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Submission on the:

Draft Report of the Independent Review of the Agvet Chemicals Regulatory System

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On behalf of the National Toxics Network Inc.

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National Toxics Network

The National Toxics Network (NTN) welcomes the opportunity to make a submission to the Draft report of the Review of the Agvet Chemicals Regulation System.

NTN was formed in 1993 as a civil society environmental justice organisation. NTN provides a central repository of technical expertise and educational materials to individuals and organisations across Australia in relation to toxic chemical pollutants, technologies and their impacts on community and environmental health.

NTN is the Australian NGO focal point for the International Persistent Organic Pollutants Elimination Network (IPEN) and works towards the full implementation of the *Stockholm Convention on Persistent Organic Pollutants* (POPs) and other global chemical conventions and agreements to which Australia is a signatory.

NTN committee members have been involved in a wide range of national government advisory bodies including the Hazardous Waste Act Policy Reference Group, the Stockholm (Convention) Reference Group, the National Industrial Chemicals Notification Assessment Scheme (NICNAS) Community Engagement Forum and Strategic Consultative Committee and the National Registration Authority/Australian Pesticides and Veterinary Medicines Authority advisory committees.

NTN has given evidence to Parliamentary inquiries, including the Senate Inquiry into the Threat of Marine Plastic Pollution in Australia; Inquiry into Unconventional Gas (Fracking) in South Australia; Inquiry into Unconventional Gas In Victoria; Inquiry into the Impacts of Air Quality in Australia.

Background

The Review Panel was appointed by the former Minister for Agriculture, Senator the Hon. Bridget McKenzie on 5th September 2019 to undertake a '*first principles review of the regulatory framework underpinning the National Registration Scheme for Agricultural Chemicals and Veterinary Chemicals'*.

The Panel has since released its draft report on the 'Independent Review of the Agvet Chemicals Regulation System' with 139 recommendations for a reform package. They are required to finalise their report to government by May 2021.

Terms of Reference

The review will examine the framework's aims, structure and operation, and make recommendations to ensure it is contemporary, fit for purpose and reduces unnecessary red tape.

In undertaking the review, the Panel will:

1) assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme
2) consider what the goals of Australian agvet chemicals regulation should be

3) consider the current and future requirements of Australia's regulatory framework for agvet chemicals

4) provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture.

The Panel will have regard to regulatory roles and responsibilities at the national, state and territory level; interactions with other regulatory schemes and arrangements; any relevant domestic or international issues; any recent changes to the current framework, including reforms agreed by the Council of Australian Governments; and the government's agenda to reduce red tape wherever possible.

The process will also review the Intergovernmental Agreement (2013) underpinning the National Registration Scheme, which was due to be reviewed in 2018.

Consultation

NTN declined an invitation to participate in the Stakeholder Advisory Committee because we had significant concerns from the outset about the Terms of Reference, Inquiry Panel make-up and consultation process.

We have significant concerns about the independence of the Panel, particularly the Chair. He appears to have a conflict of interest as he is also the current Chair of the industry lobby group the Agricultural Biotechnology Council of Australia (ABCA), which represents the interests of organisations such as CropLife Australia, Cotton Australia and the National Farmer's Federation.

The Chair's role in this lobby organisation is not disclosed on the Government website bio for him which provides a profile of Inquiry Panel members.[1] The failure to disclose this conflict of interest undermines the independence and integrity of this Inquiry and its recommendations.

We also have concerns that no independent panel members were chosen with skills in environmental management and chemical pollution.

NTN participated with this Inquiry process via teleconference. Our initial submission of concerns included evidence of extensive environment contamination with pesticides in Australia and impacts to community health. We attended two Roundtable consultations where we were only given short periods of time to speak. No minutes or summaries of the Roundtable meetings were provided. Throughout the consultation process we heard very little from Inquiry Panel members other than the Chair.

Introduction

Joanna Immig represented the environment sector for eight years on the APVMA's legislative community consultative committee before the committee was disbanded. Ms

[1] https://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-

Immig also served on the *NSW Pesticides Implementation Committee*, which oversaw the implementation of substantial reforms to the *NSW Pesticides Act* in1999. The NSW Act mandated training of commercial pesticides users, record keeping and notification of pesticide use in urban environments for the first time in Australia for any control of use legislation.

Ms Immig also contributed to the reform process to the APVMA under the Gillard Government. Unfortunately the centerpiece of the legislative reforms, which established a systematic re-registration process to ensure all products on the market met contemporary regulatory and scientific standards, was repealed under the Abbott Government in 2014[2]. The issue of *ad hoc* and decades long chemical reviews continues to this day.

Ms Immig has also written several community pesticide spray drift action kits in response to the ongoing problem of pesticide spray drift and environmental contamination across Australia.[3]

Dr Mariann Lloyd Smith was a member of the initial advisory panel that established the National Registration Authority (NRA), the forerunner to the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Dr Lloyd Smith continues to participate in the United Nation's processes for the consideration of chemicals to be listed under the Stockholm Convention on Persistent Organic Pollutants. There are currently eighteen pesticides listed on the Stockholm Convention for global elimination or restriction.[4] Australia is a party to the Stockholm Convention but has failed to ratify the new pesticide listings, which effectively means they cannot be enforced in Australia.[5]

Summary of concerns

APVMA is not a world-class regulator and proposed recommendations seek to weaken it further

NTN does not consider the APVMA to be a world-class regulator, as is so often stated. Due to ongoing political interference, the APVMA has unfortunately become a shell of its former self. Its forced relocation to Armidale saw the loss of over half its experienced staff and productivity suffered as a result.

While the APVMA has subsequently improved its productivity in relation to assessments and approval is not achieving its current legislative objectives in relation to the protection of people or our environment from adverse exposures and impacts from the chemicals it regulates via its Adverse Experience Reporting Program or Chemical Reviews.

