CropLife Australia

August 2020

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 *Issues paper – review of the agvet chemicals regulatory system* (the Issues Paper) and commends the Federal Government on their commitment to ensuring the regulatory framework for agricultural chemicals and veterinary medicines is contemporary, fit for purpose and reduces unnecessary red tape.

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]

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

Calls for overdue, targeted and well-considered reform unheeded

Well-considered reform is required to maintain a high level of integrity in Australia's agricultural and veterinary chemical regulatory system and, in turn, maintain community confidence as well as deliver important efficiencies. Without reform, hundreds of millions of dollars will continue to be wasted every year in lost productivity to the farming sector currently and only worsen into the future.

CropLife remains concerned that 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 to deliver real regulatory efficiency.[4]

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 of Agriculture, Water and the Environment (the Department), numerous legislative reforms – which would have significant benefit to industry – are yet to be passed into legislation, 12 months after the Regulator completed its relocation.

CropLife and our members have constructively engaged in all previous reform agendas and proposed specific initiatives to improve the system. 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 world's best when it comes to agricultural chemical regulatory systems.

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

[4] *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*

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. This intent was, however, not clearly represented by the Issues Paper. The majority of the Issues Paper focused on activities performed by the APVMA and compliance and enforcement responsibilities of state and territory governments. While CropLife accepts the Panel's statement that the Issues Paper is not intended to cover the full range of possible reforms that could be canvassed, it is disappointing that more discussion regarding the interactions and overlaps between the various regulators and government agencies was not included. CropLife and our members look forward to discussing the Panel's views on the efficiency of the regulatory environment as a whole in the coming months.

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*[5] and the *Ten Principles for Australian Government Policy Makers*[6] 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*[7] and Regulation Impact Statement (RIS)[8] 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. CropLife anticipates and expects that these best practice management guides for regulation will be considered by the Panel in their draft Final Report.

The importance of ensuring the strength of the supply chain for agricultural chemicals and veterinary medicines – and consequently food security in Australia and globally – has been highlighted by the COVID-19 pandemic. It is therefore appropriate that recent consultation with the Panel indicates they are aware of this omission and will consider this aspect of the regulatory system before making their final report to the Minister.

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

6 https://www.pmc.gov.au/ria-mooc/agrp/overview/australian-government-10-principles-policy-makers

7 https://www.pmc.gov.au/resource-centre/regulation/australian-government-guide-regulatory-impact-analysis

8 https://www.pmc.gov.au/ria-mooc/extra-detail

Proposed vision statement

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

Consideration should be given, however, to the role the regulatory system has in providing our international export markets confidence that the risks associated with the use of agricultural chemicals and veterinary medicines in Australia are competently and responsibly managed. Globally, export markets are becoming increasingly sensitive to the responsible use of crop protection products and potential risks to their consumers. As a nation with an exceptionally high-standard of scientific rigour throughout the regulatory system, Australia should look to be a regional and global example of responsible and judicious use of pesticides to produce high-quality, safe and nutritious food, feed and fibre.

2. THE NATIONAL REGULATION SCHEME

2.1 State of the system

The Panel has correctly identified a number of areas of the current regulatory system worth retaining. This includes: the independent, risk-based approach to the regulation of agricultural chemicals and veterinary medicines; the scientific rigour and technical proficiency of the Regulator; the importance of assessing potential trade impacts; and the requirement to maintain and expand the current minor use grants program. There are also aspects of the regulatory environment that would benefit from further scrutiny and improvement. This could render significant efficiency gains for both industry and the Regulator, and provide greater transparency for product users and the broader community.

There is merit in exploring areas of lower regulatory concern, for which the balance between pre-market assessment and post-market compliance could be adjusted. Nevertheless, pre-market assessment must remain the predominant focus of the regulatory system to maintain confidence in the system.

CropLife agrees that the trends identified by the Panel should be considered when designing the future regulatory system for agricultural chemicals and veterinary medicines.

Consumer market expectations and social license:

As outlined by the Panel, public perception of the health and environmental impacts of crop protection products is increasingly eliciting pressure on farming systems, with a focus on a reduced reliance on synthetic pesticides.

CropLife and our members see an important role for governments and regulators to engage more proactively with the community regarding the regulatory process, to improve trust in the system. While community concerns regarding the safety of pesticides – driven largely by activist organisations and sensationalist agendas of the media – should not be ignored. It would be inappropriate for them to be a primary driver for the design and operation of the regulatory process. Instead, a robust regulatory system should be based on science and evidence. The education of consumers regarding the regulation and safe use of synthetic vs. natural chemicals, while intrinsically linked to the regulatory system, should not form a part of its design or implementation.

Importantly, critical resources required by the Regulator to ensure the safety and efficacy of agricultural chemicals and veterinary medicines should not be diverted away from their core business and community engagement should not come at the expense of regulatory efficiency.

CropLife commends the Panel's aspiration for increasing participation in 'citizen science'. Improved access to affordable monitoring and analytical equipment and techniques, and expanded epidemiological data will enable more informed and robust community discussion about agriculture's social license to operate. Care must be taken to ensure this information is provided to the community in the context of an educational format. Increasing the community's access to raw data and information, without providing appropriate extension services that allow for accurate interpretation of that information, may only serve to increase uncertainty and encourage anti-chemical activism.

The Panel's concluding remarks that the regulatory system may be expected to consider integrated and non-chemical pest management solutions as part of its approval process is contradictory to the premise of more shared responsibility towards the regulation of agvet chemicals. These fundamental aspects of pest management can be successfully managed via a collaborative approach with industry by increased utilisation and support of existing and new stewardship programs. Any suggestion that these practices should be subjected to inflexible regulatory requirements is not supported.

User and consumer safety are CropLife and our members' highest priorities. We recognise the importance of maintaining and strengthening community trust in our role in the food production supply chain. CropLife and its members have a long-standing record and commitment spanning decades to ensuring the responsible use of their products and waste management. We remain committed to the stewardship of crop protection products throughout their lifecycle, ensuring human health and safety, and the responsible and sustainable management of the environment and trade issues associated with agricultural chemical use in Australia. Our member companies contribute millions of dollars each year to stewardship activities to this end.

