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Regulator Engagement with Small Business  
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Dear Ms Underwood

Thank you for the opportunity to provide a submission to the Productivity Commission's draft research report on Regulator Engagement with Small Business.

I would like to provide some background and points of clarification in relation to the regulation of agricultural chemicals and veterinary medicines (agvet chemicals) content in the report.

The Commission, at several places in the draft report, notes reforms to agvet chemicals regulation are in development. Please note that legislation for these reforms has now been passed by the parliament (Agricultural and Veterinary Chemicals Legislation Amendment Act 2013) and will commence on 1 July 2014.

The Department of Agriculture, Fisheries and Forestry's draft submission is attached.

The department looks forward to further assisting the Commission with its report. The contact for agvet chemicals reform matters is Mr Marc Kelly.

Yours sincerely

Tom Parnell  
A/g Assistant Secretary  
Livestock Industries and Agvet Chemicals Branch

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## **Submission on the Productivity Commission's *Regulator engagement with small business* draft report**

The Productivity Commission's draft report on *Regulator engagement with small business* at several points discusses regulation of agricultural chemicals and veterinary medicines (together, agvet chemicals) by the Australian Pesticides and Veterinary Medicines Authority (APVMA). At several points the Commission notes reforms to agvet chemicals regulation are under way. This submission addresses some of the matters raised in the Commission's draft report and provides some information about progress with reform and about some particular reform measures. The submission also includes background information about agvet chemicals regulation.

### **Agricultural chemicals and veterinary medicines**

Agricultural chemicals (also known as pesticides) include a broad range of products that protect crops from one or more of a wide range of weeds, insects and pathogens. These chemicals are used in agricultural and forestry industries to ensure pest control is effective and so to aid industry productivity. In other contexts, agricultural chemicals are important in the protection of gardens, parks, buildings and other infrastructure, as well as in households for the control of a range of pests.

Agricultural chemicals are also used in human health for protecting against disease vectors such as mosquitoes and rodents. Agricultural chemicals also play a role in protecting the environment from pests such as locusts, foxes and weeds.

Veterinary medicines, such as vaccines, antibiotics, worm treatments, lice treatments and some vitamins and minerals are important for the protection of livestock from pests and to treat a wide range of diseases and conditions. These products are also essential for maintaining the health and wellbeing of companion animals, including domestic pets and service animals.

### **National Registration Scheme**

Agvet chemicals are regulated through the cooperative National Registration Scheme (NRS) for agricultural and veterinary chemicals. The NRS was agreed by the states and territories and the Commonwealth at the Australian Agriculture Council (now the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was originally signed in September 1995. The intergovernmental agreement has just been revised and renewed.

The NRS is a partnership between the Commonwealth and the states and territories with a shared division of responsibilities. Pre-market assessment and registration of agvet chemicals, as well as control of manufacturing and supply activities and compliance up to the point of retail sale, is undertaken by the APVMA (a Commonwealth authority). Control of use of agvet chemicals after sale is the responsibility of individual states and territories.

This approach is enabled by a scheme of complimentary applied legislation. The *Agricultural and Veterinary Chemicals Code Act 1994* (C'wealth) contains as a schedule to it, the Agvet Code. Under legislation made in each state, the Northern Territory and the Commonwealth (for the Australian Capital Territory), the Agvet Code operates in each state and territory to

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constitute a single national Agvet Code applying throughout Australia. The APVMA's powers and functions are defined by the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act) which established the APVMA.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider (review) active constituents and agricultural and veterinary chemical products (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products. Other provisions in the Agvet Code provide for controls to regulate the supply of chemical products; and ensure compliance with and enforcement of the Agvet Code.

With advice from other government agencies, the APVMA approves active constituents and agvet chemical products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's processes provide assurance, through rigorous science-based risk assessments, that agvet chemical use is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9 900 separate agvet chemical products registered, each of which contains one or more of around 1 800 approved active constituents.

### **Agvet chemicals regulation reforms**

Australian Government reforms to the approval, registration and reconsideration (review) of agvet chemicals are underway to improve the efficiency and effectiveness of the current regulatory system and provide greater certainty to the community that chemicals approved for use in Australia are safe. The reforms make it clear that the health and safety of human beings, animals and the environment is the first priority of the regulatory system.

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Act) was given assent on 29 June 2013. Its measures commence on 1 July 2014.

The Act encompasses a range of measures for better regulation of agvet chemicals to the benefit of chemical and chemical-user industries, the community and the environment. These measures will improve the effectiveness of the regulatory system and reduce inefficiency at the APVMA, while at the same time making processes more predictable and clear and less unwieldy for applicants and registrants.