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[2] https://www.legislation.gov.au/Details/C2014A00091
[3] https://ntn.org.au/wp-content/uploads/2010/02/ntn_spraydrift.pdf
[4] http://www.pops.int The sixteen pesticides listed for elimination are: aldrin, chlordane, chlordecone, dicofol, dieldrin, endrin, heptachlor, hexachlorobenzene (HCB), Alpha hexachlorocyclohexane, Beta hexachlorocyclohexane, lindane, mirex, pentachlorobenzene, pentachlorophenol and its salts and esters, technical endosulfan and its relates isomers, toxaphene, DDT, perfluoroctane sulfonic acid, its salts and sulfonyl fluoride
[5] http://www.pops.int/Countries/StatusofRatifications/PartiesandSignatoires/tabid/4500/Default.aspx#AU

Default setting to not act on harm

The APVMA and the industries that sell and rely on the use of Agvet chemicals, appear to have a default setting to not act when evidence is found of the impacts of hazardous and persistent pesticides. In some instances, government representatives have also actively worked at international levels to stop the listing of scientifically identified highly hazardous pesticides onto the *Stockholm Convention for Persistent Organic Pollutants*.

Australia was one of the last countries to support the Convention listing and global elimination of endosulfan and mirex for example and, despite dicofol now being a listed pesticide, it is still listed as an approved active constituent on the APVMA's website.

The Panel report reveals significant failings with Australia's regulatory system, many of which we agree with, however the remedies proposed to fix the problems are largely not ones we can support.

The Panel's recommendations will not make the APVMA a world-class regulator, rather they seek to diminish its role and no doubt they ultimately seek to disband it altogether with the proposal for a Commissioner and a scheme to allow products onto the market with only approvals form international regulators.

The Panel's recommendations would further diminish APVMA's legislated responsibilities to protect the safety of people and the environment from Agvet chemical exposures, and propose that vested industry would do a better job of protecting community health and the environment from the impacts of Agvet chemicals.

There are no recommendations that would stop the ongoing issue of the impacts of pesticide spray drift and widespread environmental contamination through off-target movement of Agvet chemicals in Australia. Failing to act on these issues will continue to needlessly expose the Australian community, environment and trade to pesticide residues, many of which have already been removed by other jurisdictions.

Current example: Bee killing insecticide Fipronil still approved by the APVMA

A recent example that illustrates how out of step the APVMA has become with actual world class regulators, is its inaction on the bee killing insecticide fipronil, an insecticide still widely used in Australia as a seed dressing, on cotton, turf and other crops. Fipronil is associated with mass bee deaths and bee colony collapse disorder.[6]

Fipronil was restricted in the European Union in 2013 and banned in 2017 based on the scientific evidence that it could not be used without causing harm. Fipronil has recently

[6] Fipronil pesticide as a suspect in historical mass mortalities of honey bees
Philippa J. Holder, Ainsley Jones, Charles R. Tyler, James E. Cresswell
Proceedings of the National Academy of Sciences Dec 2018, 115 (51) 13033-13038; DOI:10.1073/pnas.1804934115

been linked to numerous mass bee deaths in Australia[7,8] and yet the APVMA is completely silent on the issue.

The APVMA identified fipronil to be reviewed in 2003 but nothing other than a 2012 scoping report has been released. The APVMA states in the 2012 Scoping report: [9]

> *"Following the commencement of the current fipronil review in 2003, the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) subsequently nominated fipronil as a priority 1 chemical for environmental review. This followed the identification of new information, considered by international regulatory authorities (primarily the European Food Safety Authority (EFSA 2006)), showing that fipronil and its metabolites are very highly toxic to organisms in the environment, particularly aquatic and terrestrial insects. These new studies also provide additional information on the toxicity of fipronil to fish and aquatic invertebrates, bees and non-target arthropods".*
>
> *"…Fipronil products are used for a wider range of applications in Australia than in other countries, and so the potential for environmental impacts is greater…"*

Pushing an industry agenda

The Chair in his Forward to the report states:

> *"The Panel also considers that the reform package enhances human and animal safety whilst also providing increased access to safe and innovative pest and disease management options for users, including primary producers, veterinarians, environmental managers and other users of pesticides and veterinary medicines". (pg iii)*

There is no data that supports the premise of better outcomes from the proposed reforms. Given that none of the recommendations raise the bar for assessment, or provide a systematic process to re-assess existing chemicals or highly hazardous pesticides, it is simply not possible to expand access to and uses of more Agvet chemicals without expanding the pollution and harm that results from their use.

The Chair in his Forward to the report states:

> *"The package of newly designed reforms significantly changes the regulatory arrangements of the current system by embracing and leveraging modern practices and obligations, being increasingly adopted by other domestic regulatory systems and international jurisdictions. This is designed to bring the current regulatory system into the modern era where responsibility can be shared among different players within the system according to their expertise." (pg iii)*

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[7] https://www.abc.net.au/news/2021-02-18/dalby-bee-deaths-spark-fipronil-investigation/13162662

[8] https://www.abc.net.au/news/2019-06-18/apiarist-calls-for-fipronil-ban-after-bees-die/11216968

[9] Fipronil review scope document part 2: Environmental considerations summary (2012)

https://apvma.gov.au/node/18701

Much is made of the idea of 'modern practice and obligations' but no substance is provided to explain what is meant by it or how it could deliver better protections for the community, our environment and trade from the risks posed by Agvet chemicals. We read it as code for delivering on a political agenda for Agvet chemicals de-regulation rather than a desire to enshrine a truly modern science-based approach to the regulation and management of Agevt chemicals in Australia.

No examples are provided and no assessment has been undertaken of best practice regulatory approaches for chemical management in other jurisdictions. Similarly, no assessment has been made of the failure of self-regulatory models in other high-risk industries and what the pitfalls might be in applying this approach to Agvet chemical management.