CropLife ensures the responsible use of these products through its mandatory code of conduct and a suite of world-leading industry stewardship initiatives and programs, including our StewardshipFirst program. The StewardshipFirst program includes 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. We have set a benchmark for industry stewardship through disposing of and recycling farm chemical waste and containers with ***drum****MUSTER* and ChemClear®, as well as Accreditation and Training for the reseller distribution network. These are administered by CropLife's wholly-owned stewardship and safety organisation, Agsafe.

Industry development:

CropLife and our members strongly disagree that company consolidation and mergers in and of themselves have the potential to reduce competitive pressures to drive innovation. Over the last few decades, the cost of successful research and development programs delivering innovative products has increased exponentially. Consequently, one of the most significant threats to innovation is companies not being of sufficient size to resource the necessary research and development. Increasing and expanding the resources and technical expertise available for innovative research and development, whether through corporate mergers or other measures, enables further innovation in an increasingly demanding global regulatory environment.

An extension to the current patent period of 20 years [9] 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*[10] 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.

9 https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents

10 https://www.ipaustralia.gov.au/about-us/legislation/raising-bar-act

Farm practices and electronic (smart labelling):

CropLife does not agree with the Panel's view that new technologies and precision application techniques that result in lower spray volumes will inevitably make the Australian market less attractive to industry. The advances in application technology and novel, innovative product delivery methodologies provide the plant science industry with opportunities to adapt and deliver innovative solutions to pest management.

The Panel's view that the regulatory system should capitalise on the vast amount of expertise and data being generated from farm businesses, universities and the private sector is supported.

As discussed further in Section 7.7, CropLife and our members fully support the development and implementation of smart labels that are machine-readable, to accommodate advances in application technology. The regulatory system must be able to adapt to new technologies.

Additional trends for consideration by the Panel

Consideration should also be given to the following:

- Impact of farm enterprise consolidation, which may be important for harmonised control of use;
- Facilitation of "stage-gating" for non-traditional crop protection products e.g. biorationals, such that various aspects of the regulatory process may be approached via a risk-based approach, with some aspects requiring more or less regulation depending on the risk;
- Facilitation of innovative small and medium-sized enterprises in bringing new technologies to market; and
- The susceptibility of the system to unnecessary litigation as a barrier to access to technology.

2.2 Core objectives of the future system

CropLife supports the overarching primary purpose statement and the simplified hierarchy of objectives.

The proposed objectives are generally supported, with some minor amendments suggested:

- Amend "To promote primary industry" to be "To support primary industry";
- Ensure that the regulations make clear that "To support primary industry" addresses both productivity and sustainability; and
- The objective "To protect animal welfare" is unnecessary as it is already included in the main objective "To protect the health and safety of people, animals…"

While CropLife does not oppose the proposal to remove the current objective "supporting domestic chemical manufacturing", the regulatory framework must protect continuity of supply to ensure domestic food security. As highlighted by the Panel, the current objective referring to fostering domestic chemical manufacturing is not supported by any legislation and appears instead to be an aspirational statement. The COVID-19 pandemic has highlighted 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.

CropLife agrees with the Panel's view that the current objectives for efficiency, transparency and risk-based science are more appropriately expressed as principles governing the design of the system.

2.3 Principles that underpin the system

CropLife supports the principles proposed to guide design and reforms to the future agvet chemicals regulatory system, particularly that "the system should be based on sound science, and be evidence and risk-based in its decision making" and "decisions of the national regulator overseeing approval of agvet chemicals should continue to be independent from government."

The regulation of crop protection products must be entirely independent from commercial, activist and political influence. This ensures that all regulatory decisions are independent and based on credible science with the ultimate objective of protecting the health of users, consumers, animals and the environment.

2.4 Risk- versus Hazard-based system

CropLife fully supports the current risk-based approach to regulation. Any proposal to move towards a hazard-based, precautionary system would be strongly rejected, as it 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.

As highlighted by the Panel, 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.

It is important for governments to provide for appropriate and rigorous regulation of crop protection products. It is equally important, however, that any regulation must be mindful of the effects that poorly considered, duplicative and excessive regulation will have through increasing production costs, discouraging investment and innovation, while not delivering any improvement in safety, health or environmental outcomes. It is inappropriate and confusing for agvet chemicals regulated under a robust, risk-based regulatory framework to be subject to the recently introduced Globally Harmonized System of Classification and Labelling of Chemicals (GHS), which operates on a hazard-based system.

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. The failed implementation of GHS in New Zealand is a key example. There, GHS is not implemented in practice due to the already existing and similar labelling requirements enforced by the New Zealand Environmental Protection Authority. GHS is appropriate for unregulated hazardous chemicals and for all hazardous chemicals in developing countries that don't have an appropriately funded, independent and technically proficient agricultural chemical regulator.

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 Therapeutic Goods Administration (TGA) approved labels for pharmaceutical chemicals received and continues to 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 of Agriculture and Water Resources 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[11]. The additional GHS hazard and precautionary statements to be included on the small, already crowded APVMA approved agvet chemical labels 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.

All state governments except for Victoria and Western Australia have implemented Safe Work Australia's Model Regulations, with compliance mandatory 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.

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

3. REGULATION AND CONTROL OF USE OF AGVET CHEMICALS

3.1 Regulation of the supply of agvet chemicals

CropLife agrees with the Panel's view that the current approach to the regulation of agvet chemicals of a single national regulator should remain unchanged.

3.2 Leadership of reform

CropLife has been vocal in not supporting the introduction of a Governance Board for the APVMA in the form proposed at this time. The APVMA's previous Governance Board was abolished in 2007, following recommendations made in the independent Review of Corporate Governance of Statutory Authorities and Office Holders (the Uhrig Review).[12] 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.

CropLife and our members do not, in principle, oppose governance structures like a board of directors. It is essential, however, that appropriate analysis and genuine industry and farmer consultation be conducted regarding the development of a governance arrangement that could add genuine value to the APVMA, rather than just adding an additional layer of costly administration and management.

Despite our lack of support for the urgency and necessity of a Governance Board for the APVMA, CropLife has previously provided the Department with specific criteria required for a Governance Board to be effective and protect the independent evidence- and science-based decision-making of the APVMA.

