticide. The current technology-agnostic definition did not require amendment to accommodate biological pesticides.

CropLife supports the Panel's recommendation to amend the *Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016* to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries. This recommendation would provide an invaluable opportunity for streamlining and improving the current import process.

5.7 Allowing consideration of benefits prior to refusing a registration

CropLife supports the provision of a process that enables the APVMA to consider whether the risks associated with the use of a product would be justified where an extraordinary outcome or net environmental benefit is demonstrable. Under these circumstances, it would be necessary to ensure that the registration conditions of a product were related to certain, specific conditions of use to ensure that any associated risk could be adequately managed.

Provisions must be made to ensure that this process could not be abused by registrants who were dissatisfied with the APVMA's decision not to register a product, which could result in considerable administrative burden on the behalf of the Regulator in defending its decision.

5.8 Protecting intellectual property

CropLife has long advocated for the introduction of additional data protection for the addition of minor uses to existing product labels, as originally proposed in the Streamlining Regulation Bill 2018 and carried over into the APVMA Board and Other Improvements Bill 2019, currently before the Senate. This proposal complements the crop groupings project and minor use programs. The duration of additional data protection periods should reflect the cost of data generation and identified industry priorities, as discussed in more detail in CropLife's submission to the Streamlining Regulation Bill 2018.

Similarly, CropLife supports the Panel's recommendation to provide for data protection (five years) for information provided in support of a research permit/exemption. The Panel's opinion that this will encourage the development of local research information and incentivise registrants and holders of such data to seek registration for relevant use patterns is likewise supported.

CropLife does not support any reductions to the levels of data protection afforded by the current system. The proposal to reduce data protection timeframes for information provided during a chemical review process from eight to five years, simply because that would be more consistent with provisions in New Zealand, is rejected. Significant effort and cost are involved on behalf of registrants to develop data to support a chemical review process. Reducing the data protection period may have the perverse outcome of disincentivising registrants from developing that material, resulting in the removal of safe and effective products from the Australian market. CropLife does, however, support the Panel's proposal to expand the scope of information eligible for data protection during the course of a chemical review to include any confidential information provided by the registrant and relied on by the APVMA to support a reconsideration decision.

CropLife also supports the Panel's view that the negotiation of data access and compensation is a private negotiation between companies and should not form part of the regulatory system.

6. CONTRIBUTING TO SUPPLY CHAIN RESILIENCE

6.1 Sourcing active constituents

CropLife and our members do not support any recommendation that would reduce regulatory requirements for crop protection products and subsequently undermining and damaging public confidence in Australia's robust regulatory system.

Frequently, the various active constituent manufacturing sites utilise different manufacturing processes or equipment, which can result in variations in impurity profiles. These variations pose varying degrees of risk to the environment, users and consumers. Accordingly, all reputable international jurisdictions require each source of specific active constituent to be registered separately.

CropLife and our members do not support the recommendation for 'substance level' approval for active constituents. Such a process would remove traceability from the supply chain and expose the system to abuse by disreputable operators and those attempting to illegally import substandard material into the Australian market. The APVMA must retain its ability to conduct an independent assessment of all technical material entering Australia and verify that it meets the requisite chemical and toxicology requirements.

CropLife recognises this is an area of compliance and enforcement that has traditionally not received an adequate level of resourcing. Consideration of a specific monitoring program at the point of entry into Australia is warranted to ensure all suppliers are meeting their current obligations for both active constituents and formulated products.

6.2 International alignment of veterinary manufacturing standards

CropLife recognises that Animal Medicines Australia and the Veterinary Manufacturers and Distributors Association have expertise in this area and defers to their assessments on these recommendations.

6.3 Building assessment capacity beyond the APVMA

The Panel's view that increased use of third-party assessors may contribute to building national capacity for regulatory science skills and expertise is supported. CropLife has long advocated for this approach, which would enable the APVMA to formally recognise third-party scientific assessors, as outlined in the lapsed *Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018*.

If implemented effectively, efficiency gains could be achieved by broadening the APVMA's capability for assessing applications in a timely manner. By offering long-term contracts with associated quality and performance caveats, the timeliness, consistency and reliability of scientific assessments could be greatly improved. The potential for the secondment of suitable Australian and overseas staff is crucial to ensure that the Regulator has access to expert regulatory scientists to overcome any potential shortages within the Regulator.

