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Agricultural and Veterinary Chemicals First Principles Review
Department of Agriculture, Water and the Environment
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Comments on the Issues Paper - review of the agvet chemicals regulatory system - future reform opportunities

Who we are:

GeneEthics is a non-profit educational network of citizens and kindred groups. We want the precautionary principle, scientific evidence and the law rigorously applied to all proposed uses of genetic manipulation (GM) techniques, synthetic chemicals and their products.

The Australian Food Sovereignty Alliance (AFSA) is a farmer-led civil society organisation made up of organisations and individuals working together towards a food system in which people can create, manage, and choose their food and agriculture systems.

Our Submission:

GeneEthics and AFSA thank the Panel for the opportunity to have our say on the Issues Paper, discussion questions and other material.

Recommendations

We recommend the following priority goals for concerted and prompt action:

1. Consolidate, redraft and rationalize into a single piece of federal legislation, all the laws and regulations used to administer AgVet chemical affairs nationally, with corresponding statutes and regulations in all states and territories, to be negotiated through an inter-government agreement;
2. Restore the Chemicals Reassessment and Re-registration Act cancelled in 2014, to establish a comprehensive, effective and efficient chemical reassessment and re-registration regime on a fifteen-year cycle of review;
3. Transfer primary responsibility for setting Maximum Residue Levels (MRLs) in the human food supply to FSANZ. Recruit other regulators to do the same for animal feed;
4. Embed the Precautionary Principle (as defined in S391(2) of the EPBC Act) in APVMA legislation, regulation and practice, to prioritise effective hazard and harm prevention for human and animal health and our environments;

5. Shift the onus of scientific proof for the safety and efficacy of all agvet chemicals off regulators and civil society, onto the applicants, patent owners, producers and distributors;
6. Replace the APVMA's regulatory science regime with genuine scientific methods, processes and principles, to eliminate best guesses and gap-filling from regulatory decision-procedures;
7. Create an open and transparent regulatory system that facilitates the timely participation of the interested and informed public, and civil society advocates, in all the APVMA's affairs regulatory affairs, including membership of the Governance Board;
8. Publish all applications, complete raw data, and documentation of technical assessments, without the interested public or investigators having to resort to expensive FoI requests;
9. Transfer Ministerial and Departmental responsibility for the APVMA from the Department of Agriculture, Water and Environment, where achieving the $100 billion export goal by 2030 drives the policy agenda, to the Health Department, where protecting public, health, safety and the environment are appropriately the top priorities;
10. Develop a labelling standard in consultation with users and the interested public, against which to measure the adequacy of all farm and domestic AgVet chemical labels, for clarity, comprehension and compliance;
11. Prioritise for review, using the EU model, all chemicals registered last century. First reassess chemicals that failed EU, US, Canadian or New Zealand assessments and are restricted or deregistered there;
12. Require that peer-reviewed papers and data be submitted, to validate all company-generated and commissioned data, and to ensure that corporate trial results are replicable and verifiable.

We propose a new vision statement for the APVMA:

> "Australia's agricultural and veterinary chemicals regulatory system will exercise precaution, to preserve and enhance human, animal, plant, and ecological integrity and health, by providing all land and water managers and veterinarians with access to those agvet chemicals that independent contemporary Australian scientific research and evidence shows are safe, efficacious and not banned or restricted in other jurisdictions."

Comments on the Review Panel's stated priorities

The Panel has considered and is disposed or inclined to:

1. The critical importance of Australia's future regulatory system being based on risk, not hazard alone. … and incorporates hazard assessments along with exposure and use, to determine chemicals suitable for use and the safest way of using them.

- The Precautionary Principle should also be integrated into AgVet chemical legislation so that the whole system is geared to hazard identification and minimisation as a preventative measure, in addition to the risk management that is now the key focus. Exercising precaution sets standards and attitudes that acknowledge and encourage the duty of care to be observed before, as well as after, a chemical is registered for use.

2, There is little justification for considering any changes to the current approach of a single national regulator for the supply of agvet chemicals.

- We agree, but the single national regulator must also accept responsibility to ensure that all jurisdictions and institutions responsible for monitoring, compliance and enforcement are willing, able, and empowered partners that are well-resourced to robustly participate in deploying and managing the parts of the regulatory system and products they administer.

3. Recommends a national approach to compliance and enforcement of agvet chemicals use that employs a consistent set of compliance and enforcement tools. … licensing of chemical users;

monitoring and investigative powers; record-keeping requirements; and the full suite of admin actions, plus civil and criminal penalty provisions, with a consistent range of available sanctions.

- We agree that a uniform national approach is desirable, but reaching agreement on compliance, monitoring, enforcement and other provisions must not result in a race to the bottom - adoption of the weakest standards agreeable to all jurisdictions.

- A barcode on every chemical container would enable it to be scanned and data automatically fed to a database register, every time the contents are used. A state repository of chemicals applied could increase user accountability and the collected information would enable the government agency to more effectively monitor and audit use. Publicly available, anonymised, collective data would enable interested citizens and advocacy groups to track overall use, have a say, and contribute their own data, to enrich the system. Monitoring, enforcement and compliance could be enhanced.

4. Removing from the scope of the agvet chemicals regulatory system products with limited relevance to primary production or animal welfare. As examples this would include most consumer goods, pool and spa chemicals, antifouling paints and some veterinary products. This would give a clearer 'identity' to the agvet chemicals regulatory system as it supports Australian primary production, veterinarians, and non-urban land management.

- We strenuously disagree with this proposal. There is no other regulator that has the capacity or focus to effectively take on the very important responsibilities of assessing and regulating toxic products for domestic use. The Panel nominates Australian Consumer Law (ACL) and the ACCC as surrogates but they have no comparable capacities, roles or relationships with state and territory regulators like the agvet chemical regulatory system. The agvet chemicals regulatory system owes a responsibility to the whole Australian community as the use of its registered products impacts everyone directly or indirectly.

5. Restrictions of 'veterinary use only', where warranted for animal welfare, … the minimum, and to the extent not already addressed through scheduling, injectable veterinary products should require the direct involvement (either in administration or under their instruction) of a veterinarian.

- We agree with this proposal, however, achieving its objectives may be complex. For instance, the cost of specialized veterinary care may often be a disincentive so that some graziers and animal owners may fail to deliver required care to their animals, exacerbating the animal safety, health and welfare breaches that are already too common.

6. Considerable potential in more effective data mining arrangements in the regulatory scheme of the future.

- Mining data that is already publicly available is acceptable and patent protection is already afforded to proprietary information. However, data mining must not be used to disguise the flaws and serious deficiencies of ‘regulatory science’, which is an inadequate assessment methodology. For instance, it is no substitute for deficiencies in the scientific data that applicants submit. Where data gaps exist, applicants must be required to produce further evidence, rather than the regulator expending resources to fill data gaps with best guesses.

7. A consultative mechanism, like the UK model, with active functions that give it momentum and a greater likelihood of being sustained over time.

- The UK model has been in operation since 1996 and has not produced significant positive results, now merely overseeing plan agreed to in 2012. The Panel should more widely

explore other models and seek the advice of experts in the field. Models of consultation are reviewed here. https://link.springer.com/chapter/10.1007/978-1-4615-5311-3_4

8. The Australian regulatory system needs to take full advantage of the work of comparable regulators, so that Australian effort is only focused on the issues that are unique to Australia.

- The work of comparable overseas and international regulators must include their critiques, restrictions and banning of agvet chemicals, as well as their adoption and registration. For instance, the EU only extended the registration of glyphosate in 2018 for five rather than ten years, and the chemical is likely to be banned when next reviewed. The APVMA is staunchly defending its assertion that glyphosate-based-herbicide (GBH) formulations are all safe if the label instructions are followed, despite accumulating evidence to the contrary.

9. Benefit in an operational group of regulators across jurisdictions focused on addressing and working through issues that need solving. … whether there would be merit in reinvigorating the Registration Liaison Committee to focus on its original intent.

- Inter-agency consultation and liaison will be essential so that all jurisdictions effectively co-operate in deploying all the components and functions of an integrated system. However, open and transparent reporting should also be built into the system so it is much more than just the domain of privileged insiders who can unilaterally make decisions that affect us all. Scant information is publicly available about the Registration Liaison Committee, its original intent, membership, past operations or decisions. The effective participation of independent experts and the interested public in redesigning and implementing new regulatory regimes is essential.