If a Board were to be introduced, the direct and associated costs should be fully funded by the Federal Government as an appropriate contribution to the effective operations of the Regulator. Without government funding, the cost of a governing board would be an additional direct cost to the farming sector, further limiting access to crucial crop protection products by farmers. The approximately $600,000 a year cost attributed to the APVMA Governance Board, as referenced in Senate Estimates[13] 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.

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

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

CropLife is not opposed to the introduction of an overarching, temporary steering committee, with representation from industry, to oversee implementation of any future regulatory reform. This arrangement could assist with ensuring any reform is implemented efficiently and pragmatically. The effectiveness of such a committee, however, would be highly dependent on its representation and terms of reference. Careful consideration regarding the appropriateness of those selected to participate in the committee would be essential for its success.

Options 3, 4 and 5 as outlined in the Issues Paper are not supported, as they have the potential to compromise the Regulator's scientific integrity and political independence.

3.3 Control of use

CropLife strongly supports the 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.

As a matter of principle, 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 for assessing the relative risks of using crop protection products in a manner that is not outlined on registered product labels on farmers.

CropLife remains concerned that the former Council of Australian Governments (COAG; now National Federation Reform Council, NFRC) 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.

Expanding the labels of registered agricultural chemical products to include minor uses and specialty crops ensures that Australian farmers have improved access to important crop protection tools via a legal, regulated pathway. Where label registration has not yet occurred, APVMA permits provide an alternate legal and regulated pathway where there are no registered alternative crop protection options.

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.

CropLife does not have a strong view regarding the most appropriate pathway to create a nationally consistent control of use program. Option 3 as outlined by the Panel does not appear feasible. It appears to replicate the approach taken to date, with little success.

The regulatory framework must protect continuity of supply to ensure food security. 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. Food safety and security are national issues and, accordingly, the control of use of critical farm inputs that ensure ongoing food safety and security – including crop protection products – should be managed nationally.

3.4 Shared responsibilities between industry and government

CropLife is generally supportive of shared responsibilities between industry and government regarding the safe and responsible use of agricultural chemical products where appropriate. This is evidenced by our strong commitment to product stewardship and mandatory code of conduct.

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 an additional statutory duty of care for registrants is redundant and unnecessary for CropLife member companies. Recognition of CropLife membership and subsequent requirement for adherence to the mandatory code of conduct would be recommended if a statutory duty of care were to be implemented.

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 35.8 million chemical containers and 745,341 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.[14]

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 all member companies to ensure that all Intermediate Bulk Containers (IBCs) supplied with products are part of a returnable scheme. Already, more than 90 per cent of products supplied in IBCs by CropLife member companies are eligible. 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.

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

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.

As such, CropLife rejects the Panel's suggestion that the majority of agvet chemical companies take part in the co-regulatory APCO framework through a condition of registration. Through our mandatory code of conduct, CropLife membership ensures that packaging materials for all products are eligible for participation in a return or recycling scheme, where they exist.

3.5 Compliance and enforcement

CropLife is supportive of a national approach to compliance and enforcement regarding the safe and responsible use and supply of agvet chemicals. The Panel's view to a national approach to compliance and enforcement of agvet chemicals is supported, as is the proposal to design such a system that allows the Regulator to focus their regulatory activities on those that pose the greatest risks to the integrity of the system.

It is important that once off-label use provisions are harmonised between state jurisdictions, the approach to managing those measures and monitoring compliance with them is also harmonised. Implementing harmonised state control of use laws pertaining to off-label use of agricultural chemical products but allowing for variation in enforcing and managing those laws, will fail to reduce confusion among farmers, agronomists and manufacturing companies attempting to adhere to those legal requirements.

As resources available for monitoring and compliance enforcement vary between jurisdictions, the ability to appropriately manage such uses would also vary between jurisdictions, creating additional inequalities. A nationally consistent compliance program would mitigate this.

CropLife has long advocated for increased compliance and enforcement powers to be granted to the APVMA, which were introduced in the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013*. The APVMA appears to have utilised the increased ability to enforce compliance to good effect. Noting the significant and growing problem of counterfeit and illegal crop protection products around the world, it is crucial that the APVMA has all necessary powers and ensures that its compliance and enforcement efforts remain focused on the highest threat and risk areas to the community and farming sector.

An appropriately funded regulatory scheme should reflect the commitment of all interested parties to enforcing the scheme. As both the APVMA's and state and territory compliance and enforcement capabilities perform a public benefit function, CropLife recommends it be funded through general revenue, to further improve the Regulator's capability in this important area. An appropriately funded minor use and specialty crops program that provides growers with registered products and uses is urgently required before nationally harmonised compliance and enforcement provisions are introduced.

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;
- Not be restrained by the budgetary constraints of the federal and state and territory regulators;
- 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.

4. SCOPE OF THE REGULATORY SYSTEM

4.1 Proposal to limit scope to chemicals used by primary producers, veterinarians and non-urban land managers

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. Reducing the APVMA's product category regulatory scope will substantially improve the efficiency of the APVMA's core registration operations. Removing such products from the APVMA's regulatory focus will allow it to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

Removing the regulatory duplication of whole viable seeds is also 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 Office of the Gene Technology Regulator, Food Standards Australia New Zealand 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 does not support the proposal to remove home and garden and non-urban land management pesticides from the scope of the APVMA. The Panel acknowledges the importance of building a regulatory framework that responds sensitively to growing community concerns and maintains community trust in the use of agvet chemicals. 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.

CropLife does agree with the Panel that these products are of low regulatory concern. However, as they are identical to the products registered by the APVMA and proper use remains important, it is appropriate that they remain in the regulatory system.

CropLife does support the Panel's view that regulatory effort should be rationalised to more accurately reflect the regulatory risk posed by a particular product or chemical, to 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,[15] which could be used to develop a simplified pathway to market for these products, without compromising the integrity of the regulatory system or confidence in it by the wider community.

