CropLife AUSTRALIA

*Representing **the best** of the plant science industry*

SUBMISSION ON THE SENATE INQUIRY INTO THE INDEPENDENCE OF REGULATORY DECISIONS MADE BY THE APVMA

14 November 2018

1 INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife makes this submission on behalf of our member companies who are the innovators, developers, manufacturers and formulators of chemical and biological crop protection products, and agricultural biotechnologies for plant breeding.

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is globally recognised as a world-leading regulator that makes decisions based strictly on science and evidence. CropLife acknowledges there is no genuine cause to question the independence of the APVMA's scientific assessment and decision-making process. It is vitally important that the APVMA remains as an independent, science and evidence-based regulator. It is also crucial that the community has confidence in the regulator. Media commentary that provides no scientific evidence for perceived concerns, serves only to unnecessarily undermine that confidence.

While there is no evidentiary basis for an inquiry into the independence of the APVMA, CropLife welcomes the opportunity to participate in any process that leads to increased awareness of the importance of agricultural innovations to the Australian community and the robust, independent regulatory system to which they are subjected.

A cost-recovered regulatory system, in and of itself, 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 similar to those in operation in comparable jurisdictions overseas.

Baseless and sensationalised speculative media reporting with no scientific or evidentiary foundation should not force or guide the hand of independent government regulators. Crop protection products, such as the herbicide glyphosate, are essential tools for Australian farmers to farm productively in an environment that is under constant pressure from weeds, pests and diseases. These tools are equally important to environmental land managers in controlling noxious weeds in our pristine national parks and reserves. For the sake of Australian agricultural productivity and the protection of human health and the environment, APVMA regulatory decisions must not be based on, influenced or driven by ill-conceived "populist" views.

Primacy must be given to independent experts on matters such as these. The inadvertent perpetration of misunderstanding and misinformation by media and other commentators unnecessarily escalates community concern and erodes community confidence in our world-leading science and evidence-based regulatory system.

1.1 Primacy of science and evidence-based regulatory systems

The safety of the products of the plant science industry, for both users and consumers, is CropLife and our members' highest priority. The scientific evidence supporting the herbicide glyphosate's safety is clear and overwhelming and covers more than 40 years of significant use around the world. Over 800 scientific studies, independent regulatory safety assessments and reviews by government agencies and regulators globally, support the fact that glyphosate-based products are safe and do not cause cancer when used according to registered label directions.

Glyphosate has attracted significant international scrutiny and critique since a Californian jury determination in August 2018. Much of the jury's determination and the media commentary that followed has not been based on evidence or science. It is also important to note that this is a legal process that has not been finalised. While CropLife welcomes public and media interest in crop protection innovations and their regulation, it is crucial any debate on farming and agricultural chemistry is informed and based on scientific evidence and independent assessment.

2 INDEPENDENCE OF THE APVMA

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is globally recognised as a world-leading regulator that makes decisions based strictly on science and evidence. The APVMA frequently makes complex, science-based regulatory decisions based on comprehensive hazard and risk assessments. Where identified risks cannot be appropriately mitigated, applications to register new products are refused by the APVMA, and existing products or uses are removed from the market. While in some cases these decisions may have significant negative consequences for CropLife members or grower industries and attract considerable political and community opposition and media attention, the APVMA consistently acts in the best interest of the Australian public by committing to science and evidence-based regulatory decisions.

Any assertions that the APVMA is subject to undue external influence from the industry it regulates based on its regulatory position regarding glyphosate are incorrect and baseless. Numerous comprehensive independent regulatory safety assessments and reviews by government agencies and regulators globally reached the same scientific conclusion as the APVMA – that glyphosate-based weed control products are safe and do not cause cancer when used according to the label directions. In fact, every independent, science-based regulatory agency globally (including; Germany, New Zealand[1], Canada[2], the US[3] and the EU[4,5]) has comprehensively evaluated glyphosate and found it safe to use in accordance with label directions.

2.1 The role of the International Agency for Research on Cancer

The 2015 classification by the International Agency for Research on Cancer (IARC) that glyphosate is a 'probable carcinogen' to humans has raised community concerns about the herbicide. In 2016, the APVMA commissioned an independent scientific assessment of glyphosate by the Department of Health following the release of the IARC's report and found there were no grounds for its approved uses to be reconsidered. These seemingly different conclusions should not be used as a basis to question the APVMA's independence from industry influence. While the conclusions of the IARC and the APVMA appear different, they are in fact, assessing different outcomes – "hazard" vs "risk".

It is important to note that the IARC is not a scientific regulatory agency responsible for making and enforcing regulatory decisions and does not conduct risk assessments, nor does it consider the entire scientific body of knowledge available on substances under assessment. Instead, the IARC plays a role in advising regulatory bodies on potential hazards, allowing the relevant regulatory agencies to consider if there are any associated risks and manage them appropriately.[6] The IARC very narrowly determines the potential for a specific compound to cause cancer under some circumstances, even if those circumstances are completely unrealistic and unlikely to occur. The IARC's hazard classification simply means glyphosate is as much a probable carcinogen as shift work or consuming red meat, processed meat or beverages above 65 degrees. Aloe vera, pickled vegetables, coconut oil and several key agents used in chemotherapy treatment are all on the IARC lists of possible or probable carcinogens. From over 1,000 assessments, the IARC has only ever found one substance to be 'probably not carcinogenic'.

