

Dr Alison Bleaney OBE  
MB ChB FACRRM  
Tasmanian Public and  
Environmental Health Network  
sthelensmedc@vision.net.au

Agricultural and Veterinary Chemicals First Principles Review  
Department of Agriculture, Water and the Environment  
GPO Box 858  
Canberra ACT 2601

[reviewsubmissions@agriculture.gov.au](mailto:reviewsubmissions@agriculture.gov.au)

27 August 2020

### **Re: Submission into Independent review of the agvet chemical regulatory framework**

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.*

To do so the APVMA (and its Board of Directors) must act in the public interest of all Australia and Australians. I note in the Summary of the Issues Paper that “The *panel recognises the current system has successfully protected the health and safety of people, animals and the environment in Australia for the last 25 years.*” I would dispute this statement.

Starting afresh, the aims of an Australian agvet chemical regulatory framework in broad terms could well be stated as: *Primarily to protect the health and safety of Australia —its people, animals and environment— and thereby support Australian agriculture/aquaculture by taking a contemporaneous and independent scientific and hazard-based approach to regulating agricultural and veterinary chemicals.*

The definition of hazard and risk assessment depends completely on independent, objective and rigorous systematic review and evaluation of all toxicity studies. Risk assessments can no longer be used for licensing pesticides as supposedly safe to use “according to label directions” if there are no safe levels of exposure as with endocrine disrupting chemicals (EDCs). It is an extremely unsafe way of regulating single pesticides/biocides or even an agvet product in the real world. A hazard-based paradigm must be taken for endocrine disrupting chemicals (EDCs) as has been taken for carcinogens and persistent organic pollutants. As Dr Leo Trasande says (and I paraphrase): “*Policy predicts exposure; exposure contributes to disease and disease costs the economy.*”<sup>1</sup> He points out that the different costs due to disease in the US and the EU is driven by the differences in policy i.e. risk-based as opposed to hazard-based.

My 2018 submission to the Senate Inquiry into the independence of regulatory decisions made by the APVMA and related matters (included), covered most of the urgent issues detailed in the issues paper and is referenced. Nothing to my knowledge has so far been addressed. Two years later and the science is increasingly telling us that the current regulatory framework is not fit for purpose, does not protect human and environmental health and does not act in the public interest.

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<sup>1</sup> [https://www.cmu.edu/igs/sustainable/2020\\_webinar\\_edcs/](https://www.cmu.edu/igs/sustainable/2020_webinar_edcs/) Webinar:Endocrine-Disrupting Chemicals (EDCs) -Implications for Human Health (Aug 13 2020) Dr Leo Trasande, Institute for Green Science.

I reiterate that these areas need urgently need to be reformed:

- Separation of funding and all ties to the chemical companies that are being regulated is of the utmost importance; financial profit should not and cannot outweigh health and social justice issues. Power and authority must be used with a keen sense of fairness and justice, understood and transparent to all users and recipients. Humans must advocate for flora, fauna and the environment.
- Consistency across States and Territories with allowance for variations due to climate and special circumstances must be considered; in essence a national approach.
- Monitoring of pesticide use, application and pollution effects is a totally inefficient, costly and unsafe method of attempting to control pesticide use especially with EDCs.
- Control of regulation, sale and therefore use should be a single national responsibility with no wriggle room for unsafe practices and shifting blame and responsibility between States and Federal government departments.
- Accountability for all steps in the new framework has to be a priority.
- Consultation needs to be considered, respectful and useful and tokenistic 'engagement' with 'community stakeholders' is no longer acceptable.

Several additional papers<sup>2,3,4,5</sup> are included to support my position along with a letter to Minister Littleproud (Min. for Agriculture and Water Resources) written in July 2018 about the urgent need to reform the APVMA. Interestingly I raised the issue of imidacloprid and the pollution of the Great Barrier Reef in the letter and only yesterday this insecticide made the ABC News again<sup>6</sup> with a paper detailing the very low levels of imidacloprid (1 to 5 micrograms per litre) needed to impact prawn health in waterways. It also details how oysters being filter feeding bivalves concentrate this pesticide within them and derails their immune system making them less resistant to disease. Imidacloprid was banned in France and the EU in 2018 due to adverse environmental (toxicological) effects. The APVMA only began reviewing it in 2019 and may make a decision regarding registration in 2021 stating "*following the evaluation of new scientific information about risks to the environment, and to ensure safety instructions on products meet contemporary standards*". This is not acceptable.

