Chemistry Australia
The Business of Chemistry
Essential for Life

Chemistry Australia Limited ABN 77 063 335 615
Level 11, 10 Queen Street, Melbourne, VIC 3000
PO Box 422, Flinders Lane, VIC 8009
T +61 3 9611 5410 F +61 3 9611 5499
E info@chemistryaustralia.org.au
W www.chemistryaustralia.org.au
@AusChemistry

14 November 2018

Senator Glenn Sterle
Chair
Senate Standing Committee on Rural and Regional Affairs and Transport
References Committee
Parliament House
CANBERRA ACT 2600

Dear Senator,

Inquiry into the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)– Chemistry Australia Submission

1. Chemistry Australia welcomes the opportunity to provide this submission to the inquiry into the independence of regulatory decisions made by the APVMA.

2. Chemistry Australia (formerly the Plastics and Chemical Industry Association) is the peak national body representing the chemistry industry. Chemistry Australia members include chemicals manufacturers, importers and distributors, logistics and supply chain partners, raw material suppliers, plastics fabricators and compounders, recyclers, service providers to the sector and the chemistry and chemical engineering schools of leading Australian universities.

3. The chemistry industry is one of the largest manufacturing sectors in Australia. Our industry employs more than 60,000 people, with every job creating five more in related supply chains. The industry contributes $11.6 billion to gross domestic product, and supplies inputs to 109 of Australia's 111 industries.

4. Chemistry Australia members manufacture, import and distribute a broad range of products regulated by the APVMA. Chemistry Australia members also supply raw materials and services, including research and development, to businesses subject to regulation by the APVMA.

5. While industry has for many years expressed concerns about the efficiency and timeliness of the APVMA, the APVMA's application of sound scientific principles to regulatory decision-making is on par with the regulatory agencies of other advanced economies. Australian farmers, consumers and governments, can, and should, have full confidence in the APVMA and the regulatory decisions it makes.

6. With respect to the Committee's terms of reference, Chemistry Australia would make the following comments:

a. the responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators;

In terms of assessing the comparability of the APVMA responsiveness and effectiveness against equivalent international regulators, it is important to understand the context in which the APVMA operates**.**

Australia's crop production represented about 3% of total global crop production in 2017[1]. Total leviable sales declared to the APVMA for 2017 was $A3.2 Billion[2]. This amount includes sales of crop protection products, animal medicines, pool chemicals, sanitisers, wood preservatives and anti-fouling treatments. By comparison, total 2017 crop protection sales in the European Union and United States were $A18.8 Billion and $A7.95 Billion respectively.

Seen in this context, the APVMA has the same regulatory task as equivalent international regulators while operating in a much smaller economy and market. This challenge requires the APVMA to target its regulatory focus on those products or issues that represent the greatest risk to human health, the environment and Australia's agricultural trade. To effectively meet this challenge, the APVMA must also take full advantage of the regulatory activities of other trusted international regulators when deciding where to focus its resources. Such approaches work to the advantage of Australian farmers, consumers and the economy.

b. the funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making;

The APVMA is funded by fees, levies and charges imposed on the industry it regulates. While such cost recovery accords with current Commonwealth policy, the APVMA's current cost recovery framework deviates significantly from Commonwealth cost recovery guidelines.

Under the APVMA's current cost recovery arrangements, many of the fees and charges imposed on registrants do not reflect the full cost to the APVMA of undertaking the work associated with the fee or charge. Indeed, most fees and charges represent approximately 40% of the actual cost incurred by the APVMA. The 60% shortfall is covered by a levy on product sales.

The 60% discount on fees and charges under the APVMA's existing cost recovery framework results in inefficiency as consumers of APVMA services avoid paying the actual cost of those services. As a result, users of the APVMA are encouraged to over-consume APVMA resources because there is no appropriate price signal.