For an accredited assessor measure to be implemented effectively, the resultant legislative instrument must clearly indicate where the responsibilities and boundaries lie for sign-off by the third-party assessor and APVMA delegate. A panel of accredited assessors endorsed by the Regulator will overcome the concern (whether perceived or actual) that registrants could "shop around" for an assessor who will support their application. International assessors could be used in certain scenarios. Local expertise would be required in some cases given the unique aspects of the Australian environment, agricultural industry and regulatory environment.

7. FUNDING THE REGULATORY SYSTEM

7.1 Improving transparency and equity by modernising cost recovery

The Cost Recovery Implementation Statement (CRIS) model was initially designed for the APVMA in 1984. The Regulator needs a cost recovery regime that is fit for purpose in today's dynamic changing environment.

An imbalanced sales-based levy subsidises chemicals of low market value (as a percentage of total sales) by taxing those of high market value, which:

- creates disincentives for research and development (R&D) in the industry where R&D is the key source of future growth;
- creates perverse incentives for products to be registered that may have little or no value to the Australian community. This increases the costs of regulation and delays the registration of higher value chemicals; and
- increases the input costs of Australian farmers (who have limited capacity to pass these costs on) and reduces the range of chemicals offered than would otherwise be the case.

As identified by the Panel, this approach is inconsistent with the Government's charging framework because it enables significant cross-subsidisation.

In 2012, the then Department of Agriculture initiated a First Principles Review of the cost recovery arrangements for the APVMA. The final report titled *First Principles Review of Cost Recovery at the Australian Pesticides and Veterinary Medicines Authority* was published in 2014. Not one of the recommendations have been implemented.

A second First Principles Review was commenced in 2018 but remains uncompleted. In the absence of this work by the Department, the APVMA revised an outdated costing model, with the *Agricultural and Veterinary Chemicals Code Amendment (Cost Recovery) Regulations 2020* issued on 14 May 2020.

The major issues repeatedly raised by industry that have been ignored include inefficiencies at the APVMA; subsidisation by industry for public good activities; lack of a costing/resourcing model being adopted by the APVMA that would support changing volumes and resourcing needs of industry; and improved timeliness.

The current CRIS model is based on outdated financials for year ended 30 June 2019, distorted by significant abnormal costs circa $10 million. This distortion is related to the relocation of the APVMA to Armidale and corresponding increased employment/contractor costs through redundancies and establishment of a workforce at the new location, duplication of overheads across two sites, significant investment in various business reengineering initiatives without the corresponding savings recognised, and a $3 million+ allowance to build up cash reserves.

Accordingly, based on current funding streams, the APVMA is more than adequately resourced to support the recommendations arising from this review and introduce the step-change required to support the next generation regulatory system, without incurring any additional costs to industry or government.

Any change to the CRIS model needs to support greater transparency in funding received and continual improvement in the APVMA's timeliness and efficiency performance.

We concur with the Panel that consideration of an alternate option to the old revenue raising model supporting the APVMA's CRIS is needed. A funding structure that promotes innovation, supports agility for industry to respond quickly to external events (such as impacts associated with a global pandemic) and reduces financial and timeliness inhibitors to enter the Australian market, is required. In this regard, prioritising applications by work categories and not by individual product is seen as a viable option to enable the APVMA to identify and fast track applications supporting innovation, as outlined in Section 5.2.

The Panel acknowledges that the relatively small market for agricultural chemicals compared with markets like the US and European Union, can create significant commercial constraints on industry. While CropLife acknowledges that the cost of product registration is similar in Australia to that of international jurisdictions on a dollar-for-dollar basis, this economy of size means that registering each product use pattern equates to a considerably increased cost to industry. Confounding this imbalance, registrants in Australia carry the cost of funding almost all of the APVMA's functions via a cost recovery arrangement, while international regulators receive varying degrees of public funding. The Panel states that aspects of the regulatory system relating to market size cannot easily be overcome by governments. We do not accept this position as there are a range of measures that government could undertake to mitigate and minimise the inherent market size challenges such as:

- Offsetting commercial loss on patents due to mandatory regulatory assessment prior to sale;
- Keeping regulation system costs at a minimum;
- Better data protection; and
- Enforcement of data protection for additional uses (use, and recommendations for use of products which are not labelled for a protected use pattern established by the innovator or an alternative supplier later in an active's lifecycle).

