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Committee Secretary  
Senate Standing Committee on Rural and Regional Affairs and Transport  
PO Box 610  
Parliament House  
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**RE Submission to the Senate Inquiry into the independence of regulatory decisions made by the APVMA and related matters.**

I am a rural GP with a keen interest in agvet chemicals especially pesticides (biocides) and their effect on environmental and human health. I have worked on issues relating to these matters consistently since 2005 after a pesticide laden helicopter crashed in the water catchment supplying our town drinking water and our local oyster farmers water. I have had communication with several Government Departments and the APVMA since this time. I am a member of The Society of Environmental Toxicology and Chemistry (SETAC) and a committee member of National Toxics Network Australia (NTN). I have been an author on several published articles relating to catchment and drinking water protection.

The aims of the APVMA are stated as: *To protect the health and safety of Australia —its people, animals and environment— and support Australian agriculture by taking a scientific and risk-based approach to regulating agricultural and veterinary chemicals.*<sup>1</sup>

Its business plan (2018-2019) has a different emphasis when declaring its aims: *The APVMA aims to operate a system for regulating pesticides and veterinary medicines that uses the best science, systems and processes to register products that advance Australia’s agricultural productivity and animal health. Business and operational improvements at the APVMA aim to improve regulatory efficiency for clients and stakeholders while delivering a system that is open and transparent and gives opportunity for public input.*<sup>2</sup>

Herein lies the dilemma. Is the health of the Australian public and environment its prime *raison d’être* or is it to advance Australia’s agricultural productivity with its prime clients those of chemical industry and agriculture?

APVMA will argue that its aims are both, but its actions do not translate to the safety and protection of the Australian public and environment (including Australian farmers), as its prime aim before that of the agriculture industry. Therefore, they can no longer be seen to be working primarily in the public interest.

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<sup>1</sup> <https://apvma.gov.au/node/33246> (sourced 28/10/2018)

<sup>2</sup> <http://www.agriculture.gov.au/SiteCollectionDocuments/about/budget/2018-19/2018-19-apvma.pdf> (sourced 28/10/2018)

The APVMA continues to show disregard for the urgent need to review pesticide assessments to prevent harm to the environment, and human health.

In 23+ years since to start of the APVMA, of the hundreds of pesticides that APVMA inherited from the start of the registration process in Australia only approximately 75 have been reviewed with the rest grandfathered into approval and use.<sup>3</sup>

The APVMA show an extreme reluctance in reviewing pesticides for reasons of safety many years if not decades after their initial registration. The removal of the process in 2014 to mandatorily reassess all registered products after 10-15 years of use, as is the case in the US and EU, in the light of contemporary knowledge remains a deep flaw in the system and does not assist in the process of ensuring that the pesticides used are indeed safe to be use.

In 2015 APVMA listed 19 chemicals for review; have prioritised 5 but only one has been scoped prior to a review start.<sup>4</sup>

The APVMA do not adequately assess pesticide products for:

- real life effects in the Australian landscape allowing for changing climates (e.g. drought, more heat and volatilisation), cyclone events and unseasonal rainfall and there is no monitoring of environmental health outcomes with pesticide use either episodically or over time by any Government body.
- effects of adverse effects. Responsibility is passed to the States to allow use of pesticides and ensure monitoring and compliance with label instructions. This arrangement does not work as there is minimal monitoring and compliance enforcements in most States. Adverse incidents that should require an urgent review of safe application practices (i.e. label instructions) are not followed up on due to issues between State and APVMA requirements/ regulations/ red tape etc. No single body strives to keeps records of pesticide use (what, where and when) and how much is used – any records only required to be kept for aerial spraying and those only for 2 years. Issues regarding adverse effects are often dismissed as it seems there is no access to reliable information as to what pesticides may have been used when. Insurances do not pay the adversely affected without “proof” and APVMA are extremely reluctant to acknowledge adverse effects even with “proof”.
- baseline testing against uniquely Australian flora or fauna including threatened species e.g., the Tasmanian Devil.
- mixture effects which typically occur in the receiving environment. At present, it is a case of simply hoping that adding in a safety factor will cover these many unknown interactions. The peer reviewed science suggests this is inadequate and non-predictive of actual risks<sup>5</sup>. International bodies such as the World Health Organization now acknowledge the need for considering mixtures in chemical risk assessment and regulation. This would align toxicological risk assessment with the clinical sciences and their long tradition of investigating drug-drug interactions.