1 https://www.epa.govt.nz/assets/Uploads/Documents/Everyday-Environment/Publications/EPA-glyphosate-review.pdf
2 https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2015/glyphosate/document.html
3 https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073
4 http://www.efsa.europa.eu/en/efsajournal/pub/4302
5 https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa
6 https://monographs.iarc.fr/wp-content/uploads/2018/06/CurrentPreamble.pdf

In contrast, the APVMA determines whether a "hazard" poses any realistic risk to humans, animals or the environment, by analysing the way a substance is used and the likelihood and extent of exposure to that substance. Unlike the majority of publicly available studies, the data generated for regulatory assessment by the APVMA must be compliant with good laboratory practice and adhere to OECD (Organisation for Economic Co-operation and Development) Test Guidelines, where applicable.

Every independent, science-based regulatory agency globally (including Germany, New Zealand[7], Canada[8], the US[9] and the EU[10,11]) has comprehensively evaluated glyphosate and reached the same scientific conclusion as the APVMA – that glyphosate-based weed control products are safe and do not pose a carcinogenic risk when used according to the label directions.

Importantly, in 2017 the European Chemicals Agency (ECHA) conducted a hazard-based assessment of glyphosate, similar to that conducted by the IARC, and concluded that "no hazard classification for carcinogenicity is warranted for glyphosate."[12]

Contrary to many recent misinformed media reports, the World Health Organization (WHO) did not classify glyphosate as a probable carcinogen. Three of the four branches of the WHO (International Programme on Chemical Safety, Guidelines for Drinking-Water Quality and Core Assessment Group) are on record stating glyphosate presents neither a cancer nor human health risk when used according to label directions. With the fourth branch being the IARC. In fact, the WHO and the Food and Agriculture Organization's jointly administered expert scientific group recently found that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet.[13] The largest, prospective study examining the potential effects of pesticide exposure, the US Agricultural Health Study, investigated the risk between glyphosate exposure and non-Hodgkin lymphoma, analysing data from over 89,000 farmers and their spouses. The study found no association between glyphosate and non-Hodgkin lymphoma – regardless of the exposure level.

2.2 Concerns with the IARC assessment of glyphosate

The IARC has been widely criticised before and after its assessment of glyphosate for its lack of transparency and outdated hazard-based assessment methodology, which does not serve the best interests of the community, more often causing confusion and misleading the public.[14,15,16] Allegations of significant conflict of interest and bias on behalf of the IARC panel assessing glyphosate, which resulted in a monograph that manipulated, altered and ignored inconvenient data, were exposed by Reuters[17] in October 2017.

The IARC classification of glyphosate was based on their conclusion that there was "sufficient evidence of cancer in experimental animals" and "limited evidence" of cancer in humans. The Reuters article revealed, however, that a draft of the chapter on animal studies obtained during legal proceedings in the United States came to a significantly different conclusion and was edited substantially in order to reach a probable carcinogenic finding. In ten cases, a negative conclusion regarding glyphosate's carcinogenicity was either deleted or replaced with either a neutral or positive one. In one case, the assessment panel ignored the original researchers' statistical analysis, and that of a secondary independent panel, instead inserting their own analysis of the data in order to arrive at a positive association with cancer.

7 https://www.epa.govt.nz/assets/Uploads/Documents/Everyday-Environment/Publications/EPA-glyphosate-review.pdf
8 https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-re-evaluation-decisions/2015/glyphosate/document.html
9 https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0073
10 http://www.efsa.europa.eu/en/efsajournal/pub/4302
11 https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa
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13 http://www.fao.org/3/a-i5693e.pdf
14 https://www.theatlantic.com/health/archive/2015/10/why-is-the-world-health-organization-so-bad-at-communicating-cancer-risk/412468/
15 https://www.chemistryworld.com/news/who-cancer-agency-criticised-for-outdated-chemical-risk-methods/1017633.article
16 https://www.sciencedirect.com/science/article/pii/S0273230016303038
17 https://www.reuters.com/investigates/special-report/who-iarc-glyphosate/

Regulators and agricultural chemical companies internationally are under increasing pressure to improve transparency regarding the conduct and outcome of both research studies and regulatory assessment processes. It is therefore deeply concerning that the scientists who served on the IARC's glyphosate assessment panel were unwilling or unable to address the allegations made in the Reuters article. In fact, the IARC advised members of the panel against discussing their work or disclosing documents and informed them that the IARC "does not encourage participants to retain working drafts of documents after the monograph has been published." The IARC has, to date, divulged no useful information to determine how they arrived at the conclusion that glyphosate is a "probably carcinogen" in humans. In contrast, the scientific decision-making process employed by the European Food Safety Authority (EFSA), the United States Environmental Protection Agency (US EPA) and the APVMA can be freely accessed online.

The Reuters article also revealed that the head of the IARC's glyphosate review team withheld unpublished research by the US National Cancer Institute in which he had participated, which demonstrated no link between glyphosate exposure and cancer. It was further revealed that, despite being generated two years prior to the IARC's assessment of glyphosate, the data was not published until after the glyphosate Monograph was published, apparently due to the large amount of data that required assessment.

