AERIAL APPLICATION ASSOCIATION OF AUSTRALIA LTD.

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AAAA Submission

National Ag Vet Review Draft Report and Recommendations

Contents

Executive Summary

AAAA is strongly supportive of reform and improvement of the national agvet system – and has made consistent policy contributions to the issue over the last 20+ years.

The Panel is to be congratulated in clearly identifying many long-standing and unresolved policy issues that continue to put Australia at a competitive disadvantage and which serve to reduce access to safe chemicals, restrict innovation and the adoption of better practices, and add unique and unnecessary costs for Australian chemical users.

The draft report of the Panel identifies a wide range of issues that are ripe for improvement, many of which AAAA is able to support.

However, many critical recommendations come with very negative outcomes, processes, impacts and costs that cannot be supported by AAAA.

There is an apparent lack of evidence that the Panel has deeply considered the possibly negative consequences of many of the recommendations.

This is a critical impediment to supporting many recommendations where the problem identified is accurate, but the proposed remedy is either:

- too indirect to be of impact
- adding cost and further bureaucracy for no guaranteed outcome, or
- creating great uncertainty for the future of the national scheme of agvet chemical regulation and use and could leave industry – and particularly applicators – in a worse position.

Conversely, some recommendations only seek to implement part of industry suggestions and leave the key problems unresolved - and will likely create new problems.

In many cases, the drafting style of the recommendations in linking an initiative that could be supported with a methodology that cannot be supported puts AAAA in the position of having to oppose the entire recommendation.

For example, linking recognition of industry stewardship programs to newly created 'general obligations' and then adding additional costs succeeds in presenting a great initiative in such a way that it cannot be strongly supported in the current form.

In other cases, the recommendations appear to be a solution in search of a problem.

In particular, all of the recommendations that seek to establish the position of Commissioner and the accompanying powers and duties fall on the basis of AAAA not supporting this concept. This is a troubling outcome as many of the issues deserve resolution – just not through that structure.

Consequently, AAAA hopes that the final draft of the Panel will separate out any recommendations regarding a Commissioner (or abandon the concept altogether) from the underlying valid identification of issues and offer more direct solutions.

Many of the problems identified could be addressed through direct improvements to the APVMA – even while recognising that the APVMA is not the entire system, and that it is again 'under new management'. However, the potential impact a rapidly improved APVMA and related systems and labels can have on the entire health of the agvet chemical system should not be underestimated. AAAA is certainly enthusiastic about recent modest changes in direction at APVMA and believes a great deal more can be achieved via this approach – especially in the short term.

A significant number of key recommendations do not provide enough detail that would permit support, nor do they consider likely consequential risks or poor outcomes. This is particularly concerning given the significant number of previous reform attempts that are available to inform the Panel and which should have provided an appropriate springboard for long overdue but underdelivered reform.

There are also a significant number of recommendations where AAAA's 'support' or 'not opposed' position is highly conditional on further detail, resolution of the many problems we have identified and greater consultation with the parties that actually have a significant and practical stake in improving the Australian agvet system – AAAA included.

As this is a draft report, AAAA is hopeful that further input from industry at this stage will result in a rethink of those recommendations opposed, and potentially a recasting of the approach to achieving significant reform without the potentially negative outcomes identified in this submission.

Many of the *principles* discussed have AAAA's support – including single point control of use, national licencing, labelling simplification, use pattern and permit reform and improved recognition of industry stewardship programs – but AAAA concerns over the practicality of actually achieving some of these major reforms potentially without the support of the States and Territories should be addressed.

Further urgent consultation with industry on these issues and major amendments to the draft report and recommendations would greatly improve the direction of the report, the practicality and impact of recommendations and potentially garner much greater support.

AAAA's major concerns are outlined below, as well as in comments on each recommendation.

Implementation Committee

AAAA strongly recommends that the Panel add to the recommendations the establishment of a small, focussed, high level AgVet Reform Implementation Committee that would guide and provide input to the government and and APVMA on all elements of the reform package.

As a minimum, AAAA believes the following bodies should be represented, depending potentially on the issues/reforms being dealt with at a particular time:

- AAAA
- Croplife
- NFF
- Ground Rig Association
- Other peak bodies / experts as required eg DrumMuster when discussing waste management…

Commissioner and related powers

AAAA's key concern is whether the creation of the Commissioner and all of the new powers (and significant costs) accruing to that position is a valid and effective approach to fixing the many problems in the existing system.

AAAA's position having considered the draft report carefully is to oppose the creation of this new structure because of:

- the clear tension being created between the Commissioner and the APVMA
- the significant number of unknown and unexplored consequential effects
- the lack of clarity in terms of the codification of the Commissioner's powers
- the potential creation of a secondary registration pathway that may undermine the 'full' registration scheme
- the lack of any coherent chemical registration program improvement program (or broader overt system of continuous improvement and quality assurance of government processes) that would identify and remove impediments that are currently creating many of the problems identified
- the lack of consideration of the consequential impacts of major reform proposed of the control of use system, especially no details on the creation of offences and defences, the treatment of existing 'harm' provisions, and the potential for States and Territories to retain 'residual' powers and thereby leave industry in an even worse position than now
- previous clear failure of the Department of Agriculture to act effectively in the same space
- the significant increase in costs to end users, with no consideration of national and community benefits or industry costs in simplifying processes for government by undertaking work on accreditations and stewardship programs.

In brief, creating another level of bureaucracy and potentially a competing framework with the APVMA especially is not seen by AAAA as effective reform. Without a more detailed business or RIS case, it may simply represent activity with no certain improvements. This should not be confused with genuine reform that leaves all participants in a better space.

Failure of the Commonwealth Department of Agriculture to improve or even effectively oversight the system over the last 20 years should not trigger support for recommendations that seek to expand and provide more resources to the same ineffective Department – even with repackaging. The record of performance in this space cannot be ignored.

AAAA is not convinced by the argument that creating statutory requirements attached to the Commissioner would, of itself, provide the reform momentum required or the 'future-proofing' of the system against policy changes or changes of government.

Many of the problems identified could simply – and very quickly and more cost-effectively - be remedied by changes to existing policy – often within the APVMA – that under the new CEO only recently appointed, is already making positive headway in this space. These range from label simplification to recognition of industry programs to label 'use' table reforms and more urgent implementation of the APVMA Stage 2 Drift Management Reforms already agreed.

Many problems identified are not structural but policy driven, and so the recommendations regarding major structural change (ie the Commissioner) are curious.

AAAA understands that because of the structure of the draft report and recommendations, opposing the establishment of the position of Commissioner outright will have significant consequential impacts on many other recommendations that AAAA would prefer to support – outside of the Commissioner issue.

AAAA encourages the Panel to reconsider the structure of the report and recommendations so that sensible reforms that offer genuine advantages are able to be supported by industry – in other words they be decoupled from the separate proposal to establish the Commissioner – if the Panel decides to persist with the Commissioner model rather than abandoning it in preference to more direct reforms.

AAAA would not be surprised or alarmed if the position of Commissioner was deemed to be superfluous to achieving genuine reform by simply providing the same policy powers and initiatives recommended to an expanded and resourced APVMA, or perhaps even getting the Commonwealth Department of Agriculture to improve its performance and interest in the area within existing resources.

Control of Use

The whole National Registration Scheme is underpinned by cooperative arrangements between the States, Territories and Commonwealth that are a significant improvement over the previous disjointed system of individual State/Territory Registrars of Chemicals.

AAAA is sceptical of the Commonwealth's ability to efficiently and effectively take over control of use from the States and Territories in anything other than a cooperative referral of powers from the States and Territories – regardless of how much AAAA believes that is a long overdue reform.

The almost complete lack of detail in the draft report regarding what new Commonwealth control of use legislation might look like (including in the provided Appendices of the draft report) is of great concern at this stage of the reform process.

The lack of detail regarding the potential treatment of offence provisions (including any detail on the application of *mens rea* vs strict liability), defences, enforcement and a range of other elements is most concerning.

Further, the lack of detail regarding how any Commonwealth law might operate in recognition of the wide range of other State/Territory law that affects chemical application (not just control of use) makes it very difficult to discuss this issue on the basis of the Panel's work to date.

A key concern to AAAA is how the States/Territories may react to the Commonwealth takeover in terms of retaining residual powers in State/Territory legislation – potentially creating a range of 'double jeopardy' situations that would leave chemical users in a worse state than the current laws.

Much more detail on this issue should be provided at the earliest opportunity – including on the States/Territories dispositions to the reforms, and industry's practical concern at the user level of working in this currently 'unknowable' regime.

This is a major error on the part of the Panel and industry is simply not able to understand how the proposed system will function or what the consequences for industry may be.

Due to the lack of detail provided in the report and recommendations regarding this critical reform and the essentially cooperative nature of the National Registration Scheme, AAAA is unable to support the current recommendations without a more cooperative approach being embedded in the recommendations.

Cost recovery

AAAA is strongly opposed to the recommendations regarding cost recovery due to their lack of consideration of community benefit, contribution to the national interest including food security, the economy, agricultural production and safety, and industry investment in product stewardship, training and accreditation programs.

