Public Health Association of Australia submission on review of the agvet chemicals regulatory system
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Preamble

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public’s health in Australia.

The PHAA works to ensure that the public’s health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people’s health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.
Introduction

PHAA is pleased to respond to the discussion paper outlining proposed changes to the agricultural and veterinary chemicals (agvet) regulations in Australia.

We have some serious concerns about the assumptions underpinning, process, and scope of the review, and at the same time want to make constructive input to the content. Both aspects of this are outlined in our responses below.

1) Do you support the proposed vision for the agvet chemicals regulatory system and is it sufficient to meet the needs of all stakeholders?

PHAA is prevented from giving unqualified support for the vision because of limitations evident in the Issues Paper. It is reasonable that Australian farmers should not be unfairly disadvantaged in the international market place. However, the assertion that “timely access to a similar range of approved agvet chemicals to their overseas competitors” will resolve this situation is not established by the evidence provided. The Issues Paper does not present evidence of a lack of timely regulatory determinations.

a) What, if any, other considerations should be included in the vision?

Generally, most propositions in the vision sound quite reasonable. However, there is a business as usual underlying approach, as demonstrated by “Agvet chemicals are the primary way in which agricultural businesses manage pests, weeds and diseases”. How deeply the “while preserving human, animal, plant and environmental health” principle will be adhered to in implementation of the system is critical. What the Issues Paper is not capturing is that this review give us the opportunity to rethink how the agricultural and veterinary (livestock industry) chemicals fit into the bigger picture of humans’ relationship with the natural environment and our economic system. It is silent on the current global environmental changes within which these agricultural and economic systems exist.

Second, COVID-19 shows that we need to fundamentally rethink our approach to both agriculture (outside the scope of this paper) and to chemical use and regulation. Protecting the natural environment, ecosystems and other non-human and non-human related species is fundamentally important to achieving the other objectives, and need to have priority in any regulatory system. A re-focus on more ecological approaches to agriculture would enhance agricultural businesses ‘green’ credentials, and also reduce the adverse ecological impacts of agriculture.

This review gives Australia the opportunity to start to rethink some of these basic assumptions.

The vision statement should include other users and have health priorities listed first as the overarching requirement, for example:

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

Those most at risk must be identified as stakeholders. The people exposed to the highest level of agvet chemicals, specifically pesticides, and consequently most at risk from pesticide-induced disease if and when it occurs, are the applicators of chemicals. Accordingly, they should be identified as stakeholders.
b) Do you have any suggestions for reforms that could assist in achieving this vision that are not canvassed in this paper?

A clearer agency vision for APVMA is required. It should be understood as having no greater or lesser responsibility to consider Australian conditions than similar agencies internationally with their local conditions. APVMA is recognised as a valued contributor to international consensus on pesticides. An immediate priority which should have been recognised in the Issues Paper, is to maintain the authority of the APVMA despite the potential loss of senior staff following relocation to Armidale. The situation warrants appraisal, with potential allocation of government funds in support.

The pandemic has given greater strength to the need to build a framework that ensures the efficacy and safety of veterinary medicines. Treatment of zoonotic diseases requires efficacious veterinary medicines to ensure animals are prevented or treated for zoonitic diseases e.g. drontal allwormer to prevent hydatid tapeworms or vaccines for prevention of leptospirosis. Antibiotic efficacy and correct labelling and antimicrobial stewardship (correct use and consumption of antimicrobials) is essential to prevent antimicrobial resistance and spread of resistant microbes.

The framework arising from this review should build stronger health impact assessment and environmental impact assessment processes into the assessment system.

1. Is the National Registration Scheme working as needed?

2) Do you agree or disagree with the future trends identified and their implications for the agvet chemicals regulatory system?

The Panel identifies a long list of future trends. However, evidence is not presented in the Issues Paper to support these assertions.

a) Are there additional implications for the regulatory system posed by the trends identified that the panel has not adequately addressed? If yes, please provide details

The veterinary medicines regulatory system framework changes have not been explained adequately in the Issues Paper, therefore it is difficult to provide comments.

Global warming, climate disruption and other ecological changes are going to have a huge impact on agriculture. These include warming and climate disruption, water availability, salination, changes in pests and weeds, as well as friendly plant symbionts and natural pest controllers. The regulatory system needs to factor in how these affect the need for and potential unintended consequences of chemical use within the environmental and human health protection frames.

b) Are there other trends that the panel needs to consider in designing the future system?

In designing the future system, veterinary medicines and biologicals need to be the subject of strong safety and efficacy assessments in the context of the animal species being dealt with, and the epidemiology of disease in Australia. The future system must have the capacity to fast track registration of emergency treatments or biologicals e.g. incursion of exotic zoonotic disease like dog rabies where oral rabies bait vaccines may be needed.
3) Do you support the proposed overarching primary purpose statement for the agvet chemicals regulatory system being safety and access?

The primary purpose statement is supported by PHAA. The purposes now specified are essentially those currently notified (apart from deletion of any reference to local manufacturing), but now explicitly, rather than implicitly, accorded priority.

a) Do you agree that the proposed hierarchy of simplified objectives provides greater clarity of their relative importance and is this supported? If not, why?