10. Regulatory activities (i.e. chemical reviews) provide an obvious public good, but compliance and international engagement activities are more closely related to the regulated entities.

- We disagree. Compliance, monitoring and enforcement of regulated entities should provide essential information and intelligence on their activities that must be open to public scrutiny and engagement.

11. There is a case for activities associated with advising and supporting the minister and parliament (senate estimates briefing etc.) being funded by government. … in the interests of the Australian public (accountability and transparency) rather than regulated entities.

- In our view, all of the regulators activities must primarily be conducted “in the interests of the Australian public (accountably and transparently) rather than regulated entities.” Without the regulator’s existence and operations the regulated entities could not earn and maintain their social licence to operate. The Regulator, the Minister and the Parliament are the Australian community’s servants - our eyes, ears and watchdog, however funded. The APVMA must be funded at arms length from the regulated entities, to ensure its decisions are not tainted by the influence of its clients.

Comments on the Panel’s flagship reform proposals

1. Increasing national consistency of control of use
    - **Agree**
2. Removing consumer and non-primary production products from the system
    - **Disagree:** these products require the strong regulation and clear accountability that only a federal regulator can achieve, with co-ordinated state backing. There are no other viable regulatory options currently available.

3. Introducing a benefits test
    - **Agree**: cost/benefit analyses, worst-case scenarios and scoping studies of the impacts of all regulatory decisions are needed.
4. Changing the way chemical product efficacy is managed
    - **Qualified Agreement:** efficacy is a key public interest value that the APVMA must critically assess so that all users and those affected are not misled or cheated. Without efficacy assured, the hazards and risks of any product cannot be justified.
5. Introducing a registration by reference approach
    - **Qualified Agreement**: such references must not be used to justify minimised or fast tracked assessments. Agvet chemical restrictions, deregistrations and negative findings in other jurisdictions must also be adopted on precisely the same basis as positive references.
6. Introducing smart labelling
    - **Agree**: but the labelling regime must be a lot smarter than the present system. An enhanced model must offer must simpler, clearer and more accessible information, in diverse languages and at the comprehension level of a 14 year old, electronically.
    - Innovative label technology can bring multiple efficiencies, support traceability, facilitate emergency response, minimise user errors and enhance communication between stakeholders. This should make registration, monitoring of compliance, and enforcement more feasible and economical.
7. Introducing an accredited assessor scheme.
    - **Disagree**: privatisation and outsourcing of the regulator's responsibilities are not in the public interest. Failsafe protections against corruption and nepotism and the maintenance of standards would be problematic.

Answers to the Issues Paper questions

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

To quote Senator Bridget McKenzie, "A 21st century agriculture sector demands a 21st century regulatory framework". We agree but, for us, this means phasing out old production and management paradigms that depend on synthetic agrochemicals, while embracing innovative and sustainable non-chemical farming techniques and practices instead.

We consider the approach to chemical dependency is outdated (Norton and Alwang 2020; Pannel and Claassen 2020). Endeavours should be made to phase out artificial, hazardous and risky chemicals and better train farmers in different approaches to safer and more environmentally friendly agricultural practices (Flaccavento et al. 2020; Carlisle et al. 2019).

The approach taken should focus on supporting integrated and holistic farming, such as regenerative agricultural systems. These can offer a point of differentiation and competitive advantage for Australia's excellent reputation in food standards. An example is the premiums gained from organic produce and high-quality meat sold in domestic and international markets. According to Goh (2020), "consumers are interested in buying organic food products from countries where there is a reputation for organic quality and standard through the certification process". Thus, a paradigm shift and better use of resources can have long-term beneficial effects on the reputation of Australian produce.

Industry Snapshot	IBISWorld 2015	Australian Organic 2014
5 Year Annual Growth	13.9%	15.4%
Businesses	2,732	2,567
Exports	$40.7m	$340m

Organics accounts for 1.5% of Australia's $130 billion food industry and could be 12-17% over the next 20-30 years (Organic Federation of Australia, personal communication 2016)

Figure 1. Economic figures of Australian organic farming. Source: Australian Department of Agriculture (2017).

Regenerative and organic production systems that reflect international best practice and trends are essential alternatives to depending on depleting, intensive, chemical inputs. Allocating substantial R&D resources to the development of new non-chemical systems for Australia is a priority, yet most funding now goes to intensifying high input systems to maintain business as usual.

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

- Regulation should prioritise animal, environmental and human health over chemical access and efficiency.
- Reinstatement of the re-approval and re-registration scheme for agvet chemicals (to align with the approaches of agvet chemical regulators in the EU (cycle of 10 years) and the US (cycle of 15 years).
- Replacement of regulatory science with the genuine, tried and tested scientific method for collecting and evaluating data. Regulatory science is not intellectually credible or precautionary. The regulator must use independent, peer-reviewed and published scientific data when making decisions to register agvet chemicals.
- A focussed and effective agvet chemicals regulatory scheme should include constant monitoring, enforcement and accountability.
- Consideration of agricultural workers and their occupational health and safety must be primary responsibilities for key stakeholders throughout agricultural supply chains.
- Allocating research and development resources to phasing out synthetic chemical inputs and promoting farm practices that are internationally accepted, recognised and in growing demand.
- All chemicals must have passed comprehensive safety tests before being approved and frequent reviews must be conducted of data collected during commercial use.

b) Do you have any suggestions for reforms that could assist in achieving this vision that are not canvassed in this paper?

- Assess chemical use applications according to the landscape and biological regions rather than state-based boundaries - this would assist in prioritising animal, environmental and human health.
- A robust conversation about the priorities for R&D programs is required, to transition towards the needed changes that will embrace organic, biodynamic and regenerative farming systems. R&D decisions should have wide community input and consensus, especially as the research is relevant to the health and safety of all citizens, and taxpayers pick up a substantial part of the bill for agricultural R&D.
- Transfer to Food Standards Australia New Zealand (FSANZ), the process of initiating and setting allowable Maximum Residue Limits (MRLs) of synthetic chemical residues in the human and animal food supplies. FSANZ would set MRLs in accord with maintaining and enhancing the long-term health and safety of humans and other animals as its top priorities. APVMA would then derive from the MRLs that FSANZ had set, the allowable rates, timing and agronomic conditions under which synthetic

chemical spraying could be conducted, before, during and after the production of food crops.

- The Precautionary Principle should be integrated into AgVet chemical legislation so that the whole system is geared to hazard identification and minimisation as a preventative measure, in addition to risk management that is now the key focus. Exercising precaution sets standards and attitudes that acknowledge and encourage the duty of care to be observed.
- We suggest benchmarking proposed new regulations against those that the Californian Department of Pesticide Regulation use. This thorough, comprehensive, precautionary and detailed regulatory framework is available online (Department of Pesticide Regulation 2017). The body that regulates pesticide use in the state of California is independent and includes the use of reduced risk pest management practices in their vision statement (https://www.cdpr.ca.gov/).
- The scientific journal Nature recently published a paper that unveils the magnitude and macro-economic relevance of ecological agricultural practices, arguing that biological control resolved invasive pest threats in multiple agricultural commodities, ensuring accrued (on-farm) benefits of US$14.6–19.5 billion annually (Wyckhuys et al. 2020).
- We propose that special care is given to safeguarding Australia's good reputation as a globally recognised producer of safe, clean, high-quality agricultural and animal products, an international commitment that is increasingly recognised (Wang et al. 2020). According to the Centre for International Economics report for the Australian Council of Learned Academies (2015, p.41), "reassuring consumers of the superior quality of Australian products is a key factor in successful export market activities".
- No off-label chemical usage should be allowed under any circumstances. This is unacceptably risky, may stall emergency responses, and confuses public health data reporting.
- Farmers should be required to keep records of the chemicals, including the time, quantity and location of use, so that audits can be conducted. Smart phone apps would be a simple and cost effective means to record and store reliable data.

The Issues Paper proposes, "to ensure greater integrity of the system, areas identified for improvement" which include:

- monitoring of chemical residues in domestic produce and the environment,

This is a commendable goal, which we support, if it is comprehensive and has prevention of harm as its goal. Who will pay for the process, how, when, where and, most importantly, what will be done with the results of monitoring? A lot of monitoring is merely to assuage genuine public concerns and, without positive action, such exercises allow disasters to accumulate long-term.