In particular, the recommended approach of charging by an hourly rate for regulatory services and approvals - that are core business to government - makes no provision for downward efficiency pressures to be applied to ensure costs recovered are minimised.

As AAAA has pointed out in many submissions to government regarding cost recovery, the first step should be to construct an efficient, outcome-driven system to reduce costs, and only then seek to recover the cost of the most ***efficient*** delivery of those remaining processes that do not deliver a community benefit.

Simply handing industry a bill for the clear inefficiency of government is neither prudent, fair, sound nor sustainable.

Similarly, the recommendations regarding greater recognition of industry stewardship and competence accreditation schemes are undermined by the proposal to pass costs to industry.

The draft report seems to recognise the benefits of industry schemes including high uptake, great credibility, higher competence and far greater efficiency than government could contemplate using their own schemes or regulation.

However, the Panel seems to conclude that government need bring nothing to the table, even though industry has underwritten these schemes and already paid the costs of development, delivery and ongoing maintenance.

The Panel's recommendations will not create a co-regulatory system. A more cooperative stance must be engineered into the Panel recommendations that accounts appropriately for the investment industry has already made in its programs and which seeks to reduce assessment costs and bear them as a community benefit in improving the system and outcomes.

These recommendations should be recast to ensure that new systems are in fact built within a new co-regulatory environment where government and industry can work together to deliver a far better national agvet system.

Chemical Labels

The various recommendations that result in a new policy to simplify labels are welcome and supported – especially in terms of improving the 'use' table and improving consistency of access to use patterns and refocussing labels on core information for users.

However, some recommendations seem to persist with the contradictory and flawed approach of wanting ever more information included on labels – often in an attempt to atone for poor baseline training of ground applicators. This tendency to use labels as a dumping ground must be abolished.

A key shortcoming of the Panel's approach is the lack of a clear system that will deliver more effective labels.

While various of the Panel's recommendations are insightful and by themselves are an improvement (ie maintaining a strong science and risk management basis, reforming the 'use' tables to climate zones, ensuring the equitable treatment of aerial application), their effectiveness could be multiplied if they are made to occur within a coherent system that will reimagine labels for the future.

AAAA strongly recommends amendment of those recommendations and the implementation of outcome focussed principles to guide regulators and industry towards better labels and processes to deliver them.

The following is from the AAAA submission to the Panel and AAAA again recommends the convening of an expert panel to help overhaul labelling directly:

> "This is where Government should be looking closely to move to a comprehensive approach to redefining what a label is and how it works – and integrating the use of advice/calculators etc that are not physically mentioned on the label.
>
> A key outcome to move this discussion forward should be a **high-level working group** to help redesign the Agvet system approach to labelling that is modern and includes:
>
> - label simplification as a key outcome
> - label clarity as a key outcome
> - use of electronic media
> - use of approved reference material not on the physical label
> - recognition of industry accreditations that go to competence or systems
> - build on a genuinely nationally consistent control-of-use system for issues such as record keeping
> - build on an effective national system of training that does not require the label to 'make up' for poor training

- permits appropriate variability of use across similar crops or situations (already available in some States/Territories but not consistent)
- permits buffer assessment based on scientifically relevant information not on label (see APVMA Drift Management Policy Stage II reforms – yet to be delivered)
- focus on relevant agricultural regions or crop or use patterns rather than the current State/Territory table of use (based on the pre-NRA/APVMA State Registrars of Chemicals – rather than any use patterns or geographic demands)
- how these innovations and new flexibility may be applied generally to all labels, not just new labels or labels subject to review"

A Systems Focus

While AAAA can see within the recommendations the intent to establish a system of continuous improvement through various isolated components, AAAA believes a stronger and more overt recommendation is essential to ensure the new AgVet system has the necessary tools to establish and maintain a ***systems*** focus.

AAAA refers the Panel to its earlier submission which contains the following recommendations which could easily be adopted in the final report and used to improve and amend existing recommendations (for example on consultation – where AAAA opposes the proposed approach):

> "There are a number of critical systems missing from all regulators involved in the national scheme which should assist the review team in identifying why there has been no significant progress in the regulation of Agvet chemicals over the last 20 years.
>
> These include:
>
> - **Continuous improvement** – of regulator processes and systems, or lack of systems. The lack of genuine engagement with industry and end-users (including the States/Territories) – not just registrants – is evidence of how far removed APVMA is from a coherent system of continuous improvement.
> - **Quality Assurance** – a focus on both processes and outcomes to ensure regulators are well focussed on their own performance and are able to identify and repair/reform their own processes that are impediments to better performance.
> - **Access to Expertise** – while some level of basic competence is a reasonable expectation of Departmental, APVMA and State/Territory regulatory staff, it is not surprising that many staff do not have specific knowledge of either chemical use patterns in the field, application technology (such as aircraft) or nozzle performance parameters or drift management technology. While there are clear exceptions to this observation – with APVMA having some very talented experts in their areas – the surprising element is that there is no system in place to 'normalise' government access to experts from industry or academia.
> - **Genuine Engagement and Consultation** – APVMA (*or the Department*) have no systems in place to ensure regular, formalised or structured discussions with industry and especially end-users.

General Comments – Draft Report Text:

Chapter 1

1.2 If the Panel recognises greater reliance on 'skilled professionals' why not hold agronomists to the same licencing and accountability standards as 'contract sprayers'? (p3)

1.2 Correctly identifies the need for a better system that can cope with change (eg drones etc) – but no mention of the need to assess new tech etc in terms of risks and manage them in line with the same principles of risk management applied to existing technologies, practices and applicators- ie a level playing field. See, for examples, AAAA policy position paper (www.aaaa.org.au / Resource Centre / Policies) on the need for drone drift assessments because of the different platforms being used as distinct from the apparent haste of States to approve drone spraying without this level playing field. (p10)

1.4 Strong support for risk not just hazard assessment process, but a useful understanding is that a product should not be dismissed as unmanageable (from a risk perspective) without the regulator being charged with taking a *problem solving approach in conjunction with expert support* – ie better application practices derived from advice from AAAA for aerial. The current system prescribes against this by only involving the registrant and not seeking wider innovation to address identified risks (eg 24D permits initial failure for aerial – solved by consultation with AAAA / closed handling systems for molinate and others etc) (p16). Partly identified and briefly dealt with on p17 and in REC 3 – but may need elevation to ensure implementation and include the words 'problem solving'.

1.5 Strongly support concept of outcome based regs and appropriate co-regulatory culture. This will be essential to combatting the current complexity of all labels – which have reached the point of continually setting compliance traps for users due to their complexity, internal inconsistency and application of different standards for different application methods with zero recognition of varying levels of competence and accountability (pp19-22)

Chapter 2

2.1 While AAAA strongly supports the panel's recommendation and discussion around the need for a single national control of use law, we remain sceptical regarding any progress to be achieved in the short to medium term through negotiation with the States. AAAA went through this process for over a decade with the PSIC committee looking at constructing a simple national system for pilot licencing where all the heavy lifting (training, competence, assessment, accreditation, database etc) had been done by AAAA but the general agreement was whiteanted by a minority of States for whatever unsound reasoning. (p27-28)

2.1 Cost of reform – AAAA thinks this is a significant underestimation of the savings available through a national single law system. There would be the significant and very real savings through simplified labels that remove the current Table Of Use State basis of all labels (a hangover from the original Registrar of Chemical days when the current scheme/NRA/APVMA

was established) that will increase productivity and safety by more consistent label access to use of chemicals in slightly different situations which is currently illegal (outside some variations in Vic, SA and NT through their legislation). (p28-29)

2.2 AAAA supports the panel's finding that APVMA has little to no appetite or tools to encourage, approve or facilitate innovation (p34) over its history, although there are some early signs that this is changing. While there has been some improvement driven through the work of NWPPA and AAAA with APVMA, the outcome in the field remains limited. The Stage 2 drift management reforms – long touted and yet to be implemented – are a good example of a better system being stifled by the key regulator dragging their feet – but again, this appears to be changing. For many years, the outcome of APVMA policy (especially its Drift Management Principles) has been so flawed as to lock in 'worst practice' and ignore better ways of doing things. Facilitating and encouraging innovation must be a power clearly enacted in the new system – up to and including the power to direct APVMA to change practices, policies and systems where they are clearly operating against innovation (p34).

2.2 Advocacy – see also above – AAAA strongly supports the role of a 'champion for improvement' within the system that does not currently exist. What little improvements have been made have been achieved despite the lack of interest from the Commonwealth Dept of Ag in playing this role or the APVMA being open to better ways of achieving outcomes (p34)

2.2 The single paragraph here outlining an admirable commitment to the Commissioner facilitating and focussing on continuous improvement is strongly supported, but AAAA does not believe the concept is as strongly supported in the recommendations as it potentially could be. (p37)

Chapter 4

4.2 The panel does not seem to understand the licencing arrangements that are in place for aerial application and has not identified or supported the potential benefits from focussing on licencing businesses rather than individuals.

While AAAA strongly supports national single licencing, the current situation is that all States/Territories recognise AAAA's Spraysafe accreditation as the *de facto* national competency standard for issuing a chemical distribution licence for aerial application to an individual pilot, in addition to holding relevant CASA licences. So for aerial application at least, there is reasonable national consistency, good training, sound assessment etc.