A unified and simplified primary purpose is helpful. Focus needs to be revised to: protect the environment and the health and safety of people, animals, plants; and to provide users with access to safe chemicals. However, this purpose introduces some interesting concepts, such as “to safely control the pests and diseases of plants, animals and places”. The threat identified is to “the health and safety of people, animals, plants and the environment” by pests, but this framing of the issue sidesteps the threats chemicals and the farming methods that rely heavily on them make to people, animals and plants themselves, many of whom are actually part of the natural environment.

b) Are there objections to removing the domestic chemical manufacturing objective? If so, what are the objections?

While this is a valid industry development goal for the chemicals sector, it is not appropriate to be included as a goal for the regulator. The Issues Paper does not provide evidence to justify the removal of domestic chemical manufacturing as an objective. The COVID-19 pandemic has demonstrated that relying on overseas global supply chains poses a risk of lack of supply and so greater domestic self-reliance is important. Given post-COVID-19 perspectives on encouraging local manufacturing, it may be viewed as contrary to current Australian government policy.

c) Do you agree that the current objectives for efficiency, transparency and risk-based science are more appropriately expressed as principles governing design of the system? If not, why?

Yes

d) Are there other objectives that should be considered?

This review gives us the opportunity to rethink how we relate to the natural environment and other species within a planetary health and One Health framework. We draw your attention to PHAA’s One Health policy position statement.

However, the language of the Issues Paper suggests that a new way of thinking about agriculture and livestock management that is respectful of the natural environment has not actually been incorporated into the thinking behind the Paper. For example, “Ensuring the protection of people, animals, plants and the environment should always be at the heart of the regulatory system...significant health and safety consequences”, while true, show that this document actually maintains an unhelpful humans-against-nature paradigm. This promotes the use of chemical restraints on other species rather than using alternative farming techniques that the Issues Paper identified earlier on as an emerging trend in agricultural practice and consumer behaviour that needs to be accommodated. The language, for example “that threaten the health and safety of people, animals, plants and the environment” illustrates this; “threaten” is a loaded word, and the idea that the environment is also threatened by pests is a strange sounding idea. Further, the paper does not recognise that the reason for many of these ‘threats’ is because of the way agriculture is practiced; large monocultures, dense livestockling, over-stocking based in an industrial agriculture business model.
4) Do you support the principles proposed to guide design and reforms to the future agvet chemicals regulatory system? If not, why?

The Issues Paper does not appear to include references to the presumed impact of the principles above and beyond what might be achieved on the basis of best practice. It is therefore difficult to assess support for them.

For example, in relation to “independence- decisions of the national regulator overseeing approval of agvet chemicals should continue to be independent from government”, good practice would also establish the regulator as independent from industry. Evidence-based regulation should be grounded in governance arrangements that permit balance of all interest and stakeholder groups, with final decision making by an agency able to act as independent arbiter in the broader public interest.

a) How could these principles be enshrined to ensure they are met?
They would need to be articulated in the enabling legislation. For principles to be effective in practice, they need to be supported by compliance requirements, enforcement measures and penalties for non-compliance.

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

A risk-based focus is needed with the risk levels identified for people, animals, and the environment so that the toxicity of each agvet can be assessed, and periodically reassessed, as already done for industrial chemicals by the Australian Industrial Chemicals Introduction Scheme (AICIS, formerly NICNAS).

Discussion of risk in the Issues Paper does not appear to be scientifically robust and well-informed. The essential difference between hazard and risk is that hazard involves the capacity of an agent to cause harm, while risk is the likelihood of harm occurring in a particular circumstance of exposure. Specifying circumstances of exposure is the key consideration, and indicates a requirement for supporting data. The Issues Paper does not mention exposure when addressing risk.

APVMA demonstrably assesses pesticides on the basis of either hazard or risk depending on the data available. Arsenic-containing insecticides cause cancer and are not registered in Australia, on the basis of hazard. APVMA demonstrably regulates glyphosate on the basis of risk. The agent may be used in particular circumstances if there is compliance with particular requirements. Starting with this example, and by reference to the APVMA website, regulation of pesticides on the basis of risk is the manner in which most pesticides are licensed in Australia.

The registration, in Australia, of any pesticide which is accompanied by any type of qualification or restriction on how that pesticide may be used, exemplifies assessment based on risk. Such conditions include use of the agent being restricted to certain crops, application of the pesticide being permitted only if certain nozzles, spray arrangements and/or particular equipment is used, a requirement to use personal protective equipment, a requirement to label or otherwise notify users of safe practices, and limitations based on geography or climate conditions all connote determinations adopted on the basis of risk rather than hazard.

Regardless if there is a risk or hazard (or mixed) based system, the key issue here becomes one of deciding what level of risk from exposure we as a society are prepared to accept. The regulation/legislation should include a requirement for this to be decided not by the committee, but by a governance group including community as well as agriculture, veterinary and industry input.
The statement “many products would be lost from the market that do not post a risk to human health, animal health or the environment if used correctly”, assumes correct use. Experience shows that incorrect use for multiple reasons is fundamental to human behaviour, and so as part of a hazard/risk-based assessment process, the potential for incorrect use must be built into the assessment and regulatory process.

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

6) What governance structure might be best for delivering the Australian Government’s responsibilities in the national regulatory system?

An independent and properly resourced national regulator with statutory powers is the primary requirement. The regulator should set the national guidelines, but the States and Territories are best placed to monitor the use of agvet chemicals in their different jurisdictions.