The European Commission for instance does not use a self-regulatory model for Agvet chemical regulation. Their program is a science-based decision-making process, which embraces both hazard identification and risk management and is underpinned by the principles of precaution and 'no data no market'.

Despite the Chair declaring *'responsibility can be shared among different players within the system according to their expertise'*, there appears to be little role for civil society in the proposed 'modern' system.

The Panel's position is not in keeping with international best practice in chemical regulation. Both the United Nation's Environment Program[10] and The Global Best Practices on Emerging Chemical Policy Issues of Concern under the Strategic Approach to International Chemicals Management,[11] recognise the fundamental role of civil society to ensure *'transparency and inclusiveness in the intergovernmental decision-making process'*.

Given the large-scale business of Agvet chemical sales, it is inconceivable that self-interest in making profits for shareholders, will be put aside to better serve the public interest to improve health and environmental safety and protection from Agvet chemicals.

The Chair in his Forward to the report states:

> *"The Panel understands that great change can be daunting, especially for those directly impacted…" (pg iii)*

Great change can be daunting and it depends on who is being daunted and by what. We argue that the current scientifically documented impacts of Agvet chemicals on the environment and people's health are already evidence of the harm caused by the inadequate regulation of Agvet chemicals in Australia. This is something that should be

[10] https://www.unep.org/civil-society-engagement/why-civil-society-matters/civil-society-unit
[11] https://www.saicm.org

daunting to everyone and we should be doing all we can to stop further harm from occurring. The proposed recommendations would not achieve that.

While Australian farmers may well be amongst the most innovative and efficient in the world, NTN believes that they, along with consumers and the environment, have been let down by a regulator and government that has failed to keep pace with community expectations, breakthroughs in the science of toxicology and, substantial changes in regulatory approaches to pesticides in other countries which serve to protect pubic health, environment and trade.

Inquiry has not conducted a first principles review

The Inquiry report states:

> *"The review was to examine the agvet chemicals regulatory framework's aims, structure, and operation, and make recommendations to ensure it is contemporary, is fit for purpose and reduces unnecessary red tape". (pg vii)*
>
> *"A first principles review by its very nature was always going to result in suggestions for significant change of a system nearly 30 years old". (pg viii)*

If the Panel were genuinely conducting a first principles review of the current regulatory framework, it should have undertaken an assessment of the effectiveness, or otherwise, of the regulator's delivery on all of the objectives of its' governing legislation, not just those that concern gaining more efficiencies for the introduction of more Agvet chemicals onto the market.

In implementing the Code under the *Agricultural and Veterinary Chemicals Code Act 1994*.[12], the regulator should have regards to:

> *(2) This Code is to be implemented in a manner that:*
>
> *(a) recognises that the health and safety of human beings, animals and the environment is the first priority of the system for regulating chemical products and their constituents, in part to ensure that the use of chemical products at the present time will not impair the prospects of future generations; and*
>
> *(b) reflects established best-practice principles for the assessment and management of risk, based on science; and*
>
> *(d) recognises that the use of chemical products that pose unmanageable risks to the health and safety of human beings, animals and the environment is not appropriate in Australia; and*
>
> *(e) promotes community confidence in the regulation of chemical products and their constituents, is open and accountable, and gives opportunity for public involvement and participation; and*
>
> *(f) secures compliance with this Code through appropriate, proportionate, consistent and effective compliance and enforcement measures.*

[12] https://www.legislation.gov.au/Details/C2016C00999

There has been no first principle assessment made by the Panel of these safety and environmental protection objectives of the Regulator and how its proposed recommendations would deliver better outcomes on these objectives.

Rather, the Panel's recommendations seek to change the objectives and goals of the regulator to suit an industry focused agenda.

The Panel also steps outside its Terms of Reference and provides recommendations for the regulatory framework to increase the value of Australian agriculture. The regulator's role is not to advance the profitability of Australian agriculture.

> *"..provided recommendations for reform of the regulatory framework to increase the value of Australian agriculture and allow Australia to remain competitive in global markets, while ensuring the safety of humans, animals, and ecosystems" (pg vii)*

Factors that didn't guide the Panel's recommendations

The Panel says key factors that influenced its recommendations include:

- ***The need to maintain and enhance health, safety and environmental protection.***

It is clear to those with public and environmental health expertise that none of the proposed recommendations will meaningfully deliver on this in any way. For instance, the prescriptive recommendations for increased surveillance and monitoring, if they ever got funded, would do little to afford actual protection in the use of or exposure to Agvet chemicals. While the data would certainly be useful, these programs are not a proxy for the protection or enhancement of health, safety or the environment.

If residues are found in monitoring programs, should they ever be funded, all it is likely to demonstrate is that exposure and harm has already occurred. The Panel recognises the harm documented in the scientific literature, noting: (pg 52)

> *"There is a vast scientific literature available that describes the detrimental effects of chemicals in general on human and environmental health worldwide. For example, the Panel received from the National Toxics Network an array of references to overseas studies demonstrating the impacts of pesticides on human health. Many of these chemicals have similar exposure pathways in Australia and could be expected to have comparable potential detrimental human health outcomes. Additionally, there are numerous studies on the presence and potential detrimental effects of these chemicals on the health of the Australian environment, to complement the extensive studies found in the international literature".*

While the Panel acknowledges the problem and the importance of this research, it then goes on to downplay it by suggesting that (pg 56):

"It also recognises that such findings, if taken in isolation, could underpin public disquiet about the use of chemicals, and could impact public confidence in the future pesticides and veterinary medicines regulatory system".

This statement illustrates the bias of the Panel to cherry pick the science it likes to suit the recommendations it wants. These are not isolated findings or incidences. It's a pattern of pollution that is widespread in water, air, soil and animals and it is a situation we should all be concerned about and seek to fix it.