The problem is that every State requires their own licence – and fee – and various COAG attempts to improve this situation through the Mutual Recognition of Licences is yet to bear any real fruit. Even where licences are recognised by other jurisdictions, other jurisdictions may still require the issuing of their own licence for individuals and businesses.

Business licencing is even more inconsistent, with Tasmania making it a condition of business licencing that the aerial business hold the AAAA Spraysafe business level accreditation, while

Victoria requires business to either be Spraysafe business accredited or 'operate at a substantially similar level' – and we cooperate with both jurisdictions to provide our checklist, auditors guide etc. No other State/ territory mentions Spraysafe business level accreditation and WA is the outlier by not requiring business licensing at all.

AAAA believes a simpler approach is to not licence pilots at all but to licence businesses, and make the business responsible for only employing appropriately qualified pilots (eg Spraysafe accredited, CASA licenced), and ensure the business keeps a record of the pilots working for them and who completed which job – which is already done anyway. Then the business could be required to have certain useful systems or operate IAW agreed national protocols, could be required to be Spraysafe qualified or equivalent and would be licenced once nationally.

This system was proposed through PSIC in the 2000's and had some State / Territory support but came to nothing. (p84)

4.2 It appears the Panel is not up to speed with the proposed APVMA Stage 2 Drift Management reforms, APVMA's work with the NWPPA, and the existing development of an online Spray Drift Management Tool to better match application requirements in the field to more accurate real-time risk assessments. It appears that what the APVMA is already close to delivering is what the Panel is imagining and a briefing on this from APVMA or NWPPA may be instructive (p 88-89)

4.4 Labelling – The panel has identified some but not all issues that would support a move to smart – electronic labelling. Additional issues include:

- Labels have become a dumping ground for information that is seeking to atone for poor training. Get the training right, and the labels can be simplified.

- Labels are simply too complex to be understood without hours of study. Conflicting advice is often on label, and some jurisdictions continue to play the 'gotcha' game with applicators where honest mistakes have been made due to label complexity and competing advice on the same label.

- Labels have very little flexibility to enable risk acceptance by landholders / users within the context of a particular cropping situation or balancing label compliance with a positive agricultural outcome – eg potential efficacy trade-offs, but being overall 'better off'. An example might be conflict between needing crop protection but the label prohibiting application when rain is forecast, or even definitional issues about 'rain' versus a few drops – which has even been the subject of regulatory action by a State agency.

- While specific safety information and warnings are critical information on label, they should not be overcomplicated by new requirements proposed for general obligations etc.

AAAA does not believe smart labelling or electronic labels or Q Scans are a panacea if there is not a deeper simplification of labels from the users' perspective as distinct from the regulator, registrant or control of use perspective. (pp 94-98)

Detailed Recommendation Comments

Chapter 1	AAAA Response	Comment
1. Recommendation The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system. 'A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to safe products and uses.'"	Supported	Could be improved by adding something at the end on 'through systems and accepted principles of continuous improvement, QA and sound consultation.
2. Recommendation The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives: • safeguard animal health and welfare • support primary industries • protect Australia's trade • contribute to biosecurity preparedness.	Supported	

3. Recommendation The Panel recommends that the following principles should govern the design and implementation of the new regulatory system: • The regulatory system should be based on risk, not on hazard alone. • Processes and decisions should be objective, independent and science based. • Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry. • Risk management measures should be reviewed as new information becomes available. • The system should be efficient and outcomes-focused by making use of streamlined and fit for purpose regulation. • The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products. • The system should be adaptive to new technologies, practices, and knowledge. • The regulatory system should support a resilient supply chain.	Supported	No overt mention of systems approach that facilitates continuous improvement / QA etc – this would be an improvement

Chapter 2 **4. Recommendation** The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.	Supported, but…	AAAA is very concerned as to how such an approach would be 'welcomed' by the States and Territories and what that might mean for the fundamentally cooperative basis to the National Registration System. AAAA also recognises the failure of previous reform attempts in this space and the reluctance of some jurisdictions to play a positive role in reform. However, establishing a strident approach to a previously somewhat cooperative system may be counterproductive, with industry and especially applicators wearing the significant risks attached. A key concern is what will happen to the State legislation provisions regarding 'harm' – this could result in a potential double jeopardy where the Commonwealth law applies in addition to State law. Poor outcomes will be the result if this is not well coordinated – such as is the case with APVMA unilaterally requiring record keeping on label when this is already a requirement of State law – but slightly different in terms of what is to be recorded – thereby adding complexity to the system rather than simplifying it. AAAA support (see above) is conditional on ample opportunity for industry issues to be heard during the drafting phase of any new Commonwealth law and to provide some level of equivalency with or clear improvement on current approach – eg aviation licensing of business only with licence condition to include using Spraysafe accredited pilots…/ offence / defence provisions / strict liability / consistent application of requirement to ground,air and drones…

5. Recommendation The Panel recommends that the need for, and the scope, role and form of a new IGA are considered as part of this review's implementation. The Panel recommends that the existing IGA be extended until this time, recognising that there are some matters, such as those relating to funding, that are unlikely to be resolved in the interim period.	Supported	See comments above regarding the need for a well-coordinated legal drafting process required to ensure double jeopardy is not created.
6. Recommendation The Panel recommends that should there be a need for an IGA in future, it should reflect the lessons learnt from the shortcomings of the current IGA including that it: • provides that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail • requires any jurisdiction that departs from the IGA approach to provide a public reason for such departure • mandates minimum resource levels for regulating control-of-use, to effectively meet assurance and compliance obligations (perhaps as a proportion of each jurisdiction's domestic production value) • requires regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals • requires regular publication (or input to the Commissioner's reporting) of performance against these indicators and targets or goals.	Supported	See comments above regarding the need for a well-coordinated legal drafting process required to ensure double jeopardy is not created.

7. Recommendation The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship.	Opposed	AAAA is concerned that the creation of a Commissioner may establish potential competing legal claims and powers between Commissioner and APVMA CEO. While AAAA does not disagree with the rationale behind some of the problems that led the Panel to recommend the establishment of the position of Commissioner, AAAA cannot support the recommendations due to great reservations regarding the reach, costs, lack of detail and potential lack of impact of such a recommendation. In particular, with AAAA's experience of dealing with CASA and the ATSB (led by Commissioners) it is critical to ensure that there is clear resolution of the potentially competing legal heads of power between the entities and between the Commissioner and APVMA CEO. This has not been addressed. There is little evidence that the Commonwealth Dept of Ag, given consistent failure or lack of action in this policy space over many years, could be entrusted to improve performance of the APVMA or accountability of the overall system alone. The powers made statutory under the Commissioner concept would have to be clear and detailed. This has not been adequately explained. The role and powers of the Commissioner should not be seen as a surrogate for the importance of the effective management and leadership of the APVMA and conversely, the Commissioner's role cannot be allowed to be so unresponsive that it can be sidetracked or sidelined in terms of getting better outcomes from APVMA or too removed from control of use legislation and outcomes. This would present a very fine balancing act that is probably beyond the skills and structure outlined. (p36) AAAA understands how attractive the Commissioner role may be to the Panel, but not enough consideration has been given to how similar roles and functions could be fulfilled by either the CEO of

		APVMA or the Commonwealth Department of Agriculture.
8. Recommendation The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.	Opposed	See AAAA concerns as outlined in RECs 4 and 7 Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag)
9. Recommendation The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.	Opposed	See AAAA concerns as outlined in REC 7. Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag)
10. Recommendation The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.	Opposed	AAAA has long supported improved consultation in this regulatory space, however, the approach of the current recommendation cannot be supported in its current form without further consideration being given to ensuring the Stakeholder Forum is not able to be targeted by activist interests with a new platform to execute an anti-science and anti-chemical agenda. AAAA thinks there are better ways to manage this issue of consultation and access than through a formal forum providing direct advice and thereby creating significant expectations. AAAA believes that the strong Panel commitment to a science and risk management-based approach to the AgVet system is a critical principle that should not be compromised. Consequently, AAAA recommends that instead, a Forum be established that will enable discussion around continuous improvement that focuses on key players including registrants, applicators, and end users (farmers etc) which could potentially play an ongoing role in this area and would be more likely to provide government with practical, outcome based advice focussed on improving the system – without

		political considerations that could be dealt with either by the Minister or Department separately through a stakeholder engagement strategy for the wider community. AAAA clearly does support a separate Forum for State/Territory regulators (as they currently are) and the APVMA and Commonwealth Dept of Ag. However, this should supplement and not replace a requirement for APVMA to have its own consultation 'fora' for both states, registrants and end users – something that is currently missing. AAAA also supports the establishment of Expert Forums based on particular issues, but suggests at commencement that a number be made standing/ongoing committees such as one dealing especially with, for example, aerial application and ground application issues, and another focussed on label simplification, another on training and competency issues etc (p37)
11. Recommendation The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag/APVMA) Grants - AAAA is unsure of the meaning or intent or detail of this recommendation as none is provided. However, the concept of their being available a suitable budget and grant program to support industry and others in the development and implementation of improvements for chemical application is supported. The current minor use grant program given as an example is not available for aerial application due to the definitional issues AAAA has identified in previous submissions. The overall permit system is not working for aerial application (other than in very limited circumstances) and is in urgent need of reform.

