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Australian Pesticides and Veterinary Medicines Authority

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Additional submission to the Productivity Commission inquiry into Regulation of Australian Agriculture

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CONTENTS

EXECUTIVE SUMMARY

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is providing this additional submission in response to a request from the Productivity Commission's *Inquiry into the Regulation of Australian Agriculture*.

The key matters which relate to the APVMA fall under *Section 6, Regulation of technologies and agricultural and veterinary chemicals* of the draft report. The draft report includes a draft recommendation relating to the APVMA:

> *The Australian Pesticides and Veterinary Medicines Authority should make greater use of international evidence in its assessments of agricultural and veterinary chemicals (including by placing greater reliance on assessments made by trusted comparable international regulators). Reforms currently underway in this area should be expedited (Draft Recommendation 6.2)*

It also includes the draft Information Request:

> *How well does the regulatory framework for technologies and agvet chemicals perform? Are the institutional arrangements and regulatory objectives underpinning the OGTR and APVMA appropriate and up to date? What improvements could be made? (Information Request 6.1)*

The key matters which the APVMA has included in this submission are:

- the time and cost required to achieve chemical registration and increasing use of international evidence
- statutory timeframes
- labelling of agvet chemicals under work health and safety regulations
- implementation of reforms to streamline regulation of agvet chemicals
- scope for more significant reform, including the arrangements and objectives underpinning OGTR and APVMA and potential duplication.

1 APVMA USE OF INTERNATIONAL EVIDENCE IN ITS ASSESSMENTS OF AGRICULTURAL AND VETERINARY CHEMICALS

The Australian Pesticides and Veterinary Medicines Authority should make greater use of international evidence in its assessments of agricultural and veterinary chemicals (including by placing greater reliance on assessments made by trusted comparable international regulators). Reforms currently underway in this area should be expedited (Draft Recommendation 6.2)

The draft report and previous APVMA submission provides an overview of the policy position of the APVMA under which international data and assessments are accepted, standards adopted and decisions are considered.

The APVMA has in the past, and continues to, utilise international data and assessments in its decision making process.

The APVMA uses data generated in overseas countries (international data) to the extent that it is relevant to the use of a product in Australia. Under OECD principles, data generated in one OECD country according to OECD test methods, must be accepted by other OECD governments, based on the MAD (Mutually Acceptable Data) principle. This requirement applies to data for pesticides and biopesticides and includes toxicity data, environmental toxicity and environmental fate data, chemistry data, and residues data.

Data generated internationally using VICH guidelines are also accepted by APVMA. In general, data packages provided to overseas regulators are generated according to test methods prescribed by these international bodies.

The APVMA has published a list of adopted international technical guidance material that is accepted for assessment by the APVMA for registration of agricultural and veterinary chemical products (refer http://apvma.gov.au/registrations-and-permits/data-guidelines).

Nevertheless, the APVMA is looking to expand its use of international data and assessments, and has run a series of consultations with industry over the last 18 months, with the most recent consultation on more detailed guidance for industry on accepted international data, standards and assessments for agricultural and veterinary products closing on 17 June 2016.

The consultation papers outline criteria about how international data, standards and assessments can be better utilised as part of the risk assessment that the APVMA is required to undertake as part of the approval of an active constituent, registration of a product or approval of a label. The APVMA is finalising the guidance material in consideration of submissions received for publication on our website. A copy of the consultation papers are attached to this submission in **Attachments A and B**.

While the APVMA can develop guidance material, it is ultimately up to industry to provide international assessments and data when submitting their application to the APVMA.

Apart from very limited circumstances, it is unlikely that the APVMA would accept a decision from an overseas regulator as the sole justification for registering or cancelling a product or active constituent approval. There are many elements that influence a regulatory decision, including the legislative framework and statutory criteria against which decisions are to be made, how a chemical is to be used and the farming systems within which it is to be used, climatic and environmental conditions and other relevant systems and policies that exist in a country.

For example, although the foundations of the legislation of most regulators have common themes, there are elements that are not common to all. Each regulator must make decisions as per the criteria set out in the legislation of their jurisdiction. It must also consider conditions of approval, label requirements, and compliance

and monitoring regimes needed to support the decision. These components are strongly influenced by the different legislative, political, environmental and agricultural features of each country within which the regulator operates. These components form part of the regulatory environment.