- ***The speed at which the world is changing – expectations of what constitutes a modern responsive regulatory system have been rapidly evolving and the science and technology associated with pesticides and veterinary medicines continue to advance.***

The Panel's recommendations seek to rapidly move Agvet chemical regulation into the future while leaving its mistakes in place. The review fails to afford the same consideration of desirable speed in adopting the assessment of advances in the science and toxicology that demonstrate the harms caused by Agvet chemicals and developing the appropriate regulatory response to that situation.

Many other jurisdictions for instance are tackling the issues of mass bee and pollinator deaths by banning the chemicals that are causing it.[13] International regulators are assessing the impacts of endocrine disrupting chemicals and tackling pesticide spray drift, and the toxicity of chemical mixtures. On reading this report however, it's as if none of those issues are somehow relevant in Australia.

Climate emergency and ecological collapse

The greatest threat to the planet and the greatest moral challenge of our times is only afforded half a page in the Panel's report, once again illustrating the lack of seriousness with which it takes the protection of health and safety of people and our environment.

The Panel provides an unbalanced assessment of the rapidly changing situation from the point of view of access to chemicals for agriculture only (pg 12). The Panel completely ignores the science that the toxicity and mobilisation and re-mobilisation of legacy pesticides (such as the organochlorines) will significantly increase the risks of pesticide use, which has enormous implications for the ongoing protection of health and safety and environment.

The only recommendation the Panel makes in relation to it proposes to increase access to Agvet chemicals without reconsideration of the changed risk profile of the chemicals (pg12):

[13] The EU agreed a ban on all outdoor uses of the neonicotinoid insecticides clothianidin, imidacloprid, and thiamethoxam on 27 April 2018, in order to protect bees.

"The Panel's proposed reform to remove the artificial barrier to access to uses imposed by state and territory borders, replacing them with a regionally based approach is one element of increasing the flexibility of the future regulatory system to deal with changing environmental conditions."

No solution for ongoing chemical review problem

The review fails to adequately address the decades old problem of lengthy chemical reviews and the failure of the regulator to promptly review and remove hazardous products from the market if required.

The Panel's recommendations in relation to this seek to tweak rather than recommend a world-class mandated systematic chemical review and re-registration program as other regulators in the EU, USA, Canada and Japan have done.

Without providing any data or references, and relying on anecdote only, the report dismisses the idea of mandated review schemes and disparages all the regulators who have such schemes in place by stating (pg 69):

"*The Panel understands these international chemical review schemes are running considerably behind schedule in each of the markets that conduct reviews on a rolling basis".*

"The Panel has heard anecdotal reports that chemical reviews in overseas markets may lead to chemicals being withdrawn – and thus to loss of chemical access for users – for reasons other than unacceptable risk."

The Panel goes even further revealing its inbuilt bias:

"Relevantly, chemicals can also be banned in overseas markets on the basis of political decisions made despite scientific evidence that the chemical does not pose unacceptable risks; the Panel does not support political intervention in what should always be a scientific and evidence-based process"

No evidence is supplied to support these statements and they appear to be lines from an industry song sheet, merrily repeated by the Panel. It's totally unacceptable that the Panel didn't thoroughly investigate at least some of those international schemes.

It is the lack of scientific application in Australia, and political interference with the regulator, that explains why pesticides such as neonicotinoids, chlorpyrifos and paraquat are still in wide use. Other jurisdictions recognise these chemicals cannot be used safely and have removed them. Science drove their decisions, not opinion and not politics.

- ***Upholding social licence and trust in the regulatory system – community perceptions of chemical use continue to become more demanding, as do our trading partners' attitudes and expectations of our treated commodities.***

The negative impacts that Agvet chemicals are continuing to cause on our health and planet are not 'community perceptions' they are actual harms identified in the independent peer reviewed science. For instance, there are actual pesticides measured and shown to be causing actual harms in the Great Barrier Reef. The pesticides detected in people's urine and blood and nursing mother's breast milk are not perceptions, they are real exposures. Residues in produce are not perceptions, they are real.

The community, and our trading partners, will no doubt continue to demand their health and environment is protected and restored, not further sacrificed due to unnecessary Agvet chemical exposures.

The broader community never put their hands up and asked for their food to be produced with hazardous pesticides that pollute the air, soil and waterways and give people and other animals cancer and diseases and effect their capacity to reproduce. There's never been a 'social licence' to pollute and harm with Agvet chemicals and there never will be.

The fastest growing sectors in food production and consumer demand are organic and regenerative agricultural practices that produce healthy food while repairing and enhancing the environment. The same is true for our trading partners and their consumers. This is the direction the world is going in.

The proposed expanded access and reduced regulatory requirements for Agvet product entry, will only serve to expand market residue risks on the domestic market and to our trading partners. More use of Agvet chemicals can only lead to more residues. No recommendations appear to address this issue. The proposed publically funded monitoring programs are most unlikely to ever be funded and implemented.

- ***Australia's small market share – the relatively small size of the Australian pesticide and veterinary medicine market mean that producers have access to only a fraction of the chemical uses available to their overseas competitors. Innovative thinking is necessary to find ways to counter this significant hurdle to competitiveness.***

No evidence or data has been provided in the report to substantiate this claim. Australia is a very high volume user of Agvet chemicals. The market is not so small that the producers of products can't afford to supply the necessary data for the extension of uses for its products.

The APVMA's latest Performance Update from the 24th February 2021[14] doesn't point to any problem with respect to the APVMA performing timely assessments and getting products onto the market.