12. Recommendation The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.	Opposed	AAAA does not support the role of the Commission, however, the intent of this recommendation should stand alone as a separate recommendation that should be the responsibility of the AAAA proposed Reform Implementation Committee or of a repurposed Department of Agriculture.
13. Recommendation The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.	Opposed	AAAA does not believe a return to an APVMA Board offers any advantages to improving the performance of APVMA. If anything, the previous performance of APVMA under a Board (regardless of its advisory or 'full powers' basis) does nothing to recommend the reestablishment of a Board. AAAA's work with CASA provides another example as to the ineffectiveness of Boards in government agencies, loss of Ministerial accountability, loss of consultative mechanisms and perhaps most critically, no change to the trajectory of the organisation in terms of performance. AAAA believes from its experience over several decades that the critical appointment of an appropriate individual with an open culture and a proven track record and commitment to systems based management focussing on continuous improvement as the CEO of government agencies such as APVMA (or CASA, ATSB or others) is far more impactful than constructions such as Boards. While government Boards may play some political role in providing further protection to Ministers from controversy, they do not appear – on the evidence – to play a significant role in improving organisations' performance.

14. Recommendation The Panel proposes the establishment of 2 formal and one ad hoc consultation mechanisms by the Commissioner to consider, and offer advice to Ministers and the Commissioner as appropriate on, the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are: • a Stakeholder Forum • an Operational Forum • an Expert Advisory Panel (as needed).	Opposed	See earlier comments for REC 10 - Stakeholder forum will not function well with proposed stakeholders. At least an additional forum for pesticide users such as applicators and standing panel of experts to provide input on label language etc Indirect advice to APVMA via the filter of the Commissioner is clearly not supported and the APVMA should separately address issues of consultation as per previous submissions to APVMA on improving their stakeholder engagement.
15. Recommendation The Panel recommends the Stakeholder and Operational forums have terms of reference consistent with those set out in Annex 10 and Annex 11.	Opposed	See earlier comments for REC 10 - Scope too limited by constituencies / lack of practical focus rather than ideology
16. Recommendation The Panel recommends that the Commissioner establish a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The biennial reports would review progress in implementing the reforms decided by the Government in light of the Panel's current report. Reporting should commence 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact. Performance measures, as a minimum, should address: • health impact	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) AAAA is not opposed to the concept outside of the creation of the Commissioner position, however, support is conditional on the performance parameters that are important to users of the system to be consulted and included. Additional parameters including audits and outcomes of audits, investigations, prosecutions, failed prosecutions, successful appeals, vexacious claims etc (in terms of the control of use performance) would be very useful in guiding improvements to the system, as would knowledge of delays with APVMA applications or even overarching outcome information such as the number of aerial application approvals from APVMA compared to ground (currently rating about 1 in 18 approvals - indicating

– establishing formal human, animal, and environmental health risk indicators – number and nature of adverse experience reports and pharmacovigilance findings, and time taken to respond to adverse experience reports and any consequential actions. • industry impact – supply, use and disposal of pesticides and veterinary medicines. • community impact – social attitudes – community outreach and engagement. • regulator performance – number and type of regulatory decisions by the APVMA and Commissioner – number and type of audits and compliance activities, including information and education campaigns. • responsiveness to community concerns raised.		significant impediments to gaining aerial approvals through the current APVMA system).
17. Recommendation The Panel recommends that the Commissioner establish health risk indicators for Australia, similar to those used in the European Union, and publish outcomes in its reporting of performance measures.	Opposed	Australia should be very wary of adopting anything from Europe given the different ag systems, the role of activists etc – and no clear outcome based in science or risk. AAAA believes this adoption would likely serve to establish tension with the key scientific based regulator APVMA and would add nothing useful to existing assessment processes.

18. Recommendation The Panel recommends the retention of statutory timeframes for the APVMA to complete its pre-market assessments as a vital input measure to the regulatory system and recommends that statutory timeframes should be expanded to a range of other decisions, such as licensing and responsiveness to the Stakeholder Forum, in the future regulatory system to improve transparency and accountability.	Supported	See also comments to REC 16 - Transparency and accountability are essential to improving any system and can also be a real positive for any agency that is actually performing well. Baseline figures and regular benchmarking are also a useful feature of continuous improvement systems. Establishing an APVMA 'performance dashboard' that is valued by industry and users would be well worthwhile – with input from industry.
Chapter 3 **19. Recommendation** The Panel recommends that the Commissioner be assigned responsibility to build a surveillance system fit for the needs of a 30-year future. The system should: • Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions. • Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) Use reporting through user records – Opposed. AAAA believes the benefits from such a cost intensive, invasive and otherwise concerning proposal have not been appropriately identified or quantified, especially where surely the focus should be on outcomes in terms of safe food and produce through sound use and application – something the proposed expanded residue testing regime would support. The use of existing record keeping by applicators would add significant cost and despite platitudes from the panel in terms of the security of data and the sacrosanct nature of government processes regarding record security, privacy and non-use for compliance activities, this is already not industry or for that matter community experience in other areas. A great deal more detail, research and assurances from government would be required to change AAAA's mind – especially given the current practices of some jurisdictions.

20. Recommendation The Panel recommends that the Commissioner develop arrangements to curate all such sources of information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag/APVMA) Important to also provide open access to available education resources or at least a central website pointing to resources or organisations conducting such programs
21. Recommendation The Panel recommends the Commissioner consider how to best utilise and capitalise on current record keeping requirements for use of pesticides and veterinary medicines in Australia.	Opposed	AAAA is very concerned with possible direction this REC could take including privacy, red tape and cost issues as outlined in REC 19. A key concern is that this REC and accompanying discussion demonstrates an apparently limited grasp of the numbers of records created, difficulties with access to the internet in regional Australia (if this is an avenue for access to reporting of records etc) and no recognition of the legal implications and defences against self-incrimination available rightly to applicators.
22. Recommendation The Panel recommends a Government-led national domestic produce monitoring program be established.	Supported	AAAA sees this element of the proposed overarching system proposed in REC 19 as acceptable and useful – while the other components touching on user records and additional monitoring as not acceptable. If the produce residue monitoring system is working well, there is no need for the other expensive and likely non-productive elements of the monitoring scheme.
23. Recommendation The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.	Supported	See above

24. Recommendation The Panel recommends the Commissioner finalise the design of the domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residues Survey, primary producers, manufacturers, state and territory governments, and the community.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) AAAA is not opposed to the intent.
25. Recommendation The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.	Opposed	See comments above. This appears to be a solution in search of a problem that doesn't exist. AAAA believes that any monitoring program as described is best done on a targeted, risk informed basis – especially due to the significant costs and practical implications. In addition, AAAA has experienced first-hand in Tasmanian examples of use of selected data to damage legitimate, safe industry- regardless of the best efforts to provide context and relevant scientific discussion of the meaning of results.
26. Recommendation The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.	Opposed	See above

27. Recommendation The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.	Opposed	See above – especially the involvement of the Stakeholder Forum which would serve to undermine any confidence in a risk-based, scientifically rigorous approach or targeting.
28. Recommendation The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.	Opposed	AAAA is concerned due to its experience in Tasmania of the attempted application of drinking water standards to an agricultural setting. AAAA is not opposed to specific investigations etc based on actual events, but this appears to be a significant cost for questionable outcome that is probably within the jurisdiction of the States/Territories.
29. Recommendation The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.	Opposed	See above

30. Recommendation The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.	Opposed	AAAA is opposed to the requirement to force applicators to report various issues when this clearly cuts across the principles of natural justice – and especially where such reporting would take place without the protections and considerations, for example, of this taking place within a 'just' culture such as happens in aviation safety reporting through the ATSB under the *Transport Safety Investigations Act.* As a minimum, the legal defence from self-incrimination should apply. Without these protections for licence holders, AAAA cannot support this significant expansion of a scheme where no consideration has first been given to improving the current scheme through education rather than compulsion. However, there may be potential to expand the existing adverse experience reporting system to include where applicators identify labels that are overly complex, contradictory or in need of review – akin to the current AAAA Chemical Label Improvement Program.
31. Recommendation The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.	N/A - Vet	
32. Recommendation The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.	Not opposed	Only in terms of improvement of current adverse experience scheme.

33. Recommendation The Panel recommends sound information sharing practices be established between the APVMA and the Commissioner to allow APVMA access and the opportunity to respond to those matters relating to the registration and exemption of products, or the supply of those products.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag)
34. Recommendation The Panel recommends the Commissioner establish an interface that provides users and the public with contemporary details of validated adverse experience reports. The Panel also recommends the interface support the streamlining of submission of adverse experience reports.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) Emphasis must be on VALIDATED – ie based on tested samples as applicable. AAAA experience in Tasmania is instructive, especially regarding the role of the media in attacking a safe and highly regulated industry on the basis of poor or misrepresented science – an example that eventually led to a completely different cause being scientifically established (ie oyster poisoning due to deoxygenation rather than pesticides) – but the damage had already been done in the public domain.
35. Recommendation The Panel recommends that trends identified through system surveillance data be reported publicly in the Commissioner's biennial report.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag)
36. Recommendation The Panel recommends that the residue monitoring results of domestic produce and environmental water and adverse experience reports should be publicly available, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken.	Opposed	See comments above.