The last paragraph from Blumberg's paper<sup>7</sup> (section copied below) on agrochemicals really encapsulates major unresolved issues with the approach taken by APVMA in not attempting to prioritise health and environmental safety over company profits; farmers, bystanders and pesticide users become the 'unwitting middlemen'. Unfortunately, farmers and their families also suffer significant health problems due to pesticides. Blumberg is looking at obesity but basically discusses health, especially the multiple ill effects promulgated by EDCs and epigenetic changes due to pesticides. I have underlined some very significant summarisation statements. Precaution would

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<sup>2</sup> <https://doi.org/10.1016/j.mce.2019.110680> 2020, Warner et al; Mechanisms of action of agrochemicals acting as endocrine disrupting chemicals

<sup>3</sup> [10.1016/j.chemosphere.2020.127841](https://doi.org/10.1016/j.chemosphere.2020.127841) 2020, Le Magueresse-Battistoni et al; Exposure to pollutants altered glucocorticoid signaling and clock gene expression in female mice. Evidence of tissue- and sex-specificity

<sup>4</sup> <https://doi.org/10.1016/j.mce.2020.110982> 2020, Luque et al; Health Effects of Agrochemicals as Endocrine Disruptors

<sup>5</sup> [www.thelancet.com/diabetes-endocrinology](http://www.thelancet.com/diabetes-endocrinology) August 2020 Kahn, Linda G et al.; Endocrine disrupting chemicals: implications for human health Volume 8, Issue 8, 703 - 718

<sup>6</sup> <https://www.abc.net.au/news/rural/2020-08-25/imidacloprid-pesticiderun-off-impact-on-prawns-oysters-health/12580762>

<sup>7</sup> <https://doi.org/10.1016/j.mce.2020.110926> 2020, Blumberg et al; Agrochemicals and obesity

seem to be a sensible starting point in the regulation of the thousands of agrochemicals currently registered for use, let alone those proposed for registration.

*“There are many possible modes of action for how agrochemicals can promote obesity as discussed above. What is missing is a systematic effort to understand which of the many agrochemicals in current use can lead to adverse health outcomes, including obesity and through which molecular pathways they act to exert these effects. Current practice in toxicological research is becoming focused on “adverse outcome pathways” and “molecular initiating events”. These are useful paradigms for simple systems, but it is abundantly clear that agrochemicals can act through multiple pathways. These cellular signaling pathways interact with each other in complex ways. It is likely that individual chemicals act at multiple levels on metabolic homeostasis. Moreover, humans are typically exposed to poorly defined mixtures of chemicals that may interact in combinatorial ways that can be additive or inhibitory. Typical agrochemicals are also applied as mixtures that include so-called “inert ingredients” that may not be inert and whose composition and levels are not required to be reported. Much remains undiscovered about the possible molecular mechanisms for agrochemicals and their relationship with the obesity epidemic. Epigenetic changes may underlie the transgenerational effects of early life obesogen exposure; however, we know very little about the operational molecular mechanisms and even less about how the effects are transmitted across generations. The contributions of the gut microbiome to human health and disease are becoming widely appreciated, yet the effects of agrochemicals on the microbiome are only very poorly understood. Many more epidemiological and molecular studies will be required to clarify these issues.”*

If we attempt to prove adverse effects regarding EDCs, epigenetic changes and multigenerational effects in humans with old epidemiological methods that are not fit for this purpose, difficulties ensue especially due to lag times for adverse effects and the average lifespan of humans. How long do Australians have to wait for further ‘sufficient’ proof in the face of all the scientific proof, inexact though it may be?

We need to change both our toxicological tool kit and our pesticide policy direction and regulatory framework to ensure the ability to undertake appropriate and safe pesticide assessments.

We have more than enough reasons to take far more care and caution than we have done to date.

Our children and their children cannot undo what we have and are knowingly inflicting upon them.



Alison Bleaney