In justifying a governance change by an additional level of deliberation, the key assertion made in the Issues Paper that ‘no single person or agency with ultimate authoritative responsibility and management of agvet chemicals regulation’ warrants scrutiny. Regulatory complexity, when overseas sources of materials predominate, and where there is a requirement for interaction between Commonwealth and State and Territory authorities, is not confined to agvet chemicals. A similar scenario applied to pharmaceutical drugs, industrial chemicals, and certain categories of food. For each of these categories, there is no single person or agency with ultimate authoritative responsibility and management to a greater extent than APVMA is responsible for pesticides and veterinary medicines.

The veterinary medicines regulatory authority may be better associated with the Therapeutic Goods Administration (TGA) in Canberra, under a One Health framework for medicines regulation, and with two Ministers (Health and Agriculture).

PHAA would support a combination of Options 2 and 3; the key issues here would be a Board independently appointed (i.e. not appointed at the discretion of the relevant minister, to reduce scope for political appointments), with a mix of community, industry and independent members.

Extending this, there may be an opportunity here to review chemical regulation in Australia more broadly by having one national chemical regulator with branches for agvet, industry and other classes of chemicals that can share expertise and cross fertilise knowledge and experience. How, for instance, does the renewed APVMA link with AICIS?

PHAA agrees with “The panel is inclined to seek a governance arrangement that: provides clearer leadership for the regulatory system overall; identifies the different roles of Commonwealth and state and territory governments” but are cautious about the meaning of “gives more weight to industry and user responsibilities in the future”. It is unclear what this means in practical terms. PHAA would not support any system that facilitated industry capture.

a) Do you see merit in a time-limited High-Level Steering Committee to drive implementation action on the regulatory reform agenda?

A steering committee with representation from all stakeholders, including industry, health and the community, is needed for all stages from reform introductions, through to implementation and oversight. This committee should not be time-limited.
7) Which of the three reform options outlined do you support and why?

The various options are described in operational detail without reference to how any one of them would alter outcomes in respect of previously decided pesticide registration or incongruities. Options 2 to 5 all fail the ‘simplicity’ principle enunciated earlier; they would all add one or more ‘boxes’ to Figure 2. Accordingly, option 1 is endorsed.

a) Which option is likely to deliver the best chance of consistency in control of use and the greatest likelihood of success and why?

PHAA supports the idea of nationally consistent regulation. Option 3 – reinvigorated IGA, or Option 1 – Expanded Applied Law. Option 3 brings a workable method for standardisation across our Federal system, but see 7) above.

b) What risks do you foresee in implementing any of the options proposed?

Apart from Option 1, more decision making/guidance/data input to be ultimately addressed by the regulator, with no specified benefit as documented in the Issues Paper.

Option 2 has the most risk, and is more likely to engender pushback from states, and least likely to get support from government.

8) Do you support the addition of co- and self- regulatory approaches to agvet chemicals management (across all levels of a product lifecycle like the Australian Packaging Covenant) to deliver more effective and efficient outcomes than direct regulation alone?

The regulatory framework must continue to ensure strict adherence to the guiding principles.

In addressing ‘shared responsibilities between industry and government’, section 2.4 makes the case for industry being involved in the agvet chemical regulatory system: the system whose primary purpose is to address health and safety. The proposed innovation does not involve ‘influence’ but ‘shared responsibility’. However, industry, rather than any other stakeholder, is the focus. Thus, the argument is made:

“The Panel believes, in general, Australian industry is committed to the manufacture and supply of safe and appropriate agricultural chemicals, and their responsible use (‘as little as possible, as often as needed’).”

PHAA notes that there is no evidence provided in support of this belief. Indeed, according to shareholder primacy upheld in case law in Australia,\textsuperscript{2} the text might better have read:

\textit{The panel acknowledges, in general, Australian industry is committed to the greatest financial return to shareholders as may be achieved by maximising the sale of its products, while remaining within the limits of all legal constraints.}

When implementing a co-regulatory approach, the Issues Paper does not specify any area, matter or activity as excluded because such involvement would be inappropriate or invalid. Shared responsibility in relation to assessment of risk by the regulator should be specifically excluded.

a) Do you support the panel’s proposal for a holder accreditation scheme? Would the proposed levels of accreditation provide greater incentives for industry compliance?

This is generally supported, on the condition that an oversight mechanism is in operation.
b) Is there additional value in limiting the scope for a holder based on the nature of the registration?  
This should be a consideration based on the hazard/risk-level.

d) Do you have suggestions for how existing assurance schemes such as GMP could be used to streamline assessment processes?  
This is managed in the therapeutics sector by sharing the GMP site and process assessments with comparable regulators.

e) Is there value in a statutory duty of care on industry and/or users to strengthen incentives for responsible use of chemical products to minimise risks to human health, animals and the environment?  
Both industry and the regulator should have a duty of care to ensure user and exposed safety. Users also have a duty to use chemicals responsibly, so the duty differs at each level of the supply-use chain.

The phrase ‘duty of care’ is a critical element in tort law, or the law dealing with harm that one party may do to another. If a person is injured due to the failed operation of manufactured product, the manufacturer will be liable for damages, if a court holds that the manufacturer had a duty of care to the injured person. Conversely, a manufacturer may mount a defence by establishing that a duty of care did not exist in the circumstances before the court. A statutory duty of care would abolish that defence.

