



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

14 November 2018

Committee Secretary
Senate Standing Committees on Rural and Regional Affairs and Transport
PO Box 6100
Parliament House
Canberra ACT 2600
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Dear Committee

Re: Senate inquiry into the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

On 16 October 2018, the Senate moved that the following matter be referred to the Rural and Regional Affairs and Transport References Committee for inquiry and report by 1 February 2019: The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

To support the committee in this inquiry, I have provided an outline of the APVMA's regulatory framework and described the context for Australia's chemical reconsideration process.

In Australia, agricultural and veterinary (agvet) chemicals are regulated under a cooperative statutory scheme. The APVMA is responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia. State and territory governments are responsible for regulating and monitoring how chemicals are used. The APVMA administers the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code) and the broader suite of supporting legislation and regulations. Determination of agvet policy and the legislative framework is the responsibility of the Department of Agriculture and Water Resources.

The APVMA's primary purpose is to protect the health and safety of people, animals and the environment. The Australian people expect us to do a thorough job to ensure chemical products are safe – and that is what we do.

In many cases, the products we regulate are intrinsically hazardous. Pesticides, herbicides, fungicides and parasiticides protect the environment, animals and agricultural crops from pests and diseases. We regulate agvet chemical products using a structured process combining scientific methodology, legislation and risk assessment to ensure products are safe to use and do not adversely impact trade.

Our regulatory responsibilities extend from registration and manufacturing through to the point of sale. Compliance and monitoring powers in our legislation provide a mechanism to undertake post market surveillance and testing that ensure the continued safety and effectiveness of registered products. When a problem is identified, we act quickly based on the science and data available and take appropriate action.

The reconsideration of registered chemicals is a legislated process that involves the nomination of an active constituent or class of chemicals to be reviewed in detail by the APVMA. In determining the priority and the need for a review, the APVMA considers new scientific data and evidence relating to the continued safety and effectiveness of a chemical.

Reviews may focus on one or more areas of concern including environmental safety, worker safety, public health, residues or trade or, less commonly, product efficacy. The scope of a review is determined by the specific concerns about the chemical and involves open and transparent consultation with stakeholders and the public.

Many chemical actives and products we register have the potential for harm, but a harm that is minimised and brought within safe levels when appropriate risk mitigations are in place. Mitigations are applied throughout the supply chain, from those important first steps of product commercialisation, right through to how agvet chemicals are stored, used and reviewed. The strength of the National Registration Scheme for agvet chemicals comes from the sum of all parts, including registration, labelling, state and territory control of use and APVMA reviews.

As the national regulator, we are committed to continuous improvement and leadership of Australia's National Registration Scheme for agvet chemicals. Through effective governance and reporting, we monitor, measure and adjust our regulation to enhance our performance and improve safety outcomes. Responding to changes in our operating environment is essential as the APVMA strives to meet the expectations of clients, stakeholders and government.

As Chief Executive Officer, I welcome the opportunity to demonstrate the APVMA's commitment to continuous improvement and reaffirm our independence by responding cooperatively to any requests from the Committee. To facilitate your work, we have compiled documents and provided links to information that we think will be of assistance. The information provided in **Attachment A** addresses lines of inquiry mapped to the terms of reference, points A through F.

Explanatory notes provide direction on why the APVMA considers the information relevant to our comprehensive review of glyphosate and the chemical review process more broadly. Documentation exemplifying our regulatory engagement process, improved assessment performance, funding arrangements, capability development and management of the relocation to Armidale is also attached.

If you require further information, please contact me on

Yours sincerely //

Dr Chris Parker

ATTACHMENT A

Senate Inquiry: The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Submissions due: 14 November 2018

Report due: 1 February 2019

Terms of Reference:

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA), with particular reference to:

- 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;
- 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;
- 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;
- d. the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products;
- e. the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner; and
- f. any other related matters.