In Australia, the APVMA must consider state and territory legislation and control of use regimes, environmental protection regimes, adverse experience reporting mechanisms and food testing systems, which all contribute to and impact upon a regulatory decision.

Conditions of approval or registration are also included as part of the regulatory decision. For the decision of one regulator to be adopted by another, post-approval systems and schemes, such as compliance, need to be operating at comparable levels.

There may be components of decisions that may not be appropriate to be adopted in Australia. For example, if conditions were placed on herbicides used in the EU, these would probably not be automatically transposed to herbicide use in tropical Queensland due to requirements of state legislation to protect the Great Barrier Reef or different use profiles (e.g. aerial vs ground application) of the herbicide in Queensland, associated with a different risk profile for workers/bystanders. Similarly, Australian instructions for use that prescribe slopes and rainfall patterns are not able to be adopted internationally as they are region specific.

Certain veterinary medicine products under the EU system have stringent post-market reporting requirements, making the pre-market assessment process less onerous.

Having said this, an applicant may present argument to the APVMA that decisions of an overseas regulator may be relevant to their application, noting that the burden of proof to make the case rests with the applicant and must contain the necessary scientific evidence and/or assessments to support the argument.

The APVMA is currently exploring whether it would be possible to accept decisions by the New Zealand regulator relating to non-food producing veterinary medicine products. Consultation with industry is expected to occur before the end of the year.

The APVMA notes reference in the report to a delay in varying the product registration for a vaccine for Bovine Ephemeral Fever following a change in site of manufacture, with the suggestion that increased use of overseas evidence would have assisted in this case. In this circumstance the APVMA did assess overseas data, noting data was being progressively generated and provided to the APVMA during the assessment process. The APVMA notes this application was assessed under the pre-1 July 2014 legislative reforms to the Agvet Code. For applications submitted after 1 July 2014, it is necessary for applicants to submit all relevant data at the time of lodgement. In addition, the July 2014 reforms introduced a more structured approach to providing pre-application assistance (PAA) to provide applicants the opportunity to receive advice before submitting an application. While the initial implementation of PAA did not deliver the intended benefits, the APVMA redesigned its approach in consultation with industry. The revised PAA approach was implemented in November 2015 and has been well received by industry. These changes from 1 July 2014 assist applicants to submit more complete applications, which in turn improves timeliness of decisions.

2 STATUTORY TIMEFRAMES

The APVMA commenced assessment of 5106 applications and finalised 5148 applications in 2015-16 with 68 percent of applications finalised within the statutory timeframe. The APVMA has various types of applications that vary from minor administrative applications to very complex and time consuming applications.

In the June 2015-16 quarter, the percentage of applications finalised within legislative timeframes was at 76 per cent, a significant improvement on the previous three quarters which were all at 64 per cent. There were significant increases in timeframe performance in product applications for both pesticides (at 72 per cent) and veterinary medicines (at 85 per cent), which are both up from the previous quarters. Additionally, 75 per cent of applications for approval of actives and 71 per cent of permit applications were completed within timeframe.

The draft report mentions the APVMA not meeting statutory timeframes. The definitions for the calculation of timeframe performance changed with the legislation implemented on 1 July 2014. The APVMA commissioned Oakton (the agency's external auditors) to examine the impact this change had on timeframe performance statistics. In summary:

- if the definitions that apply today were applied to applications processed before 1 July 2014, timeframe performance would have dropped from 91 per cent to 33 per cent – significantly below the 69 per cent average recorded since 2014
- similarly, the actual (or elapsed) time taken to finalise an application from the time it was lodged with the APVMA would increase from 3.1 months to 7.8 months prior to 1 July 2014 – compared to an average of 4.6 months since 2014.

Nevertheless, the APVMA is committed to improving its efficiency in delivering decisions and as initiated a range of activities, including:

- recruiting more regulatory scientists to work on applications
- ongoing internal business process improvements – to remove the internal red tape involved with assessing applications and recording decisions
- more proactive management of staff workloads to better phase the processing of applications, particularly with high volume application types
- management of workplace health to minimise unscheduled leave
- a dedicated resource to focus on project managing overdue applications – while this reduces overall timeframe performance, it is important to reduce overdue applications to underpin future improvements
- assuming responsibility for the health assessments previously done by the Department of Health from 1 July 2016 – given historical issues with timeliness of health assessments, the APVMA will now be able to more aggressively manage delivery of these assessments.