- building national capacity in regulatory science capabilities,

We profoundly disagree with the precepts and practices of regulatory science, as explained in a previous submission. The methods and rules of scientific inquiry, developed, tested and used over many centuries, should also be utilised in all regulatory assessments and processes. So-called regulatory science has no credibility, rigour or replicability, filling data and knowledge gaps with best guesses and assumptions. Where such gaps exist, regulators must be empowered by law to require applicants to submit additional evidence.

- using data and intelligence gathering to assist and guide regulatory functions and focus.

Like monitoring, gathering data and intelligence is useful but it raises more questions than answers unless it is well resourced, systematic, and done with clear, coherent purposes.

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

We agree that "Consumer demand for organic, minimally treated, and/or sustainably produced products continues to grow rapidly." This is a life affirming and healthy trend that all levels of government should encourage and support with the reallocation of research and development resources to develop these cleaner options.

They should be backed with regulations that minimise the use of, and pubic exposure to, toxic synthetic chemicals, so everyone's overall quality of life is enhanced, chronic illness and disease decline, and demands on health services are reduced.

We agree that there are increases in "consumer awareness, access to information and scrutiny related to agvet chemicals and provenance and traceability in the food system more generally" but we do not accept the claim that these are "leading to a greater level of regulatory accountability."

True accountability is a reciprocal relationship that is enhanced when it involves full reporting, being answerable, and responsive to both praise and criticism. The APVMA must do more to build genuine and enduring public confidence and trust based on real performance.

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.

Toxic chemicals approved last century need to be reviewed and phased out, to achieve Senator McKenzie's vision of bringing agvet chemical regulation up to date.

The paper notes "the panel is interested in what mechanisms are needed to build a regulatory system that responds sensitively to these community concerns, and maintains community trust in the use of agvet chemicals."

Industry and regulators should not see the public as adversaries, nor as over-demanding customers and clients, but as partners and collaborators in the quest for safe and sustainable systems and products to nurture this and future generations. The chemical industries must transcend the pursuit of maximum profits at any cost, where the costs of impacts on human and ecological welfare are routinely externalised and imposed on the whole society. Regulators must re-envision their role as protectors of the public interest, not champions of the chemical industry.

Electronic (smart) labelling is an obvious and appealing solution to a multitude of conceptual, communication and compliance problems with existing, deeply flawed, label systems. It may be used to deliver messages in multiple languages, to deliver information at the point of use as well as the point of sale, and to provide user feedback on substance performance and efficacy. The success of an electronic approach will very much depend on how the system is designed and deployed. Comprehensive public participation (not consultation) in every aspect of its creation, deployment, and ongoing operation will be key to overall success. If it serves sectional interests, is created only by 'experts', or is imposed top-down, it will fail. Smart labels must not replace or stall the improvement of printed labels already on product packages.

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

The trend towards local, sustainable food needs support, when designing the future agvet regulatory system. The transition to regenerative agriculture systems being adopted by

many Australian farmers will support and enhance human and animal health, and fragile environments and bioregions that are irreplaceably losing nutrients, soil and water. A focussed and effective agvet chemicals regulatory scheme must include constant monitoring, enforcement and accountability.

The fast growing aquaculture industry is increasing its use of more agvet chemicals that may have very significant impacts on marine and inland aquatic ecosystems, so require new approaches to assessment, regulation and licensing. Aquaculture uses a vast array of chemicals including limestone and lime, chemical fertilizers such as superphosphate and urea, and also "oxidants, coagulants, osmoregulators, algicides, herbicides, fish toxicants, antifoulants, therapeutants, disinfectants, anesthetics, agricultural pesticides, and hormones." (Boyd and McNevin, 2014)

The cumulative, synergistic and long term impacts of chemical formulations - on public and animal health and safety, and all environments, must be a part of agricultural chemical assessment processes, as this is the only way to get a true picture of chemical impacts.

Regulators should accelerate the trend of more openness and transparency of data and decision-making within corporations and other institutions. Hiding information behind a screen of Commercial in Confidence claims is no longer credible. The public has a right to know and it is not acceptable that negative data or dealings are hidden from view. FoI, Senate Estimates questions and committees of inquiry after the fact are very imperfect tools for outing what vested interests want to hide.

3) Do you support the proposed overarching primary purpose statement for the agvet chemicals regulatory system being safety and access?

Safety and efficacy should be the primary purposes of agvet regulation. Safe and efficacious chemicals will be registered and accessible while those that fail registration will rightly not be accessible.

The Issues Paper claims that: "Lack of access to chemicals that are available to farmers in other countries puts Australian farmers at a costly competitive disadvantage."

But access is a two way street. If farmers in other countries do not have access to chemicals because scientific evidence found them to be unsafe or not fit for purpose, then Australian farmers should not have access to them either.

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?

To achieve this vision in the future:

There is some merit in the Australian system "being more closely aligned with international agvet chemicals regulators, processes, and timelines." For instance, the US and EU systems of periodic re-assessment and re-registration of all agvet chemicals should also be instituted here. However, groupthink and follow-the-leader can result from such close collaborations and collegiality, where critical fact checking, scepticism and fearless interrogation of applicants are absent. The issues paper rightly notes the global concentration of ownership of agvet chemicals but does not confront the undue power and influence this can impose on everyone else.

There is merit in the goal that "The regulatory system should be consistent in its application and implementation across the states and territories." But that overlooks the widely varying priorities, policies and resourcing of activities in diverse jurisdictions and environments. The

industry levies that are collected to fund the APVMA's assessment and licensing may need to be extended to resourcing the implementation, monitoring and compliance activities of each jurisdiction as well.

We disagree strongly that regulators and the regulatory system "should specifically aim to foster innovation in all its forms among chemical companies, veterinary medicine manufacturers, other industry groups, farmers, environmental managers, and the broader Australian science community." Their legitimate role is to be the community's eyes, ears and watchdog so promoting innovation or picking winners among potential products is inimical to their being an objective and unbiased referee on everyone's behalf.

We agree that "The system should aim to foster and build national capacity to assess and manage the safe and effective use of agvet chemicals throughout Australia." However, it should also have the role of minimizing the use of agvet chemicals and making policies that encourage and assist the transition to the regenerative and agroecological systems essential to sustaining future generations when oil, phosphates and other scarce inputs are fast depleting, soil and water are constricted, and climates are changing.

We strongly agree that "Compared to current arrangements, the future system should be more transparent and accessible to stakeholders and interested members of the public." The discovery of documents during class actions after harm is done to health and the environment on a mass scale is a useful trend but it is just too little, too late to really serve the public interest. The whole system must be responsive to new research data, open interactions, and precautionary.

Another worthy goal is that "The system should function as an asset rather than a barrier for Australia's primary industries, veterinary industries and environmental managers, while maintaining public respect and confidence." The system must also function as an asset rather than a barrier for the whole community. Unless the whole regulatory regime, in all jurisdictions, is open, transparent and responsive to the interested and affected public, it will never win respect or confidence.

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?

The system should be transparent, including not just capacity of farmers and chemical manufacturers to navigate the system but other stakeholders such as consumers and environment groups having access to information about chemical use in Australia. There should be a national register of what chemicals are applied, in what amount, and where. Internal work prioritisation in decision making, not talking about what people know, that is not their transparency issue.

d) Are there other objectives that should be considered?

We disagree with the panel's proposed hierarchy of objectives. They should be:

1. To protect and enhance the health, safety and welfare of the whole biosphere, including people, animals, plants and other living organisms.

2. Provide safe and timely access for qualified users, to thoroughly safety-assessed and regulated agvet chemicals.

3. To monitor and advise on the status of regulated and banned chemicals in all jurisdictions, so that trade is not unnecessarily disrupted.

4) Do you support the principles proposed to guide design and reforms to the future agvet chemicals regulatory system? If not, why?

> "the principles the panel considers important include consistency, efficiency, certainty, transparency, objectivity, independence, simplicity, shared responsibility and accountability."

But objectivity cannot be achieved or maintained using a regulatory science regime. We therefore advocate that the regulatory system should employ and observe the Scientific Method, its standards of proof and its modus operandi. The evidence, which applicants submit to support, their applications must be held to the same scientific standards of objectivity, independence and rigour.