[14] https://apvma.gov.au/node/79686?utm_source=APVMA+Newsletters+and+Communications&utm_campai

The APVMA Performance Update states:

> *"The Australian Pesticides and Veterinary Medicines Authority (APVMA) continues to demonstrate improvements in its timeframe performance, finalising 96% of all applications within timeframe in the December quarter 2020, ahead of the 94% recorded in September quarter 2020.*
>
> *This included an increase in the rate of product applications completed on time with both pesticides and veterinary medicines increasing to 99%, up from 98% in September quarter 2020.*
>
> *The APVMA also achieved improvements in the percentage of major product applications finalised within timeframe, with major pesticides and veterinary medicines applications increasing to 99% and 93% respectively at the end of the December quarter 2020.*
>
> *The results of the December quarter 2020 performance report reflect the APVMA's commitment to providing a robust and efficient regulatory system that provides Australians with timely access to safe and effective agricultural and veterinary chemical products that support agricultural productivity and improved animal health".*

- ***Shared responsibility – co-regulation is being increasingly adopted in modern regulatory systems and provides for greater accountability on all parties within the system.***

Despite claims of shared responsibility and co-regulation being increasingly adopted in modern regulatory systems, relevant examples are lacking in this report. Where and how has it been adopted and demonstrated to improve the management of Agvet chemical regulation? What are the quantified improvements in relation to the protection of health and safety and the environment?

Saving industry money while continuing to externalize costs

The report provides only rudimentary accounting of the forecasted benefits of the proposed recommendations of $160 million in reduced regulatory costs over ten years. Industry has everything to gain while the broader community and environment continue to pay ever more costs.

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The report makes no attempt whatsoever to estimate the costs or benefits to community health, the environment or trade as a result of reduced regulation or even maintaining the status quo.

It must be anticipated that with expanded access to products that will not undergo independent assessment by the regulator, nor be able to be readily recalled or removed by the regulator should there be problems, that risks will increase to community health, the environment and trade.

There will be costs associated with increased risks, which may well far exceed the projected $160 million in industry savings over ten years, which in the scheme of Agvet chemical sales, is not even a significant saving.

Concerns about single national law for control of use

The bulk of the projected key cost savings, $75 million, come from the recommendation to introduce a single national law for improved control of use and the compliance and enforcement resources to support a single national law a further cost saving of $37 million. That's a lot of cost saving eggs in one basket.

The handing over of power from the States and Territories to the Commonwealth of the control of use of Agvet chemicals seems highly improbable and it would be untenable to consider that the Commonwealth would force this upon State and Territory governments if they were unwilling. There was no obvious support for this proposal from state or territory regulators and WA and QLD were vocally unsupportive.

One thing we do agree on however is the need to address the failings of control of use throughout Australia. There needs to be much better feedback loops between the levels of Government so that control of use and adverse experiences can inform registrations and regulatory actions of harmful Agvet products and inadequate labels.

We support the need for greater uniformity in control of use laws however we also acknowledge there may well be specific and valid reasons why there are differences in approaches and these should not be swept away in the desire for cost savings, especially if that brings no benefits to community health and environmental protection.

We have grave concerns about the responsiveness of a Commonwealth control of use agency to localized breaches in the use of Agvet chemicals. Are they going to turn up and prosecute for instance when a Council grounds person sprays fipronil for ants and kills the local beekeepers hives? Are they going to turn up when insecticides sprayed on macadamias drift and contaminate people's rainwater tanks and a neighboring aquaculture business? Are they going to turn up when defoliating herbicides used on cotton crops are killing the local town's trees and people's backyard vegetable garden? Are they going to turn up when an insecticide used in the common areas of a block of apartments makes some residents so sick they can't return to their homes? Are they going to turn up when there's a major fish kill in a waterway as a result of pesticide runoff?

We are also deeply concerned a national control of use approach would leave compliance activities open to ongoing political interference. It would be a high-risk strategy in terms on ongoing protection of people and the environment to introduce this.

We do support the need for transparency and predictability across the life cycle of the product (pg X) but we question what the Panel means by this. Does it mean for instance, if an Agvet chemical ends up in a waterway through off-site movement that the product owner will be liable for the harm it causes?

In terms of life cycle assessment, there's been a spate of pesticide pollution incidents that highlight the need to be thinking about the regulation of Agvet products from a circular materials supply chain point of view. As our economy becomes more circular these issues will need to be considered and factored into registration decisions.

Hundreds of home gardeners recently lost their vegetable gardens as a result of herbicide-contaminated compost made from green waste. The manufacturer of the compost Suez was surprised the herbicide survived the composting process and the laboratory investigating which herbicide/s may have caused the damage state it may be difficult to detect because the herbicides can still be active in the parts per billion which is below the limit of detection for many laboratories.[15]

Exposures to Agvet chemicals can't just be risk managed

The Panel states:

> "…*it recognizes there can be detrimental effects of chemicals in general on human, animal, and environmental health worldwide. Consequently, the exposure of people, animals, plants, and the environment to these products requires robust, evidence-driven regulation, grounded in the principles of risk management*" (pgxi).

This is a concerning statement on several fronts. First of all it assumes ongoing exposures of the entire population and environment to Agvet chemicals. Secondly, it implies that the current regulatory system is not evidence-driven or grounded in the principles of risk management.

There are already scientifically documented detrimental effects occurring from exposures to Agvet chemicals and products in Australia. These detrimental effects are occurring as a result of products that have already been subject to assessment and risk management.

The notion that these detrimental exposures could be risk managed fails to take into account that in order to adequately assess and manage risks there does need to be exposure data as well as consideration of all the hazards of the chemicals/products in question. If quality exposure data are not available how can a risk assessment to protect community health and the environment even be conducted?

[15] https://www.abc.net.au/news/2021-02-14/toxic-garden-compost-kills-vegetables-victorian-gardeners-angry/13152164

A plan to knowingly expose the entire population and environment repeatedly to multiple chemical products at the same time, which the above statement implies, based on evidence-driven regulation and risk assessment, would require robust and extensive exposure data, which simply doesn't exist.

Australian authorities do not conduct routine bio monitoring on the human population or other animals to determine what chemicals they are already exposed to and in what quantities and combinations. We are all being exposed to Agvet chemicals from multiple sources, including from residues in our food (including seafood), water, air and soil.

