Chemistry Australia
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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)– Response to questions on notice.

As requested by the Committee at its hearing on 7th December 2018, Chemistry Australia is pleased to provide the following responses the questions on notice.

Question 1

"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."

The APVMA's quarterly performance statistics clearly demonstrate the impact of both the speculation surrounding and, ultimately, the decision to relocate the APVMA from Canberra to Armidale. The table below illustrates the APVMA's quarterly on-time performance for pesticide applications during the period 1 July 2016 and 30 September 2018

Q3 - 2016	Q4 - 2017	Q1 - 2017	Q2 - 2017	Q3 - 2017	Q4 - 2018	Q1 - 2018	Q2-2018	Q3 - 2018
82%	50%	30%	24%	36%	72%	76%	77%	80%

In December 2016, the then CEO of the APVMA wrote industry stakeholders concerning an emerging issue in relation to the APVMA's ability to assess applications. The CEO advised stakeholders that with staff departures the APVMA had lost 50% of its chemical residues team and that it had exhausted all avenues to bring new people in or identify suitably qualified external assessors to address the immediate issues.

The CEO also advised that the APVMA was understaffed in the pesticides, health assessment, environment and chemical review areas due to key staff being on long term leave, others departing the agency and difficulties recruiting suitably skilled and experienced people.

While the APVMA has always struggled to meet the statutory timeframe requirements, in 2017, after the announcement of the move to Armidale, it significantly underperformed.

Question 2

"Examples of the negative consequences relating to APVMA's relocation that you mentioned in the last paragraph of your submission."{

The negative consequences associated with moving the APVMA from Canberra to Armidale include:

- The loss of experienced staff with considerable institutional and regulatory knowledge and experience.
- A loss of staff continuity has extended the delays in the completion of reconsiderations and applications.
- The APVMA and other regulators have indicated that it takes between 3 to 5 years for new recruits to be fully effective as a regulatory scientist. Hence, due to the loss of experienced staff, it will take time to re-establish the capability of the APVMA in Armidale.
- The Canberra region has a number of other agencies that require a similar professional skill-set to the APVMA, including the Therapeutic Goods Administration, Department of Environment and Energy, Office of the Gene Technology Regulator and Food Standards Australia New Zealand. Sourcing suitably qualified and experienced staff is likely to be easier in the Canberra region. This also represents a significant risk to the APVMA's currently staffing levels. Should any of these other agencies undertake a recruitment drive, current staff at the APVMA may be prefer to move-on to roles that offer greater certainty and/or stability with these agencies.
- The suite of legislative reforms that were introduced in 2013 were designed to improve the regulatory efficiency and timeliness of the APVMA, including reforms that would have improved the quality of applications received by the APVMA. As stated above, the uncertainty surrounding the relocation of the APVMA that resulted in staff departures and the loss of institutional knowledge and expertise also impacted the realisation of the benefits that the 2013 reforms were designed to deliver.
- The delays in the processing of pesticide applications in 2017, delayed farmers access to the products to assist them deal with pests and improve productivity.
- While Armidale is a large regional centre, travel to and from Armidale is simply not as convenient as it is for Canberra. Moving the APVMA to Armidale makes it more difficult for stakeholders outside NSW to meet and consult face-to-face with APVMA personnel. It also increases the costs associated with such activities and may also require staff to be out-of-the-office for longer periods while travelling.

APVMA's formalised process to identify and prioritise chemicals for review

During questioning, Senator Rice stated that the APVMA did not have a formalised process akin to the Priority Existing Chemicals Assessment process employed by NICNAS to prioritise agricultural and veterinary chemicals for review. My response to the Committee indicated that the APVMA did have a similar formalised process. I would refer the Committee to section s.30 of the *Agricultural Veterinary Chemicals Code Act* 1994 and the attached documents (extracted from the APVMA's website) that demonstrate the scope and nature of the APVMA's formalised process to identify and prioritise chemicals for review.

If you have any further questions regarding these responses, please don't hesitate to contact me on 03 9611 5411 or by email at blee@chemistryaustralia.org.au.

Yours faithfully

Bernard Lee
Director – Policy and Regulation
Chemistry Australia

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Chemicals nominated and prioritised for reconsideration

Identifying and nominating particular chemicals for review is an ongoing process. The APVMA regularly assesses chemicals nominated for review to ensure the highest risks are being targeted based on up-to-date information.

During 2015 the APVMA conducted extensive consultation with the public, industry and federal and state government agencies to seek input on prioritising a list of 19 chemicals, or types of chemicals, the APVMA had identified for review.

Following consultation, five chemicals have now been prioritised for detailed scoping prior to commencement of any reconsideration of the regulatory action. The remainder are prioritised for reconsideration after the first five have been commenced.