Independence from government has failed, for instance, when the Chemical Re-assessment and Re-registration scheme was cancelled in 2014, on the basis of an election promise to the chemical industry. It is also absolutely essential that the APVMA is independent of the influence from the corporations whose products and actions it regulates.

We oppose efficiency and streamlining as core principles since they always unfairly serve the interests of regulated entities. And if the regulator were also "considering how the market can drive registration holders to make optimal choices about their chemical products" its objectivity and independence would be further compromised.

Consistency among the various entities operating and managing the whole agvet system would be essential to minimize cross-border and other ways around the rules.

The great diversity of social, environmental and political circumstances in other countries makes overall harmonisation with international regulatory systems, processes and timeframes unlikely to succeed. Where harmonization is possible, it must be on a reciprocal basis so that chemicals are treated similarly - restricted or banned in both jurisdictions and only approved at the highest standard in both.

Simplicity, certainty and clarity are valuable traits for legislation but only if the law is also responsive to community standards and expectations, precautionary, comprehensive, enforceable, and flexible enough to anticipate altered future circumstances.

The optimum functioning, transparency and accountability of the regulatory regime depends on full, free and fair community participation in all aspects of the operations and decision-making of the system.

a) How could these principles be enshrined to ensure they are met?

Legislation and the operating procedures of the new system must be designed, starting from and embodying the core principles. The design and implementation processes must open and responsive to public scrutiny, critique and iterative amendment so that they are designed to best serve both the public and private interests.

b) Do you have suggestions for additional principles that should be considered by the panel?

The Precautionary Principle is now incorporated into many treaties and pieces of legislation where it is effective, and instrumental in lifting the requirements for more contemporary, independent, diverse and robust scientific evidence as the basis for better protecting health, safety and the integrity of ecological systems.

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?

Risk assessment relies on prior hazard identification and evaluation. But as hazards are often not evident in advance the identification and assessment of hazard, harm and risk must be an ongoing, iterative process. We are wary of the frequent assumption that all risks are manageable and reject this as the basis for approvals.

To assert that “the APVMA is: a 'one stop shop' in relation to registrations with hazard identification, risk assessment, risk management and risk communication capability to span its full range of functions“, is meaningless without the precautionary principle also being in operation.

Australia urgently needs an agvet review regime like that cancelled in 2014. Successful chemical review schemes have operated in the EU since 1994 and in the USA since 2006.

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

We reject the Issues Paper case for the dominance of risk over hazard in chemical assessments. Hazard minimization and risk management are intertwined and cannot be logically or practically separated.

We agree that “hazard and risk are not mutually exclusive” - they are interdependent. We also concur that “hazard is an intrinsic part of the process of risk assessment.” So hazard identification, assessment and minimization are crucial to generating scientifically comprehensive, robust and responsive systems.

Risk and risk management alone are inadequate guides to designing and implementing effective regulatory systems. Relying on users’ imperfect interpretations of weak and uninformative labels as the chief mode of risk management is unacceptable.

Frequently regulators assume that all risks can be managed, yet have little power or will to allocate sufficient resources to resourcing compliance, monitoring and enforcement capabilities. Clear lines of management and responsibility are needed so that non-compliance is pro-actively found and rectified.

The paper asserts that “the APVMA is: a 'one stop shop' in relation to registrations with hazard identification, risk assessment, risk management and risk communication capability to span its full range of functions“. The precautionary principle is also needed to toughen this rather passive stance.

It is not sufficient that the APVMA is “accountable to the community through the Parliament of Australia and its committees.” The community must also have much more direct and effective access to the APVMA and its functions, and the regulator must be much more directly responsible and responsive to public representations and actions.

Maximise the diversity, independence, objectivity and expertise of those engaged in governing the regulatory system. Minimise the actual and potential conflicts of interest of all participants in governance processes.

7a) Do you see merit in a time-limited High-Level Steering Committee to drive implementation action on the regulatory reform agenda?

Any such committee needs to be broadly representative and appointments must be open, transparent and public. Any such committee must first and foremost represent the public interest. The sunset on such a committee must be set beforehand to ensure it does not lapse into permanency.

7b) Which of the three reform options outlined do you support and why?

We prefer Option 1 (Expanded applied law model).

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

Option 1 Expanded applied law model

We believe this option will deliver the best chance of consistency in control of use and the greatest likelihood of success. It would also give consumers the most comfort that a uniform, consistent position would apply nationwide. One of the effects of COVID-19 has been a dramatic movement away from national governance, with each State or Territory effectively determining its own path. While constitutionally confusing (and possibly even challengeable from a legal point of view), the governance during the pandemic has unequivocally reminded us that the States formed the system of national governance in the first place, and in a crisis can just as effectively unbundle it.

An expanded applied law model may be our best protection for consistency in control, though we query whether, with their re-found independence, States will be united in applying Commonwealth legislation as a single national law. We note for instance the Panel has mentioned COAG as a forum for keeping States accountable in the event they fail to sign up fully to an applied law model. But COAG no longer exists. It is not yet known what remit the replacement National Federation Reform Council has, nor how public its consideration and decision-making will be. All we know at this stage is that its primary objective is to "focus specifically on job creation in response to the COVID-19 pandemic" (Department of the Prime Minister and Cabinet, 2020). This seems a much too narrow focus, if keeping States accountable is the objective.

Extra Expansion

We question whether under this model there might be a practical role for local government and even other authorities such as Landcare and catchment management authorities, such as those that exist under Victoria's catchment management framework: "In Victoria Integrated Catchment Management (ICM) underpins the sustainable management of land and water resources, and contributes to biodiversity management. Through this approach, the Victorian Government and its partners seek to achieve sustainability and ensure the long-term viability of natural resource systems, and human needs for both current and future generations." (Victorian Department of Environment, Land, Water and Planning 2020).

We note the Issues Paper speaks of outsourcing assessment to third parties. If this is a serious proposition, then surely sharing the regulatory role with bodies tasked with environmental care and management should be equally palatable. These bodies could be partnering with local landholders and farmers to assist with on-the-ground advice and monitoring on matters such as chemical storage, use and disposal.

Option 2 Commonwealth exercising its full constitutional reach

It is almost impossible now to divorce this option from the effect of COVID-19 on Australian

governance. We do not believe the constitutional reasoning in this option still holds the compelling effect it would have had pre-pandemic. We suspect that an act of the Commonwealth exercising its full constitutional reach may be met with reluctance from the State governments to accept the regulatory regime.

Option 3 Re-invigorating the existing Intergovernmental Agreement on control of use

We note the Panel proposes an Intergovernmental Agreement (IGA) that underpins the applied law arrangement forming the subject of Option 1. We support this approach in Option 1, rather than attempting to rely on re-invigoration of the existing IGA alone under this Option 3 proposal.

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

The States may not participate in a national scheme, as outlined in b) above.

Consistency in control of use, and variable resourcing to implement an effective monitoring, compliance and enforcement regime, may be difficult to achieve among all jurisdictions.

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?

No. Co-and-self regulation is unacceptable as there is great potential to enable licensees to circumvent, compromise and game the regulatory system for their industry's benefit.

However, we do endorse a life-cycle system of analysis and management for all agvet chemicals – from factory, farm and food, to production, use, disposal and final fate.

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?

Yes. Accreditation should be subject to monitoring and periodic performance review.

b) Is there additional value in limiting the scope for a holder based on the nature of the registration?

Yes.

c) Do you agree with the panel's proposal for formal training requirements for users to access (purchase) agricultural chemicals above a certain volume?

Yes. But the volume of chemicals used should not be the only trigger for training. Higher hazard and risk categories of agvet chemicals should also require more training and oversight.

d) Do you have suggestions for how existing assurance schemes such as GMP could be used to streamline assessment processes?

We do not agree with streamlining (fast tracking) assessment or any other processes.

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?

Yes, but only if the “statutory duty of care” were enforced. The carrot and counselling approach that most federal regulators adopt is just a recipe for corporate recidivism, as we see with regulating the Banks, Therapeutic Goods and aged care, for instance.

f) Can you think of any alternative or additional measures the government could implement to strengthen the responsibilities of regulated entities and users?

It would be worth looking at the effectiveness of APVMA’s compliance, monitoring and enforcement functions. We recommend the laws be enhanced to impose greater personal liability, as well as corporate responsibility, for breaches of the various regulatory instruments under APVMA’s remit.