15 https://apvma.gov.au/node/871

4.2 Co-regulation of agricultural chemicals and veterinary medicines

CropLife supports the continued co-regulation of agricultural chemicals and veterinary medicines under the same regulatory framework. As a result of the cross-over between assessment criteria, staff at the APVMA are suitably qualified to assess both agricultural chemicals and veterinary medicines. In addition, a single regulator allows staff to gain experience in both streams, ensuring a larger pool of regulatory experts across both agricultural chemicals and veterinary medicines. Separating the regulation of agricultural chemicals and veterinary medicines would lead to greater specialisation of regulatory staff towards one stream or the other, further compounding the shortage of appropriately qualified regulatory staff in general.

It is likely that costs to registrants would increase if agricultural chemicals and veterinary medicines were regulated separately, as costs associated with administering the legislation would be doubled. However, as they are two entirely separate industries, it is not appropriate that any cross-subsidisation in the registration effort of the APVMA between the two categories of products occurs.

5. GAPS IN THE CURRENT REGULATORY SYSTEM

5.1 Assessment of chemicals by boundaries other than state borders

CropLife and our members are, in principle, supportive of considering whether there is merit to assessing crop protection products by boundaries other than state borders. 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.

Assessing crop protection products by region has merit where there are genuine biological reasons, such as soil type. The APVMA currently assess streamflow as part of their environment assessments, which is not restricted by state or territory boundaries.

Care must be taken, however, to ensure that 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.

CropLife and our members are not convinced that assessing crop protection products by pest type would provide similar benefits. Grouping of pests is currently performed during research and development by assessing the sensitivity of different species from the same family to a chemical to determine whether efficacy claims apply to multiple species. Implementing a "pest grouping" assessment boundary would not be applicable for all chemicals.

5.2 Benefits Test

The concept of providing a pathway by which the APVMA can better prioritise and manage their workload is supported. CropLife is not supportive, however, of a Benefits Test as a condition of registration, similar to the process in New Zealand. This type of benefits test poses barriers to registration that can significantly delay the registration of products.

In order to achieve the outcome of providing the APVMA with a mechanism for prioritising and managing their workload, CropLife proposes a more nuanced approach to focusing regulatory action be considered. This could simply involve increasing the Regulator's resources for assessing innovative application types with the aim of reducing timeframes in those areas (for example, by 10 per cent). This would not only focus regulatory attention on new actives/products, but also new formulations/combinations etc. to assist with issues such as resistance management, by ensuring growers have access to these products in a timelier manner. This approach would be based on application type, rather than specific active constituents or products and the ability of the registrant to demonstrate a clear benefit to the agricultural industry or society.

The current inability for the APVMA to prioritise applications it receives prevents it from being able to participate in Global Joint Reviews. Enabling the APVMA to implement some kind of prioritisation process will therefore 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.

Further consultation with industry and the APVMA would be required to determine which application types would be included in the approach and whether the existing application types remain appropriate for a prioritisation process.

5.3 Assessment of chemical combinations

The panel acknowledges that the European Food Safety Association (EFSA) recently completed two pilot studies investigating the cumulative effects of pesticide residues. These studies concluded that the consumer risk for dietary cumulative exposure is below the threshold that triggers regulatory action in the EU.[16]

The APVMA currently assess the potential environmental risks associated with chemical combinations where mixtures are compulsory. As the Panel acknowledges, however, it would not be possible to consider every possible combination of chemicals.

In addition, the current pharmacovigilance and adverse experience reporting program provides the APVMA with the power to investigate potential impacts of chemical combinations as required, via the chemical reconsideration (review) process.

5.4 Utilisation of Data Mining to improve efficiency

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 would not be subject to misuse. International data mining is already widely used by registrants to support Australian registration applications.

Data mining for agricultural chemicals poses unique challenges due to the involvement of biological systems, which are often subjected to uncontrollable variables such as the weather. As a result, it can be very difficult to compare data sets.

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.

16 https://www.efsa.europa.eu/en/news/cumulative-risk-assessment-pesticides-faq

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, however, for regulators to undertake this work, as it would add a significant additional layer of complexity to the Regulator's responsibilities.

CropLife does not support mandatory requirements to report pesticide use data to the Regulator. It would, however, be useful information to collect where permits are used to give confidence to move minor use patterns to label claims.

5.5 National domestic produce and environment monitoring system

It is a long-held CropLife position that any produce and environment monitoring should be managed and appropriately funded by the Commonwealth. 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. 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 National Residue Survey (NRS), is that compliance among growers is good and the risk to consumers from pesticide residues is low. It is important to note that the NRS monitors the presence or absence of agricultural chemicals and veterinary medicines, or other contaminants, in produce, according to maximum residue limits (MRLs). MRLs are set by the APVMA at levels that pose no risk to human health and are not likely to be exceeded when used in accordance with the directions on the label. In 2018-19, more than 99 per cent of samples indicated compliance with registered label directions.[17]

The need for such 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*. This Inquiry is currently examining 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. It is essential that the scientific method behind the approach to produce or environmental monitoring is sound, transparent and appropriately validated.

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

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 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 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 agvet chemicals industry of poorly communicated results, due to inadequate monitoring and reporting schemes, in terms of reputational damage cannot be understated.

Similarly, in order to fulfil a meaningful purpose, monitoring programs must be associated with adequate trace-back processes. The NRS utilises such a trace-back process, to ensure that any 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.

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 minor use and specialty use program that provides growers with registered products and uses is urgently required, however, before national reporting programs are introduced.

6. COMMUNICATION AND ENGAGEMENT

6.1 Community engagement

It is crucial that the Australian public has confidence in the APVMA, as an independent, science- and evidence-based regulator of agricultural and veterinary chemical products. CropLife supports the Panel's view that the APVMA should identify, in consultation with governments, community and industry, the information required to support the agvet chemicals sector and the community.

The APVMA and the Department should both play greater roles in educating and reassuring the community regarding the Regulator's purpose, processes and decisions. The APVMA has been absent in this space, specifically in the last few years when there has been a critical role to play. 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.

In December 2019, the APVMA began consultation on their draft Stakeholder Engagement Framework and accompanying Stakeholder Engagement Activities. The final Framework and Activities have not yet been published. CropLife commends the APVMA's plans to engage with the broader community regarding their role in the regulation of agricultural chemicals and veterinary medicines in Australia and instill greater confidence in that process. This activity again highlights why government should be covering the cost of the public good activity of the APVMA.