37. Recommendation The Panel recommends that the results of these programs should be collated and published in an informative and educational manner. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.	Not opposed	See comments above. Extreme care is required in providing appropriate context and scientific rigour that will not permit this info to be used inappropriately.
38. Recommendation The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.	Not opposed	However, AAAA is unsure how this requirement would be different to existing arrangements. Also, this REC requires the triggers developed being consulted and codified and open for removal or review depending on their effectiveness – and the lack of duplication with existing requirements. AAAA also believes the re-review period should be pushed out to 5 year minimum other than in exceptional circumstances – as codified Transparency would be improved by codifying a way of capturing industry expertise in a problem-solving model during the review – see 24D, molinate and other AAAA experience etc.on APVMA committees (now not used) – where the current legislation for APVMA effectively freezes out any other organisation or individual other than the registrant of APVMA – as the report highlights at (p 69)
39. Recommendation The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.	Supported	See comments above. Reviews should be pushed out to 5 year minimum other than in exceptional circumstances – as codified

40. Recommendation The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.	Supported	See comments above. This puts enormous pressure on APVMA – some additional information surrounding the sorts of non-relevant issues might be advisory.
41. Recommendation The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.	Supported	
42. Recommendation The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) See comments above.
43. Recommendation The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.	Supported	
44. Recommendation The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.	Not opposed	However, AAAA notes that consideration must also be given to available effective alternatives and to the potential economic and environmental impact of not having access to a particular chemical that has no viable alternative – eg 1080 poison.

Chapter 4 **45. Recommendation** The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.	Opposed	AAAA does not believe that the Panel has made an effective case for what is seen as additional regulation, red tape and liability (similar to a double jeopardy situation when viewed with control of use law). In particular, the lack of analysis of overlap with existing legal liability especially through WHS law is concerning. AAAA is of the view that the development of a single control of use legislation would be the appropriate time to define different jurisdictional aspects of legal coverage and liability / offences, rather than pursuing this approach of what are clearly additional responsibilities. If they are not additional – why have them and what function do they serve? If they are additional, then where is the detailed RIS and economic impact analysis, and how will they fit in with the yet unimagined control of use regime?
46. Recommendation The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.	Not opposed, but…	AAAA strongly supports the greater recognition of industry programs – but not within the context of creating general obligations – which appears to be a duplication of existing law anyway. AAAA support is withing the context of criticisms and opposition in the comments above to REC 45 and the creation of general obligations in the first place. The two recommendations – REC 45 and 46 - should be rewritten to ensure that recognition of industry programs is a stand alone REC and is not conditional on the separate proposal to establish general obligations which are simply duplications of existing legal obligations – which have the potential to thereby create legislative competition, tension and duplication – all for the cost of industry to resolve in the courts. Of course, AAAA is strongly in support of the recognition of industry programs that deliver

		superior outcomes – but the problem of potential duplication – and jurisdictional overlap as outlined above - must be addressed first. One of the key reasons (for AAAA and others in indsutry) to establish an industry-driven program or accreditation scheme is to address the sad duplication of liability created by various jurisdictions, the differing government demands made using different language for the same outcomes from different (or sometimes even the same) agencies, and the total lack of coordination in terms of any 'whole-of government' approach to how industry is meant to function on a day to day basis. This major consideration is on top of other benefits including effective and credible training, meaningful change programs and broader-than -government legislative and compliance driven focus onto critical issues such as culture, capacity building and systems based resilience. To understand this gives a better understanding why recognition of industry schemes is often a far more effective measure than any simplistic compliance program on its own – even though baseline outcome based legislation/ regulation has a valuable role to play in underpinning minimum acceptable standards and often 'picking-up' the freeloading non-adopters that may still exist in any industry.

47. Recommendation The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).	Opposed	New and additional red tape regardless of existing law and the REC and accompanying text fails to make any detailed assessment of the existing legal obligations it would effectively duplicate.
48. Recommendation The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.	Supported, but…	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) National licencing as a concept is strongly supported, but with an additional recommendation to adopt the system outlined in the general comments for Chapter 4 at the beginning of this submission. Support is also conditional on details being available and transfer of similar outcomes for current aerial licencing. This REC could be further simplified as per previous AAAA recommendations about business licencing, no individual pilot licencing, but businesses required to keep records of pilots doing which job. AAAA also believes that a significant missing link in accountability within the current system in the lack of accountability of agronomists who are not licenced or regulated in any significant way despite

		playing a significant and increasing role in the recommendation of chemicals. A key step forward to address this critical 'missing link' would be to engage with CCA and recognise their programs for Certified Agronomists.
49. Recommendation The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.	Supported	See comments above. AAAA's Spraysafe program is an obvious first candidate because of its existing universal recognition by all State/Territory jurisdictions for pilots. Consideration can then be given to expanding recognition to the entire Spraysafe program (business, pilots, mixers) and then consider how to recognise or encourage AAAA's AIMS program (Aerial Improvement Management System) that is an enhancement of the Spraysafe program and covering all legal responsibilities.

50. Recommendation The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system. The following are the Panel's proposals for initial licensing schemes under the new national licensing framework: • supply of internationally registered products • good manufacturing practice • supply or use of substances for research purposes • supply of hormonal growth promotants • dealings with Stockholm Convention substances • supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products) • aerial application of pesticides (pilots and contractors that employ pilots, drone operators) • ground applicators • commercial pest controllers (pest management technicians) • special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.	Supported	See comments above. Also, which 'ground applicators' are to be licenced? - as States have different approaches – depending on being a contractor or not and licencing is neither universal nor consistent between States… there should simply be a level playing field between all aerial applicators and all ground applicators – depending on what their National Association (if they have one) can offer… AAAA does not believe drones should be licenced for application until they can provide evidence that their particular platform/nozzle combination can deliver label compliant spray quality, rate, water volume etc. There are also a range of relatively standard equipment used on aircraft that are not available on drones. See AAAA's Policy on Drones at www.aaaa.org.au / resource centre / policies. The States are running way ahead of the science and the capability/training/maturity of the drone industry.

51. Recommendation The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.	Supported	As long as aerial is based on recognition of Spraysafe for aerial application. Who is an 'operator' – is it the person with their hand on the tap or the business overseeing the job? There is a need to better understand the difference and interrelationship between competency (individual) and due diligence systems (business) and the accurate use of the correct terms. Ground application training and competencies etc – to what standard? Given the current state of national competencies that seem to talk about everything except actually doing the job as an applicator within a risk management environment, monitoring etc.
52. Recommendation The Panel recommends that the Commissioner completes the work of HACCUT to establish training standards for restricted chemical products and Schedule 7 poisons, and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides and veterinary medicines.	Supported	Although AAAA notes that in existing schemes and because of the quality of training through Spraysafe, Sched 7s are permitted for pilots/businesses and this should be maintained in any national licencing system. General licencing competencies should cover these requirements as they currently do for aerial. The key issue is that the competencies should be written by people who actually know what is required. Current national competencies are not fit for purpose.

53. Recommendation The Panel recommends that competency standards be established for roles introduced through other recommendations in this review. These include: • accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6) • government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.	Supported	Competency standards and licencing should be introduced for agronomists – or an acceptable industry scheme recognised – eg CCA
54. Recommendation The Panel recommends that where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Commissioner.	Not opposed	With the realisation/ warning that this may compromise the viability of existing low throughput training schemes and therefore that should also be a consideration in assessing any new proponents.
55. Recommendation The Panel recommends that the Commissioner work with the ASQA and industry associations responsible for industry-based accreditations to ensure quality of training outcomes, and that training is adapted to meet the needs of pesticides and veterinary medicines users into the future. The Panel suggests that the Commissioner examine the benefits of micro-credentials when developing the standards.	Not opposed	However, it must be recognised ASQA is the problem not the answer. The expert panel from peak bodies as outlined by AAAA and quoted in the report is far more likely to deliver useable competencies that should then be rubber stamped by the Skills Council that created the current mess and then ASQA. AAAA notes that is does not have the resources to become an RTO and all approaches to cooperate with existing RTOs have been rebuffed due to the low throughput nature of the training and the inability of RTOs to secure significant profit from the AAAA expert, specialised training programs ie it is all about the $$ in the National Training

		Framework, not the quality of outcomes or the 'fit for purpose' nature of the successful candidates. AAAA has a number of concerns regarding 'micro-credentials' including the likelihood that significant overarching and interrelated competencies from critical competencies will be lost eg knowledge of regulations, risk management, human factors. AAAA concerns go back to the threshold question of what should an applicator know – with the current training for ground applicators being widely accepted as deficient.
56. Recommendation The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart-label content.	Opposed	For any competent applicator, this information is already available on the SDS and through training. Further cluttering up already extremely long and complex labels with additional information is not warranted and fails to recognise the reality of AAAA's suggested improved approach to labelling in the 'general comments' at the start of this submission under section 4.4 – and especially point 1. Labels should not be a dumping ground for information that should be held by all applicators through good training, SDS etc. And labels should not be attempting to make up for poor training that is not delivering 'fit for purpose' applicators. Whether additional information can be provided electronically through an education or supporting document to a label (eg SDS) is not being challenged – it is simply to try and keep labels focussed on the critical information to do the job.

