Australian Government

Australian Pesticides and Veterinary Medicines Authority

FEBRUARY 2016

Submission to the Productivity Commission inquiry into Regulation of Australian Agriculture

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) welcomes the opportunity to provide a submission to the Productivity Commission's *Inquiry into the Regulation of Australian Agriculture*.

The AVPMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemical products proposed for supply and use in Australia.

The APVMA evaluates the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected.

The APVMA recognises the importance of ensuring its approach to chemical registration is risk based and cost effective and is an approach that facilitates more timely introduction of innovative chemical products while maintaining confidence that chemicals are safe to use.

As an operational regulator, the APVMA does not have direct control over the legislative framework within which it operates. Nevertheless, the APVMA has identified a range of initiatives to reduce the burden on the regulated sector that can be applied without the need for legislative change. These initiatives include:

- better profiling of applications and the risks involved and establishing faster pathways to register products or make variations, including through on-line self-assessment, notifiable variations and compliance with standards
- increasing the use of assessments conducted by comparable regulators both domestically and internationally
- aligning technical guidelines and guidance material to those agreed internationally through recognised forums such as the OECD, VICH and CODEX, and
- seeking efficiencies in process through more contestable provision of assessment services and streamlining internal business processes to speed up the assessment of applications.

This submission provides a high level overview of the various initiatives and specifically addresses the second major area raised in the *Issues Paper* regarding the scope for Australian regulators of agvet chemicals to recognise the tests and standards developed by their overseas counterparts.

The APVMA will closely monitor our progress in implementing these improvements and work with industry to ensure the initiatives deliver real benefits to the regulated sector.

1 ROLES AND RESPONSIBILITIES OF THE APVMA

The APVMA has been the statutory authority responsible for the regulation of agvet chemicals since 1993. Over time, the scope of products regulated by the APVMA has grown due to advances in technology, increased numbers of generic products, changes to farming practices and a shift to products for the increasingly large companion animal sector. Despite these changes, the regulatory framework under which the APVMA operates largely requires the same approach to assessment and registration of products as it has for the last twenty years.

Before agvet chemical products can be legally sold, supplied or used in Australia, they must be evaluated and registered by the APVMA through the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS).

More than 11 000 pesticide and veterinary medicine products are currently registered in Australia, including products for treating crop and garden diseases and pests, and medicines for treating agricultural and companion animals.

The APVMA takes a systematic, scientific, evidence-based approach to decision making. We evaluate the safety and performance of chemicals intended for sale in Australia, to ensure that the health and safety of people, animals, crops and the environment are protected. Registered products must also not unduly jeopardise Australia's trade with other countries.

Our work supports primary industries—agriculture, forestry, horticulture and aquaculture—by allowing the supply of safe, effective animal health and crop protection products. Our work also supports consumers, by ensuring that household and garden pesticides, pool chemicals and pet products are safe to use.

Our role extends beyond registration of pesticides and veterinary medicines to encompass a range of activities aimed at protecting Australians and ensuring that products are safe. We license and audit veterinary manufacturers to ensure adherence to APVMA-prescribed manufacturing standards. We also monitor the market for compliance, and review and take regulatory action on registered pesticides and veterinary medicines when concerns are identified.

The APVMA is a portfolio agency of the Minister for Agriculture and Water Resources.

1.1 Legislative framework

The APVMA is established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Administration Act). The Administration Act sets out the role of the APVMA to undertake the responsibilities conferred on it by the states and territories under the NRS.

Functions and powers are conferred on the APVMA by the Administration Act, the *Agricultural and Veterinary Chemicals Code Act 1994* (Agvet Code Act) and the *Agricultural and Veterinary Chemicals Code* (Agvet Code). The Agvet Code provides for the evaluation, registration and control of agricultural and veterinary chemical products and related matters.

The APVMA is a corporate Commonwealth entity under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act).

1.2 Functions and Powers

The APVMA is responsible for assessing and registering agricultural and veterinary chemical products proposed for supply and use in Australia, and for controlling them up to the point of retail sale. The states and territories are responsible for regulating and managing the use of agricultural and veterinary chemical products once they are sold.

The key functions of the APVMA, which are set out in section 7 of the Administration Act, are to:

- assess the suitability for sale in Australia of active constituents for proposed or existing chemical products, registered chemical products and labels for containers for chemical products
- ensure that approvals and registrations for active constituents for chemical products, chemical products and labels for containers for chemical products comply with the Agvet Code, and the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations)
- provide information to the Australian Government and its agencies, and the states and territories, about approved active constituents for proposed or existing chemical products, registered chemical products and approved labels for such products, and cooperate with the Australian Government and its agencies on matters relating to the management and control of chemical products
- collect and publish relevant information and statistics on approvals and registrations granted and permits and licences issued under the Agvet Code
- with the Australian Government and its agencies, and the states and participating territories, facilitate a consistent approach to the assessment and control of agvet chemicals
- exchange information relating to chemical products and their use with overseas and international bodies that have similar functions to those of the APVMA, and
- report to or advise the Minister on matters relating to the performance of the APVMA's functions.