In 2017, it was revealed by The Times (London, UK) that Dr Christopher Portier, a statistician invited to advise on the IARC's glyphosate assessment team, received US$160,000 from law firms bringing claims against glyphosate manufacturers to act as a litigation consultant – with the contract signed the same week that the IARC glyphosate Monograph was published.[18] This conflict of interest was not declared by Dr Portier in a letter urging the European Commission to accept the IARC classification of glyphosate. Dr Portier, affiliated with the activist group Environmental Defence Fund, not only advised the glyphosate assessment team, but chaired the IARC committee in 2014 that proposed glyphosate as a substance to be studied.[19]

These allegations raise substantial concerns regarding the integrity of the IARC classification and caution against giving greater weight to one outlying assessment of a chemical when all other independent, scientific assessments arrive at a unified contrary conclusion.

2.3 Science and evidence-based regulatory decisions

CropLife recognises that it is crucial that the regulation of crop protection products is 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 Australians, animals and the environment. Recent events in the EU highlight just how concerning external influence on the regulatory process can be, with politicians caving in to misguided activist pressure and failing to support their own regulator's science-based regulatory decisions. The EU's re-authorisation process for glyphosate highlights the alarming and increasing influence of activist organisations on regulatory decisions in the EU.

The sheer volume of false and misleading material by certain activist organisations as a means to undermine evidence-based, scientifically rigorous regulatory processes is deeply concerning and sets a dangerous precedent for future similar decision-making processes in the EU. These experiences serve as a stark warning for Australian regulatory processes to remain free from any external undue influence, whether it be commercial, activist or political.

18 https://www.thetimes.co.uk/article/weedkiller-scientist-was-paid-120-000-by-cancer-lawyers-v0qggbrk6

19 https://geneticliteracyproject.org/2017/10/17/viewpoint-christopher-portier-well-paid-activist-scientist-ban-glyphosate-movement/

2.4 Funding arrangements of the APVMA

The APVMA receives its funding via fees, charges and levies imposed on agricultural and veterinary chemical registrants. In contrast, 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[20] ($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.[21] 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.[22]

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 National Industrial Chemicals Notification and Assessment Scheme (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.

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. 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. Any consideration that a cost-recovery funding arrangement facilitates inappropriate commercial influence on the regulatory process would not be limited to the agricultural and veterinary chemical 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. 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.

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.

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

21 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

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

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.[23] A full government appropriation funding model that covered the costs of regulating agricultural and veterinary chemicals in Australia would enable industry to focus their investment on the considerable costs associated with product innovation, providing farmers with more targeted, sustainable and efficient crop protection tools. It is important to note that significant legislative reform would be required to enable transition to a full government appropriation funding model.

A government funding scheme for agricultural and veterinary chemical regulation would also have broader benefits to Australian farmers. Under a cost-recovered funding scenario, the costs associated with registration are borne significantly at the farm gate. A government funded regulatory system would spread the costs associated with food production and safety across the entire population that enjoys the benefits of Australia's high-quality, fresh and safe produce derived from farmers' use of these products.

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

3 REGULATION OF AGRICULTURAL CHEMICALS

3.1 The regulatory environment

In Australia and across the world, agricultural chemicals are subjected to robust, rigorous and independent regulatory systems and assessments. Australians can take confidence from the fact that crop protection products, like glyphosate, are among the most highly regulated products in Australia. Agricultural chemicals are only registered for use when they present no unacceptable risks to users, the public or the environment. The APVMA is responsible for regulating these chemicals in Australia and is globally renowned for its comprehensive, rigorous, science and evidence-based assessments.

The APVMA is an independent statutory authority, which sits within the Agriculture portfolio and regulates agricultural and veterinary chemicals according to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code). The APVMA's legislation is developed and managed by the Department of Agriculture and Water Resources. As such, the Minister for Agriculture and Water Resources has overall policy responsibility for agricultural and veterinary chemicals. The APVMA works with FSANZ to conduct assessments of agricultural and veterinary chemical residues in food and to set maximum residue limits (MRLs).

The APVMA regulates agricultural and veterinary chemicals and monitors compliance with the Agvet Code up to the point of sale. Beyond the point of sale, the states and territories are responsible for control of use of agricultural and veterinary chemicals and enforce the Food Standards Code (including MRLs). Agricultural and veterinary chemical residues in Australian food and produce are monitored by both FSANZ and the Department of Agriculture and Water Resources' National Residue Survey.

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* (SUSMP).

3.2 The APVMA

The APVMA undertakes a comprehensive pre-market risk assessment of crop protection products, ensuring they are safe for use and for the environment, before they can be made available to Australian farmers and other users. Consistent with other international agricultural chemical regulators, as well as other Australian chemical regulators, the APVMA utilises a risk-based, weight-of-evidence approach to assess the full range of risks posed by a chemical product. This approach also considers how human exposure can be minimised through instructions for use and safety directions.

The APVMA takes new data and scientific information into account when considering the ongoing safety of a registered product. Under Section 161 of the *Agricultural and Veterinary Chemicals Code Act 1994* (Figure 1), agricultural chemical registrants have a statutory obligation to provide the APVMA with any relevant new data regarding their products, as and when it becomes available. Information is relevant if it either contradicts the current information entered in the record or shows a product or constituent may not meet the safety, trade or efficacy criteria.

161 Notification of new information to APVMA

(1) If:

(a) the holder of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product; or

(b) the holder of a permit in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product;

becomes aware of any relevant information in relation to the constituent or in relation to the product or of any of its constituents, the holder must, as soon as the holder becomes aware of the information, give that information to the APVMA.

(1A) A person commits an offence if the person contravenes subsection (1).

Penalty: 300 penalty units.

(1B) Subsection (1) is a civil penalty provision.