Not mentioned in the Issues Paper with reference to a statutory duty of care is the increased likelihood of successful litigation, and consequential award of damages, against pesticide manufacturers. The vast bulk of such claims involve the same generic products on sale in Australia and in many similar countries such as USA and UK. With the prospect of relevant claims more likely to succeed in Australia, the Issues Paper might have considered a scenario of Australia becoming the favoured jurisdiction for the pursuit of such claims.

9) Should detection and investigation measures be augmented to better treat the risks posed by agvet chemicals?  
Yes, however moving resources from the initial assessment to compliance end of monitoring chemicals needs to be done cautiously, particularly where new entities are being introduced, and particularly if they are domestically invented. For overseas products, this would depend on how and who carried out the initial assessment and how this fits into Australian conditions.

The repeated specification in subsections (a) to (d) below of resources and/or responsibilities that the regulation should or could have, cannot be addressed in the absence of input from the regulator. The Issues Paper makes specific and repeated reference to information provided by stakeholders, and implicitly, given the particular context, this includes chemical manufacturers. Appropriately, therefore, relevant input is notified on the first page of text in the Issues Paper under the heading Foreword:

“To date, the panel has had the benefit of considerable input from a key stakeholder consultative group, a range of regulated entities, and the key national regulator itself.”

By comparison with repeated references to information from stakeholders, the Issues Paper does not describe or introduce any matters as having been raised by the regulator.

b) Do agvet chemicals regulators have appropriate resources, appetite and/or incentive to use the detection and enforcement tools they have? If not, how could this be addressed?  
As for 8 (e), these tools need to be supported by appropriate penalties to discourage non-compliance.
c) Are you confident that regulators will detect non-compliance (in particular, that which poses the greatest threats to human and animal health and the environment) and respond appropriately? If not, what should/could be done differently?
The community is likely to have limited confidence about prompt detection of non-compliance by regulators. Annual reports need to be provided on non-compliance and the regulator’s resulting actions.

d) Should agvet chemicals registration-holders be screened in some way to ensure they are reputable? Why or why not?
Yes, to reduce overall reputational harm to the sector.

3. What chemicals are currently regulated?

10) Do you support the proposal to remove consumer products and pool and spa chemicals, anti-fouling paints and certain over-the-counter companion animal products from the agvet chemicals regulatory system? If not, why?

Discussion of this matter in the Issues Paper is not informed by information as to how much of current resources for agvet chemical regulation are allocated to, for example, consumer products. The matter presumably involves, possibly among other considerations, statutory requirements to be met by the regulator (APVMA) in relation to the product categories under consideration.

Notwithstanding the need for more information, the principle addressed in this section is reasonable. The matter is not simple: reducing the scope of one authority may impact resources and responsibilities exercised by another authority with ramifications for both. ACCC exercises responsibility for, amongst other things, consumer product safety. A comprehensive assessment is needed. For example, distinction between chemical safety in home pools and municipal pools.

Removal is supported for most consumer products of low risk, however, domestic-use garden chemicals closely related to farm-use chemicals, e.g. Roundup, should still be included in the agvet regulatory program. The focus needs to be on hazard/risk or purpose of chemical, not location of use. Urban and peri-urban use locations pose perhaps increased risk because of increased potential to human exposure.

a) Do the benefits of the proposed removal of these products outweigh the risks? If not, why?
More information is required regarding specific examples.

b) Are the new definitions of a plant protection product and veterinary medicine supported? If not, why?
Yes.

c) Do you agree that certain product uses, such as those administered by injection, warrant the direct involvement of veterinarians, separate to the controls under the poisons scheduling?
Veterinarians should be required if there is no guidance provided in the poisons schedule. Most livestock vaccines are injected and do not require involvement of veterinarians, although the person injecting the vaccine needs to be trained, ensuring the product is administered according to label directions, e.g. subcutaneously and not intramuscularly for Gudair vaccine.
11) Are there areas where the approach to agricultural chemicals and veterinary medicines should be different?

a) Should there be separate requirements specified in the legislation for veterinary medicines and agricultural chemicals? If so, what should these requirements be?

Yes. Again this is a question of purpose; medicines fit into the Poisons Schedule while chemicals for other uses should be subject to an agvet regime. Antibiotics present an important case. With the need to prevent further, and reduce existing, multiple antibiotic resistance issues, they need to be used and regulated as medicines. This could be achieved under a combined veterinary and human medicines framework – One Health regulatory framework.

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

12) What are the merits of considering boundaries (other than state/territory) that might be relevant to the use patterns of agvet chemicals use?

If the intent of these reforms is to establish national regulatory regime, then removal of generic state/territory references and replacing that with a mix of jurisdictional, ecological zoning use permissions alongside their guidelines seems logical. State and Territory boundaries are useful for officers to monitor agvet applications in their jurisdictions. However, unique or significant areas could be identified for special care and monitoring, such as runoff of agvet chemicals into the Great Barrier Reef. Given that ecological zones do not adhere to existing state/territory boundaries, so zoning that fits natural demarcations such as an ecological zone (water catchment, climate, soil type, representative species, land use), makes sense. More research is needed to support this concept, and cross-jurisdictional monitoring arrangements will need clarification. Further information and advice from APVMA staff would be beneficial.

a) What are the merits of considering regions of significant environmental interest, such as those adjacent to the Great Barrier Reef, or unique environmental values, for restrictions or bans on some agvet chemicals use?