Further investigation to determine whether the regulatory system could reduce the impacts of these barriers is warranted.

As the process of funding is complicated, the process of setting the funding model should be left to the current CRIS process that is underway. Both the Regulator and industry are collaborating in this process.

CropLife is supportive of investigating avenues by which cross-subsidisation can be removed or minimised in the regulatory system. While CropLife is not supportive of capping the sales levy at an upper limit, there is merit to assessing whether the current levy structure can be modified. Increasing sales can result in increased risks and costs associated with regulating a product, with the sales levy designed particularly for that purpose. Lowering the sales levy once the initial cost of registration has been fully recouped, however, may be appropriate.

The Panel's consideration of ensuring the funding model of the Regulator does not disadvantage small and innovative registrants is supported and mitigation strategies should be considered, where appropriate. However, the inclusion of a payment plan for smaller registrants is an ill-conceived idea that fundamentally misunderstands the real-world market impact.

A fully modular approach to determining fees has merit. However, this approach would require further consideration and consultation to ensure the modules are fit for purpose, as it would impact the application process as well as fee determination. The introduction of a modular approach to determining application fees must also consider the efficiency and appropriateness of the modular application framework. The current modular levels require review. For example, the current module 2.3 assumes a full data set of product chemistry. An additional chemistry module that assesses limited chemistry studies would be beneficial in scenarios where a full chemistry data package is not required, e.g. where storage stability data is required to address a new pack size. Similarly, an additional module is required for toxicology and WHS that allows assessment of toxicology and worker exposure without the requirement for both modules 3.3 and 6.2. While CropLife supports the consideration of utilising a fully modular approach to applications and fee determination, the benefits associated with non-modular items such as Items 12, 5 and 6 must be retained.

Charging an hourly rate for each application may in fact incentivise the Regulator and individual assessors to be less efficient and to perform unnecessary work and focus more on maximising revenue rather than minimising risk. Setting fees to reflect actual average time spent on the relevant assessment module, and hourly rates reflecting level of assessors involved in the relevant task, should be considered. The review states the opposite of this with the qualification that using external assessors, cost estimates and pressure from applicants would be enough to "ensure" cost are kept to an efficient minimum. History does not support this.

The three underlying principles from the Department of Finance's Cost Recovery Guidelines are:

- Efficiency and effectiveness
- Transparency and accountability
- Stakeholder engagement

The recommendations made by the panel addresses effectiveness, but not efficiency, transparency but not accountability. There are no recommendations to set targets around hours to process modules, or overall timeframes to complete registrations. For example, having a maximum number of hours or a maximum timeframe to complete a registration would encourage efficiency.

Similarly, there is no accountability should any targets or timeframes not be met.

It is common business practice for there to be consequences for not meeting contracted timeframes and KPI's. However, there is no recommendation in this review for relief for registrants if timeframes and KPI's are not met.

Consideration should be given to ensuring that cross-subsidisation in APVMA regulatory effort between agricultural chemicals and veterinary medicines does not occur. As they are two entirely separate industries, cross-subsidisation is not appropriate.

A cost-recovered regulatory environment poses no scope for undue influence from the industry it regulates. CropLife recognises, however, that the perception of independence by the Australian public and therefore confidence in the APVMA would be considerably increased under a public funding arrangement. This would align the APVMA with the Office of the Gene Technology Regulator, which is entirely funded via government appropriation, receiving more than $8 million each year to conduct its regulatory responsibilities.

Comprehensive public funding for the APVMA would address and neutralise the ongoing criticisms from activist organisations who claim the APVMA is not independent of industry as a result of its funding structure. Comprehensive public funding would significantly reduce barriers to market entry for smaller registrants and facilitate the deployment of new products by small and medium businesses tailored for lesser grown crops and smaller industries.