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<sup>3</sup> <https://apvma.gov.au/node/10971> (sourced 28/10/2018)

<sup>4</sup> <https://apvma.gov.au/node/10876> (sourced 28/10/2018)

<sup>5</sup> Kortenkamp&Faust;2018: Regulate to reduce chemical mixture risk. pp. 224-226, Vol. 361, Issue 6399, *Science*. <http://science.sciencemag.org/content/361/6399/224.full> (sourced 28/10/2018)

- the effects of pesticides with endocrine disrupting capabilities<sup>6,7</sup>, and the issues of low dose effects, non-monotonic response curves<sup>8</sup> adverse effects in development at 'developmental windows'. Human health<sup>9,10</sup> is openly talking about the contribution of chemicals to these real issues and society and Governments are picking up the enormous costs – chronic disease management, loss of earnings, disability and carers payments, hospital costs for an increasingly sick population e.g. diabetes, obesity, cancer. The list goes on, and the costs are escalating.

For decades, ecotoxicologists have stated that NOEL/LOEL (NOEL = no observed effect level; LOEL = lowest observed effect level) methodology is an unsound scientific concept and should no longer be used. It would seem obvious that the use of these types of statistical analysis (NOEL and LOEL) should not be allow regulators (APVMA included) to determine policy which is to the detriment of animal, human and environmental health.<sup>11</sup>

- epigenetic effects,<sup>12,13</sup> including inter and multigenerational sublethal effects including alterations to phenotypes.
- the historical use of pesticides already in the environment/waterways – spatial and temporal.

The recent refusal by APVMA to review glyphosate (last reviewed in 1995) is incomprehensible in the light of current international science. I enclose my submission to APVMA regarding the need for a review for completeness. Two recent articles add to the urgent need to thoroughly review the adverse effects of glyphosate especially regarding the long-term effects of endocrine disruption/epigenetics on reproduction and chronic disease and cytogenetic/genomic damage on human cells<sup>14,15</sup>.

Meanwhile the Australian Government and the Queensland Government continue to extoll the virtues of 'managing' pesticides when it is blatantly apparent that they have not and cannot with their current minimalistic approach. The adverse effects of pesticides from agricultural practices and

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<sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726844/> (sourced 28/10/2018)

<sup>7</sup> <http://press.endocrine.org/doi/10.1210/er.2015-1093> (sourced 28/10/2018)

<sup>8</sup> [https://e360.yale.edu/features/scientists\\_warn\\_of\\_low\\_dose\\_risk\\_of\\_endocrine\\_blocking\\_chemical\\_exposure](https://e360.yale.edu/features/scientists_warn_of_low_dose_risk_of_endocrine_blocking_chemical_exposure) (sourced 28/10/2018)

<sup>9</sup> DOHaD and EDCs: Past, Present, and Future. <https://www.youtube.com/watch?v=JY5Alq0WhUg> "Nothing in disease aetiology makes sense except in the light of altered tissue programming!" (sourced 28/10/2018)

<sup>10</sup> Grandjean, 2018; Time scales of developmental toxicity impacting on research and needs for intervention. *Basic Clin Pharmacol Toxicol*. (sourced 7/11/2018)

<sup>11</sup> Bleaney: Letter to Editor, IJES Feb 2012.

<https://www.tandfonline.com/doi/full/10.1080/00207233.2012.668087?scroll=top&needAccess=true> (sourced 28/10/2018)

<sup>12</sup> Burgio, 2018; Environmental Carcinogenesis and Transgenerational Transmission of Carcinogenic Risk: From Genetics to Epigenetics. *Int. J. Environ. Res. Public Health*, 15, 1791. (sourced 7/11/2018)

<sup>13</sup> Grandjean, 2018; Time scales of developmental toxicity impacting on research and needs for intervention. *Basic Clin Pharmacol Toxicol*. (sourced 7/11/2018)

<sup>14</sup> Milesi, 2018; Perinatal exposure to a glyphosate-based herbicide impairs female reproductive outcomes and induces second-generation adverse effects in Wistar rats. *Archives of Toxicology* [https://d3n8a8pro7vhmx.cloudfront.net/yesmaam/pages/680/attachments/original/1532460188/Milesi\\_glyphosate\\_reproduction\\_rats\\_2018.pdf?1532460188](https://d3n8a8pro7vhmx.cloudfront.net/yesmaam/pages/680/attachments/original/1532460188/Milesi_glyphosate_reproduction_rats_2018.pdf?1532460188) (sourced 28/10/2018)

<sup>15</sup> Santovito, 2018; In vitro evaluation of genomic damage induced by glyphosate on human lymphocytes. *Environmental Science and Pollution Research*.