2 APVMA INITIATIVES TO SUPPORT LOWER REGULATORY APPROACHES TO REGISTRATION

2.1 Application profiling and registration pathways

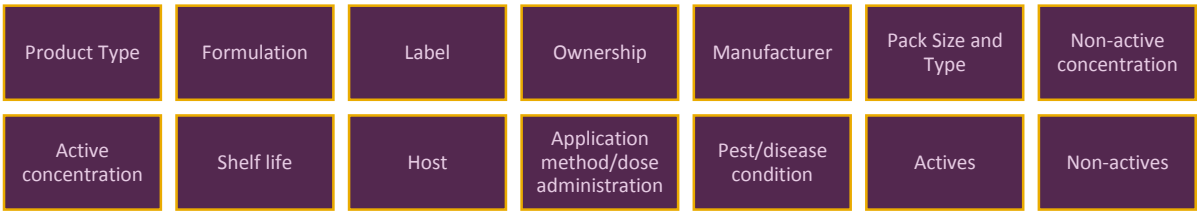
The APVMA is undertaking a range of activities to better align the regulatory effort relating to the registration of agvet chemicals to the risks involved, thereby reducing the regulatory burden on applicants for certain types of applications. There are a range of broad and interconnected areas of work planned to achieve this goal:

1. development of an application profiling tool
2. providing on-line self-registration system for lower regulatory risk products
3. expanded list of variations to registrations that can be notified to the APVMA
4. applying standards and monographs for low risk products
5. using crop groupings to support broader product registration without needing to submit certain data.

2.1.1 Application profiling tool

The APVMA, with the assistance of the University of Melbourne, has profiled the various applications it receives and established criteria for where a lesser degree of regulatory intervention may be needed. In broad terms, the criteria revolve around the risks involved with the application itself, how much information the APVMA already has about a particular product and whether there are alternative sources to assist the APVMA to be satisfied about the statutory criteria for agvet chemicals. The key elements of applications that determine the level of regulatory intervention needed to complete the assessment (Figure 1).

Figure 1: Elements that make up an application



These elements have been analysed to identify a range of combinations which result in products being of ‘low regulatory risk’ that could be dealt with by an on-line self-assessment system. These elements combine to create the framework which articulates the ‘risk appetite’ of the APVMA and underpins the development of the application profiling tool to determine if a product application is suitable for self-assessment or the development of standards to streamline the registration process.

2.1.2 On-line self-assessment

The APVMA is currently developing the capability for on-line self-assessment for those approval, registration and variation applications deemed to be of low regulatory concern. This will result in immediate approvals and a reduction in the number of assessments (in the traditional sense) being undertaken by the APVMA, providing greater capacity to focus on applications requiring more detailed consideration.

It is expected that this system will be rolled out initially as a 'pilot' for some of the 'simpler' application types with the capability for expansion over time as, and when, resources allow. The initial phase is anticipated to cover identical product registrations (repacks) where both products are held by the same registrant with consideration also being given to registrations based on APVMA standards.

2.1.3 Expanded list of notifiable variations

The APVMA will establish a mechanism to expand the list of notifiable variations which will allow for certain types of product, formulation and label changes where the changes are considered low risk, to be assessed through the self-assessment pathway rather than through a full application process as is currently the case.

As a first step, the APVMA is looking to put in place a notification mechanism for:

- A variation to the identity of any other registered products included as part of the instructions for use on the label (provided the product has the same APVMA approval number).
- A variation to the label to meet the requirements of the labelling code including changes to storage and disposal of containers or products, resistance management statements and mode of action statements.
- A variation to the label to reflect decisions of other regulators in respect of poisons scheduling and first aid instructions
- A variation of the net contents of a veterinary chemical product within the range recorded in the product register provided that the variation will not affect the instructions for use or disposal. This is currently only available for agricultural products.

It is intended that other notifiable variations will be developed over time.

2.1.4 Increased use of standards for low risk products

The APVMA will increase the use of standards to define the conditions under which we are satisfied of the relevant statutory criteria for safety, efficacy and trade in relation to a particular group of products. Products that meet the requirements of the standard could achieve registration through the self-assessment process rather than through the application and assessment process currently utilised for these types of applications.

We will be working closely with industry to identify and prioritise the development of standards. We will also be developing guidance material for industry about how to develop a standard.

The APVMA is trialling this approach with the development of a standard for dairy sanitisers. A guidance document for industry about how to develop standards for low risk products is being developed alongside this work. Other products currently identified for consideration are pool chemicals, anti-fouling paints and certain home garden or household products.

2.1.5 Crop groupings

The APVMA is contributing to the government's initiative for *Improved access to agricultural and veterinary chemicals* through the establishment of crop groupings lists. This project will establish an official crop grouping list aimed at reducing the regulatory burden for producers by giving greater access to more uses of agricultural chemicals.

By grouping crops together the APVMA can maximise the use of data generated in certain crops through extrapolation to a group of related crops, with little or no additional data needed where use practices are the same or similar. This will reduce the cost of bringing chemicals to market and achieve greater access to chemicals.