We also question whether more transparency around the investigations could be provided to the public along with more meaningful data around APVMA’s investigations and treatment of allegations raised. At present the information provided on APVMA’s website around compliance and monitoring is quite high level and thus doesn’t give much of a picture of the effectiveness (or otherwise) of this function.

For instance, the “Summary of Investigations” table, currently on the APVMA compliance and monitoring tool (2020a), lists 280 allegations raised in FY19-20. Yet a scan of the APVMA’s list of consequent actions only records 75 (and some of those could be “double counts”). Cases closed are listed at 174. There is insufficient detailed data available to reassure the public that the APVMA is enforcing the regulations strictly and efficiently.

9) Should detection and investigation measures be augmented to better treat the risks posed by agvet chemicals?

Yes, but this may be for the states to implement under the APVMA’s direction, in an integrated system. Australia is too large for effective federal monitoring and enforcement. Having a national repository, review and registration scheme that makes all data publicly available, especially to environmental experts, should facilitate independent vigilance.

Monitoring and compliance must be a central role within the system. The States and Territories must be more adequately resourced for their role in this work.

a) Do agvet chemicals regulators need more effective and nationally consistent tools and sanctions than they already possess to manage the risks for which they are responsible?

Yes. Regulators at every level of government require these to optimise their capabilities and effectiveness.

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?

This is a policing role, so employ experienced investigators and law enforcers.

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?

Independent professional and citizen scientists might be better resourced to engage in monitoring and detection work, to better secure compliance.

d) Should agvet chemicals registration-holders be screened in some way to ensure they are reputable? Why, why not?

Yes. The licensing systems for ammonium nitrate, firearms and other potentially dangerous activities, already in place and functioning, may serve as models.

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?

No. They require regulation and a federal expert regulator is the appropriate body for the task. A national chemicals regulator of domestic and non-industrial products is needed to ensure consistency and caution, protecting user health, welfare and safety. APVMA deregulation of these substances would create a dangerous vacuum that must be filled.

A survey of regulatory and assurance systems in other jurisdictions globally may offer a model for action in Australia, especially that deployed in California.

a) Do the benefits of the proposed removal of these products outweigh the risks? If not, why?

No. Members of the public are at more risk than expert users from un-tested, un-assessed and unregulated products, and governments owe them a duty of care that must be met.

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?

Yes. However, the cost of their service may disincline some users to retain the experts, raising animal rights and welfare problems that other remedies may not easily fix.

11) Are there areas where the approach to agricultural chemicals and veterinary medicines should be different?

Independent experts who have no conflicts of interest should be engaged in this discussion and assess health impacts along with performance.

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

The regulator and other authorities have cross-border legal, moral and ethical responsibilities to maintain and enhance the integrity of significant cultural, biological and geographical regions such as sacred indigenous sites, World Heritage and Ramsar listed locations, high value wilderness and old growth areas, marine parks or other zones that are especially vulnerable to being compromised, by spray drift, chemical runoff or the accumulation of chemical residues.

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 uses?

Such bioregions have high value for indigenous habitation, nature conservation, wilderness tourism, recreational activities, and other activities and which far outweigh any competing economic or other uses such as growing sugarcane that pollutes the environment and causes obesity when overused in junk foods. The policy resolution of such competing uses should not be left to markets to resolve as they commonly externalize the costs of the collateral damage that pollutants do.

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?

We favour such reviews but not by the registrant. This work should be independently undertaken, with full public participation in the process. Those tasked with reading and interpreting the content of labels must have a say in whether or not they effectively communicate important messages.

Regular reviews should be a feature of the whole agchem regulatory system, as we assert elsewhere. Ad hoc and open-ended reviews of the system create uncertainty and a lack of clarity for everyone and that is unacceptable.

c) Is it possible to establish pest groupings?

This is unclear. Do you mean, plants, animals and microorganisms? Surely such groupings already exist.

13) Would a benefits test as proposed be a useful addition to the agvet chemicals regulatory system?

We favour comprehensive cost/benefit analyses and would also like worst-case scenarios to be constructed so the system is fully prepared to promptly and effectively respond to new scientific and epidemiological evidence of adverse events and conditions. It is no longer satisfactory that some chemical reviews can take decades to complete and that pollution continues unabated while the system fails to raise the alarm and respond as necessary.

a) Are the benefits outlined appropriate?

The Issues Paper proposes that “benefits can cover such things as: agronomic; economic; social; health; environmental; contribution to resistance management;” where a cost/benefit analysis may contribute to rational and precautionary decisions.

However, no benefits could derive from the ”likely consequences of the public not having access; and whether the new pesticide fulfils an unmet need.” Maximising public access to the whole regulatory system – from chemical factory, to field, to food – is a positive good. But a recipe for disinformation and disaster would be inviting the agvet chemical industry to create new unmet and unimagined ‘needs’ – when Big Pharma, for instance, routinely concocts new human ailments that can be resolved with its drugs and other products.

b) Are there additional benefits that should be considered?

On the contrary, the seven categories of ‘benefit’ that the “panel is disposed towards including in a benefit assessment’” are so broad and general that any “weight of evidence assessment of risks versus benefits prior to registration” would be inherently biased in favour of approval. We reject that.

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

Back to the drawing board.

The first point is not a purpose - forming only “part of the assessment and final regulatory decision for registration or reconsideration for all applications.”

The second purpose is to “demonstrate up front that the product would have national benefits”, to justify prioritising its assessment and approval. As ”national significance” is

undefined, no benefits could derive from fast tracking such an application through the approval process.

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

Yes, it is absolutely essential. With hundreds of 'active' constituents and 11,000 formulations registered, often for use in tank mixes and other combinations, synergies and accumulations of synthetic chemical ingredients must be explored and resolved, as a matter of top priority.

According to Cox and Surgan (2006), "Inert ingredients can increase the ability of pesticide formulations to affect significant toxicologic end points, including developmental neurotoxicity, genotoxicity, and disruption of hormone function. They can also increase exposure by increasing dermal absorption, decreasing the efficacy of protective clothing, and increasing environmental mobility and persistence. Inert ingredients can increase the phytotoxicity of pesticide formulations as well as the toxicity to fish, amphibians, and microorganisms. To enable independent research and risk assessment, inert ingredients should be identified on product labels and not claimed as confidential business information."

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?

Research is being done internationally which proves that chemical formulations should include toxicity data of the active and "inert" ingredients, as well as their combinations (De Farge et al. 2016; Mesnage and Antoniou 2018; Pereira et al. 2009; Zhu et al. 2014)

Zhu et al. (2014) suggest that "pesticide mixtures in pollen be evaluated by adding their toxicities together, until complete data on interactions can be accumulated." Australia has the expertise and resources to lead the way in developing such toxicity assessment frameworks.

Extensive work has already done overseas during the past decade. Since 2009 "The regulation of plant protection products (PPPs) in the European Union (EU) now requires the cumulative risk to be considered, according to the regulation 1107/2009. … The EU project ACROPOLIS (Aggregate and Cumulative Risk of Pesticides: an on-line integrated strategy) developed a general system for probabilistic modelling of cumulative and aggregate exposure within the EU. … Aggregate exposure is defined as total exposure from dietary and nondietary sources. … ACROPOLIS allows the user to take into account exposures from the use of several product types and use scenarios." (Kennedy, M. C, 2014)

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?

The APVMA should begin to require applicants to submit data on the cumulative and synergistic profiles of the formulations they seek to register. Without such information, APVMA assessors cannot adequately fulfil their task of protecting the health, safety and integrity of people, animals and plants to satisfy and reassure to public.

CSIRO, the Research and Development Corporations also have a responsibility to allocate funds to the research and development of such methodologies as part of their agricultural innovation strategies.

c) What skills and tools are needed in Australia to allow consideration of the impacts of synergistic

impacts of chemicals?

Toxicology and epidemiological studies and experiments, in the lab and the fieldcould provide Australian data on the cumulative and synergistic impacts of farm chemicals.

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

Refer to our comments on Page three, point six.

d) What standards should operate to ensure data integrity, confidentiality and use?

ISO 27001, the standard most commonly adhered to by data collection entities.

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

We do not favour process duplication, so we propose that a national domestic produce monitoring system be designed to incorporate and strengthen an amended version of the National Residue Survey. It should be designed to eliminate the flaws in present surveys.