More proactive and effective engagement with the media by the APVMA and the Department is required, to ensure that sensationalist, misinformed commentary is not permitted to dominate the public discussion regarding the safe use and regulation of agvet chemicals. 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.

Similarly, CropLife recommends the Regulator engages proactively and effectively with local councils to educate them regarding the APVMA's regulatory activities and scientific assessment processes. This is not part of the APVMA's draft Framework. Local councils are often the first point of contact for residents regarding concerns they may have with the safe use of pesticides in their community. This has resulted in a number of local councils reviewing their pest control strategies and even ceasing the use of some products that the APVMA has determined are safe and effective when used according to label directions.

Under the APVMA's current cost recovery arrangements, industry is subsidising the costs associated with a number of public good activities. This includes stakeholder engagement activities aimed at educating the community regarding the APVMA's regulatory activities. 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 if these specific public benefit functions were financed via a public funding arrangement.

6.2 Stakeholder consultative forum

In principle, CropLife supports the implementation of a formal consultative forum for stakeholders, similar to the UK model. A clear purpose with well-defined objectives must be developed to ensure the Panel is sustainable and contributes positively to the regulatory process. We do note, however, that the current acting Chief Executive Officer of the APVMA has recently started taking a number of actions in terms of stakeholder engagement.

Care should be taken regarding the forum's representation, to ensure it is reflective of society and does not simply provide a voice for activist organisations fundamentally opposed to the use of agricultural chemicals and veterinary medicines, 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.

The APVMA currently undertakes public consultation on various regulatory matters, as required, 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 timeframe, 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.

Any consultative forum for public engagement that provides specific public benefit functions should be funded by government.

7. SIMPLIFYING THE REGULATORY ENVIRONMENT

The Panel correctly observed that the current agvet chemicals regulatory system is a complex, multi-layered network of primary legislation and supporting legislation, instruments and policies, with responsibility shared across multiple agencies and jurisdictions. This review provides a unique opportunity for this complex regulatory framework to be examined more closely.

Too often, the interactions between multiple regulatory and government agencies result in considerable delays and reduced efficiency in the regulation of these products. In addition, these interactions can result in confusion among the regulated industries, end users of the products and the general community regarding the responsibility for ensuring the safe and responsible use of agvet products. This review provides an opportunity for any inefficiencies experienced as a result of the interactions and possible overlaps between the APVMA, Therapeutic Goods Administration, Safe Work Australia, Office of the Gene Technology Regulator, Food Standards Australia New Zealand, the Dangerous Goods Code etc. to be examined in detail.

The Therapeutic Goods Administration of the Department of Health is responsible for classifying agricultural and veterinary chemicals into schedules, which sets the level of control on their availability and requirements for labelling and containers, to be implemented by the states and territories. These schedules are published in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

The delays and unpredictability associated with poison scheduling have long been a serious concern of the plant science sector, as they lead to unnecessary delays to the introduction of new and innovative crop protection products to the Australian market. All too often, and for reasons outside of the applicant's control, one of the three lodgment deadlines for scheduling applications each year are missed, delaying the introduction of critical crop protection tools that Australian farmers desperately need. Many crop protection products have short annual application windows and the four-month delay until the next lodgment deadline is effectively an entire farming season.

Poison scheduling is a necessary and useful undertaking, ensuring adequate controls on how medicines and chemicals are made available to the public. CropLife's concerns are specifically regarding the inefficiency and unpredictability of the process, which not only delay the introduction of new and innovative products into the Australian market but are also out of step with the Global Joint Reviews (GJRs) process. Agricultural chemical products associated with GJRs are registered and available for use in all GJR international jurisdictions other than Australia. This is solely due to unnecessary processes and structural delays associated with poison scheduling in Australia. These unnecessary and costly delays in product availability will continue until the scheduling system significantly improves its timeliness and predictability.

Previous attempts to improve efficiency within the poisons scheduling process regarding agvet chemicals have had the commendable intention of rectifying these pitfalls, however, they have not delivered on their intent.

CropLife members also experience inefficiencies by attempting to adhere to both the *Australian Dangerous Goods (ADG) Code* and the *International Maritime Dangerous Goods (IMDG) Code*. Due to minor differences between the two Codes, imported chemicals in Intermediate Bulk Containers (IBCs) must be relabeled from IMDG to ADG if transported within Australia after arrival, at a significant cost to registrants. Likewise, IBCs must be re-labelled from ADG to IMDG if transported by sea. CropLife encourages the Panel to examine this process more closely and proposes that the dangerous goods requirements in Australia be aligned with international requirements.

Similar efficiencies would be realised by removing the requirement for embossed/indelible ink signal words on agricultural chemical containers. This requirement is specific to Australia, which makes it difficult, time consuming and costly to obtain suitable containers.

Any product classified under Schedules 6 or 7 of the Poison Standard requires containers to either be embossed with, or have written in indelible ink, the word "POISON." Schedule 5 products can either follow the same requirement or use the alternate words "NOT TO BE TAKEN" or "NOT TO BE USED AS A FOOD CONTAINER". Alternatively, they can have a permanent adhesive label. In practice, these requirements are inefficient and reduce flexibility in the use of containers in stock at manufacturing sites. In addition to providing no perceivable benefit to product users, this requirement simply creates an unnecessary additional regulatory requirement to which CropLife's members need to adhere. The COVID-19 pandemic has highlighted that any potential impediments to the crop protection product supply chain have the potential to significantly impact Australia's food security and should be mitigated.

CropLife is keen that the Panel acknowledges the need for action regarding the regulatory environment in Australia as a whole and how more efficient mechanisms could be implemented to deal with changing regulatory requirements.

Crop protection products have one of the most complex regulatory requirements of all chemicals in Australia. The regulatory environment includes a mixture of federal legislation (administered by the APVMA), state and territory legislation (control of use), model federal legislation partially adopted and/or modified in state legislation (e.g. GHS labelling) and federal codes fully referenced in state legislation (e.g. ADG Code).

Subsequently, there is often a long lag-period before reform is enacted on following changes to update obsolete legislation. Again, a prime example is the COAG 2010 (now NFRC) direction to the now Agriculture Minister's Forum to develop a national framework for harmonised agricultural chemical regulation in Australia, which still has not yet been delivered.