3 LABELLING OF AGVET CHEMICALS UNDER WORK, HEALTH AND SAFETY REGULATION LABELS

Incidents resulting from the absence of GHS labelling on agvet chemical labels

During Senate Estimates in February 2016, Safe Work Australia (SWA) was asked to confirm that the additional requirement to label agvet chemicals according to the Globally Harmonised System of Classification and Labelling (GHS) was not prompted by any worker incident.

The question was taken on notice, and SWA's written response referred to several incidents where the absence of GHS labelling resulted in harm to the community. SWA said that:

In their response to the 2006 Consultation Regulatory Impact Statement for the hazardous chemicals framework, WorkCover NSW highlighted several agricultural chemical incidents where APVMA approved labels were identified as not communicating the hazard which resulted in the incident, including a fatality caused by the use of carbon disulphide as a grain fumigant. The APVMA label contained no information about the flammability of this chemical.

A recent incident involving a herbicide called 'Hotshot' has also highlighted inadequate labelling. The health hazards which resulted in the hospitalisation of a bystander were not communicated on the APVMA label. These hazards would have been communicated on a GHS label. (Safe Work Australia 2016b, p. 1)

The APVMA scientifically assesses each application to make a decision to approve, register or refuse it. The APVMA uses a scientific, evidence-based approach and aligns its regulatory efforts with the risks associated with each chemical. Risks are considered in terms of both the likelihood of exposure and the potential effects of exposure. Part of the assessment is also reviewing certain information, known as the relevant particulars, intended to be printed on a product label.

Risk assessments are carried out in relation to chemistry, toxicology, residues, work health and safety, environment, animal safety and efficacy.

APVMA assessments consider:

- both chronic (long-term) and acute (short-term) effects
- physicochemical effects (such as flammability or corrosiveness)
- potential for exposure to a product or its residues during handling (including transport, storage and processing), use and after application, including disposal of product and containers
- workers likely to have long-term interaction with agvet products, such as spray contractors.

Risk management measures are placed on a product to reduce any identified human health risks to an acceptable level. These include engineering controls, safety directions, use restraints, scheduling recommendations and requirements for the use of personal protective equipment.

The APVMA has labelling requirements and instructions for use that include warnings and precautions to mitigate any risk. These statements have safe handling of the product and first aid requirements in the event of an accident.

A chemical product needs to meet the labelling criteria with the label containing adequate instructions relating to:

- the circumstances in which the product should be used

- how the product should be used
- the times when the product should be used
- the frequency of the use of the product
- the withholding period after the use of the product
- the re-entry period after the use of the product
- the disposal of the product when it is no longer required
- the disposal of containers of the product
- the safe handling of the product and first aid in the event of an accident caused by the handling of the product.

In addition to agvet chemical legislative requirements, agvet chemical products are also subject to other relevant regulatory requirements that support worker health and safety throughout the supply chain (Poisons Scheduling, the Australian Code for the Transport of Dangerous Goods by Road and Rail and requirements for product-specific safety data sheets that underpin workplace risk assessments).

Agvet chemical regulation is underpinned by usage controls, including compulsory training and accreditation requirements in many cases and supported by industry codes of practice that apply throughout the supply chain.

The APVMA is aware that Deloitte Touche Tohmatsu (Deloitte) was appointed by the Department of Agriculture and Water Resources to conduct a review of any duplication of effort and unnecessary costs in relation to agvet chemical products that arises from complying with both work health and safety legislation and agvet chemical legislation.

The APVMA will continue to work with Safe Work Australia to assist industry with determining which GHS hazard and precautionary statements (required for each hazardous chemical classification) are equivalent to, or substantially the same, as APVMA approved agvet chemical labelling statements to minimise duplication.

By way of clarification, the draft report references two examples that suggest the lack of GHS statements on agricultural chemical product labels leading to work health and safety incidents. The APVMA notes carbon disulphide has not been registered in Australia as a grain fumigant for since 2004 and if it were to be registered for those uses today, the APVMA would require flammability signal words. The second example which involves the herbicide Hotshot, where a bystander 500 metres from a spray activity contracted an allergic reaction, is not clear how this incident would have been avoided with the introduction of GHS hazard and precautionary statements.