Note: Division 2 of Part 9A provides for pecuniary penalties for contraventions of civil penalty provisions.

(2) Information is relevant information if it:

(a) contradicts any information entered in the Record, Register or Record of Permits for the constituent or product; or

(b) shows that the constituent or product may not meet the safety criteria, the trade criteria or the efficacy criteria.

(2A) A corporation is taken to be aware of any information if a related corporation is aware of that information.

(2B) The question whether 2 corporations are related to each other is to be determined in the same way as that question would be determined under the *Corporations Act 2001*.

(3) Any information given to the APVMA under this section must be given in writing signed by the holder.

Figure 1: Section 161 of the Agricultural and Veterinary Chemicals Code Act 1994

The regulatory system for agricultural and veterinary chemical products in Australia is outlined for initial registration (Figure 2) and ongoing assessment (Figure 3) to ensure new scientific information is considered in a timely manner. Under this regulatory scheme, the ongoing human, animal health and/or environmental safety of an agricultural or veterinary chemical product is constantly monitored.

This system provides a highly responsive regulatory review system, whereby a formal review or 'reconsideration' that focusses on new scientific information, rather than a purely administrative process, can be initiated at any time.

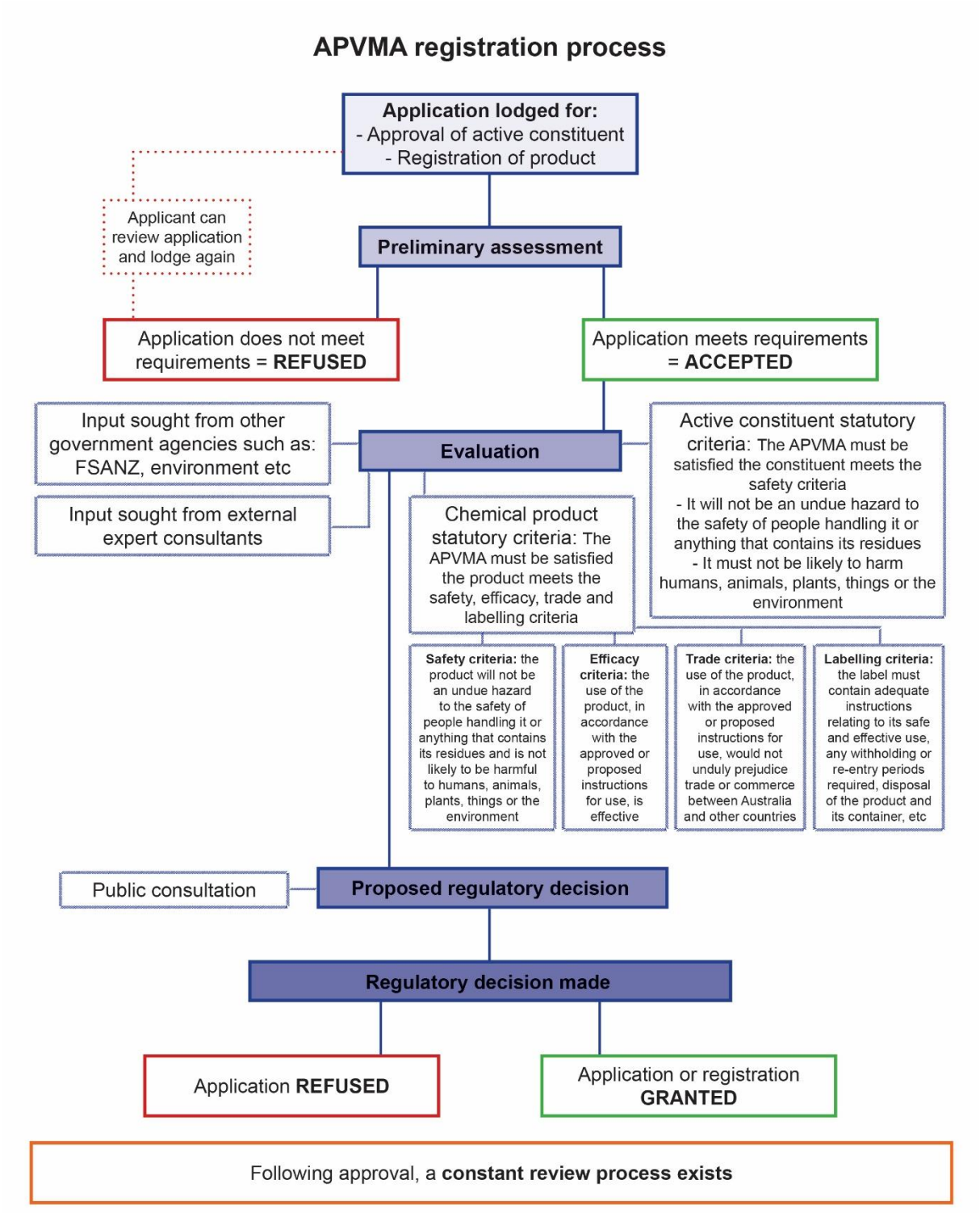

Figure 2: The regulatory system for registration of agricultural and veterinary chemical products in Australia