While FSANZ's National Residue Survey is a worthy scheme, key shortcomings include chemical users appearing to know when and where the surveys may be done and adjusting their chemical usage accordingly. Randomisation and confidentiality are essential to ensure objective results, free of potential bias.

The long delay in publishing the results, and rationalisation of the reasons for some samples falling outside the acceptable range, render the survey results irrelevant to compliance action.

a) Should data on residues in domestic produce be publicly available?

Yes, we support this 100%. The raw and processed data and the methodology used to collect it should all be published for independent review, assessment and critique.

b) What should core design principles of such a system encompass?

Transparency, accountability and duty of care to end-users should be the key design principles. Safety for citizens, animals and the environment are paramount.

The principles of scientific research should be observed – formulate a hypothesis, designing an experiment to test the null hypothesis, and collect and interpret data randomly collected, replicable data gathering and analytic methods, using control groups and being open to independent review and critique. The regulatory science regime that APVMA now employs should have no role.

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

Publication online of all water, air and soil monitoring results – including all official, citizen scientists and anecdotal reports – would assist consistency within and between jurisdictions.

a) Would monitoring systems (for both water and the environment) based on risk priorities be effective?

Map the locations where chemicals are sold, as a guide to where they are used. This may assist with decisions on what should be monitored in particular locations and suggest priorities. Matching the maps to water, air and soil monitoring results will also assist.

Licences or permits that specify particular geographical locations, crops, or land uses may also serve to focus attention.

b) Are there specific environments that should be a priority for monitoring?

Prioritise environments where vulnerable people, animals and plants live. The fragile habitats and ecosystems where rare or endangered species live should also be prioritised.

c) Should monitoring results be published and how often?

Yes. As close to real time as possible so they are always relevant and engaging. They should be the responsibility of states, local government, and other utilities.

Engage with community groups such as Landcare, citizen scientists, and offer training in environmental monitoring and sampling to the interested public.

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

Develop a labelling standard in consultation with all users and the interested public, against which to measure the adequacy of all farm and domestic AgVet chemical labels, aiming to optimize label clarity, user comprehension and willing precautionary compliance from all parties.

We commend the Panel for its aspiration to encourage “a mindset of prudent initiative on the producer's part”, with “active engagement as both desirable and reflective of the current best practices of Australian industry.” Overall the agvet chemical industry has a disgraceful record of supplying products that harm public and animal health and safety and the environment. Strong enforceable regulation and holding registrants to account for the impacts of their products are the only things likely to stem the misbehaviour that has characterised the industry’s past performance.

a) How would consumers prefer to receive information?

Simple, succinct and clear labels on packages. Readily accessible, comprehensive and easily understood online information in a variety of languages, aimed at people with at least an English reading and comprehension age of fourteen.

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

Regulators must be the primary communicators of all their doings, decisions and directives. Every means of mass communication, social media, print and electronic, of balanced, fair and objective information on all aspects of all agvet chemicals – warnings, wise use, precautionary safety advice, contents, emergencies, etc.

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

Yes. But we think there may be better models than that proposed. For instance, the UK Chemicals Stakeholder Forum (UKCSF 2020) also claims to enable discussion between

stakeholders, government and regulators in support of effective chemicals and waste management. This may also serve as a model for Australia, with a broader brief, wider membership and more successes than the Pesticide Forum.

The UK Pesticides Forum appears to run out of steam. It was formed in 1996 and comprises representatives of 26 organisations covering the farming (conventional and organic), farming equipment and pesticide industries; environmental and conservation groups; education and training; consumer interests and trades unions (Health and Safety Executive 2020).

The Forum's main task now appears to be monitoring the implementation of the UK's National Action Plan (NAP) to meet the obligation on Member States under Article 4 of EU Directive 2009/128/EC to establish a framework for Community action to achieve the sustainable use of pesticides. It was transposed in the UK by the Plant Protection Products (Sustainable Use) Regulations 2012 (the PPP (SU) Regulations 2012; SI 2012 No' 1657).

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

Make it as broad and diverse as possible, maximising the independence and minimising the conflicts of interest among participants.

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

Yes. For instance, Zoom meetings open to community participants would be appropriate.

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

We prefer Option 3 - continue to assess repack applications as per the current process. It is concerning that APVMA is looking for ways to increase efficiency and practicality as this risks compromising safety. Repacks should be treated no differently than pioneer products. Repack applications present the opportunity to reassess the science behind adoption of the pioneer product to confirm if it remains valid. Have issues with the product arisen since it was last assessed? Is there recent international experience that needs to be considered?

Repack labels are never identical to labelling on the pioneer product, so they require reassessment. For instance, if the repack label makes new or variant promotional claims to differentiate it from the pioneer, the size of the repack varies, or the mode of delivering and applying the formulation differs from the original for marketing or other reasons, these demand safety assessment.

a) Are there likely to be any increased risks with a product if option 1 is adopted?

Yes - the Issues Paper itself says "This approach significantly reduces the administration burden for the regulator and the applicant and **completely removes the need for any assessment by the regulator**". A scheme that absolves the regulator of assessment cannot be in the interests of users, consumers, animals or the environment?

b) In option 2, is it reasonable to cancel the registration of all repacks following cancellation of the pioneer product (except in circumstances where the registration holder is in possession of appropriate data and product information)?

Yes, we submit that this is the only logical and fair response. They purport to be substantially equivalent to justify their registration, so must also be deregistered.

c) Are there alternative options for dealing with repack applications?

The prudent measure would be to treat a repack application as a pioneer application in each case. This gives the regulator the chance to assess with a “modern”, informed data set rather than rely on past decisions and data as still sound.

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

Efficacy data and assessment must be required for all agricultural and veterinary products. Useless or less than optimally efficacious products will encourage overuse and cheat unsuspecting users. The registration and sale of useless or sub-optimal products cannot be justified as the APVMA owes a clear duty of care to protect users and to the public at large, for safety and also the integrity of the wider environment.

Inefficacious products would needlessly harm the environment, sap the credibility of the regulator and dramatically reduce public trust. It would be comparable to the TGA allowing a useless or dangerous pharmaceutical into the drug supply, or FSANZ approving food processes, ingredients or products that are not true to label and do not do as they claim.

If a chemical were useless or not performing optimally at the minimum safe application rate, it would be comparable to an untested and unsafe drug being approved and administered.

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

Absolutely not. Inefficacious products would deplete public confidence in the APVMA if it allowed substandard agvet chemicals into the market. Assessing only those that may pose unmanageable hazards and risks to unsuspecting users, human health and the environment is illogical and specious. To pass the buck for failed chemicals to the courts and consumer affairs is unconscionable and against the public interest, when prevention would have sufficed.

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

Self-assessment and self-regulation, even with the potential sanctions proposed, are entirely unsatisfactory. If this option were to have any chance of being fair and equitable to users, very few complaints from dissatisfied users must be needed to promptly trigger the APVMA’s statutory duty, to call in the efficacy data for assessment and action.

The US EPA’s tacit approval model has failed. For instance, “In 2016, Monsanto Company began selling a genetically modified soybean seed that tolerates dicamba. … The U.S. Environmental Protection Agency gave Monsanto Company, BASF Corporation, and E.I. du Pont de Nemours and Company (DuPont) approval to sell dicamba-based herbicides for use with the genetically modified crops. Shortly after the EPA approval, farmers who had planted non-modified seeds near fields that were being sprayed with dicamba reported their crops were dying.” https://www.consumernotice.org/legal/dicamba-lawsuits/

In April 2020 the U.S. Court of Appeals for the Ninth Circuit found the 2018 registration of dicamba was unlawful, disallowed Monsanto’s registration of the chemical, so using the new dicamba formulations has been illegal in the USA since June 2020. But this action took five years, hundreds of widespread farmer complaints and a jury trial in which $265 million was awarded against Monsanto and BASF, for destruction of the Bader Orchard.

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 three dot points in Option 3 are also unacceptable. Outsourcing efficacy assessment is a recipe for corruption and data massaging, overseas efficacy assessments will not be reliable in Australia's unique environmental conditions and farm management practices, and if the threshold were objectively the applicants' "past behaviours and current stewardship practices", most would be disqualified from holding licences at all!

For instance, consider the records of harm to human health and the environment, proven in courts and other fora around the world, against many of "CropLife Australia's members (that) represent 85 per cent of crop protection and 95 per cent of crop biotechnology products used by Australian farmers." https://www.croplife.org.au/about/our-members/

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

If standards were set they should certainly not only be designed for the benefit of applicants. Credible standard setting bodies do work that serves the public interest, not primarily the profit motives of corporate entities.

a) Should the use of standards be limited to products of low regulatory concern? Why/why not?