Term of Reference	Inclusion	Explanatory Note
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;	APVMA chemical review process webpage	Sets out the nature of APVMA's chemical review process
	APVMA chemical review webpage	Sets out the nature of APVMA's chemical review process
	Chemicals nominated and prioritised for reconsideration	Lists chemicals that have been nominated for reconsideration
	Listing of chemical reviews webpage	Lists current, completed and discontinued reviews
	Registrations and permits webpage	Reflects an aspect of APVMA's registration and permits process
	Reviewing decisions webpage	Provides information to stakeholders on how to seek review of APVMA decisions
	Seek review of a decision webpage	Provides information to stakeholders on how to seek review of APVMA decisions
	Legislative basis webpage	Details the legislative basis for reviewing and reassessing the safety of agricultural chemicals in Australia
	Legislative framework webpage	Details the legislative basis for reviewing and reassessing the safety of agricultural chemicals in Australia
	APVMA Fact Sheet on Glyphosate	Provides information around the nomination and consideration of glyphosate
	APVMA March 2017 Final Regulatory Position Report on Glyphosate	Provides information around the nomination and consideration of glyphosate
	APVMA News on Regulation of Glyphosate in Australia	Provides information around the nomination and consideration of glyphosate
	APVMA Review of EOS (Earth Open Source) on Roundup and Birth defects	Provides information around the nomination and consideration of glyphosate
	APVMA Review of IARC Monograph 112 (Glyphosate), Tier 1	Provides information around the nomination and consideration of glyphosate

	APVMA Review of IARC Monograph 112 (Glyphosate), Tier 2	Provides information around the nomination and consideration of glyphosate
	APVMA September 2016 Regulatory Position Report on Glyphosate	Provides information around the nomination and consideration of glyphosate
	Glyphosate Chemical Review webpage	Provides information around the nomination and consideration of glyphosate
	Trade Advice Notice on Glyphosate in the product DuPont Glyphosate Herbicide	Summarises the APVMA's assessment of an application to vary the use of a registered agricultural product containing glyphosate
	Trade Advice Notice on Glyphosate in the Product Pintobi Attack Herbicide	Summarises the APVMA's assessment of an application to vary the use of a registered agricultural product containing glyphosate
	Trade Advice Notice on Roundup Attack Herbicide	Summarises the APVMA's assessment of an application to vary the use of a registered agricultural product containing glyphosate
	Proposal not to place glyphosate under formal reconsideration	APVMA's regulatory decision report for glyphosate
	Communication between applicants and the APVMA webpage	Explains the communication requirements and sets out what the applicants can expect from the APVMA in terms of communication. These requirements and values extend to the review and reassessment processes
	Consultation and Collaboration (Stakeholders) webpage	Offers a broad description of the APVMA's stakeholder consultation process
	Stakeholder input announcement closed 30 June 2015	Invites stakeholders to provide written submissions in relation to the review process for a set list of chemicals
	IARC monograph 112 on Glyphosate (IARC Report)	Serves as the basis for the APVMA Tier 1 and 2 Reviews of the IARC monograph 112
	Freedom of Information requests webpage	Outlines how people can get access to information held by the APVMA
	Service Charter Webpage	Sets out APVMA standards for client service

	European Food Safety Authority Reassessment of Glyphosate	Independent international reviews to glyphosate
	FAO and WHO 2016 Pesticide Residues in Food Report	Independent international reviews to glyphosate
	Harmonised Classification and Labelling Report on Glyphosate	Independent international reviews to glyphosate
	New Zealand EPA Glyphosate Review Lay Summary	Independent international reviews to glyphosate
	WHO Report on International Expert Consultation on Chronic Kidney Disease of Unknown Etiology	Independent international reviews to glyphosate
	News: APVMA finds no grounds to place glyphosate under formal reconsideration	Media statement about the APVMA's assessment of glyphosate in response to the IARC report.
	Discussion Paper: A proposal to change the scheduling and management of APVMA GMP audits	Sets out proposed changes to good manufacturing practice (GMP) audits including a proposal to introduce a transparent risk-based schedule for assigning audit intervals
	Risk Management Webpage	Describes risk framework and its role in the APVMA's approval, registration and reconsideration functions
	<ul style="list-style-type: none"> • 2014 Gazettes 1, 2, 4, 5, 8, 11, 12, 13, 16, 17, 20, 22, 25, Special Gazette 16 October • 2015 Gazettes 2, 6, 7, 9, 13, 15, 16, 17, 20, 22, 24, 25 • 2016 Gazettes 2, 5, 6, 7, 8, 10, 11, 12, 15, 19, 20, 21, 22, 23, Special Gazette 14 December • 2017 Gazettes 1, 10, 13, 15, 20, 22, 24, Special Gazette 20 March • 2018 Gazettes 3, 6, 8, 11, 19 	These Gazettes do not concern glyphosate, but rather deal with reviews and assessments. Some Gazettes reflect decisions made as a result of review decisions. Others summarise APVMA assessments of certain active constituents.