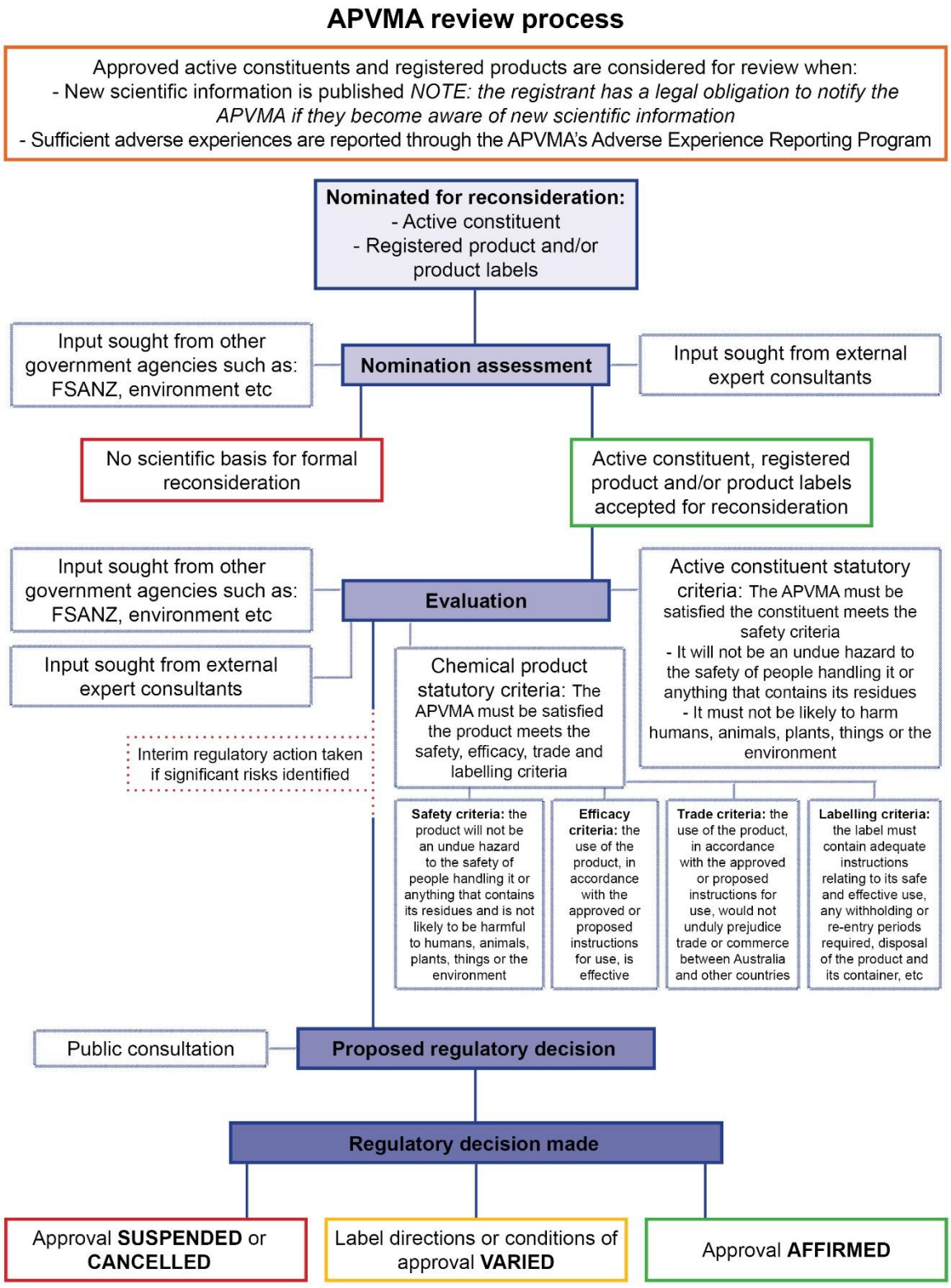

Figure 3: The regulatory reconsideration process for agricultural and veterinary chemical products in Australia

3.3 Assessment of the ongoing safety of agricultural chemical products in Australia and overseas

APVMA regulatory decisions following nominations for reconsideration are based on science and evidence, not the commercial interests of the various industry stakeholders affected by the APVMA's decisions, or the political pressure resulting from activist, anti-modern farming campaigns that rapidly permeate the media commentary and community sentiment. Anyone can nominate a chemical or chemical product for reconsideration by the APVMA, however, a nomination is only accepted where there is a scientific basis for the nomination.

Examples of the types of information the APVMA would take into account when considering a nomination include:

- Regulatory decisions from counterpart authorities in other countries such as de-registration, restriction of use or change in use patterns. **Note:** in order for the APVMA to take overseas regulatory action into consideration, the products and use patterns must be relevant to Australian conditions;
- Adverse experience reports that have been classified as being probably related to a chemical that has been used according to the approved label;
- Confirmed reports of pesticide residue violations, including trade issues such as the rejection of exported agricultural produce;
- New credible scientific evidence (for example: high-quality, peer-reviewed scientific literature and international scientific assessment reports by the WHO or FAO) that indicate a new or higher risk than was determined when the product was first registered;
- Confirmed or substantiated reports of product failure or lack of efficacy;
- Information submitted to the APVMA in compliance with existing statutory obligations (s. 161); and
- Information obtained by state and territory authorities in their administration of control of use functions[24].

In 2015, following the classification of glyphosate as a 'probable carcinogen' by the IARC[25], the APVMA proactively self-nominated glyphosate for reconsideration. In doing so, the APVMA commissioned an assessment of the IARC report by the Department of Health's then Office of Chemical Safety. Far from highlighting a failure of the regulatory system in Australia, the APVMA's swift and comprehensive response to the 2015 IARC monograph on glyphosate demonstrates how responsive and transparent the APVMA's processes are.