Details and key issues in relation to the five we have prioritised, plus the full list we consulted on, are below.

Before the formal review commences, the APVMA will undertake a range of preparatory work, including:

- determining the detailed scope of each review
- development of a work plan setting out expected milestone completion dates
- holding discussions with industry and user groups to ensure that all relevant information is received by the APVMA before the commencement of the review.

Priority	Chemical	Reasons for reconsideration	Status
1	Dithiocarbamates	• Public health[1] • Worker safety[2]	Detailed scoping to commence in 2017
2	Second generation anti-coagulant rodenticides	• Public health • Worker safety • Environmental safety[3]	
3	Cyanazine and simazine	• Worker safety • Environmental safety	
4	Phorate	• Public health	

[1] Public health includes a consideration of mammalian toxicology and the risk to people from exposure to residues in food.

[2] Worker safety includes a consideration of mammalian toxicology and the risk to people using chemical products, re-entering treated areas and handling treated materials.

[3] Environmental safety includes a consideration of ecotoxicology, environmental fate and the risk to organisms from exposure to chemicals in the environment during use and remaining in the environment after use.

Abbreviations

ADI	Acceptable daily intake
ARfD	Acute reference dose
EFSA	European Food Safety Authority
EU	European Union
JMPR	The Joint FAO/WHO Meeting on Pesticide Residues
MRL	Maximum residue limit
PPE	Personal protective equipment
REI	Re-entry interval

URL: https://apvma.gov.au/node/10876
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Australian Government
Australian Pesticides and Veterinary Medicines Authority

System to prioritise nominated chemicals for review

Agricultural and veterinary chemicals nominated for review by the APVMA are given an order of priority according to the level of concern that led to the nomination. This priority is based on advice received from APVMA's external advisory agencies: the Department of the Environment and the Office of Chemical Safety, as well as from the APVMA's own experts in residue chemistry and target animal or plant safety and efficacy. Chemicals prioritised for review are listed in the priority candidate review list (PCRL).

The APVMA and its external advisory agencies use a scoring process to prioritise nominated chemicals for review, based on key criteria of concern including human health (toxicology and occupational health and safety), environment, residues and trade, and target crop and animal safety and efficacy. The priority for each chemical nomination is determined by assessing it against each of the criteria and evaluating the outcomes. The PCRL provides an indication of the chemicals with the higher levels of concern or chemicals that have been assessed as being of concern by multiple agencies.

Human health (toxicology and occupational health and safety)

Chemicals that are nominated for review are assessed for their effect on human health against the following criteria:

- Special concerns
  - demonstrated or potential adverse effects in humans
- Acute and chronic risk
- scheduling of the chemical
- exposure to the chemical from food
- Regulatory action taken overseas (for example, Canada, the European Union, the United Kingdom, the United States of America)
- non-hazardous substances
- hazardous substances
- other toxicity (health hazard)
- industrial exposure in Australia
- form of concentrated chemical (includes formulated products)
- exposure to working strength chemical (mixing, loading or application)
- frequency of application
- post-application exposure (handling of treated crops and animals).
- Toxicity

- User exposure

Environment

Chemicals that are nominated for review are assessed for their effect on the environment against the following criteria:

- Environmental exposure
  - form and method of application
  - volume of use (kilograms per annum)
  - scale of use (hectares per annum)
  - persistence (soil or aquatic half-life)
  - bioaccumulation potential
  - mobility or leaching potential
- Environmental toxicity
- aquatic toxicity
- terrestrial bird or mammalian toxicity
- terrestrial plant toxicity
- other non-target organisms
- Sensitivity of receiving environment
- Demonstrated adverse effects
- Regulatory action taken overseas on environmental grounds (for example, the US Environmental Protection Agency, the Canadian Pest Management Regulatory Agency, or the European Union.)

Residues and trade

Chemicals that are nominated for review are assessed for their impact on residues and trade against the following criteria:

- Absence of maximum residue limits
- Reported incidents of residue violations
- Reported incidents of adverse effects on trade
- Compatibility with other countries' maximum residue limits
- International regulatory action
- Residues resulting from use according to the label and the appropriateness of existing directions (for example, hydroponics versus field use).

Note: Dietary exposure is considered under human health.

Efficacy

Chemicals that are nominated for review are assessed for their efficacy against the following criterion:

- Lack of efficacy (confirmed report(s) of serious incident(s) of chemical failure; substantial incidents of chemical failure).

Target animal and crop safety

Chemicals that are nominated for review are assessed for their effect on target animal and crop safety against the following criteria:

- Reported incidents of phytotoxicity and adverse interactions with target crops
- Reported incidents of adverse effects to treated target animals.

URL: https://apvma.gov.au/node/10851
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