Areas of particular ecological significance or with valuable alternative economic use that might be damaged by chemical use (including organic farming initiatives) should, on a case by case basis, be subject to specific restrictions.

b) What are the merits of mandating five yearly label reviews (by the holder) to remove where appropriate state references and aligning with the review of safety data sheets?

PHAA supports the necessity for periodic reviews to be conducted.

c) Is it possible to establish pest groupings?

This may not be straightforward since non-pest species may have similar vulnerabilities to particular chemicals, so an ecological approach would look at some other way to identify species of interest. However, it is useful to think of degrees of severity of ‘pests’ so that producers and consumers learn to accept less ‘perfect’ produce when this is more aesthetic than actually harmful. This is one change that would signal greater acceptance of the need to live with rather than fight against the natural environment and other species.
13) Would a benefits test as proposed be a useful addition to the agvet chemicals regulatory system?

The benefit to risk balance need to be assessed on a case-by-case basis, without the health of people, animals and the environment being compromised by short-term economic advantage. Specification of benefits are presumably included in submissions currently made to the regulator. However, a statutory requirement to consider benefits was not addressed in the context of the primary purpose statement. The governance arrangements for deciding what is in the national (or local) interest and “where the overall benefits outweigh the risks posed by their use” need to be very clear and robust. Interest needs to include a nature respecting frame to that decision integral to the economic/trade frame.

a) Are the benefits outlined appropriate?
Yes

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

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

This requires careful consideration of specific evidence. The Issues Paper does not address specific harm to people caused by agvet chemicals, and by pesticides in particular. In respect of cancer causation in applicators, combinations of pesticides have been assessed by, for example, the IARC evaluation of ‘work as an insecticide applicator’. Though the likelihood of an increased risk of cancer was recognised some time ago through that evaluation, the vast bulk of research involving pesticide carcinogenicity done since then has involved specific agents. There is little scientific knowledge on disease caused by chemical, and specifically pesticide, acting in combination, both in respect of epidemiology or in studies using rodents. Further information is required in this matter.

a) How might consideration of the impacts of chemicals (cumulative and synergistic) be feasibly considered in the Australian system, given the limited progress in this area internationally?
The precautionary principle should apply, with scientific and technical guidance to be part of the decision process. From first principles, it is better to acknowledge the possibility of interactions and cumulative effects and assessment of chemicals for this a priori and set up post marketing monitoring.

b) Should Australia wait until international methodologies for assessing impacts of chemical combinations have been developed? Or should Australia have a role in assisting in their development?
There may be unique situations in Australia requiring an Australian assessment conducted under established trial conditions.

c) What skills and tools are needed in Australia to allow consideration of the impacts of synergistic impacts of chemicals?
See 14 (b) above.

15) What role could data mining and intelligence use play in the regulatory system?

Obviously, the more comprehensive the data available to any authority, the better and more beneficial will be the determinations made by that authority. The prospect of sharing data by regulators and/or enquiring of other regulators concerning data they hold centres upon addressing one central issue.
The majority of data supplied to Australian and other regulators is classified as ‘commercial in confidence’, with a relatively small amount of data currently available for sharing or accessing. This problem has not been addressed in the Issues Paper.

a) Should governments improve their data holdings and share this data among the jurisdictions to improve the management of agvet chemicals?
Yes, this is a useful data source for regulators to use as a supporting tool until proper testing is completed.

b) Should agvet chemical users be required to mandatorily report chemical use data to the regulator? On what basis? If not, why?
It is important for regulators to be aware of the volumes of chemicals in use so that trends are understood by all stakeholders, including environmental and health authorities.

c) How could data mining and analytics drive better targeting of regulatory effort?
See 15 (a) above.

16) Do you support the need for a national domestic produce monitoring system and should it be modelled on the National Residue Survey?

a) Should data on residues in domestic produce be publicly available?
Yes, as an essential requirement to ensure that agricultural products are safe and to monitor usage by agricultural producers and as an important part of building public confidence in the system.

17) How could consistency in water and environmental monitoring across jurisdictions be achieved?

a) Would monitoring systems (for both water and the environment) based on risk priorities be effective?
Risk priorities should be human health, animal health and the environment.

b) Are there specific environments that should be a priority for monitoring?
Attention needs to be placed on particularly sensitive areas for closer monitoring including any environment that has been identified through any other report process (e.g. State of the Environment Reports at national or jurisdictional level) or other legislative reporting requirement. If regulation is to become ecological or other zone focused, then monitoring ought to occur at a similar scale. This suggests a national approach with some roles delegated to a regional (not necessarily state/territory) level. All would occur under a national framework.

c) Should monitoring results be published and how often?
Reports should be annual, with even more frequent monitoring for sensitive areas.
5. How can communication and engagement be improved?

18) What information would consumers like to see more of from the national and state/territory agvet chemicals regulators?

Information about the processes themselves, the governance arrangements, what chemicals are being and have been assessed, the assessment outcomes, what breaches to the regulations and what action has been taken by the regulator and government.

Improved communication is framed by reference to skepticism (unwarranted in some cases) and misunderstanding or politicisation of the risks attributable to agvet chemicals. Misunderstanding in a growing number of overseas markets is said (in the Issues Paper) to threaten continued use and availability of certain agvet chemicals. The need to inform, and more importantly, take action in relation to a correct understanding of risk – and, implicitly, that such risks might exist – is not addressed. The burden of disease, specifically cancer, in farmers and applicators caused by agvet chemicals, specifically pesticides, should be recognised in the Issues Paper. Communication should include that despite such occurrences, there is (at least in the past) no risk to the wider community.

a) How would consumers prefer to receive information?