In 2014, following the completion of a comprehensive review of the insecticide fenthion, which was previously used to control fruit fly, the APVMA cancelled or varied all registered uses of products containing fenthion due to approaching unacceptable risks to both human and environmental health. Subsequently, the active constituent was voluntarily cancelled by the registration holder and all remaining registered products were removed from the market as a result. This example reflects the commitment of the crop protection product industry to product safety.

The fenthion decision was made by the APVMA based on a thorough scientific investigation and was undertaken in the face of considerable criticism and angst from affected grower industries. In fact, a Senate Inquiry was held to examine the implications of the restriction on the use of fenthion on Australia's horticultural industry, which questioned the APVMA's conclusion to remove products containing fenthion from the market. While the decision was clearly an unpopular one with affected industries, the scientific evidence rightly drove the regulatory action taken by the APVMA to ensure the health of Australians was protected.

24 https://apvma.gov.au/node/10966
25 https://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf

The APVMA often initiates interim regulatory action during a formal reconsideration to mitigate any risks identified in relation to the use of the chemical under investigation. In this manner, unacceptable risks associated with the use of an agricultural or veterinary chemical product can be managed prior to the finalisation of a complex and lengthy formal reconsideration.

In 2011, the APVMA suspended the use of all products containing the insecticide dimethoate and issued new instructions for use that no longer allowed the use of dimethoate on certain food crops. This interim regulatory action was initiated following a comprehensive dietary risk assessment. The reconsideration process was finalised in October 2016. Similarly, in 2000, the APVMA implemented several interim regulatory measures including label amendments with updated directions for use, first-aid and safety directions, and environmental warning statements for products containing the insecticide chlorpyrifos. This was due to unacceptable environmental and occupational health and safety concerns.

The risk of crop damage from spray drift attributed to the use of the herbicide 2,4-D is currently being assessed by the APVMA as part of a formal reconsideration of the chemical. In October 2018, the APVMA suspended all registered labels for products containing 2,4-D and issued new label instructions. This interim action was taken prior to finalisation of the formal reconsideration process, in recognition of an immediate need to take regulatory action and mitigate the risk of spray drift associated with the use of 2,4-D. CropLife members willingly participated in the suspension process and swiftly complied with the APVMA's requirements, again demonstrating a strong commitment to product stewardship and responsible use of their products.

All proposed regulatory decisions relating to the reconsideration of an existing product are subject to a comprehensive and transparent period of public consultation prior to being finalised.

Reconsideration timeframes

Prior to July 2014, chemical reconsiderations were not time-limited. That is, the APVMA was not required to complete reconsiderations within a statutory timeframe. Instead, the timeframe of each reconsideration varied, determined by its scope. While the current average time for the APVMA to complete a reconsideration is three years, some of the more technically complex reconsiderations, those with large datasets or those with large numbers of products to consider, have been active for more than 10 years. Often, external consultants or experts at other government departmental agencies are engaged to complete technical assessments.

Under the previous legislative requirements, companies were permitted to provide information relevant to the reconsideration at any time. While it is extremely important that the APVMA has access to all available scientific information in order to conduct their detailed assessments, allowing for the provision of additional data during the reconsideration process often resulted in the revision of component risk assessment reports. This, in turn, required additional consultation and publication, significantly delaying the finalisation of the review.

Legislative amendments that came into effect on 1 July 2014 limited the maximum prescribed timeframe to complete a formal reconsideration to 57 months and a prescribed formula was developed to determine the appropriate timeframe required to assess each chemical. Companies are still required by law to immediately provide any relevant, new scientific information to the APVMA that either contradicts the current information entered in the record or shows that a product or constituent may not meet the safety, trade or efficacy criteria. In order to be considered as a part of the reconsideration process, the new data must, however, be provided within defined timeframes (with exceptions where absolutely necessary).

These legislative amendments ensure that future reconsiderations will be conducted in a more transparent, predictable and efficient process. Unfortunately, while a number of significant chemical reconsiderations were tracking to be completed by their newly determined statutory deadlines during 2017 and 2018, CropLife believes the relocation of the APVMA to Armidale from Canberra and subsequent loss of experienced staff delayed their finalisation.

Health Canada's Pest Management Regulatory Agency

In 2006, Health Canada's PMRA introduced a cyclical re-evaluation process to ensure the ongoing use of pest management products continues to be acceptable according to current regulatory standards. Under the scheme, registered pesticides must be re-evaluated every 15 years after registration. In addition, the PMRA may initiate a Special Review when new scientific information emerges that questions the health or environmental conclusions of the most recent registration assessment, or a member of the OECD prohibits all uses of the product. As a Special Review may be initiated at any time, the relevance of a simultaneous 15 year re-evaluation program is extremely diminished. In some cases, products under routine re-evaluation have been subjected to a Special Review at the same time due to a ban in an OECD member country. This creates unnecessary duplication of effort and administrative burden for the regulator.

The PMRA has publicly stated that the current re-evaluation workload is not sustainable, and the agency lacks the resources to cope with the upcoming wave of re-evaluations. There are more than 70 active constituents scheduled for cyclical re-evaluation. This number is, however, 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. Similarly, as of June 2018 there are 23 active constituents subject to a Special Review. Although these reviews typically take around two to four years to complete, the PMRA has indicated that they expect almost half (43 per cent) to exceed four years.