Recognition of the extremely complex, interconnected and evolving environment the agricultural chemical and veterinary medicines industries are operating in demands the acknowledgement that any future reform is likely to require amendment.

Rather than follow recent precedents like the GHS labelling, which was foisted on industry without recognition of existing measures to manage user safety, the future regulatory environment must be designed to reflect the broader operating environment and be flexible and responsive to change. Similarly, mechanisms such as those used in the ADG Code should be preferred where changes to the Code can be made without having to change each state or territory's regulations. This will avoid the ill-conceived introduction of model regulations that are selectively adopted or modified and then embedded in each state or territory's own regulations.

7.1 Repack options

CropLife and our members are supportive of simplifying and streamlining the repack application process and can see merit in further exploring the Panel's recommendation that repack applications become a declaration/notification process. An opportunity for the Regulator to confirm that a formulation is in fact the same as the reference product must be retained.

In the event that the registration of the pioneer product is cancelled, CropLife and our members consider it appropriate to also cancel the registration of all repacks, except where the registration holder is in possession of appropriate data and product information.

7.2 Efficacy as a criterion for registration

While CropLife agrees with the Panel that there is merit to investigating whether the current efficacy requirements and assessment process remain appropriate and fit for purpose, the proposal to remove the requirements for efficacy assessments entirely for crop protection products is not supported.

CropLife acknowledges that the efficacy of agricultural chemical and veterinary medicine products is covered by Australian Consumer Law. The Panel is correct in their view that the consequences of a product being inefficacious would, in some cases, be considered a safety factor, which requires scrutiny by the Regulator. CropLife and our members contend, however, that the consequences of a crop protection product being inefficacious go beyond human safety and could contribute to the spread of a significant pest, or potentially to the development of resistance.

In general, CropLife members do not experience significant delays to registration approval as a direct result of efficacy assessments. Regardless of whether the data is required by the Regulator, CropLife members will generate efficacy data to determine use recommendations and resistance management data.

CropLife is interested, however, in further exploring options to amend the current efficacy requirements and streamline the assessment process. This would potentially allow reallocation of some of the APVMA's resources into other assessment areas and create efficiencies throughout the assessment process. Further consultation with the APVMA, industry, governments and growers is required to identify the specific requirements for demonstrating efficacy in Australia.

CropLife is supportive of the APVMA utilising accredited external efficacy assessors to allow the assessment to be completed prior to the application being submitted to the Regulator. CropLife is also interested in further exploring the potential for increased reliance on international efficacy assessments, providing that local conditions were not instrumental in determining efficacy. This may allow more clarity and simplification of the requirements for Australian-specific efficacy data to support an international assessment.

The proposal to establish arrangements where the past behaviours and current stewardship practices of an applicant warrant reduced pre-market scrutiny of a product's efficacy is not supported. Such an arrangement could erode community confidence in the regulatory system and be used by activists to promote the incorrect view that industry has "captured" the APVMA.

7.3 Greater use of standards

The Panel's view that maximizing the use of standards could lead to significant efficiencies for both the Regulator and industry, by simplifying and streamlining the regulation process, is supported. Any framework for setting standards should be developed collaboratively by industry and the APVMA. CropLife and our members see a role for industry to contribute to the initiation, development and amendment of standards, where appropriate, noting that the Regulator has an important role in setting and amending standards as required.

The use of standards should be limited to products of low regulatory concern, to minimise the risk to both the registrant and growers.

7.4 Acceptance of international regulatory decisions

CropLife and our members support the Panel's view that the Australian regulatory system should take full advantage of the work of comparable regulators and focus regulatory effort on the issues that are unique to Australia. Further consultation with the Regulator, governments, industry and growers is required to further identify and characterise these unique requirements.

The APVMA currently has the ability to utilise international data and regulatory assessments to assist in making regulatory decisions. This considerably reduces the administrative burden on the Regulator and streamlines the registration process. In our members' experience, this

practice has resulted in improved assessment timeframes. Any proposal to increase this utlisation of international regulatory data to accept regulatory decisions should not be considered without concurrent implementation of a registrant accreditation program, as outlined by the Panel in Chapter 2 (shared responsibilities) of the Issues Paper.

A default acceptance of decisions from comparable international regulators may not be appropriate for all assessment areas. As identified by the Panel, international assessments may not adequately consider Australia's unique environment and practices. Further characterisation of those unique conditions would assist in determining which aspects of an international regulatory decision may be acceptable (e.g. chemistry and manufacture, human health) and where local data were necessary (e.g. residues and trade, efficacy and crop safety and environment). Greater clarity regarding the requirement for Australian-specific data and more efficient utilisation of data assessments from relevant international regulators would more effectively reduce duplication by the APVMA.

CropLife supports the Panel's view that an international decision to ban an agricultural chemical or veterinary medicine should not influence the registration status of that product or active constituent in Australia. As correctly stated by the Panel, the APVMA's decision to ban a specific chemical must be based on the Regulator's satisfaction that the statutory criteria for registration continue to be met.

CropLife is of the opinion that the APVMA should be responsible for determining the comparability of another regulatory system to maintain the independence of the Regulator in making science- and risk-based decisions without political influence.

7.5 Minor use and emergency permits

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

In the 2014 Federal Budget the Federal Government committed an initial $8 million over four years towards helping farmers gain improved access to safe and effective agricultural chemicals. Further funding of $4 million over two years was announced in the 2018 Federal Budget towards correcting the market failure caused by a mandatory regulatory system, by better enabling the inclusion of minor uses and specialty crops on agvet labels. In August 2020, the Government committed to an additional 12 months of the *Improved Access to Agricultural and Veterinary Chemicals* program with funds to be allocated in the upcoming Federal Budget.

These investments, leveraged by additional funding from CropLife, its members and research and development corporations, have begun to deliver significant value to the Australian agricultural sector through the approval of label uses for minor use crops and specialty uses. In 2017:

- 360 unique crop/pest issues were identified by grower industry bodies;
- 160 of these had no identified solution, for which 51 new potential solutions were identified by registrants; and
- An additional 64 new solutions were identified by registrants adding to existing options proposed by industry.

The economic gains achieved 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.