Aside from missing data to conduct risk assessments, there are most certainly limits to risk management. The *Stockholm Convention* for instance lists pesticides that are toxic, persistent, bioaccumulative and move around in the environment. You simply cannot risk manage a pesticide that has those hazard properties.

With growing health burdens and costs to the community such as cancer, reproductive failures, immune dysfunction and endocrine disorders we need to ask the question - is it prudent to continue to allow widespread exposure of the population and the environment to Agvet chemicals that can directly cause these effects?

With the evidence of harm that is already available in the scientific literature why would we continue on a path that would allow more exposure to harmful Agevt chemicals with even less regulatory oversight?

Responding to recommendations

There are 139 recommendations in this report, many of which go into prescriptive details beyond the expertise or Terms of Reference of the Panel, and which are unsupported by reliable evidence and scientific data.

Many recommendations assume the appointment of another layer of expensive bureaucracy in the establishment of a Commissioner who would sit within the Department of Agriculture, which we do not support. Even though we might agree with some concepts within some of the recommendations, if they assume a Commissioner we have not directly supported them.

Many of the recommendations that have merit could be incorporated into the APVMA's existing legislation and practices without the need for more bureaucracy. We would also like to see the oversight for the APVMA moved to the Department of Health to take it one step away from the potential of direct political influence.

Other recommendations assume the establishment of a national approach to control of use regulation, which we do not support, as there has been inadequate assessment of this proposal in order to make an informed decision.

There are numerous recommendations, which in one way or another attempt to bring practices outside of regulation into play. Some proposed schemes such as licensing of

products that have been approved by international regulators are designed to cost shift burdens onto the public purse while allowing industry to bypass the regulatory scheme.

As a general principle, we do not support self-regulation or co-regulation of Agvet chemicals as by definition these products are highly hazardous and designed to kill living organisms. They have on many occasions caused enormous harm to health[16,17] and safety, the environment and trade[18,19].

The Agvet chemical industry as a whole has not shown itself to be one that can be trusted to self-manage for the good of people and planet. There are far too many examples of their serious failures and we are all paying the costs for the impacts of their products on our health and environment.

We will limit our specific comments to other relevant recommendations or where we have detailed points to make. No comment on a recommendation does not mean we support that recommendation or do not have concerns.

Recommendation 1:

The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system.
"**A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to safe products and uses."**

We do not support this recommendation:

- *The recommendation contains words that are values laden and open to interpretation such as 'trusted' 'enhances' and 'safe'. Trusted by whom? Enhances in what way? Does this mean genetically engineered? Safe to what? No pesticide product can ever be described as 'safe' since it is deigned to kill living organisms.*

- *An Object in legislation is a specific and legal piece of wording not a corporate vision statement.*

  The current Object of the Agricultural and Veterinary Chemicals Code Act 1994 reads:

  Object of Code

  The object of this Code is to make provision for and in relation to:

[16] https://www.nature.com/articles/s41467-017-00349-2
[17] https://ehjournal.biomedcentral.com/articles/10.1186/s12940-020-00611-z
[18] https://pesticides.australianmap.net/1996-january-moree-cattle-contamination-pesticide-detected-chlorflurazuron/
[19] https://www.smh.com.au/national/copping-a-spray-20030118-gdg4kw.html

(a) the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and

(b) the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products.

- *We would like to see the existing Object expanded to more explicitly cover 'all formulating ingredients'*

Recommendation 2:

The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives:

- **safeguard animal health and welfare**
- **support primary industries**
- **protect Australia's trade**
- **contribute to biosecurity preparedness.**
-

We do not support this recommendation:

- *It is confusing in relation to the proposed Object in Recommendation 1*
- *It contains no mention of protecting public health and the environment, which is the first priority of the Regulator*
- *The current legislation already adequately defines the implementing principles of the Act:*

(2) This Code is to be implemented in a manner that:

(a) recognises that the health and safety of human beings, animals and the environment is the first priority of the system for regulating chemical products and their constituents, in part to ensure that the use of chemical products at the present time will not impair the prospects of future generations; and

(b) reflects established best-practice principles for the assessment and management of risk, based on science; and

(c) balances regulatory effort and any burden imposed by the system of regulation on:

(i) holders of approvals, registrations, permits and licences; and

(ii) the domestic industry for manufacturing and formulating chemical products and their constituents; and

(iii) the users of chemical products;

with the risk of the use of the products and constituents to the health and safety of human beings, animals and the environment; and

(d) recognises that the use of chemical products that pose unmanageable risks to the health and safety of human beings, animals and the environment is not appropriate in Australia; and

(e) promotes community confidence in the regulation of chemical products and their constituents, is open and accountable, and gives opportunity for public involvement and participation; and

(f) secures compliance with this Code through appropriate, proportionate, consistent and effective compliance and enforcement measures.

Recommendation 3:

The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:

We do not support this recommendation, although we support some principles noted below:

- **The regulatory system should be based on risk, not on hazard alone.**

  What? The regulatory system is already based on assessments of hazard and risk, although datasets for exposure are incomplete which makes risk assessment less reliable.

- **Processes and decisions should be objective, independent and science based.**

  Sine qua non

  **Note this principle conflicts with your first principle since 'risk' is not science-based per se.*

- **Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.**

  Sine qua non

- **Risk management measures should be reviewed as new information becomes available.**

  If new information becomes available the first action of the regulator should be to review the product to assess whether it can still be used according to the requirements specified in legislation. What if the new information that comes to light

raises fundamental concerns such as a chemical recently being listed on the Stockholm Convention or an international regulator has withdrawn a product from use to safety concerns, or formulating chemicals have been identified as endocrine disruptors, or spray drift is occurring etc.

- **The system should be efficient and outcomes focused by making use of streamlined and fit-for-purpose regulation.**

  It already is.