57. Recommendation The Panel recommends that the opportunities to enhance labelling through additional smart-label content be actively pursued and implemented with a stronger sense of urgency than has been the case to date. The result should be safer use, a more informed user as well as an improved user experience.	Supported	Within the context of points above. AAAA notes the very important role to be played in this area as a result of the proposed APVMA Stage 2 drift management reforms and online tool as developed and promoted by the NWPPA, and would welcome the panel discussing the importance of these reforms across a wide range of issues – including being a useful trial with the States of E labels.
58. Recommendation The Panel recommends that the Commissioner continues to scan the technology horizon to identify additional emerging technologies that may assist with labelling reform.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) – which AAAA assumes would have been a core role of both the Dept of Agriculture and the APVMA anyway.
59. Recommendation The Panel recommends that the regulatory assessed elements of the label approved by the APVMA be limited to that information which is not assessed by other regulatory systems.	Supported	Especially if this leads to shorter more focussed labels from the user perspective…see dot points above
60. Recommendation The Panel recommends the product label must comply with general conditions of registration to ensure the risks of the product can be managed. To implement this, the Panel recommends the establishment of general statutory conditions of registration to which the product label must comply, along with urgent completion of a labelling standard. Where relevant, compliance with the labelling standard would be made a condition of registration (or form part of the licence to supply overseas registered products). More details of these proposed conditions are provided in Annex 6.	Supported	AAAA believes a more standardised approach to label content – including an agreed 'aerial application approval standard' – would be a useful step forward in speeding up approvals – standardising APVMA staff approach to label language and simplifying labels. Standardisation of labels is critical – same info – same place / removal of ambiguity and conflicting requirements. AAAA recommends the APVMA establish a Chemical Label Improvement Program - with APVMA working with industry, registrants and end users' input as part of an overarching Continuous Improvement System – eg based potentially on the existing AAAA CLIP model based on reports from users, but with a requirement for labels to be updated to address identified and agreed shortcomings or inconsistencies.

61. Recommendation The Panel recommends manufacturers should be permitted to (and indeed, should be encouraged to include) include additional personal protective information on product labels, provided it is not inconsistent with the regulatory assessed label elements.	Opposed	This flexibility seems to undermine the previous recommendations' approach that would support more standardised labels. Manufacturers should be encouraged to provide additional information – but not on the label – either the SDS, tech sheets, electronically via a product website or through training and marketing. Alternatively, this function could be built into an overhauled and more effective Pubcris online system that could be added to by registrants through a 'new information/support' portal.
62. Recommendation The Panel recommends that every 5 years, at a minimum, the registration holder must conduct a review of label content to ensure the information on the label is current and remains correct – noting that emerging scientific evidence or consumer concerns could also trigger a review, including a labelling review, at any time (see chemical review discussion in Chapter 3).	Supported	It appears this could be very powerful in the context of current generic product labels not being supported or updated and the ongoing challenge of different chemicals operating under different policy streams depending on when they where originally assessed. This could be even more useful as a trigger to improve labels or simplify or standardise – ie linked to new APVMA simple standards (eg standard aerial application statements etc) and Chemical Label Improvement Program – see above.
63. Recommendation The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the regulatory assessed elements of label requirements and not against the 'approved label'.	Opposed	AAAA is cautious regarding this REC as its intent is not clear and as it may run beyond the scope intended in the accompanying text which deals mostly with the need for labels to be kept up to date. Perhaps this could be reconsidered once all of the other elements of the new label system are seen to be working as a 'system' – rather than as a series of individual changes. Further discussion is required.

64. Recommendation The Panel recommends that the Commissioner be empowered to publicly report a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent. • The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reports on the state of the system.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) However, AAAA believes that a strength of current arrangements is their voluntary nature and the reach (now) of the DrumMuster program which AAAA members also use. AAAA recommends that any measures to be taken in this area are discussed firstly with the existing managers of the only successful scheme in operation and that nothing be done without the support of the current scheme ie DrumMuster.
65. Recommendation The Panel recommends encouraging industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations (see Section 4.1).	Not opposed	However, AAAA notes that waste management principles are already incorporated into AAAA training such as Spraysafe, is a requirement for Spraysafe business accreditation, and AAAA has worked with the NSW EPA to provide an acceptable means of compliance for aerial spraying facilities including waste reduction and management. The AAAA AIMS program also contains considerable impact in this area. There is a clear need for the recommendation to focus attention not on the sectors doing a good or great job, but on supporting participation in existing programs and ensuring companies who are not accredited or participating get appropriate attention – including through audit and potentially additional licencing conditions. For example, where does ground application rinsate go? A focus on the lowest performing first makes a great deal of sense in terms of lifting average performance and reducing actual environmental harm.

66. Recommendation The Panel recommends good disposal practice be considered as conditions for relevant licences.	Opposed	See comments above Voluntary approach works fine for aerial. However, perhaps consideration be given to additional attention to companies not participating in accepted industry accreditations – but this could be done through audit programs. In this context it is worthwhile noting that routine surveillance auditing of ground applicators is extremely rare – and unheard of in many jurisdictions.
67. Recommendation The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) However, given there are existing industry Waste Management Agreements under the National Packaging Covenant, wouldn't that be a relevant starting point? IBC recycling is currently a missing link in a closed loop process and would be welcomed.
68. Recommendation The Panel recommends that veterinary medicine products compounded by a veterinarian or a pharmacist, for any animal treatment are brought within the scope of the future regulatory system for veterinary medicines but are exempt from requirements of registration where they comply with prescription by cascade.	N/A - Vet	

69. Recommendation The Panel recommends that the prescription cascade provides that registered products must be considered first and compounded products are prescribed as a last resort in order to address an issue that is unable to be addressed through suitable and reasonably available registered or exempted products.	N/A - Vet	
70. Recommendation The Panel recommends that the prescription cascade is finalised and implemented by the Commissioner under the single national law for control-of-use.	N/A - Vet	
71. Recommendation The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.	N/A - Vet	
72. Recommendation The Panel recommends that the APVMA works with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are funded speedily to enable the exemption described in recommendation 68.	N/A - Vet	
73. Recommendation The Panel recommends establishing a national rule for pesticides under the single national law for control-of-use that sets out the requirements for a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use.	Opposed, but…	It pains AAAA to have to oppose this recommendation. However, despite AAAA's strong, long term position in support of a nationally consistent approach to control of use legislation, it is impossible to support such a wide ranging and potentially impactful recommendation without further details regarding how the transition would be made from the

		current system and what legislative model would be used. The devil is very clearly in the detail – that is missing - including what positive parts of existing legislation at the State/Territory level would be kept eg flexibility regarding labels etc. While the provided Annexes give limited insight into the thinking of the Panel, there is a need for greater detail regarding offence provisions, legal defences and potentially greater detail to help industry understand the likely content of the stated intention. AAAA is particularly concerned, as previously stated, with the potential for this approach to create a double jeopardy for industry, while not simplifying the compliance issues at all – especially where States have in their legislation various provisions dealing with either 'harm' to people, the environment or other crops/native veg etc. This is an extremely complex area given the variability and differences between States, not to mention the number of different agencies with different cultures that range from assisting industry to get it right to straight out hostility and a compliance attitude to match. This recommendation should not become be an excuse to adopt the most draconian law selected from the states, nor should it be left so impotent so as to only cover some of the current State legislation from control of use.

74. Recommendation The Panel recommends establishing a national rule for veterinary medicines under the single national law for control-of-use that sets out the requirements for a veterinary medicine's responsible use, including a prescription cascade that applies to all animal use, and the records that must be kept establishing responsible use.	N/A - Vet	
Chapter 5 **75. Recommendation** The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.	Supported	This approach may lead to considerable efficiencies and a sharper focus of APVMA on risk. However, AAAA does have some concerns with the complexity of the proposed definitions and the potential for unexpected consequences.
76. Recommendation The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.	Not opposed	See comments above
77. Recommendation The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.	Supported	

78. Recommendation The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) Clarity – is this in ref to Rec 77 only?
79. Recommendation The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.	Opposed	AAAA is also concerned with the potential of such a list to become a focus/vehicle for activist activity in an effort to have chemicals banned – which would directly undermine the trusted, science based and risk management driven chemical assessment system. AAAA is also concerned that this could potentially lead to an increase in red tape depending on how this is integrated or not into the current system.
80. Recommendation In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary.	N/A - GMO	

81. Recommendation The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia. Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) However, in addition, AAAA has grave concerns with how this REC will translate to ensure protection of fair competition issues – with potential significant impact on Australian manufacturing, products with uses unique to Australia and security of supply. In particular, AAAA wonders how this approach might simply provide an alternate pathway that completely undermines any interest in registering products in Australia through the normal channels. The potential for this REC to whiteant the existing registration and risk based system is real – even if the attraction / benefit is to try and improve access to chemicals. It appears that the consequential effects of this system do not appear to have been countenanced by the Panel or tested in anyway. This REC may have very significant impacts for example on aerial application which is not permitted in the EU (other than by exemptions when it suits them) or in the case of chemicals abandoned in other countries for specific issues, for example due to resistance (eg molinate), but which are still highly effective in Australia. Does this mean that very useful and safe application methods will simply be abandoned in the long term? If this REC were to go ahead, close monitoring of 'equivalency' will be required during the transitional period, including a system to ensure companies already operating in Australia can challenge the proposed recognition if it is in fact simply a means of subverting the Australian regulatory system. However, AAAA believes considerably more work is required before this REC achieves anywhere near the level of certainty and downside risk management that would be required for it to proceed.