The Department has received grant applications totaling over the $8 million allocated. This shows significant demand and need for an additional and ongoing funding commitment.

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, however, dependent on adequate resourcing within the Regulator.

CropLife commends the APVMA on their approach to assessing and issuing emergency use permits. The recent fall armyworm incursion and the APVMA's swift response to assessing and issuing a range of emergency use permits to control the pest highlight the importance of such a process for managing biosecurity pest incursions.

To encourage registrants to include additional uses on labels as data become available to support them, increased data protection for new label use patterns on existing registered products should be considered. Currently, when the primary data protection has expired from an initial application, new label use patterns can be developed at significant cost to innovators, which receive five years data protection by the APVMA when registered.

Unfortunately, the current data protection provisions are ineffectual due to the off-label use of products containing the same active constituent, as users follow the instructions registered by the innovator. Compliance and enforcement action is rare in regard to this practice and, compounding the issue, it is legalised by some states under their off-label use scheme. Again, this scenario highlights the necessity of harmonised control of use and compliance provisions.

The ultimate effect of this regulatory pitfall is that innovators are less inclined to invest in developing new use patterns. Subsequently, growers are denied access to valuable crop protection tools and industry levy payers are required to invest in generating data to support permit applications.

7.6 Chemical review timeliness and efficiency

CropLife agrees with the Panel that chemical reconsiderations should focus on specific areas for which new, credible scientific information indicates a review is warranted, rather than requiring the APVMA to reassess all aspects of the original approval. The APVMA already has the ability to focus a review on specific assessment areas for which data indicates a review is required. For assessment areas where there is no new scientific information to justify a reconsideration, the APVMA may remain satisfied that the regulatory criteria continue to be met by the original regulatory assessment.

CropLife supports the Panel's view that chemical reconsiderations (reviews) should be risk-based and triggered by new information, rather than calendar-driven. Similarly, the Panel's view that calendar-driven reviews do not provide better outcomes in terms of human, animal or environmental safety is supported. The Panel has correctly determined that calendar-driven reviews require considerable additional resources. Internationally, these reviews are supported by significant public funding that the APVMA does not receive. Any shift to a calendar-based review system would place enormous pressure on the APVMA's resources, which would have the likely outcome of delaying the review process and distract the Regulator from assessing genuine areas of concern.

In 2006, Health Canada's Pest Management Regulatory Agency (PMRA) introduced a 15-year cyclical re-evaluation process. In addition, the PMRA may initiate a Special Review at any time, diminishing the relevance of a simultaneous 15-year re-evaluation program considerably. In some cases, products under routine re-evaluation have been subjected to a Special Review at the same time. This creates unnecessary duplication of effort and administrative burden for the Regulator.

Despite considerable public funding, the PMRA has publicly stated that the current re-evaluation workload is not sustainable. With more than 70 active constituents scheduled for cyclical re-evaluation, the agency lacks the resources to cope. The number of re-evaluations is expected to increase significantly over the next 10 years, as around 370 older active constituents re-evaluated in the early 2000s are scheduled to enter the cyclical re-evaluation system.

Canada's burdensome re-evaluation process has already resulted in lengthy delays to finalisation timeframes and as such, the PMRA is on the brink of being completely overwhelmed by this massively increased workload.

The EU re-assessment program is similarly not delivering the desired outcomes in a timely fashion, with few scheduled re-assessments finalised since its introduction in 2007. When compared with single jurisdiction countries, such as Australia, the US and Canada, the EU regulatory system, with the ability to split the considerable regulatory burden of re-assessing all chemicals every 10 or 15 years[18] among member states, should be more capable of managing a cyclical re-assessment program. Noting that approval is extended where the re-assessment is delayed for reasons beyond the control of the applicant[19], it is difficult to see just what this process is achieving, other than draining the regulator's resources, clogging up the regulatory system and distracting European regulators from reacting to, and assessing genuine areas of concern.

The US EPA also conducts registration reviews of registered pesticides every 15 years and has the ability to conduct a Special Review at any time. As of the end of the 2017 financial year, the US EPA had completed and implemented the final decisions of less than one-third of registration reviews commenced since 2007.[20]

Similar to Health Canada and the European regulatory systems, the demonstrated inability for the US EPA to implement a successful, efficient re-registration program, despite receiving substantial government funding, serves to highlight that such programs are not feasible and do not serve the best interests of the community. The inability for these much larger and highly resourced international regulators to cope with the increasingly burdensome cyclical re-evaluation shows why introducing a similar, unnecessary and duplicative calendar-based system in Australia should be avoided.

7.7 Smart labels

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, transport and use restrictions continue to remain affixed to the container to ensure that the ability for growers to use products safely and responsibly is not compromised.

It is important to recognise that there is a 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.

The provision of physical labels incurs considerable costs to the registrant, not only to print the labels but also to provide information when they are required to be updated. There is also considerable waste associated with these high-volume product leaflets, with subsequent poor environmental outcomes.

18 *Active substances are renewed for 15 years under the current Regulation (EC) 1107/2008 Article 14.2, and for 10 years in the preceding legislation Directive 91/414/EEC Article 4.4*

19 *Regulation (EC) 1107/2009, Article 17*

20 *https://www.epa.gov/sites/production/files/2018-03/documents/mf-accomp-reevaluation-fy17-final_1.pdf*

Ideally, a complete phase-out of physical label leaflets will be possible. 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 up-to-date information regarding the use requirements for the product, including alerts relating to chemical reviews, product recalls and label variations. As many growers may not have access to reliable communication networks, a transition phase whereby instructions for use are available to users in a physical form, should they not have the means or inclination to utilise smart labels, may be appropriate.

Further consideration of the information that is 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.

The introduction of smart labels highlights the necessity for nationally harmonised control of use and compliance legislation. While CropLife considers that the current control of use legislation allows for the introduction of smart labels, the interpretation of that legislation and specific requirements could vary from state to state, resulting in confusion and contradictions between states and territories. Importantly, some label content (e.g. dangerous goods, poisons scheduling and GHS) fall outside the jurisdiction of the APVMA and should also be considered in terms of control of use and compliance.

CropLife is supportive of mandating labels for containers above a certain volume to be machine-readable, to ensure consistency throughout the market.