For Business as Usual activities for the year ended 30 June 2019, the APVMA received funding via fees, charges and levies imposed on agricultural chemical and veterinary medicines registrants. Comparable regulators internationally receive a significant level of public funding. For example, the European regulator for agricultural and veterinary chemical products, EFSA, is publicly funded by the EU at a cost of approximately €79 million for 2017[28]

[28] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2017.pdf

($127 million AUD), while the US EPA and Health Canada's Pest Management Regulatory Agency (PMRA) operate on a partial cost recovery basis. Under this arrangement, the PMRA received approximately CAD$36.5 million in government funding in 2016-17, with an additional CAD$7.9 million received via cost recovery.[29] Similarly, the US EPA received US$128.3 million in government funding in 2017, along with approximately US$46 million via cost recovery of industry fees.[30]

While the funding arrangements for agricultural and veterinary chemical product regulation varies around the world, cost recovery is a common funding arrangement for chemical regulation in Australia. The Therapeutic Goods Administration (TGA) is responsible for regulating human pharmaceuticals in Australia. While the TGA receives some government funding in the form of an interest equivalency against reserves, the bulk of their funding is generated through registration fees and charges to industry, via cost recovery. Similarly, the costs of administering the Australian Industrial Chemicals Introduction Scheme (AICIS, formerly NICNAS), responsible for regulating industrial chemicals, are fully recovered through registration fees and charges paid by industrial chemical manufacturers and importers. Similar to Health Canada's PMRA, the regulator responsible for food safety in Australia, FSANZ, operates on a partial cost recovery basis.

The APVMA, TGA, NICNAS and FSANZ all charge registrants for the cost of a product evaluation during the registration process. In this manner, the funding arrangements for human pharmaceuticals, medical devices, industrial chemical products, foods and food additives is the same as that for agricultural and veterinary chemical products. Any consideration that a cost recovery funding arrangement facilitates inappropriate commercial influence on the regulatory process would, therefore, not be limited to the agricultural and veterinary chemical industries. Questioning the independence of the APVMA based on its cost recovery arrangements demonstrates a considerable lack of understanding of the regulatory process, not only for agricultural and veterinary chemical products, but also products from other industries.

CropLife is not aware of any evidence that suggests the cost recovery arrangements used by the APVMA, TGA, NICNAS and FSANZ result in inappropriate industry influence on those regulators' decisions. Despite all Australian cost-recovered chemical regulatory agencies being staffed with scientifically competent, reliable independent public servants and external scientific experts committed to ensuring the safety of all Australians, animals and the environment, there remains some community concern regarding the independence associated with APVMA funding arrangements which causes a serious and significant perception problem for the Regulator.

[29] https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2016-2017.html#a8

[30] https://www.epa.gov/pria-fees/annual-reports-pria-implementation

Providing general revenue funding for the functions that fall within the government's guidelines for public goods and contributing to appropriately resourcing the Regulator to supplement levies and fees would bring it into line with other Australian regulatory agencies, as well as Australia's major trading competitors.

The APVMA's total expenditure for the 2018-19 financial year was $39.9 million, of which more than 80 per cent was cost-recovered from registrants, in the form of application fees, annual fees and levies.[31] Under a cost-recovered funding scenario, the costs associated with registration are borne significantly at the farm gate. Government funding for services that provide a public good would not only significantly improve community trust in the Regulator but also lessen the costs of regulation to farmers.

A 100 per cent cost recovery policy (which under current arrangements can actually exceed 100 per cent) does not appear to be justified given the APVMA undertakes a number of ministerial and public good tasks, many of which are prescribed in the *Agricultural and Veterinary Chemicals Code Act 1994* and the *Agricultural and Veterinary Chemicals Act 1994*.

Consequently, CropLife and our members consider the following functions of the APVMA should be publicly funded:

1. Public affairs and government relations

2. The APVMA Chief Scientist (at least partially)

3. Website and publications (substantially)

   The APVMA website and other corporate publications are for both government and non-government audiences. The website is largely a platform for the communication of information to both industry and the general public.

4. Consultative committees, presentations and seminars

   The agvet industry is not the only recipient of services relating to consultative committees, presentations and seminars provided by the APVMA. Each has an element of providing information to the public and/or other government sectors involved in Federal Government policy.