Reports need to be easily obtained, regular, and easily understood by lay people. The public communications systems operated by the TGA and AICIS may provide a useful reference point for agvet communications. The TGA and AICIS include website updates, and public forums for questions and regulator responses. Different community groups and individuals understand information differently, so a variety of tested formats need to be used. Avenues for community to ask for more detailed explanations (such as FSANZ does) and receive briefings also demonstrate the commitment to openness and accountability.

b) What should be role of the regulators in communicating decisions to the wider community?

It is expected that the agvet regulator would want to provide community information about the use of chemicals, and trends in quantities, level of adverse events, and innovative approaches to reduce agvet chemical applications. The regulator should be the information source upon which the community may rely. This would improve community trust in the activities of the regulator in managing the risks from agvet chemicals. The APVMA currently provides information in lay terms. Links to the regulator site should be a feature of stakeholder sites.

19) Do you support the establishment of a formal consultative forum in Australia, similar to the UK model? If not why?

Enabling communication that contributes to a more accurate understanding of risks presented by agvet chemicals, and specifically pesticides, warrants support. However, communication by any regulator is to be distinguished from communication facilitated by a non-regulatory body such as the UK pesticide forum, which involves among other parties, input from the regulator and from industry. The Issues Paper would benefit from providing more background information relating to this.

PHAA fully supports enabling greater stakeholder engagement and better consultative mechanisms, but are keen to better understand what this actually means. How that is actually implemented is important but follows from the decisions made about the purpose of ‘consultation’.
The consultative mechanisms need to be built into the governance framework to ensure their effectiveness in actually guiding policy development for the regulator.

This approach – enables public trust in the regulatory system; addresses the failing trust in governments to look after the interests of people and the natural environment; and improves the social licence of the regulator and the industry.

Therefore PHAA supports a modification to the UK model, with the proviso that there was a transparent non-politicised method for community and NGO representation on the Panel.

a) Do you have suggestions on the possible membership and scope for a formal consultative forum in Australia?

There needs to be an ongoing formal consultative forum with representation from all key stakeholders, including the broader community, such as established by AICIS. How the community is engaged as a stakeholder is important.

Underlying these questions is a deeper question about the public’s trust in governments generally, that has declined over recent decades. The lack of willingness to believe government pronouncements about, for instance chemical safety, is one of the manifestations of this.

To rebuild public confidence in regulator and government integrity and to combat the perception that government and regulators are ‘in the pockets’ of industry interests, a new approach to governance of the regulatory system is needed. Including community interests on boards and other regulatory panels means the broader community interests can be seen to be included from the very beginning of the process. Such community interests can be community representatives, but these are more effective if they are brought into the governance process not as token individuals but through mini-public processes where they can collectively engage with experts in the field and through a facilitated process be able to make recommendations to the regulator and government that are actually incorporated into policy and practice. Governments worldwide are beginning to use such processes, particularly the South Australian and ACT governments. Numerous international and Australian examples of a parallel process around participatory budgeting exist.

A second level of confidence building is to have relevant NGOs also involved at the governance level. For instance, PHAA used to be represented on the APVMA to offer a community non-industry, non-government perspective.

Thirdly, sound reporting arrangements are critical.

b) If this model is adopted would there be benefits in forum meetings being open to the public?

This would enhance the level of transparency (linked to Australia’s commitments to the Open Government Partnership), which in itself is a confidence building measure that enhances the social license of the agvet industry. Reports from all forum meetings should be publicly available, noting that some sensitive data may not be appropriate for premature sharing.

6. How can we simplify the regulatory system?

20) Which of the 3 repack application options presented do you prefer and why?

Repack options, and the recommendations made, require due reference to the regulator, in order to be properly assessed. The Issues Paper does not provide sufficient information on risks, and relative risk, and how they might be managed. Emphasis in the Issues Paper is placed on which options might significantly reduce the administrative burden for the regulator.
Therefore we are not able to make a detailed response, beyond that simplification of process without losing regulatory strength is acceptable.

21) Which of the 3 options presented for retaining (for specific products), reducing or removing efficacy from the current agvet chemicals regulatory system do you prefer and why?

Discussion of the role the regulator might have in relation to the efficacy of the product should be framed within the context of legislation relevant to goods fulfilling any warranty in relation to their effectiveness. Such warranties may be relevant to the state and territory Sale of Goods Act, and the Trade Practices Act. Identification of any shortcomings, pertaining to the application of such legislation to agvet chemicals would inform discussion of efficacy.

Warranties in relation to the efficacy of crop-protection chemicals rarely centre upon an understanding that the product ‘works’ in some absolute sense, as is implied in the Issues Paper. Usually such warranties relate to effectiveness by comparison with a product already on the market.