- **The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products.**

  Not sure what this is getting at? Need to define 'shared responsibility'. Isn't a nationally consistent model already 'single'?

- **The system should be adaptive to new technologies, practices, and knowledge.**

  Not sure what is envisaged here? New technologies and practices should not just be accepted without due consideration of their impacts.

- **The regulatory system should support a resilient supply chain.**

  Not sure what is meant here? A supply chain of Agvet chemicals?

Recommendation 4:

The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.

We do not support this recommendation as worded, although aspects have merit:

- *There's no obvious support for this proposal coming from state or territory regulators.*
- *Both WA and QLD have raised concerns about it.*
- *No assessment has been made as to why states or territories currently have differing control of use regulations. Is it because they have different environments, different industries and different working conditions? Politics?*
- *How to improve the COAG process to achieve harmonization has not been looked at as an alternative. Why?*
- *National harmonisation tends to lead to the lowest common denominator.*
- *A national control of use regulator would be even more removed from responding to actual pesticide misuse and harm on the ground and ensuring compliance.*

- *Centralising power in the Commonwealth Department of Agriculture means the regulation would be more vulnerable to political interference, policy directions and budget cuts.*
- *State and territory governments have their Agvet regulators in either the health or environment portfolios.*
- *This recommendation has not been assessed from the point of view of delivering better safety and environmental outcomes, it has been proposed as a benefit to industry only.*

Recommendation 7:

The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Recommendation 8:

The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.

Recommendation 9:

The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.

Recommendation 10:

The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.

Recommendation 11:

The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.

Recommendation 12:

The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.

We do not support recommendations 7-12:

- *Most domestic and international jurisdictions place the regulation of Agvet chemicals within their health or environment portfolios, not within the Agriculture portfolio where it can be directly subject to political influence by powerful vested interests.*
- *No compelling case has been made as to what extra value a Commissioner located within the Department would bring to the regulation of Agvet chemicals from the perspective of protecting health, safety and the environment that can't already be addressed by strengthening the APVMA's existing legislation and reporting requirements at a fraction of the cost.*
- *A Commissioner adds an extra layer of costly bureaucracy to the system. Any money the Government is willing to spend would be better spent improving APVMA's existing legislation and reporting requirements at a fraction of the cost.*

- *A single Commissioner with so much power is vulnerable to political lobbying and interference, especially if located within the Agriculture Department.*
- *A Commissioner that hands out licenses for industry self-assessed products onto the Australian market, as well as has the responsibility for control of use, has a conflict of interest.*
- *A single Commissioner cannot replace the diverse range of expertise that is required to make independent science-based regulatory decisions on Agvet products.*
- *The establishment of a Commissioner appears to set a course to further diminish or disband the regulator.*
- *The APVMA can already auspice engagement committees, expert advisory panels and stakeholder forums.*
- *The APVMA already reports its performance against key indicators and is subject to Parliamentary oversight and accountability.*

Recommendation 13:

The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.

We support the recommendation to re-instate an APVMA Board but not according to the details above:

- *We note the APVMA previously had a Board but as part of the 2015 Spring Repeal Day, the Hon Barnaby Joyce MP, Minister for Agriculture and Water Resources abolished the APVMA advisory board.*
- *The advisory board was originally established under the* Agricultural and Veterinary Chemicals (Administration) Act 1992 *(the Admin Act) to provide advice and make recommendations to the CEO in relation to APVMA activities.*
- *Advisory board members did not represent particular interests, and were appointed based on experience in the regulation of chemical products, the agricultural chemical industry, primary production, environmental toxicology, consumer interests, public health and work health and safety.*
- *As the national regulator we recommend the APVMA be returned to Canberra.*

Recommendation 22:

The Panel recommends a Government-led national domestic produce monitoring program be established.

Recommendation 23:

The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.

We support Recommendations 22 & 23 with the provision that the data be made publically available.

Recommendation 25:
The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.

Recommendation 26:
The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.

We support the concept of Recommendations 25 & 26 for monitoring of water, sediment and soil to detect pesticide, however:

- *The Panel has grossly under estimated the costs of such a program.*
- *Clear pathways need to be articulated for what would happen when residues are detected and harm is identified.*

Recommendation 27:
The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.

We do not support recommendation 27:

- *We do not support the recommendation for a Commissioner.*
- *The Panel does not have the expertise to be so prescriptive about the design of such an Environmental Monitoring Program.*

Recommendation 28:
The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.

We can support the call for enforcing water quality standards in relation to pesticides in potable and non-potable water but would need further information on how guidance levels are determined.

Recommendation 29:
The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.

We do not support Recommendation 29:

- *This is an example of externalising all the costs of pesticide use solely onto the public purse.*
- *It's hypocritical that an industry that wants to take on self-assessment of their products outside of a regulatory scheme but they do not want to fund the compliance activities, such as monitoring to ensure their risk management is actually working.*
- *We support a co-funding model.*

Recommendation 30:
The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.

- *We support the concept of mandating the reporting of adverse experiences by all parties obliged to do so.*
- *There needs to be a carrot and stick approach applied here. Most particularly a stick, whereby holders of approvals/registrations/exemptions licences must report, and if found to have not reported, there must be significant fines applied.*

Recommendation 31:
The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.

- *We support the concept of a system wide agrochemicalvigilance approach.*

Recommendation 32:

The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.

- *We support the concept but note concrete triggers for action need to be identified to remove compounds from unsafe uses quickly. The collation and analysis be done by the APVMA and publically reported.*

Recommendation 38:

The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.

Recommendation 39:

The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.

Recommendation 40:

The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.

Recommendation 41:

The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.

Recommendation 42:

The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.

Recommendation 43:

The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.