82. Recommendation The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.	Opposed	Separate out the Commissioner role that is not supported and the use of the Stakeholder Forum that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) However, even though it is contingent in terms of the previous recommendation, there is some potential by this to be seen by some as a useful vehicle for getting chemicals or even classes of chemicals, banned from Australia. Safeguards would need to be in place to ensure this cannot happen without a basis in recognised science and risk management. However, AAAA believes considerably more work is required before this REC achieves anywhere near the level of certainty and downside risk management that would be required for it to proceed.
83. Recommendation The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.	Opposed	Consequential opposition as a result of comments above. Any consideration of this element should include a mechanism to add aerial application to the uses because of the Australian famring systems context.
84. Recommendation The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).	Opposed	Separate out the Commissioner role that is not supported and the use of the Stakeholder Forum that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) The concept of recognising other equivalent international regulators is sensible for a range of purposes, but AAAA opposition is consequential as a result of comments above.

85. Recommendation The Panel recommends the Commissioner's determination of comparable international regulators: • be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders • be conducted by the Commissioner • give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.	Opposed	Separate out the Commissioner role that is not supported and the use of the Stakeholder Forum that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag) The concept of recognising other equivalent international regulators is sensible for a range of purposes, but AAAA opposition is consequential as a result of comments above.
86. Recommendation The Panel recommends that licence holders: • must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances • be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions • be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.	Opposed	See comments above. Many of the restriction on getting products registered in Australia could be permitted through an adaptation of the existing system in Australia, rather than the radical proposal included in these preceding RECs – that has not been tested in terms of its potential downstream, longer-term impacts on the viability of the Australian registration and assessment system.

87. Recommendation The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.	Opposed	See comments above
88. Recommendation The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.	Opposed	See comments above
89. Recommendation The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).	Opposed	See comments above
90. Recommendation The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.	Not opposed	Perhaps all applications could be processed on a 'fast track' basis if the current inefficiencies in the existing system where addressed…
91. Recommendation The Panel recommends the criteria for prioritisation be determined by the Minister with advice from the Stakeholder Forum.	Opposed	AAAA is concerned that as a result of Ministerial approval being required on the basis of advice from what may be a non-technically qualified

		Stakeholders Forum, there will be little prospect of a 'Fasttrack' approach being achieved. AAAA wonders if a similar outcome/intent could not be managed through the APVMA processes that would be spelled out.
92. Recommendation The Panel recommends the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted by departmental risks.	Supported	AAAA further recommends providing flexibility into this system to ensure that novel cropping use or innovation is not hamstrung by an arbitrary line that may not recognise normal features such as micro-climates, seasonal variability etc. For example, current temperature requirements on label such as 'DO NOT spray above (eg) 32 degrees' will significantly hamper chemical use in northern Australia – even though the chemicals clearly work. AAAA strongly believes on the evidence that these widespread temperature restrictions on many labels are simply a hangover from very early labels where higher temperatures were used as a surrogate for unstable weather conditions that might lead to convection impacts on sprays. There is some suggestion from registrants that there may be an efficacy issue involved related to plant pathology and uptake, but this is not a strong scientific basis for a significant limitation being on label. APVMA should ensure that there is some flexibility within any new system, rather than just perpetuating the same or similar restrictions once the old State basis to use tables is replaced.
93. Recommendation The Panel recommends targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not correspond to climatic regions.	Supported	See comments above

94. Recommendation The Panel recommends making any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions in line with the 2019 decision of the Agriculture Ministers Forum.	Supported	However, why not just one jurisdiction instead of two? If the risk is managed in 1 jurisdiction, then surely it is transportable across State boundaries esp in light of Rec 93. – intent is to remove old hangover of State Registrar of Chem Use Tables – why perpetuate it here?
95. Recommendation The Panel recommends the expanding the support by government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing the industries that benefit from access to the necessary tools for pest and disease management.	Supported	This should include use of aerial application as an expansion of use for labels without an aerial approval or a DO NOT statement - obviously based on a relative risk assessment and on label requirements that manage any identified risks.
96. Recommendation The Panel recommends, through the proposed single national law, implementing an exemptions model as a streamlined way of authorising specific activities that would otherwise not be permitted. Exemptions for minor, emergency and research use may be made as legislative instruments by the APVMA.	Supported, but…	AAAA has considerable experience working within the CASA environment of developing and using exemptions and is comfortable with this approach. However, it must be noted that this process frequently comes under the Senate Legislative Committee scrutiny, especially where exemptions can be long-standing and the question is put why not improve the regulation itself instead of relying on an 'exemption'? Perhaps the Panel would do better to retain use of the word 'permit' to identify this system-by-exemption, but overhaul the system behind the permit to be far better than the current system and more flexible – see previous AAAA submission comments on permit reform including the establishment of a specific 'aerial application permit' category.
97. Recommendation The Panel recommends establishing specific criteria to grant an emergency, research, or minor use exemption as long as a use would not jeopardise safety, efficacy, and trade.	Supported	Not sure how this recommendation sits if the permit system is replaced with an exemption system? See also comments above in REC 96 Consider reform of the Permit system instead as recommended by previous AAAA submission on permit reform including the establishment of a specific 'aerial application permit' category.

98. Recommendation The Panel recommends expanding the authorising of emergency use in advance of the emergency, establishing 2 categories within the public listing of exemptions for 'active emergency exemptions' and 'future-emergency exemptions'.	Supported	This will be relevant where aerial application may play a role in human health, exotic disease outbreak or similar occurrence whereby the required chemical may by in a 'novel use' situation where it does not already have an aerial application approval. Available drift management, spray quality and nozzle performance modelling is readily available to permit appropriate work to be conducted quickly.
99. Recommendation The Panel recommends that, in granting an emergency exemption in advance of an emergency (a future emergency exemption), the exemption includes details of the trigger to transition from the 'future' to 'active' exemption category.	Supported	
100. Recommendation The Panel recommends the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan is in place along with quality management systems and regular independent assurance checks including audits.	Supported	Perhaps include a requirement / conditions regarding use of trained and accredited aerial application companies to ensure competence in trials and reliability/reproducibility of trials.
101. Recommendation The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.	Supported	

102. Recommendation The Panel recommends that amendments be made to the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries.	Not opposed	
103. Recommendation The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.	Opposed	AAAA is always concerned with the expansion of red tape where there is no clear link to a benefit. AAAA is not convinced such a case has yet been made.
104. Recommendation The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.	Supported	

105. Recommendation The Panel recommends a simple, consistent approach to data protection for the new pesticides and veterinary medicines regulatory system. The ability to limit the regulator's use of certain information will remain a valuable component of the future system and will continue to be of great importance to industry. This is vital to protect the value of industry investments and ensure that Australians gain access to the latest innovations in pesticides and veterinary medicines.	Not opposed	However, AAAA notes that this is not its area of expertise (see Croplife) but that data protection is a key means of ensuring ongoing research and development of new chemicals as distinct from 'off-licence / generics' that are simply a mirror label – including all the negative features of poor labelling used in the original label. AAAA hopes that the proposal for all registrants to review and update their labels – including those using mirror labels on generics - will go some way to ensuring the thousands of legacy labels in the market place are required to be kept up to date. This is perhaps another reason why a move to a modern electronic labelling regime is important – perhaps combined with some overarching requirements that apply to all products to ensure greater consistency – for example in their ability to be put out by air. A labelling standard (or other vehicle) may be useful where overarching improvements to all labels could be more widely and easily applied by electronic means rather than reprinting the label on the drum. However, in turn, that may raise some legitimate questions as to 'what is the legally binding label'. Additional consideration include rural and remote areas access to e-labels where internet and phone access may be limited.