The reforms<sup>1</sup> are in five areas, to:

- simplify and modernise agvet chemicals legislation to improve assessment processes for agvet chemical applications for approvals, registrations, permits and licenses and for reviews of chemical approvals and registrations. This reform area goes directly to the removal of unnecessary legislative constraints on the capacity of the APVMA to implement flexible and responsive approaches to managing risks associated with agvet chemical use.
- enhance consistency, efficiency and transparency of approvals, registrations and reconsiderations and proportionality of compliance enforcement by publishing and

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<sup>1</sup> The incoming government has committed to further reforms to agvet chemicals regulation and to work with industry to identify and implement further improvements to efficiency. One commitment is to remove the now-legislated re-approval and re-registration scheme.

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implementing APVMA principles, processes and guidelines to better align regulatory effort with chemical risk

- ensure ongoing safety of agvet chemicals and improve effectiveness of current review arrangements by implementing a mandatory re-approval and re-registration scheme, designed to identify potentially problematic chemicals while minimising impacts on affected businesses
- improve the ability of the APVMA to enforce compliance with regulatory decisions by providing it with a graduated range of enforcement powers
- improve consistency in data protection provisions and remove disincentives for industry to provide data supporting agvet chemicals registration and permit applications.

Commonwealth agencies, state and territory governments (as required under the NRS), the agricultural chemicals and veterinary medicines industry, agrifood sector, community and environment groups and the general public were consulted during the development of the reforms.<sup>2</sup> Stakeholders had the opportunity to make written submissions and participate in workshops and public meetings. A regulation impact statement for the reforms also captured the views of this broad range of stakeholders.

### **Risk-based regulation**

The draft report gives much consideration (appendix D) to taking a risk based approach in regulation. The draft report (page 275, box D.3) cites the Department of Agriculture, Fisheries and Forestry on the need to address the APVMA's propensity for a one-size-fits-all approach to its assessments and to ensure the APVMA matches its regulatory effort and the regulatory burden imposed on stakeholders with the risks associated with agvet chemical use.

The reforms make clear that the APVMA is to take a risk based approach to delivering regulation. New objects for regulating agvet chemicals in reform legislation set out that the Agvet Code is to be implemented through science-based risk analysis, including risk assessment and management, and that the APVMA continually update its practices to follow best practice. Risk analysis provides a scientific, structured, systematic and transparent method for making decisions. It allows the risks of agvet chemicals to be considered on the basis of relevant, reliable and sound scientific evidence within the overall context of human and animal health and safety and environmental protection.

The reforms also highlight the importance of maintaining a balance between APVMA regulatory effort, any regulatory burden imposed on the regulated community, and risk associated with chemical use. In implementing the Agvet Code the APVMA is not to impose regulatory burdens greater than is reasonably necessary to manage risks to the health and safety of human beings, animals and the environment.

Importantly, the reforms also emphasise a logical outcome of science-based risk analysis – that chemicals that pose unmanageable risks to humans, animals or the environment are not appropriate for Australia and so are not to be approved or registered. The health and safety of

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<sup>2</sup> The Productivity Commission's draft research report cites one stakeholder's concerns (Hills Orchard Improvement Group). Hills Orchard Improvement Group was not one of the more than 100 different stakeholders or stakeholder groups that provided input to the development of recent reforms to agvet chemicals regulation.

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human beings, animals and the environment is the first priority for the regulatory system for agvet chemicals.

### **Flexibility, transparency and predictability**

The draft report (page 116, box 4.1) cites a view that the APVMA is 'extremely risk averse' and inflexible in its assessments of applications for the registration of veterinary medicines and pesticides. The draft report (page 275, box D.3) also cites criticism of the APVMA's regulatory approach as not sufficiently clear, lacking flexibility and imposing unnecessary data requirements on applicants.

The reforms introduce legislative amendments that improve the efficiency and effectiveness of agvet chemical regulation through increased transparency and predictability of decision-making. The amendments provide for the APVMA to make, publish and have regard to guidelines. These are to form part of an overarching risk-based compendium of principles, processes and guidelines that would be developed, maintained and published by the APVMA.

Developing and publishing the principles and guidelines compendium for how the APVMA is to go about assessing and managing chemical risks and about requirements of applicants will improve the transparency and predictability of the regulatory system. Publishing these principles and guidelines will assist in communicating the APVMA's acceptable level of risk and regulatory posture in regulating agricultural and veterinary chemicals.

These documents (now known as APVMA guidelines) will also allow the APVMA and its regulatory partners to determine the scale of an assessment appropriate to the decision by better matching regulatory effort to risk. The compendium will improve transparency by detailing all relevant guidelines, standards and methods which would guide regulatory decisions. Applicants and registrants will have a clearer picture of what information and data needs to be submitted to the APVMA and why it is required. The APVMA will be clear about how it will deal with applicants and applications and about its processes for assessments, reconsiderations, compliance and about review of decisions.

Reforms require the APVMA to determine the scale of an assessment appropriate to the application or reconsideration before it. Legislative amendments allow flexibility for the APVMA to determine the matters it is to have regard to and the intensity of its assessment of those matters in making certain decisions. These will apply when the APVMA is considering an application or reconsideration, or determining whether to cancel or suspend an approval or registration. The APVMA will still be required to consider safety matters in all cases, but will have to determine the breadth and depth of the safety assessment required based on the risks of using the chemical on a case-by-case basis.