Standards should be set to raise the bar on safety and efficacy, not to lower it.

b) Are there any unforeseen risks with adopting a standards approach like New Zealand that wouldn't require regulation changes each time a standard is created?

We do not favour the 'Group Standards' approach used in New Zealand, which would collectively approve products assumed to be of low risk (whatever that means) and "of a similar nature, type or use." We favour "approving them as individual products." "Restrictions relating to labelling, advertising, packaging and supply," should also continue to be set for individual products. A system is also unacceptable if it has "applicants making their own determination of whether or not their substance or product accurately sits within a group standard" and is automatically approved.

c) Should the development of standards be driven by industry or the regulator?

If standards were set, the APVMA should take the lead with independent scientists, the interested public and industry participating on fair and equal terms.

d) Are there any other types of standards, or approaches to self-assessment the panel should consider?

No. Self-assessment has failed to serve and protect the public interest wherever and whenever it has operated and is unacceptable. A classic example of self-regulation gone awry is the military's spraying of PFAS in Australia and its widespread, long-lived and terrible impacts on local communities across the country.

23) Should the regulator utilise prior assessment decisions from comparable regulators to fast track registration where appropriate? If not, why?

Fast tracking for any reason whatsoever is unacceptable. However, if the regulator is allowed to review and approve registrations on an expedited basis, then a similar fast track must also apply to all the restrictions of use and de-registrations that are introduced in other jurisdictions.

To maintain fairness, balance, and a level playing field, if other regulators' decisions were to be used for the approval of chemicals, then a similar process should apply so that chemicals de-registered in other jurisdictions would also be de-registered here!

a) Do you support a registration by reference approach as outlined? If not, why?

No. US regulators, and many others around the world, are captives of the chemical industry and the revolving door between industry, consultancies and government.

For instance, the US EPA acted recklessly and illegally when fast-tracking Dicamba for over-the-top spraying on herbicide tolerant cotton and soybean. It ignored the evidence that dicamba had inherent spray-drift problems, not resolved with new formulations. In a class action, a court therefore recently deregistered the chemical and it is now illegal to use it (Gillam 2020; Rollins 2020; US Department of Agriculture 2020).

b) Is basing the approach on decisions from one or more comparable international regulatory systems sufficient?

No. It is another opportunity for groupthink to prevail. For instance, many regulators globally deny the evidence that glyphosate-based herbicide (GBH) formulations may harm human and animal health. That denial is based on the mutual support that various regulators and industry lend to each other, denying and contesting the evidence that non-Hodgkin Lymphoma can be induced in people repeatedly exposed to GBH formulations and over extended periods (Bayer 2020).

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

The uniform, copycat approach based on regulatory precedent is unacceptable for product, active constituent and label.

d) Should the approach be used for variations and reconsiderations?

The uniform copycat approach based on regulatory precedent is unacceptable for variations and reconsiderations too.

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?

We do not support such decisions being made, as we should not pick and choose our 'regulatory' friends. We can learn from all but not be ruled by their decisions. None of these decision-makers should enter into such a decision procedure.

f) What should be the requirements when considering regulatory comparability?

Regulatory equivalence as expounded in the Issues Paper ignores the extreme diversity of contexts that regulatory assessments must consider. For instance, they may differ as to: government and regulatory policy; scale, scope and modes of land, soil and water management practices; various potential exposures affecting health, and diverse environmental conditions such as climate, season, soil types, and water availability.

For example, "A typical field half-life of 47 days has been suggested," for glyphosate. But "values between 2 and 197 days have been reported in the literature. Soil and climate conditions affect glyphosate's persistence in soil" (Oregon State University: National Pesticide Information Center 2019). This diversity, which may also exist within Australia, must not be ignored.

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

Lack of an Australian Re-assessment and Re-registration scheme, to bring the registration of all agricultural and veterinary chemicals into the 21st Century, sets us apart.

Unlike Canada, the USA and EU, we are without systematic and regular review processes. The present ad hoc chemical review process is unresponsive to new information about very old chemicals still registered for use, monitoring and testing innovations, and the science of toxicology and testing. This is very unsatisfactory.

h) How might the assessment of any unique Australian matters be easily managed?

Such assessments must go far beyond mere agronomic considerations. We advocate chemical life-cycle assessments of the safety, performance and efficacy of all agvet chemicals, from their production origins to their final sequestration or decay as proposed by Caffrey and Veal (2013). This process may provide the data necessary for assessing chemicals in uniquely Australian use.

Reintroduce and pass legislation to re-establish the Chemical Re-Assessment and Re-Registration scheme.

The EU's review of pre-existing pesticide registrations was completed in 2009 (European Commission Directorate-General for Health and Consumers 2009). Out of around 1,000 active substances on the market in at least one EU Member State before 1993, about 250 passed the harmonised EU safety assessment and were re-registered. But near 67 per cent were deregistered, as industry did not submit the required evidence, the data was incomplete, applications were withdrawn, or the chemical failed the safety test.

Because Australia has no systematic re-registration scheme, many pesticides now deregistered in the EU are still registered and widely used here. This is unacceptable for public health, environmental and trade reasons. A list of Australia's most dangerous pesticides has been developed by the National Toxics Network and WWF (2010).

24) Is enough being done to address minor use permit applications, if not what more could be done?

A thorough, independent review of the whole minor use permit system is urgently needed.

a) Are there any improvements or changes to the permit system that would be beneficial?

A search of the APVMA database for 'minor use permit' produces no results. Yet "There are currently over 1,000 permits in operation relating to minor uses," says the Issues Paper. This lack of public communication about these approvals is unsatisfactory.

A search for 'permit' found just 75 results, many cancelled (APVMA 2020b). Among the current ones, for example, is 'minor use' permit PER9907, in force from 1 April 2007 until 31 March 2025, issued to the NSW Office of Environment and Heritage. The permit allows the use of five different herbicides in Forests including in: Native vegetation areas; Bushland reserve areas; and National park areas; and also in Non cropland including: Rights of way; Commercial and Industrial areas; Domestic and Urban areas; Public service areas; and Botanic gardens.

Such a long-standing, off-label and wide-ranging permit should not be classified as 'minor use', especially as many uncontrolled uses are in high-traffic public spaces, as this one is.

b) Should permits be expanded beyond the activities they currently cover? If so, what activities

would you suggest?

We absolutely oppose any expansion of the minor use permit program and call for a thorough independent review of all current permits. As the Issues paper admits, there are over 1,000 current 'minor use' permits that "cover a diverse range of commodities, pests, and chemical combinations."

So, "For example, there are permits:

- to allow annual grass weed control in barley
- allowing a range of herbicides and insecticides in hemp production
- addressing electric ants in sugar cane
- to allow the use of plant growth regulators in potatoes
- for autogenous vaccines to treat diseases and conditions in pigs, horses, cattle, sheep, poultry and dogs
- for vaccine treatments of salmonid fish.

Without the full assessments that the public expects, the regulator can also issue permits for, amongst other things:

- support industry research
- address short-term issues in GMP facilities (production facilities or clinical trial materials pilot plants for the manufacture of pharmaceutical products)
- possess material for the purposes of export
- supply product material with differing labels
- supply material that differs from the details assessed at registration."

Many chemical reviews have been underway for up to 20 years. Such glacial responses to accumulating evidence of hazards and harm, justifiably diminishes public confidence in the regulator's commitment to its principles and the effectiveness of chemical reviews. If precaution were in the APVMA's armoury, as it should be, we would expect much more prompt and timely action.

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?

We oppose any short cuts, fast tracks, accelerated timeframes, or other means to expedite assessment processes due to the possible detrimental effects. These issues are high-involvement decisions that need to be thoroughly analysed.

a) Should reviews have flexibility to consider specific issues that warrant review rather than a comprehensive reassessment of all aspects of the original approval?

For all those agvet chemicals first registered prior to 2005, we strongly favour a comprehensive reassessment of all aspects of the original approval, including the data submitted. Contemporary reviews should require that applicants submit data on the health and safety of workers, the public and the environment gathered from commercial use of their formulations over the past decade.