	Independent Review of Assessment Performance	The Independent Review contains a comparison of international arrangements
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;	Annual Report 2013-14	Sets out funding arrangements
	Annual Report 2014-15	Sets out funding arrangements
	Annual Report 2015-16	Sets out funding arrangements
	Annual Report 2016-17	Sets out funding arrangements
	Annual Report 2017-18	Sets out funding arrangements
	Cost Recovery Impact Statement	Documents cost recovery arrangements
	Amendment to Cost Recovery Impact Statement	Documents cost recovery arrangements
	APVMA cost recovery arrangements webpage	Documents cost recovery arrangements
	Cost recovery questions and answers webpage	Documents cost recovery arrangements
	PWC Review of APVMA Cost Recovery Arrangements	Details PWC's independent review of the APVMA's cost recovery arrangements
	NZ Ministry for Primary Industries Fees, charges and levies webpage	Describes fee structures for international chemical regulators
	US EPA Registration fees and waivers webpage	Describes fee structures for international chemical regulators
	US EPA Registration maintenance fees webpage	Describes fee structures for international chemical regulators
	US FDA cost recovery and levies webpage	Describes fee structures for international chemical regulators
c. the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory	Canadian Pest Management Regulatory Agency fees and charges webpage	Describes fee structures for international chemical regulators
	European Commission fees, charges and levies webpage	Describes fee structures for international chemical regulators
	Management of use of pesticides and veterinary medicines (states and territories) webpage	Lists the state and territory agencies responsible for the management of the use of agvet chemicals

governments in relation to the regulation of pesticides and veterinary chemicals;	Overview of agvet chemical regulation webpage	Provides an overview of agvet chemical regulation, describing National Registration Scheme and introducing key stakeholders
	Regulator Performance Framework 2016-17	Describes the role of the APVMA as a regulator
d. the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products;	APVMA Corporate Plan 2018-19	Sets out the purpose and strategic priorities of the APVMA
	APVMA Operational Plan 2016-17	Sets out the purpose and strategic priorities of the APVMA
	APVMA Operational Plan 2017-18	Sets out the purpose and strategic priorities of the APVMA
	APVMA Operational Plan 2018-19	Sets out the purpose and strategic priorities of the APVMA
	External Scientific Review Services (ESR) webpage	Provides a list of guidelines, standards, recommendations, reports and assessments relevant to the functions of the APVMA
	Independent Review of Assessment Performance	Reason Group conducted an independent review into the assessment performance of the APVMA
	Performance Data – 2017-18 December Quarter	Quarterly Performance report
	Performance Data – 2017-18 June Quarter	Quarterly Performance report
	Performance Data – 2017-18 March Quarter	Quarterly Performance report
	Performance Data – 2017-18 September Quarter	Quarterly Performance report
	Regulator Performance Framework 2015-16	Sets out the APVMA's plan to measure and report its performance against the Australian Government Regulator Performance Framework (RPF) in accordance with specified performance measures
	Regulator Performance Framework 2016-17	Sets out the APVMA's plan to measure and report its performance against the RPF in accordance with specified performance measures

	Regulator Performance Framework 2017-18	Sets out the APVMA's plan to measure and report its performance against the RPF in accordance with specified performance measures
	Regulator Performance Framework Self-Assessment 2016-17	Offers the results of the APVMA's assessment of its own performance using the indicators and measures set out in the relevant APVMA Regulator Performance Framework
e. the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner; and	Armidale Relocation Strategy	Outlines the APVMA's strategy for relocating to Armidale with consideration of how the APVMA will operate from Armidale and key elements of the relocation
	APVMA business operating model webpage	Details the APVMA business operating model
	APVMA Digital Strategy 2018-2022	The digital strategy is an important component of the APVMA's ability to relocate successfully
	APVMA relocation webpage	Describes the project of moving and the progress and deliverables associated with the relocation
	Government Policy Order	The legislative instrument mandating the relocation to Armidale
	Government Policy Order Explanatory Statement	The explanation informing the legislative instrument
	Operating Model for APVMA functions in Armidale	Pegasus Economics consultancy report outlining the operating model for the relocation