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. In 2016-17, 421 staff were employed with the PMRA – more than twice the number of APVMA employees – of which approximately 76 per cent are regulatory scientists with an average of more than 13 years of government experience.[26] The inability for the much larger and highly experienced PMRA to cope with the increasingly burdensome re-evaluation process serves as clear evidence why introducing a similar, unnecessary and duplicative system in Australia should be avoided.

European Food Safety Authority

Regulation of pesticides in the EU is the overall responsibility of the European Commission, with the support of the EFSA, who coordinate the risk assessment peer review. The initial individual assessments and re-assessments of active constituents are assigned to different rapporteur member states[27,28], depending on scientific ability and capacity. Once an active constituent has been approved for registration in the EU, individual national authorities are then responsible for determining in which capacity products containing that active constituent can or cannot be used within that country.

The EU's re-assessment process is managed by the European Commission (via the Directorate General Health and Food Safety or DG SANTE), with an initial assessment conducted by a rapporteur member state and a risk assessment peer review organised by EFSA. The EU re-assessment programme began with a pilot programme in 2007 and has been modified and expanded since then.

26 https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/annual-report-2016-2017.html
27 https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_approval-factsheet.pdf
28 https://www.efsa.europa.eu/interactive_pages/pesticides_authorisation/PesticidesAuthorisation

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[29] among member states, should be more capable of managing a cyclical re-assessment program. The EU re-assessment programme is, however, not delivering the desired outcomes in a timely fashion, with few scheduled re-assessments finalised since its introduction in 2007 (Table 1). Noting that approval is extended where the re-assessment is delayed for reasons beyond the control of the applicant[30], 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.

Table 1: Outcomes of the European Union renewal of approval programme*

Year	Total substances	Finalised	Pending	Comments
2007	7	7	0	Pilot programme Approval expiry 2008-2010
2010	31	24[a]	5	Approval expiry 2011-12
2012	150	30[b]	104	Approval expiry 2013-2018
2016	215	0	> 200	Approval expiry 2019-2021
2018	66	N/A	66	Approval expiry 2022-2024
Total	469	61	>375	

* As of end August 2018; [a]2 substances not submitted by applicant; [b]16 substances not submitted by applicant - *Source: ECPA (European Crop Protection Association) estimations*

Rather than directing regulatory attention to specific areas where there is credible scientific evidence demonstrating potential risks to human and animal health or environmental safety, EU regulators are instead conducting lengthy, unnecessary reviews of entire data packages, where there is no cause for concern. This distraction does not serve the best interests of government, chemical product manufacturers, farmers or consumers within the EU.

United States Environmental Protection Agency

Similar to Canada's PMRA, the US EPA conducts registration reviews of registered pesticides every 15 years to determine whether they continue to meet existing standards for registration and has the ability to conduct a Special Review at any time. As of the end of the 2017 financial year, the US EPA has completed and implemented the final decisions of less than one-third of registration reviews commenced since 2007 (Table 2). [31]

29 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

30 Regulation (EC) 1107/2009, Article 17

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

Table 2: Outcomes of the United States Environmental Protection Agency's registration renewal programme*

Year	Reviews commenced	Decisions completed
2007	25	3
2008	46	7
2009	69	14
2010	75	21
2011	83	23
2012	79	11
2013	77	8
2014	74	22
2015	84	46
2016	88	35
2017	25	49
Total	**725****	**239**

* As of end financial year 2017
** Including a total of 1100 active constituents

Source: US EPA Implementing the Pesticide Registration Improvement Act – Fiscal Year 2017, 14th annual report

Similar to Health Canada and the European regulatory systems, the demonstrated inability for the US EPA to implement a successful, efficient re-registration programme, despite receiving substantial government funding, serves to highlight that such programmes are not feasible and do not serve the best interests of the community.

3.4 Improvements to the regulatory environment

While the independence of regulatory decisions made by the APVMA is without question, it is important that all regulatory systems continually improve. As such, there is a number of areas that continue to undermine the efficiency of the regulatory system that should be addressed.

Off-label use of agricultural and veterinary chemical products

The considerable cost of regulation means that registrants only seek to register agricultural chemical product uses where it is financially viable for them to do so. In the case of minor and specialty crops, this cost of developing the necessary supporting data to meet due diligence and regulatory requirements far exceeds any potential return on investment. Similarly, the financial burden on grower groups to generate the necessary data to support an application for a minor use permit is often prohibitive. As a result, Australian producers of specialty food and minor crops are faced with numerous challenges in managing plant pests, weeds and diseases.

The responsibility for managing and enforcing legal use of agricultural and veterinary chemicals lies with the state and territory jurisdictions. Under the current control of use laws, users in some Australian jurisdictions can use agricultural and veterinary chemical products in a manner that is not specified in their registered label instructions. Allowing growers to use agricultural chemical products via unregulated, off-label pathways is not in the best interest of Australian growers or the Australian public.

Consequently, CropLife and our members do not support off-label use of agricultural chemical products as a matter of principle. These uses are not specifically risk assessed by a scientifically competent regulator for Australian conditions.

Significant initiatives exist seeking to remedy the minor use market failure caused by the lack of incentives built into the Federal mandatory regulatory system for pesticides. In coming years, these initiatives will enable the various jurisdictions to reconsider their approach to off-label use, without compromising Australian farmers' access to crucial agricultural chemical products. Ongoing support and focus by the Australian Government for these initiatives will deliver a better return for Australian farmers in the long-term.