It should be comprehensive, and as there are only few cases to be considered it should facilitate compliance.

b) Should chemical reviews be risk-based rather than driven by rolling specified timeframes?

Does this seriously propose that the higher the risk, the shorter the assessment timeframes? The regulator has spun some agvet reviews out for decades yet this Issues

Paper appears to propose that the assessment and registration of new chemicals should be expedited. That is unfair and irrational.

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

A barcode on each chemical container would enable it to be scanned with any electronic device to access more comprehensive information than that able to fit on a printed label. This may be one way to dramatically improve the low rate of attention that users pay to label warnings, use instructions and related information, because of the small print on many labels, their complexity and the limited English literacy skills of many users – especially those for whom English is not their first language.

On an electronic system, it should be very practical to make comprehensive but clear and simple information readily available in a multiplicity of languages, catering for the whole Australian community for the first time.

People are also prone to falsely inflate their level of knowledge about the risks and hazards of many products and how to use them safely. As the Productivity Commission observed, "most consumer products are not subject to any specific regulatory requirements or inspection regime to identify risky products. False assumptions may lead consumers to underestimate the risk attached to potentially hazardous products." (Productivity Commission 2006) Smart labels may help address this problem.

b) Is mandating labels for containers above a certain volume to be machine-readable supported?

We strongly advocate that all agvet chemical products should be smart labelled, regardless of the volume or quantity of their chemical contents. Even a small quantity of a toxin can have its effect if the warning label is not observed. The APVMA is insistent that all registered chemicals are safe to use provided the label warnings and instructions are followed so any failure to provide such information on every product would fundamentally discredit that claim.

c) Should Australia adopt a comprehensive use database and/or provide access to an exact copy of the label?

Providing both a comprehensive use database and a copy of the label would be a step towards maximising the opportunity for all users to be fully informed. A booklet or flier attached to each product at the point of sale may be another helpful mode of communication.

d) Should separate label approvals be removed and instead have label content specified as a condition of registration?

YES, provided the core purpose of the labels remains undiminished.

Are current labelling requirements excessively prescriptive?

NO. Specifications are already minimal in our estimation.

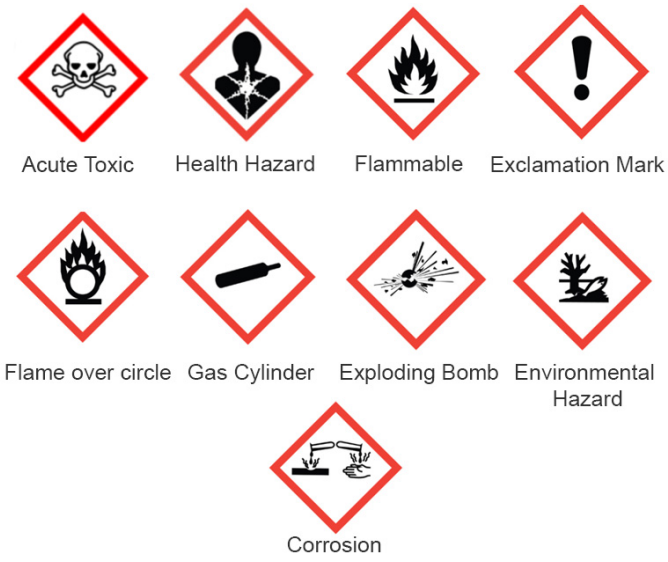
Could they be made more outcomes oriented?

NO. People's attention is already diverted to achieving the results that advertising and promotions promise, which is another reason that safety warnings are overlooked.

Smart labelling could be a benefit if linked to a tracking system that facilitated the label to

serve the dual purpose of also being an active regulatory mechanism.

Using symbols rather than words, may help to communicate hazards to users. A design similar to chemical pictograms may be desirable as an adjunct to written messaging.



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

Electronically. Monitoring the scientific and popular literature on chemical affairs, including actions to recover from the damage that agvet and other chemicals have done and continue to do, to human and animal health and environments.

a) How can parties outside of government become involved in existing international networks?

Some people are already engaged internationally, in the POPs convention for example. But the regulator could assist by facilitating further participation.

b) How can the regulator best expand and use its existing network of international assessors?

We disagree with international assessors conducting chemical assessments for the Australian context. Of course, international research and data may be used to inform Australian assessments provided it conforms to the scientific method and explores contexts and conditions comparable to those here.

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

We strongly agree that “non-government stakeholders have felt disenfranchised and have identified few channels for suggesting systemic reforms,” and this must be urgently remedied. Governments and regulators have not taken the community into their confidence, though many groups and individuals repeatedly make submissions for change that go unacknowledged and unheeded.

The effective participation of independent experts and the interested public in redesigning and implementing new regulatory regimes would materially assist in lifting these reform processes out of the torpor into which they have lapsed.

Consultative mechanisms are always essential to a number of governments purporting to collaborate on the regulation of different aspects of complex national activities.

But scant information is publicly available about the Registration Liaison Committee, its original intent, membership, past operations or decisions. The only description we can find is minimal and uninformative:

"The Registration Liaison Committee is the main consultative forum between Australian Pesticides and Veterinary Medicines Authority (APVMA) and state, territory and Commonwealth agencies about to operational management of the National Registration Scheme. The committee comprises the APVMA chairperson and representatives from the state/territory agencies in Australia and New Zealand with responsibility for primary industry, agriculture and biosecurity" (Registration Liaison Committee for the Australian Pesticides and Veterinary Medicines Authority 2020).

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

The risk identified by the Panel - third party integrity - makes us concerned with this approach. Regulatory schemes are watered down when their components are outsourced and the public interest is not well served. Trust and confidence in regulatory integrity is often compromised.

a) Do you support the scheme being based on the model in the lapsed Streamlining Regulations Bill 2019?

No, while the Bill was touted as aiming to "strengthen the protections to humans, animals, plants and the environment", the Department of Agriculture, Water and the Environment's own account (2019) discloses that the key objectives were instead:

- extending the range of application types that can be assessed as time shift applications
- providing for greater use of disallowable ministerial orders
- removing APVMA regulation of certain substances
- modernising hormonal growth promotant supply requirements
- addressing an anomaly about advertising in agvet chemical legislation
- clarifying when the APVMA can use information provided by another party to support the registration of a proposed chemical product
- allowing for certain approvals to be dealt with simultaneously as part of an application for registration

All of these goals are geared to improving so-called efficiency-to-market and do not serve the regulator's over-arching goals of human, animal and environment protection.

b) Should applicants be able to choose their accredited assessor, or should there be a panel of assessors allocated by the regulator?

If external assessors are employed, applicants should have no influence over or choice of the assessor assigned to an application. A robust regulatory regime with integrity cannot afford to be compromised when applicants and assessors co-operate or collude so measures to eliminate this problem must be used from the outset.

c) Should persons overseas be able to work as accredited assessors?

It is unclear whether this question asks about off-shoring assessments to foreign nationals or allowing Australian assessors to be domiciled overseas. We submit that assessors should be APVMA employees, though their physical location may not be decisive provided they are fully acquainted with the Australian context.

30) What additional capabilities may be needed by agvet chemical regulators to assess new technology?

The regulators should be equipped to assess new methods and systems, not only new technology which is just a small part of the overall agricultural picture.

a) Which stakeholders should agvet chemicals regulators consult with to stay abreast of current and emerging technologies?

Agvet chemical regulators must consult with all participants in supply chains from seed to spoon, including the interested public and independent experts. This is to maintain an expansive overview of all innovative methods, systems, technologies and products - the wider context in which agvet chemicals are deployed.

To be effective, the APVMA and related regulators must enable optimum hazard and risk management within the whole food, fibre, materials and beverage production industries and the diverse environments in which they operate.

The UK model that the Panel favours is not a resounding success and other examples should be sought for assessment and possible adoption.

b) What horizon scanning activities should be undertaken by agvet chemicals regulators?

The regulator needs a set of goals and targets to scan far into the future to ensure that the right of all Australians to an affordable and nutritious diet are met, while the dependence of food production systems on synthetic chemical inputs is also reduced.

Conclusions

We ask the Review Panel to favourably consider, adopt and recommend our representations in this submission.

We highlight the relevance of the Californian regulatory framework as an example of an existing system that functions very well and may serve as the model for a new system here.

Thanks you for the opportunity to participate. We are ready to engage further with the process should the Panel wish to do so.

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