The acceptance of smart labels will facilitate the adoption of local risk assessment tools for growers to increase productivity by no longer requiring unnecessary red tape and “worst-case scenario” regulation, without compromising human, animal or environmental safety. This concept expands on the one proposed in Stage 2 of the APVMA’s spray drift policy.

Currently, the APVMA 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. Therefore, 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.

8. CAPACITY BUILDING

8.1 International networks of expertise

CropLife supports further development of, and participation in international networks, noting that the APVMA and the Department already participate in a number of international committees and forums. Involvement and participation in international forums and access to international expertise is becoming increasingly important, as technology and community expectations evolve. Adequate resources must be provided to the APVMA to ensure that participation in international forums does not detract from the Regulator's core business of assessing registration applications, permits etc. Similarly, as the interest in food production systems and the use of chemical inputs increases within the broader community, there is merit in establishing stronger connections with experts and organisations with the field of scientific communication.

Providing the APVMA with the ability to prioritise the registration assessments they receive will enable greater participation in global joint reviews.

8.2 Operational regulatory working group

The Panel's view that an operational group of regulators across jurisdictions focused on addressing regulatory issues has merit. The proposal to reinvigorate the Registration Liaison Committee to focus on its original intent is supported. This Committee would be ideally placed to provide a supporting framework for technical working committees such as the National Working Party on Pesticide Application, to assist in the development of technical information to inform regulatory operations and guidance.

CropLife does not support the formal consultative forum proposed by the Panel in Chapter 5 of the Issues Paper (discussed in Section 6.2) informing regulatory operations and technical working committees. The operational regulatory working group must be familiar with the APVMA's legislation and operational processes and should operate independently from a forum primarily focused on community engagement. Participants on the consultative forum would not be expected to have the relevant level of technical expertise to contribute meaningfully to an operational regulatory working group. A more appropriate operating process would be for the objectives and outcomes of the operational regulatory working group to be reported back to stakeholders via the consultative forum.

8.3 Third-party accredited assessor

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 in regulatory scientists 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 utilised in certain scenarios. The unique aspects of the Australian environment and agricultural industry, as well as the regulatory environment, would in some cases require local expertise.

CropLife supports the proposal to implement an audit and compliance program to ensure the quality and consistency of third-party assessors. Any additional costs associated with the audit and compliance of third-party assessors should be covered by an annual accreditation fee.

8.4 Additional capabilities for adoption of future technology

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.

Determining the most appropriate process for regulating any new scientific or technological advances requires clarity regarding the potential risks that require regulation. This will ensure appropriate, proportionate regulation, rather than regulation for regulation's sake, simply because a new concept has been introduced to the industry.

Greater use of the experience and commercial nous of registrants would assist in determining likely future trends in both product and application technologies. CropLife member companies often operate according to a 10-year future view of emerging technologies. It would serve the interests not just of industry, but also the Regulator and end users, for the Regulator to have greater awareness of those emerging technologies and to be prepared for their regulation prior to their commercialisation. This currently occurs to varying degrees in countries including Canada, USA, the UK and South Africa.

By seeking annual updates from registrants regarding which new technologies are emerging through the product development pipeline would allow the Regulator to prepare for the introduction of these new technologies prior to their commercialisation and release. Likewise, participation in international forums regarding technology development and their regulation should be encouraged. However, it must be noted that these are highly sensitive commercial matters with billions of dollars annually in research and development associated with the delivery of new chemistry.

9. FUNDING THE NEXT GENERATION REGULATORY SYSTEM

9.1 Are the current funding arrangements fit for purpose?

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

A sales-based levy subsidises chemicals of low market value 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* (the Report) was published in 2014. Not one of the Report's recommendations have been implemented.

A second First Principles Review was commenced in 2018 but remains uncompleted. In the absence of this work, 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.

Implementation of the Cost Recovery Regulations 2020 are premature and a comprehensive First Principles Review of the APVMA's cost recovery arrangements is urgently required to bring the Regulator's funding arrangements up-to-date.

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 APVMA's performance (timeliness and efficiency).

We concur with the Panel that consideration of an alternate option to the old revenue raising model supporting 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 urgently 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 acknowledged that the relatively small market for agricultural chemicals compared with, for example, 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 correctly acknowledges that aspects of the regulatory system relating to market size cannot easily be overcome by governments. Further investigation to determine whether the regulatory system could reduce the impacts of these barriers is warranted.

9.2 Cost recovery arrangements in the future

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 that mitigation strategies should be considered, where appropriate.

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 OH&S 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.

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 inappropriate.

9.3 Services that provide a public good should be funded by government

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.

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.

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[21] ($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.[22] 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.[23]

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, Food Standards Australia New Zealand (FSANZ) operates on a partial cost recovery basis.

21 https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2017.pdf

22 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

23 https://www.epa.gov/pria-fees/annual-reports-pria-implementation

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 that the cost recovery arrangements utilised by the APVMA, TGA, NICNAS and FSANZ result in inappropriate industry influence on those regulators' decisions. Nevertheless, CropLife recognises that there is some community concern regarding the independence associated with these funding arrangements and a serious and significant perception problem for the APVMA associated with it. This is 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.

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.[24] 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 trust in the Regulator among the community but would 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 that 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*.

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

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

3. Website and publications

   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

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 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 of Agriculture, Water and the Environment 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.

10. CONCLUSION

CropLife commends the Panel for their aspiration to identify opportunities for fundamental changes throughout the entire regulatory system, rather than focusing on individual areas of concern and looks forward to receiving the Panel's view regarding the efficiency of the regulatory environment as a whole in the coming months.

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.

The global COVID-19 pandemic has highlighted the critical importance of ensuring Australia's farmers have access to the tools and technologies they require to provide the nation and our export markets with safe, nutritious and affordable food, feed and fibre. CropLife commends the Panel for their commitment to consider the role of the regulatory system in maintaining a robust supply chain for agvet chemicals.

CropLife and our members have constructively engaged for years in all the 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.

Noting the failure of government to date to progress previous legislative reform and make arbitrary amendments without sufficient consultation, equal standing should be given to implementing operational measures to address some of the issues outlined in the Issues Paper and above. Any future reform must also 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.

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