<https://www.pubfacts.com/detail/30324367/In-vitro-evaluation-of-genomic-damage-induced-by-glyphosate-on-human-lymphocytes> (sourced 28/10/2018)

water run-off from farm lands on the Great Barrier Reef<sup>16</sup> has been noted internationally and the Government has aimed for a 60% reduction in pesticide loads at the end of water catchments by 2018<sup>17</sup>. Yet in the Reef Plan 2016<sup>18</sup>, only 5 active ingredients of pesticides were picked out for specific care in their use. The conclusions of a 2015 talk by Andrew Negri<sup>19</sup>, Australian Institute of Marine Science, is as follows:

*Just some general conclusions now. I think that it's important, the reason we get involved in this is we think it's important that regulations and guidelines take into account the organisms that add value to world heritage areas like the Great Barrier Reef, these species that we really want to protect like corals and seagrasses, et cetera. The effects of PSII herbicides on seagrass are probably not going to affect seagrass by themselves in the marine environment. They probably add to the pressures so when we do laboratory tests the results we get really probably underestimate what happens in the real world because there are other effects of low salinity, et cetera. Maybe the formulations increasing toxicity as well. It hasn't been tested. I think that some of these, if we have new photosystem II herbicides then techniques like this are ideal for measuring their relative potency. We need to continue to communicate because by communication we can tailor the research that we do to better meet the needs of the end users.*

Andrew Negri has also explained why the other 45 pesticides so far found in the GBR waters are of as much and perhaps of more concern and details this succinctly in the article detailing 'The Problem'<sup>20</sup>;

*The Problem: In order to effectively manage potential risks posed by alternate pesticides to tropical freshwater and marine ecosystems, we need improved knowledge of the ecotoxicity of alternate pesticides to relevant freshwater and marine species.*

If food crops for export are tainted by pesticides, as has happened with tomatoes and lentils<sup>21</sup> (India has recently banned Australian imports due to glyphosate residues), the harm done to the Australian farming and export market is considerable and could easily be prevented. The 'clean and green' brand extolled by Australian agricultural exporters cannot afford to be damaged by the lack of action by APVMA. Of course, the Australian public wants to know that food products especially children's foods are free from pesticides and are yet to be satisfied that this is so.

The elephant in the room is of course the issue of the independence and rigor of the APVMA, as funding is directly reliant on the chemical companies whose products are registered for use in Australia by APVMA. Even more disturbing is that the APVMA rely heavily on these chemical companies own assessments of the chemicals. The APVMA adverse incident reporting program for the public and veterinarians is ad hoc and adversarial and the initial report from the public to the APVMA is sent the product registration holder for investigation and a report is then sent back to the APVMA within months<sup>22</sup>. I have had personal experience with this reporting system and have found it to be a very difficult and flawed process with no seeming interest in identifying genuine adverse

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<sup>16</sup> <https://www.sciencedirect.com/science/article/pii/S0269749109001304> (sourced 28/10/2018)

<sup>17</sup> <https://www.qld.gov.au/environment/agriculture/sustainable-farming/reef/reef-initiatives/grazing-impacts#targets> (sourced 28/10/2018)

<sup>18</sup> <https://environment.gov.au/marine/gbr/protecting-the-reef> (sourced 28/10/2018)

<sup>19</sup> <https://apvma.gov.au/node/19446> (sourced 28/10/2018)

<sup>20</sup> <https://nesptropical.edu.au/index.php/round-3-projects/project-3-1-5/> (sourced 28/10/2018)

<sup>21</sup> <https://detoxproject.org/imported-lentils-in-india-laced-with-glyphosate-weedkiller/> (sourced 28/10/2018)

<sup>22</sup> <https://apvma.gov.au/node/311> (sourced 28/10/2018)

effects. Many people that I have contact with no longer report using this system as they state it is a waste of time and effort.

Many Government Departments are also affected by APVMA – Health and Foods, Environment, Water – as well as Agriculture and Primary Industries. Many people’s lives and livelihoods are affected by their action and inaction, including those working in the agriculture industry. In the light of the above it would be appropriate to conclude that the Australian public, especially Australian farmers, should expect much better access to safe, environmentally sustainable products.

In summary, I have no confidence that the APVMA are working in the public interest for Australians and can safely regulate biocides and other chemicals in a timely, independent manner while incorporating current scientific knowledge and uncertainty.

My aim in submitting this letter is to bring to your attention the need for the APVMA to become independent from the chemical companies that currently fund them, and to ensure accountability and transparency. Above all, I firmly believe that the APVMA must work in the interest of public safety for all Australians when overseeing the registration of agvet chemicals and pesticides in Australia.