Some form of proof of efficacy needs to be retained as a component of registering a chemical. The statement “these companies are unlikely to risk their reputation by introducing a new product without testing it thoroughly, including (where necessary) by generating data that is specific to Australian uses” has been shown to be flawed; the VolksWagon vehicle emissions testing affair demonstrates that this is not necessarily the case. The hierarchical approach to listing and registering medicines demonstrates that many things don’t work, or have misleading claims are sold to the public. The opportunity costs to users and industry of this are both financial and the waste of time for ineffective action. Test of efficacy should not therefore be left to post marketing adverse/ineffectiveness reporting. Further, from a confidence in the regulator aspect, such efficacy data needs to be public.

a) Do you support applying option 1 to all crop protection products and non-scheduled veterinary medicines? If not, why?

Removal of efficacy as a regulatory requirement is a backward step, and unlikely to boost user confidence in the role of the regulator. Option 1, in which the supplier is not even required to retain supporting efficacy information, is not supported.

Efficacy of veterinary medicines and biologicals needs to be assessed within Australia under local production systems and disease conditions. Relying on overseas regulatory authority assessment (USA or UK) may not always be appropriate for Australian animals and conditions. Antimicrobial resistance should be included in pharmacovigilance given the significant issue of antimicrobial resistance. Monitoring of antimicrobial use and consumption should also be implemented through the regulator or in association with the veterinary medicines regulator. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicine Products provides international standards that can be used to support registration of veterinary medicines and biologicals.6

b) Do you support applying option 2 to scheduled veterinary medicines? If not, why?

Yes.
c) Are there unmanageable risks or costs if the efficacy criterion was removed or reduced from the regulatory system? If so, could you provide details?
The TGA’s “Listed Medicines” category is not a good example. There are many user complaints about impurities and adverse reactions from “so-called medicines” in this category (largely herbal and other concoctions) which involve the TGA in recall actions and penalties.

22) Would the ability to make greater use of standards be beneficial for applicants? If not, why?
The Issues Paper states:

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

This is a simplistic view which would benefit from expert input from the regulator, and specific examples or case studies.

The case for the introduction of a standards approach is not satisfactorily presented here. The example for vet chemicals refers to physical aspects such as size and application. There is little or no proper attention to grouping according to chemical structure, which is the basis for reactivity and health complications.

a) Should the use of standards be limited to products of low regulatory concern?
If a standard can be developed on sound scientific principles such as class of chemical and reactivity, it may be appropriate. However, the current descriptor of ‘low regulatory concern’ is undefined, subjective and therefore unhelpful.

c) Should the development of standards be driven by industry or the regulator?
Industry input may be useful, but the regulator’s final decision must be based on scientific principles.

23) Should the regulator utilise prior assessment decisions from comparable regulators to fast track registration where appropriate? If not, why?
This is a well-established process for pharmaceutical products in Australia and could be applied for agvet chemicals on the same principles.

The Issues Paper seems to prioritise the use of overseas determinations, to the exclusion of appropriate examination of Australian conditions and context. Determinations made by reputable authorities should appropriately be taken into consideration in Australian assessments, but should not represent the entirety of such assessments.

The concern of the regulator is that irrespective of overseas approval, the agent under examination is proposed to be used in Australia. In light of Australian conditions, potential for atmospheric exposure by applicators, and possibly, farming families may warrant adoption of limitations in application (nozzle size etc) and/or the use of protective equipment that do not match those overseas. Other matters unique to Australia may include the susceptibility of pest species, consequently necessitating, in some instances, application of higher levels of agent to achieve necessary crop protection. These types of determination cannot be made by reference to ‘trusted’ authorities.

a) Do you support a registration by reference approach as outlined? If not, why?
Yes, but see 23) above.
b) Is basing the approach on decisions from one or more comparable international regulatory systems sufficient?
No. The full unredacted dossier from the other regulator(s) is required, but the Australian regulator must make the final decision taking into consideration Australian conditions which may require some additional trials.

c) Should the approach make it one registration for product, active constituent and label?
Yes.

d) Should the approach be used for variations and reconsiderations?
The scope of this variation is not properly described in the Issues Paper, and more details are required.

e) Are the criteria for what constitutes a decision of a comparable regulatory system a policy decision appropriate for the minister, departmental secretary or the national regulator?
This should be the responsibility of the regulator, not a public servant or the politician.

f) What should be the requirements when considering regulatory comparability?
This should be based on comparable scientific and technical rigour in assessments. The TGA lists comparable regulators based on their assessment guidelines for exchange of confidential regulatory information and work-sharing assessments. There are information exchange agreements with other regulators which do not extend to commercial-in-confidence information.

g) Are there uniquely Australian issues that need to be assessed that have no international equivalence?
Yes.

h) How might the assessment of any unique Australian matters be easily managed?
This requires assessment on a case by case basis, based on the unique conditions which many not have been taken into consideration by another regulator.

24) Is enough being done to address minor use permit applications? If not, what more could be done?
There is a role for emergency or short-term use of permits, but it should not become a common alternative to access of unapproved agvet chemicals.

25) Are there changes that need to be made to the chemical review process to accelerate timeframes for completion? If so, what would these changes be?
No relevant data concerning time taken for approval under current arrangements are provided in the Issues Paper. The extent to which regulatory delay is occurring currently is required in order to assess the benefits of accelerating timeframes for completion.

a) Should reviews have flexibility to consider specific issues that warrant review rather than a comprehensive reassessment of all aspects of the original approval?
This could be a realistic approach to address the particular concerns being raised.
b) Should chemicals reviews be risk-based rather than drive by rolling specified timeframes?
A specified time frame for review should be retained as a safety backup, even if formally deferred if no information requiring full review is found. Reviews should not only be triggered by an adverse event report; some periodical sampling of users to ask about adverse events may trigger more information than just awaiting a user report.