In 2014, the *First Principles Review of APVMA Cost Recovery Arrangements* (the Review) recommended a number of important changes to the APVMA's cost recovery framework, including setting fees and charges for regulatory activities at a level that represents 100% of the cost of undertaking those activities. The Review's recommendations recognised that a cost recovery

[1] https://data.oecd.org/agroutput/crop-production.htm
[2]APVMA Gazette No. 6, 27 March 2018

regime that requires all users to "pay-their-way" is fair, equitable and crucial for the efficient operation of the APVMA. The recommendations of the Review are yet to be implemented.

All equivalent international regulators operate under cost recovery regimes that ensure the regulated industry covers the costs of regulatory intervention.

The fact that the APVMA and other equivalent international regulators operate under cost recovery regimes often results in claims that the regulators are "captured" by the industry because they are dependent industry funding. Such claims might be avoided if the APVMA was funded from general budget appropriations. However, funding the APVMA from general budget appropriation is unlikely to deliver more efficient regulatory outcomes as the APVMA is likely to be swamped with more, often poor quality, applications.

If there are to be policy changes in relation to the regulatory approach to the reconsideration of active constituents and chemical products, the cost of these policy changes should be funded from general budgetary appropriations. Budget funding of changes to the reconsideration and chemical review process would ensure a proper Treasury and Department of Finance oversight of cost and benefit of the outcome of those policy changes.

c. the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;

Chemistry Australia sees no need to change the existing roles and responsibilities of relevant departments and agencies of the Commonwealth.

The APVMA and registrants expend considerable effort establishing the necessary directions for use that ensure that products do not represent an unacceptable risk to human health, the environment, and Australia's trade. However, control of use (i.e. ensuring that products are used in accordance with the label directions) is the responsibility of the states and territories. Inconsistent approaches to control of use across jurisdictions represents a risk to human health, the environment and Australia's trade. Improved control of use compliance has been on the agenda for many years.

d. the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products;

Delays to the introduction of innovation in the crop protection sector delays farmers' access to solutions that have the potential to improve Australia's agricultural competitiveness. The introduction of the National Registration Scheme for agricultural and veterinary chemicals that established the APVMA in the early 1990's simplified the process for bringing crop protection innovation to Australian agriculture. Prior to the establishment of the APVMA, each state and territory was responsible for approving chemical use within their jurisdiction.

As noted above, Australia is a relatively small market. Companies seeking to introduce newer environmentally sustainable and productivity enhancing products in Australia need to be sure that they will recover an appropriate return on their investment in the Australian market. The introduction of data protection following the Australia United States Free Trade Agreement (AUSFTA) provided innovators with improved opportunities to recover the cost of their

investment. However, the lack of adequate control of use compliance activity by state and territories agencies continues to facilitate the off-label use of regulated products, undermining the data protection regime and the attractiveness of investing in innovation in Australia.

e. the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner;

The relocation of the APVMA from Canberra to Armidale has had a significant negative impact on the APVMA's capacity to complete chemicals review in a timely manner.

Chemistry Australia would reiterate the views it expressed to Senate Standing Committee on Finance and Public Administration Committee's inquiry into the relocation of the APVMA[3]. Chemistry Australia believes that the $28 million associated with moving the APVMA to Armidale would have been better spent on the establishment of a Centre for Regulatory Science within the University of New England (UNE).

A Centre for Regulatory Science could develop expertise and courses that specifically target the growing need for regulatory science training and which aim to lift the capabilities of regulatory agencies in Asia and other parts of the world, as well as providing training for the APVMA, the OGTR, NICNAS and other Commonwealth and State agencies. A Centre for Regulatory Science might also work with Australian Aid, United Nations donor agencies and organisations like the Asian Development Bank to develop and deliver capacity building projects around the globe.

The establishment of a Centre for Regulatory Science at UNE instead of moving the APVMA to Armidale would have avoided all of the negative consequences that have arisen from the APVMAs relocation.

7. If you would like to discuss aspects of this submission, please don't hesitate to contact me on

Yours faithfully

Bernard Lee
Director – Policy and Regulation
Chemistry Australia

[3] The operation, effectiveness, and consequences of the *Public Governance, Performance and Accountability (Location of Corporate Commonwealth Entities) Order 2016*