CropLife remains concerned, however, that the Council of Australian Governments (COAG) 2010 direction to the Primary Industries Ministerial Council (now Agriculture Minister's Forum; AGMIN) to develop a national framework for harmonised agricultural chemical regulation in Australia,[32] 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. Eight years after the initial COAG directive, these differences continue to create confusion among users and increased costs associated with compliance for industry. Substantial reform is still urgently required to create a national harmonised framework for agricultural chemical regulation in Australia to reduce confusion and costs for both industry and Australian farmers.

Capacity of the regulator and urgently required regulatory reform

It is imperative that Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing crop protection products. Despite the APVMA's commendable efforts to overhaul its internal procedures to deliver efficiency gains that have resulted in a substantial recovery in legislative timeframe performance, capacity continues to be a considerable weakness of Australia's regulatory system.

The APVMA's Chief Executive Officer, Dr Chris Parker, has confirmed in hearings of the Senate Standing Committee on Rural and Regional Affairs and Transport, that the relocation of the APVMA has been a significant cause of massive staff losses since the announcement was made on 25 November 2016. The APVMA's staff separation rate increased from 11.8 per cent in the 2014-15 financial year to 23.7 per cent in 2016-17. During the 2016-17 financial year, the APVMA lost more than 270 years of experience with the Regulator.[33] The disruption of the relocation of the APVMA is likely to be felt for some years after implementation. Consequently, substantial reform is still urgently required to assist the APVMA during this very challenging period.

The proposed legislative changes presented in both the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017* and the *Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulations) Bill 2018* (the Bill) fail to deliver the urgent and targeted reform required to streamline APVMA regulatory functions that will assist the regulator during its transition to Armidale. The proposed measures contained in both Bills are predominantly administrative corrections, aimed at delivering minor internal efficiency improvements.

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32 http://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/domestic-policy/history-of-coag-reforms/iga-coag#objectives

33 Senate estimates 24 October 2017 Question on Notice Number 28: https://www.aph.gov.au/Parliamentary_Business/Senate_Estimates/egon

4 CONCLUSION

Australians can take confidence from the fact that crop protection products are among the most highly regulated products in Australia, in a comparable manner to human medicines. Under the APVMA's world-renowned regulatory scheme, the ongoing human, animal and/or environmental safety of an agricultural or veterinary chemical product is constantly monitored via a responsive chemical reconsideration program. Regulatory action is triggered by the provision of credible, new scientific information that questions the existing regulatory conditions of a product, such that a reconsideration can be initiated at any time. Far from highlighting a failure of the regulatory sector in Australia, the APVMA's proactive and comprehensive response to the 2015 IARC monograph on glyphosate highlights the responsive and transparent nature of the APVMA's reconsideration process. Legislative amendments introduced in 2014 will ensure that future reconsiderations will be conducted in a more transparent, predictable and efficient process, to ensure the ongoing safe use of important pest management tools in Australia.

It is concerning that media-based commentary compiled of emotional speculation with no scientific basis has led to the establishment of an inquiry into the credibility and independence of a scientifically competent, globally renowned regulator. It is essential that this inquiry is based on facts and evidence and is not driven by any partisan political agenda. While questioning the necessity of this inquiry, CropLife welcomes the opportunity to constructively engage in any public debates or discussions that lead to better-informed parliamentarians and consumers and increased community confidence in the regulation and importance of crop protection innovations.

The cost-recovery regulatory model utilised by the APVMA and other chemical regulators in Australia, including the TGA, NICNAS and FSANZ poses no scope for undue influence from the industry it regulates. Nevertheless, the Government should recognise that the perception of independence by the Australian public and therefore confidence in the APVMA would be considerably increased under a public funding arrangement.

Approved and registered crop protection chemical products are safe, cost-effective, efficient, essential and sustainable tools for farmers to use to control pests, weeds and diseases and represent a core input for modern farming systems. A streamlined, effective regulator capable of delivering timely risk assessments, approvals and registrations is essential for Australian agriculture.

The Government's focus should be on developing and implementing the urgent, well-considered reform that is required to maintain a high level of integrity and, in turn, maintain community confidence in Australia's agricultural and veterinary chemical regulatory system.

APPENDIX 1:
THE PLANT SCIENCE INDUSTRY

CropLife member companies are the innovators, developers, manufacturers and formulators of chemical and biological crop protection products, and agricultural biotechnologies for plant breeding, such as genetically modified crops.

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.[34]

Consumer safety is CropLife and our members' highest priority. We recognise the importance of gaining and maintaining community trust in our role in the food production supply chain. CropLife and its members are committed to the stewardship of their products throughout their lifecycle. Significant investment in stewardship activities ensures there are no unacceptable human health risks associated with agricultural chemical use in Australia and that any environment and trade issues are responsibly and sustainably managed. CropLife ensures the responsible use of these products through its mandatory industry code of conduct and has set a benchmark for industry stewardship through programs such as ***drum****MUSTER*, ChemClear® and safety training programs run by CropLife's wholly-owned stewardship and safety organisation, Agsafe.

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 billion each year, with an impact on the environment that is similar in magnitude[35].

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 the APVMA's ability to regulate agricultural chemicals more efficiently. 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.

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

35 Australian Weeds Strategy – A national strategy for weed management in Australia. National Resource Management Ministerial Council (2006), Australian Government Department of the Environment and Water Resources, Canberra, ACT.