We do not support Recommendations 38-43:

- *Australia deserves nothing less than a mandated systematic chemical review and re-registration program such as the ones that operate effectively in comparable jurisdictions such as the EU, USA, Canada and Japan.*
- *A re-approval and re-registration program was previously included in the Agvet Code legislation, however it was repealed under the Abbott Government by the*

Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014.

- *The previously legislated re-approval and re-registration program included in the Agvet Code was arrived at after 4 years of multi-stakeholder consultation and a Parliamentary Inquiry. It was never given the opportunity to operate and be assessed on its merits. No rationale was ever given for its removal and it should be re-instated in total.*
- *It's telling and a waste of public money that seven years after the removal of the re-approval and re-registration program the Panel is still grappling with the problem of chemical reviews and coming up with piecemeal approaches to solving it.*

Recommendation 44:
The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.

We support this recommendation.

Recommendation 45:
The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.
Recommendation 46:
The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.
Recommendation 47:
The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).

We do not support recommendations 45-47:

- *Unless general obligations are enforceable under law, and operators could be prosecuted for failing to follow the obligations, they are of little value.*

Recommendation 48:

The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.

Recommendation 49

The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.

Recommendation 50:

The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system.

The following are the Panel's proposals for initial licensing schemes under the new national licensing framework:

- **supply of internationally registered products**
- **good manufacturing practice**
- **supply or use of substances for research purposes**
- **supply of hormonal growth promotants**
- **dealings with Stockholm Convention substances**
- **supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)**
- **aerial application of pesticides (pilots and contractors that employ pilots, drone operators)**
- **ground applicators**
- **commercial pest controllers (pest management technicians)**
- **special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.**

<u>We do not support recommendations 48-50:</u>

- *We do not support the establishment of a Commissioner*

- *We do not support the dilution of current license requirements for the sake of a national scheme.*
- *We do not support the range of proposals and are especially concerned about proposals to license dealings with Stockholm Convention substances and to use products contrary to established withholding periods etc.*

Recommendation 51:

The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.

We support Recommendation 51

Recommendation 67:

The Panel recommends good disposal practice be considered as conditions for relevant licences.

Recommendation 68:

The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.

We do not support recommendations 67 & 68:

- *It is unclear what is meant by 'good disposal' practice. We have significant concerns about current industry practices under the drumMUSTER and ChemClear programs. We are seeking clarification as to whether the plastic containers are incinerated and what type of recycling is occurring.*
- *CropLife Australia states in its submission to the Inquiry (pg 15) that 98% of collected chemicals from ChemClear are used an 'alternative fuel source'. We are seeking clarification about what is meant by that.*
- *Manufacturers must be made responsible for the materials in their products within a Zero Waste model and circular economy and materials supply chain.*
- *Containers need to be urgently assessed to determine whether they contain any persistent organic pollutants such as PFAS. The US EPA has recently highlighted this problem in pesticide packaging.*[20]

[20] https://www.epa.gov/pesticides/pfas-packaging
On January 14, 2021, EPA issued a subpoena under the Toxics Substance Control Act to obtain information about the fluorination process used by the company that fluorinates the containers used by the pesticide manufacturer.

Recommendation 75:

The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.

Recommendation 76:

The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.

Recommendation 77:

The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.

Recommendation 78:

The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.

Recommendation 79:

The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.

We do not support recommendations 75-79:

- *All products designed to kill living organisms should be subject to independent assessment.*
- *We do not support any proposals that chip away at the need for an independent regulator to scientifically assess Agvet products entering the Australian market.*

Recommendation 81:

The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.

Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.

Recommendation 82:

The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.

Recommendation 83:

The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.

Recommendation 84:

The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).

Recommendation 85:

The Panel recommends the Commissioner's determination of comparable international regulators:

- **be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders**
- **be conducted by the Commissioner**
- **give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.**

Recommendation 86:

The Panel recommends that licence holders:

- **must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances**
- **be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions**
- **be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.**

Recommendation 87:

The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.

Recommendation 88:

The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

Recommendation 89:

The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).

We do not support recommendations 81-88:

- *No data has been provided to justify the assumption that underpins these recommendations that Australian farmers are not able to access the range of Agvet pesticides they require in a timely manner to be competitive via the existing registration scheme.*
- *The APVMA's regular performance reviews indicate they are consistently delivering new products to the market within legislated timeframes.*
- *It is not the role of the regulatory system to provide a 'competitive advantage'.*
- *These recommendations will be costly, subject to political interference and duplicate and complicate existing registration processes.*
- *This proposal establishes a back door route for Agvet products, which bypasses the regulator and provides no accountability, transparency or recall when things go wrong.*
- *This proposal is hypocritical. If unfettered access to the Australian market is sought using international approvals then surely the same should also apply to international decisions to remove products.*
- *Adopting international decisions does not take into account Australia's unique and sensitive environments, our different climatic conditions and outlook for the climate and extinction emergencies and, how that would impact the risks associated with Agvet products.*
- *Adopting international decisions does not take into account different use patterns, efficacy and worker exposures that impact the risk profile.*
- *No examples or evidence have been provided to demonstrate that self-regulation of Agvet chemical products will effectively protect the health and safety of the Australian population and our environment.*
- *No examples or evidence have been provided to demonstrate that self-regulation of Agvet chemicals will result in less harmful Agvet products being available.*

Recommendation 90:

The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.

We do not support this recommendation:

- *It duplicates emergency powers that already exist under the APVMA's existing legislation.*
- *It risks diminishing the quality and depth of assessments.*

Recommendation 101:

The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

Recommendation 103:

The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.

We support recommendations 101 & 103.

Recommendation 104:

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

We do not support recommendation 104:

- *The APVMA is supposed to be a science-based decision maker*
- *The APVMA already takes these matters into consideration*

Recommendation 118:

The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.

Recommendation 119:

The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

We do not support recommendations 118 & 119:

- *We do not support third party assessments as this takes the process away from the regulator who needs to maintain the expertise required.*