### **Dealing with applications**

The draft report (page 79) states that some participants criticised the APVMA for being particularly unhurried in accrediting certain new chemicals for safe commercial use.

The APVMA's performance in timely and efficient assessments of chemicals has been hindered by legislative constraints to dealing efficiently with applications. The APVMA is not effectively able to refuse deficient applications or efficiently address deficiencies. Current assessment timeframes do not take into account the total time elapsed for considering an application or finalising a reconsideration (known as chemical review). In addition, applicants may provide

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data for the APVMA's consideration at any time, which the APVMA must then consider. These existing arrangements unnecessarily frustrate the finalisation of assessments for many applications and reconsiderations. This does not provide for certainty and predictability in assessment timeframes for applicants or the APVMA.

The reforms include amendments to address concerns about the time taken by the APVMA to complete applications and reconsiderations. The reforms require the APVMA to refuse inferior or deficient applications so that it only needs to assess applications that are of the required standard. The measures place the onus on applicants to ensure their applications are of the required standard to be assessed. Complete timeframes are introduced for assessments, including the total time elapsed and the time taken to provide more information. This increases certainty around when applications will be finalised.

The APVMA will assist applicants in understanding the requirements that apply to their applications by offering upfront pre-application assistance prior to submission. The cost of a reasonable amount of assistance will be off set against the fee for an application.

The reforms also introduce timeframes for reconsiderations (also known as chemical reviews). Along with other reforms to reconsiderations, this assists in reducing the current backlog and provides for consistent and more predictable completion of assessments within appropriate timeframes.

The reforms enable the APVMA to require electronic communication between it and applicants. This electronic communication will also streamline the APVMA's internal administrative processes through investment in an electronic document retrieval and management system.

A new focus on balancing regulatory effort and burden with risk and on limiting wasted effort on poor quality applications means the APVMA will be able to give greater focus on newer, safer chemicals with benefits for agricultural productivity. The reforms also remove unnecessary impediments to the APVMA's use of overseas assessments and data. This also addresses a concern raised in the draft report (page 116) that the APVMA's processes do not sufficiently recognise appropriate overseas assessments.

### **Compliance and enforcement**

The draft report (page 274) raises the importance of a structured risk based approach to enable compliance to be enforced in a way that is consistent and defensible.

The existing statutory framework for the APVMA limits its capacity to manage compliance through monitoring and enforcement. The provisions within the existing framework are not currently aligned with the contemporary compliance needs or expectations of government, community or industry. The existing provisions provide limited avenues for responding to non-compliance. The current statutory framework lacks any gradation between passive enforcement tools (such as warning letters) and stronger actions (such as suspension, cancellation, product recall or criminal prosecution).

The reforms aim to provide the APVMA with a range of compliance powers that it can use flexibly to implement its compliance strategies and enforce compliance with the Agvet Code. The reforms build on existing provisions under the Agvet Code. The existing provisions are

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important to act as a deterrent to actions that could result in serious impacts on human, animal and environmental health and trade.

The reforms introduce a modern compliance system using a wide range of tools to address instances of non-compliance in an appropriate and cost-effective manner. These tools present alternatives to criminal prosecution and provide for a response by the regulator that is proportional to the risk posed by the non-compliant behaviour. Legislative amendments improve the ability of the APVMA to efficiently administer its regulatory decisions by tailoring regulatory interventions to the seriousness of the non-compliance, to enhance protection of public health and safety and the environment. The measures are similar to those available to other regulators under Commonwealth laws and modernise current investigation and enforcement provisions, consistent with contemporary standards.

### **Feedback, complaints and appeals mechanisms**

The draft report (page 177) states that regulators need to be clear to business about the avenues for lodging or making a complaint.

The APVMA, like other regulators, provides and publishes details of its complaints and appeals processes both directly at the time of an interaction with a client and in its publications and online. Every notice about a decision the APVMA makes on an application is accompanied by information about opportunities for review of the decision. The APVMA provides a number of statutory and non-statutory opportunities for complaints and review of decisions. These include statutory internal merits review, ombudsman review, external merits review (via an application to the Administrative Appeals Tribunal) and judicial review (via an application to the Federal Court).

### **Implementation and review of the reforms**

Stakeholders will continue to play a role in the implementation of the reforms. The APVMA is engaged with the regulated community over development of systems to implement the reforms and the regulatory guidance that explains the way it will operate in its new legal framework. The Act also provides for certain reviews within the first five years, a review of the Bill's reforms after five years and rolling 10-yearly reviews of all agvet legislation, to ensure they operate as intended and remain appropriate.

### **For further information**

Further details of the reforms can be found at [daff.gov.au/agvet](http://daff.gov.au/agvet)