106. Recommendation The Panel recommends that if a party provides confidential information to a regulator and that if information is used by the regulator for a relevant regulatory decision, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor's products. • These should be consistent with Australia's established international agreements. • Information in minor use and emergency exemption applications are a special case and while this may (as is the case for current permit applications) be considered confidential commercial information, it will not qualify for data protection.	N/A	This is not AAAA's area of expertise – other than the comments above.
107. Recommendation The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products. • Equivalent protection periods should be provided for pesticides and veterinary medicines. • The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review). • These periods should only be extended as an incentive to bringing priority uses to Australia, as per the measure in the Bill currently before	N/A	This is not AAAA's area of expertise – other than the comments above.

parliament.		
108. Recommendation The Panel recommends that the periods of limitation on the regulator's use of information should be: • 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent. • 5 years for information: – relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption – provided in support of a chemical review – which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.	N/A	This is not AAAA's area of expertise – other than the comments above.
109. Recommendation The Panel recommends that if there is a public interest reason for the regulator to use information, then the regulator should be able to use that information irrespective of whether it would otherwise be subject to protection. • For example, information about a product that is unfavourable (does not support continued registration of a product or use) should not be treated as protected.	N/A	This is not AAAA's area of expertise – other than the comments above.

110. Recommendation The Panel recommends that the Commissioner be tasked with ensuring that any intellectual property protection measures for the new scheme to supply internationally registered products under licence align with the other recommendations (including consistency with international obligations), in consultation with industry.	N/A	This is not AAAA's area of expertise – other than the comments above.
111. Recommendation The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a private negotiation matter between companies.	N/A	This is not AAAA's area of expertise – other than the comments above.
Chapter 6 **112. Recommendation** The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture.	N/A	This is not an area of AAAA expertise, although the issue of quality assurance of products is clearly important, especially in the case of liability for product failure where chemical quality may be an issue – a process that often starts with (wrongly) an accusation against a 'failed' application. It will be important to retain a capacity for QA assurances in the market place, and traceability of different batches from different plants – for example.
113. Recommendation The Panel recommends that the APVMA establish a standard for each active constituent prior to its inclusion in products. The Panel expects that in establishing standards for active constituents due regard is given to matters of commercial confidentiality and intellectual property protection.	N/A	

114. Recommendation The Panel recommends that the APVMA apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard.	N/A	See comments above
115. Recommendation The Panel recommends the APVMA becomes PIC/S accredited.	N/A	
116. Recommendation The Panel recommends the APVMA develop guidance material through engagement with industry to support a streamlined transition from cGMP to PIC/S.	N/A	
117. Recommendation The Panel recommends both export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.	N/A	
118. Recommendation The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.	Supported	Perhaps this concept could also be expanded include specialists in aerial application labelling or standardised approaches developed in conjunction with industry experts eg AAAA / CPAS etc?
119. Recommendation The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.	Not opposed	

Chapter 7 **120. Recommendation** The Panel recommends that in most circumstances the pesticides and veterinary medicines industry should bear the full and reasonable costs of the regulatory functions under the new regulatory scheme.	Opposed	Consideration of community benefit must be included, especially for policing and audit processes related to licencing – see previous AAAA Submissions on APVMA cost recovery – available from AAAA.
121. Recommendation The Panel recommends that the existing levy on product sales be continued but at a reduced rate.	N/A	Outside AAAA area of expertise – but any cut in government charges is generally supported!
122. Recommendation The Panel recommends that the levy be divided into components relating to the costs incurred for undertaking different activities to minimise cross-subsidisation, with each component of the levy being charged only to those that receive the particular service.	N/A	See above
123. Recommendation The Panel recommends that where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.	N/A	See comments above
124. Recommendation The Panel recommends that hourly charging should be introduced for activities where regulatory costs are highly variable, while flat fees should be charged where there is little variation.	Opposed	Consideration of community benefit must be included – see previous AAAA Submissions on cost recovery

125. Recommendation The Panel recommends that the costs for applications for registration be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis.	Opposed	Hourly fees provide no incentive for efficiency in government agencies. Flat fees should be investigated while considering complexity or likely time taken.
126. Recommendation The Panel recommends that where Government audits are routine and predictable the costs of this service should be incorporated into the fees for the parent program, for example via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.	Opposed	Community benefit. Policing and audit are both community benefits.
127. Recommendation The Panel recommends that mechanisms be developed to allow more significant fees to be paid over time, such as through payment plans.	Not opposed	
128. Recommendation The Panel recommends 100% recovery of the costs of issuing and maintaining licences (both for supply side and use activities), including scheduled audits with predictable costs, via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.	Opposed	Audit and QA a community benefit. This system would create an incentive for States to conduct multiple audits. Cost of licencing if based on industry accreditations should be minimal or free as an incentive.
129. Recommendation The Panel recommends that the assessment of applications for accreditation, together with costs to maintain this accreditation, should be 100% recovered from the accredited parties.	Opposed	What happened to the cooperative regulation approach? This is a 'have our cake and eat it too' scenario. Government should bring something to the table where it is to attain a benefit from an industry scheme (eg improved compliance, greater efficiency, greater expertise, credibility, improved uptake, more

		regular audits, education and training, support of participants, continuous improvement, attainment of widespread superior performance to minimum compliance standards, improving sectoral culture etc) Accreditation is already charged for and paid by industry. There should be no additional cost as part of a co-regulatory partnership – especially where the industry initiative is saving government funds. Recognition/assessment of accreditations mapped against national competencies should also be free. Perhaps a middle ground is the simple acceptance of a report from an independent accessor every 5 years (co-funded) IAW agreed requirements/ standards / competencies.
130. Recommendation The Panel recommends that full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.	Opposed	See comments above and lack of incentive for efficiency
131. Recommendation The Panel recommends that a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines is maintained.	Not opposed	Although AAAA wonders how this sits with the proposed exemptions scheme – which should be free as exemptions often recognise a shortcoming of the system itself – ie ineffectiveness/inefficiency of government regulation. Exemptions or permits should be free, as they are an effective way to improve the system (community benefit) however, AAAA would also seek to ensure that this subsidy is available for the wider system of both minor use permits but also exemptions.

132. Recommendation The Panel recommends that minor use exemption applications should attract a discounted application fee with the balance of the costs recovered as an identified component of the levy on product sales payable by the registrant (or licence holder).	Opposed	See above – aren't exemptions replacing permits?
133. Recommendation The Panel recommends emergency use exemption applications should be fully recovered as a component of the levy. A small appropriation should be sought to offset some of the draw on the levy, in recognition that there is a public good element to this function.	Opposed	In a coregulatory environment, an emergency application should be seen as a service to the community or a shortcoming in the existing system and should not be charged.
134. Recommendation The Panel recommends that as chemical reviews and APVMA compliance and enforcement activities only exist to manage the risks associated with selling pesticide and veterinary medicine products in the Australian market, the costs of these regulatory activities should be recovered entirely from industry via a component of the levy on product sales.	Opposed	Regulation through an Act is a core government responsibility and consequently should be carried through Consolidated Revenue as a community benefit. It appears the Panel has decided the obvious benefits to the Australian community and the Australian economy of safe, reliable and plentiful agricultural commodities, or our international competitiveness are not valid outcomes warranting recognition. This is clearly a one-eyed, cynical view – especially in terms of trying to created a more cooperative regulatory environment.
135. Recommendation The Panel recommends that the cost of control-of-use regulatory activities should generally be recovered entirely from industry, via a component of the levy on product sales. However, wherever possible, where the beneficiary is clearly identifiable, such as applicators licensing, a fee for services approach should be used.	Opposed	Regulation through an Act is a core government responsibility and consequently should be carried through Consolidated Revenue as a community benefit. Control of use is clearly a community benefit in the same way policing of other laws is. Again, it appears the Panel has decided the obvious benefits to the Australian community and the Australian economy of safe, reliable and plentiful agricultural commodities, protected by competent,

		accountable and professional applicators - or our international competitiveness - are not valid outcomes warranting recognition. AAAA strenuously opposed this blinkered view.
136. Recommendation The Panel recommends that the costs of data mining and analysis for system surveillance and monitoring be publicly funding.	Not opposed	Although AAAA notes it is opposed to creating big data out of mandatorily accumulating chemical application records as previously suggested.
137. Recommendation The Panel recommends that the costs of environmental monitoring be publicly funded.	Opposed	Proposed scheme not supported
138. Recommendation The Panel recommends that the cost of domestic produce monitoring should be publicly funded.	Supported	Community benefit and confidence in the regulatory system and feedback for industry and government.
139. Recommendation The Panel recommends that activities of the Commissioner such as driving the reform agenda, policy development, and advisory responsibilities should remain Government funded and that all other Commissioner costs, being activities that only exist to manage the risks associated with selling products in the Australian market, should be 100% recovered from fees (e.g., licensing) or components of the levy as appropriate	Opposed	Separate out the Commissioner role that is not supported and identify alternate methods of delivering the outcome (eg repurposed Dept Ag), and thereby the funding issue. Given the creation of the Commissioner position is to largely address failings of the national regulatory scheme over recent decades, it is not unreasonable to assume that whatever is put in place (as an alternate to the opposed Commissioner role) should be paid for by government directly. It is a core role of Government and should be funded accordingly. The lack of recognition by the Panel of the benefits of reform to the national interest, jobs, safety, productivity, the economy, agricultural productivity and environmental protection is an extraordinary statement and denial of the role of government in this key policy space.

Further Information

For further information, explanation or additional consultation, please do not hesitate to contact the CEO of AAAA, Mr Phil Hurst at the AAAA Office.