26) Should smart-labels be used, what smart content should they contain and should they be machine readable?

The new technology offers significant advantages for industry. However, it needs to be considered in relation to how readily the core information with the produce as purchase, and any updates, are available to all users. Unsatisfactory risks are created if users working in the field have to go to websites, or other not readily accessed sources, for important information about chemicals.

b) Is mandating labels for containers above a certain volume to be machine readable supported?
Machine readable: yes.

7. How can Australia build national and international capacity?

27) How could the regulator and the Department of Agriculture, Water and the Environment best engage and strengthen international networks?

The Issues Paper does not provide sufficient information regarding advice from the APVMA and the Department in this matter.

28) Do you support the reinvigoration of the Registration Liaison Committee to focus on its original intent? If not, why?

PHAA considers that reinvigoration as proposed may serve a useful purpose. The overriding consideration is the degree to which the relocation of the APVMA has hindered arrangements that applied to APVMA outreach when it was in Canberra. Further information is required to fully assess this.

a) Do you support the proposed new formal consultative forum in Australia including work on regulatory operations and technical working committees?
It is not clear if the regulatory and technical expertise is sufficiently different from the role of the consultative committee, requiring a separate group.

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

This is supported in principle. Experience in the building industry demonstrates that third party assessors need to be seen to be fully independent of and arm’s length to industry and that includes direct payment by chemical manufacturers (although a user pays approach to assessment and regulation through fees paid to the regulator is supported).

b) Should applicants be able to choose their accredited assessor, or should there be a panel of assessors allocated by the regulator?
There needs to be a panel of independent assessors, and the regulator appoints the assessor for each assessment.
c) Should persons overseas be able to work as accredited assessors?
Yes, proving they are assessed for understanding of Australian conditions and regulatory framework.

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

31) Which proposed cost recovery options presented do you support and why?

The ‘Terms of Reference’ shown in Appendix A of the Issues Paper, make no direct reference to funding of the regulator or any specific financial consideration such as the charging framework. It is therefore not clear why these matters are addressed in the Issues Paper.

Community confidence in the competence, integrity and independence of the regulator is recognised as crucial. Lack of community confidence arose recently in relation to NICNAS. Rather than cost recovery, NICNAS financial operations were said to be based on the authority being ‘funded by the chemical industry’.

The prospect of the present or any changed to APVMA finances being described as ‘pesticide manufacturers funding the APVMA’ is daunting even when viewed only as a communication problem. Income entirely dependent on payments received from industry may, at the very least, be seen as identifying a conflict of interest for staff of the regulator.

a) Which combinations of the proposed options work best together and why?

PHAA supports a fair user pays system. In this case, all components of the system from producers through to chemical users and consumers should pay. For users and consumers, this share is built into the price of the product.

Australian government guidelines require recovery of costs from users of the system. This applies for the TGA and AICIS, which recover their regulatory costs from the pharmaceuticals and chemicals industry sectors through fees and levies. This should also apply to the APVMA.

A modular approach seems to the fairest.

32) Which regulatory activities outlined do you think represent a public good and why?

a) Are there other activities not mentioned that could represent a public good? If so, what are they?

The entire system of regulating chemicals under the defined purposes of this regulatory framework (“preserving human, animal, plan and environmental health”) is a public good. The approach taken in the Issues Paper as to where funding for components of this system come from seem reasonable.
Conclusion

PHAA supports the broad directions outlined in the Issues Paper for reform of regulations for agvet chemicals, specifically in relation to the primary role played by the regulator, whose determinations are made independent of any external influences. Initiatives concerning assessments made on the basis of hazard or risk as appropriate are supported by PHAA. PHAA encourages international collaboration in agvet chemical regulation, while recognising that no overseas authority will have any interest in the use of an agvet chemical under Australian climatic, agricultural or environmental conditions.

However, there are a number of questions which could not be properly addressed because sufficient details were not provided in the wide-ranging Issues Paper. Where possible we have given responses that indicate our approach. However, we may revisit our position depending on future information and clarification.

We are particularly keen that the following points are highlighted:

- That protecting the health of agvet workers, the broader community, the ecosystem and plants, animals and other living things which come into contact with agvet chemicals remain the priority with any reforms for agvet chemicals. This includes using an ecology respecting frame in decision making.
- That the aim of reducing the costs of compliance with regulation for agvet sectors should not create unavoidable risks for people and the environment.
- That communication be improved, both in regard to correct understanding of risks and the science upon which regulatory determinations are based.
- That any increased role played by manufacturers and suppliers of agvet chemicals in regulatory matters is transparent and duly acknowledged. Governance of the regulatory system needs to include all stakeholders, but in a way that enhances meaningful community input to policy and decision making and prevents industry capture. Meaningful community participation improves public confidence in the regulator.

The PHAA appreciates the opportunity to make this submission and the opportunity to contribute to improved regulation of agvet chemicals in Australia.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

Terry Slevin
Chief Executive Officer
Public Health Association of Australia

Dr Andrea Britton
PHAA Co-Convenor
One Health Special Interest Group

28 August 2020

Acknowledgements

The PHAA appreciates and acknowledges the contributions of Professor Bernard Stewart, Dr Peter Tait and Dr Joe Hlubucek in the writing of this submission.
References