   Educational and community outreach activities are aimed at building trust in and understanding of the regulatory system by the community and accordingly would be more appropriately funded by government.

5. International capability building, influencing and networking

[31] *https://apvma.gov.au/sites/default/files/images/apvma-annual-report-2017-18-tagged_0.pdf*

6. Risk mitigation oversight activities for the public good

   The APVMA's monitoring, compliance and enforcement activities are critical to supporting and maintaining the integrity of the regulatory system. This does require the APVMA to take a broad approach to monitoring and compliance. The APVMA must not only focus on product registrants and approval holders, but manufacturers and importers that deliberately seek to avoid Australia's regulatory system.

   Publicly funding monitoring, compliance and enforcement activities of pesticides will offer significant benefits to governments, industry and the community. It will:

   - ensure the magnitude and scope of compliance and enforcement activities can be effectively matched to the size of the problem. It will not be restrained by the APVMA's limited budget;
   - demonstrate that registrants and approval holders have not captured the Regulator and increase public perception of an independent compliance function; and
   - facilitate greater voluntary stewardship initiatives by industry to support government compliance functions.

   An appropriately funded regulatory scheme should reflect the commitment of all interested parties to enforcing the scheme. CropLife recommends the Federal Government increase public resourcing for monitoring, reconsideration, compliance and enforcement.

   CropLife recommends it be funded through general revenue, in line with the APVMA's international counterparts. This would improve the Regulator's capability in this important area and neutralise criticisms regarding the APVMA's independence.

   CropLife also recommends public funding of the reconsideration program as the APVMA's reconsideration program is a public benefit function.

7. Minor and emergency use programs

8. Corporate governance

   The annual report is not only an information tool for external stakeholders, but a key government reporting tool required under legislation. The annual report is used by both the Department and the Department of Finance in the preparation of consolidated reports.

   Other corporate publications are also used for a variety of purposes by government and non-government stakeholders.

   CropLife recommends the APVMA should be subject to the same productivity dividends as other government agencies, with dividends either reinvested into core operations of the agency or providing fee relief to registrants. A more equitable split between cost-recovered and government funding should encourage the APVMA and the Department to seek out and implement genuine efficiency and productivity reforms.

8. CONCLUSION

CropLife and our members are supportive of any recommendations to strengthen and support the current regulatory framework, while improving efficiencies and removing unnecessary duplication. In doing so, the scientific and regulatory independence of the APVMA is paramount and any proposals that may seek to undermine or diminish its independence or credibility, or to add additional bureaucratic oversight, are wholly rejected.

The importance of the regulatory system maintaining its technical competencies whilst significantly improving efficiencies is crucial to the plant science industry and the nation's farming sector.

CropLife is pleased that the Panel recognises that regulation should not be unnecessarily restrictive and instead be commensurate with the identified risk and must continue to be risk-based and informed by credible science and evidence.

CropLife and our members have constructively engaged for years in all previous reform agendas and proposed specific initiatives to improve the system, both in its effectiveness and its efficiency. Despite our frustration with the slow process and lack of proper implementation of these reforms, we remain committed to continuing to work constructively with the Federal Government to ensure Australia has the world's best agricultural chemical regulator.

Any future reform must be sensitive to potential disruption to the regulatory system and aim to minimise any likelihood of impacts on efficiency and productivity. Extensive legislative reform can have ramifications for both industry and the Regulator for years. This may threaten access to innovation for the Australian farming sector, because of the lack of operational capability to implement reform within the Regulator.

A detailed proposed implementation plan, including indications of timeframes and consultation opportunities, and assessment of the current regulatory environment in comparison with anticipated efficiency gains provided by the Panel's recommendations, must be provided with the Final Report. A thorough understanding of how the proposed regulatory amendments are likely to impact the regulated industries and users of regulated products over the short, medium and long term would better enable stakeholders to determine their level of support or otherwise of some of the more controversial proposals.

This regulator and associated regulatory framework are at the foundation of Australia's agricultural capability to produce safe food, feed and fibre and improve farming productivity and capability. The Report in its current state falls well short of delivering a step-change or next generation systems proposal that ensures Australia can maximise its future farming success.