4 ACCESS TO AGRICULTURAL AND VETERINARY CHEMICALS AND SCOPE FOR REFORM

How well does the regulatory framework for technologies and agvet chemicals perform? Are the institutional arrangements and regulatory objectives underpinning the OGTR and APVMA appropriate and up to date? What improvements could be made? (Information Request 6.1)

The draft report and APVMA submission outlines a number of areas of reform activities. The 2016-17 Federal Budget includes $7.3 million over four years to implement the APVMA's components of the Agricultural Competitiveness White Paper reforms.

This relates to further development and implementation of the work on lower regulatory approaches to registration, including fast-tracking assessments of low risk applications for product registration and making better use of international assessment and standards. The APVMA will utilise this funding to build the online systems to support this work, including a risk-profiling tool to support self-assessment of low risk applications. The funding also supports additional post registration compliance to monitor registration of products through these lower risk approaches.

The APVMA is currently looking at ways to reduce regulatory burden on industry when submitting applications for the registration of agvet chemicals. The goal is to develop new and more efficient registration processes, focussing initially on:

- application profiling and registration pathways
- international assessments
- technical guidance
- contestable assessment services
- crop groupings.

The APVMA is developing and introducing alternate and more efficient pathways over the next two years, supported by funding allocated through the Agricultural Competiveness White Paper.

4.1 Application profiling and registration pathways

The APVMA is seeking to ensure that regulatory effort and the regulatory burden imposed on those affected is always aligned with the risks associated with chemical use.

Different product types give rise to different risks and, as a result, the levels and types of assessment vary. Generally, lower risk products require reduced levels of assessment, currently achieved through the use of application categories that are graduated based on the level of risk. However even for those applications where the risks are well understood, some regulatory effort and consideration is given before that application can be finalised.

In order to align regulatory effort to the risks associated with the registration of agricultural and veterinary chemicals, the APVMA is looking at opportunities to reduce the regulatory burden for certain applications that meet relevant criteria. Initially, applications for active constituent approvals, product registrations and variations are included in the scope. At a later date, applications for permits and manufacturing licences may be incorporated into the review.

This is being achieved through firstly profiling applications to identify those types of applications where a lower level of regulatory intervention would be appropriate and secondly offering alternative pathways for registration and approval of these.

Two key initiatives have been implemented in the first quarter of 2016-17 namely:

- an expanded list of notifiable variations, for example:
    - address of a site of manufacture for an active constituent
    - name of any other registered products included as part of the instructions for use on a label
    - instructions for storage and disposal of containers or products
    - safety directions and first aid instructions appearing on a label of a 'similar product'
    - net contents of a veterinary chemical product within a recorded range
- online fast track-registration system – for holders re-packing their own products and registration according to standards for certain groups of products (eg dairy sanitisers).

The APVMA is actively involved with the work the Department of Agriculture and Water Resources is undertaking on a broader reform agenda for agvet chemical regulation.

5 CONCERNS ABOUT REGULATORY PROCESSES RELATING TO GM TECHNOLOGY

The APVMA is aware that industry have concerns around potential for duplication of assessment between APVMA and OGTR. Contrary to this belief, the APVMA uses any consideration by OGTR in our processes to ensure that assessments are not duplicated. The APVMA works closely with OGTR on affected products to align common requirements and ensure there are no repeated assessments. The APVMA would consider further areas for improvement if provided with specific examples about areas of duplication.

In regard to GM plant seed, the APVMA is aware of the Department of Agriculture and Water Resources reform discussions relating to possibly removing this from the scope of APVMA assessment; noting this is still being considered and has not been formally agreed at this stage.

For products such as veterinary vaccines, the APVMA would continue to seek expert advice from OGTR as part of agvet chemical registration activities, regardless of whether there are separate requirements under both agency frameworks.

GLOSSARY

Agvet chemical products	Agricultural and veterinary chemical products
Agvet Code	*Agricultural and Veterinary Chemicals Code*
APVMA	Australian Pesticides and Veterinary Medicines Authority
EU	European Union
GHS	Globally Harmonised System of Classification and Labelling
GM	Genetically modified
MAD	Mutually Acceptable Data
OECD	Organisation for Economic Co-operation and Development
OGTR	Office of the Gene Technology Regulator
PAA	Pre-application assistance
SWA	Safe Work Australia
VICH	Veterinary International Conference on Harmonization

ATTACHMENTS

Attachment A	*APVMA's Approach to the Use of International Data, Standards and Assessments – A guide for agricultural chemical products*
Attachment B	*APVMA's Approach to the Use of International Data, Standards and Assessments – A guide for agricultural veterinary products*