The APVMA will look at applying this approach to both minor use permits and product registration. Consideration could also be given to taking a similar approach to minor species (for animal related permits) in the longer term.

3 OVERSEAS INFORMATION AND ASSESSMENTS OF OTHER NATIONAL AND INTERNATIONAL REGULATORS

The government's *Industry, Innovation and Competitiveness Agenda* under which the guiding principle is that if a product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so. In line with this, the APVMA has released a policy statement (refer Attachment A) outlining that:

- APVMA will accept data generated internationally if it is relevant to Australian requirements. The only exceptions are likely to involve different environmental conditions, farming practices and situations where trade is a factor and, potentially, where Australia has significantly different dietary exposures.
- APVMA will reference international standards and guidelines as part of our technical assessments except where there are Australia specific requirements. The main standards are those of the OECD, CODEX and VICH.
- APVMA will accept hazard assessments done by overseas regulators where they are directly relevant and comparable to Australian requirements and the assessment and data that underpins it are provided.
- APVMA will consider overseas decisions as part of the risk assessment to make a decision to register a product in Australia where factors such as the hazards, uses, dose rate and exposure are exactly the same as in Australia.

Additional guidance material is currently being developed, in consultation with industry, setting out in more detail what assessments will be accepted by the APVMA from which regulators for both agricultural and veterinary products.

The APVMA also seeks to leverage any assessments that have been undertaken by other domestic regulators that may be relevant to assessment of a product registration by the APVMA, for example from the Therapeutic Goods Administration and the Office of Gene Technology Regulator.

3.1 Technical guidance

APVMA is currently aligning technical guidance material with relevant international guidance where this is available. In principle, the APVMA will reference the relevant international guidance material unless there is clear justification for imposing any Australian-only requirements.

In conducting this work, the APVMA will develop and publish on the web site a list of already adopted international technical guidance material and standards and review the 90 current APVMA data guidelines for potential to align with comparable international technical guidance material. The APVMA is also working to incorporate OECD Data Point Numbering into all relevant pesticide data guidelines. This work will support greater use of assessments made by other regulators through use of harmonised data guidelines.

The initial phase is focusing on publishing the list of international data guidelines already adopted by the APVMA with phase two focused on prioritising the data guidelines to be reviewed and developed in consultation with industry. The revised data guidelines from phase two will be rolled out as material is developed.

4 INCREASED EFFICIENCY

There are a range of initiatives the APVMA is pursuing to make its processes more efficient, including through:

- outsourcing certain assessments, and
- undertaking regular business process improvement reviews, based on an understanding of user needs.

4.1 Contestable assessment services

The APVMA supports the contestable provision of assessment services.

The APVMA already outsources the majority of efficacy assessments, 50 per cent of environment assessments and 25 per cent of health assessments. Savings in terms of budget and time for delivery of an assessment have been demonstrated and the APVMA plans to enhance this system further.

The APVMA is working on a pilot for certain efficacy and target crop/animal safety data packages to be assessed prior to an application being submitted. The aim of the pilot is to ascertain whether the proposed change to current processes will increase the efficiency of application processing while still allowing the APVMA to make quality science-based decisions.

The pilot will provide the APVMA with information about whether having data assessments conducted externally and submitted to the APVMA:

- can introduce efficiencies in application processing
- is acceptable to industry
- is acceptable to the external scientific reviewers
- should be implemented for efficacy and target crop/animal safety assessments after the pilot period is over; and/or
- should be implemented across other assessment areas.

The pilot will commence on 1 July 2016.

4.2 Business process improvement

The APVMA is committed to improving its efficiency in handling applications. The APVMA recognises the need to provide certainty for companies bringing chemicals to market by completing assessments in accordance with agreed timeframes.

A major business process improvement project is underway to:

- identify and address blockages to efficient workflow for processing applications from the time they are submitted to when they are finalised, and
- consolidate and integrate IT infrastructure to support APVMA staff in handling applications and dealing with our clients.

Initial areas of focus where changes are currently being implemented include automating the process for requesting specialist advice, simplifying the assessment form for non-technical (or minor) applications, rationalising the legacy information technology systems used by evaluators and scientific assessment areas, improving work flow systems to enable better tracking of applications and establishing a dedicated role to proactively manage applications where timeframes are not being met.

The APVMA is also looking at improving the useability of our web and on-line services for our clients, based on market research of client experience and needs and is restructuring our case management system to provide a better point of contact for applicants.

GLOSSARY

Administration Act	*Agricultural and Veterinary Chemicals (Administration) Act 1992*
Agvet chemical products	Agricultural and veterinary chemical products
Agvet Code	*Agricultural and Veterinary Chemicals Code*
Agvet Code Act	*Agricultural and Veterinary Chemicals Code Act 1994*
Agvet Code	*Agricultural and Veterinary Chemicals Code Regulations 1995*
APVMA	Australian Pesticides and Veterinary Medicines Authority's
CODEX	Codex Alimentarius or "Food Code"
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
OECD	Organisation for Economic Co-operation and Development
PGPA Act	*Public Governance, Performance and Accountability Act 2013*
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

ATTACHMENTS

Attachment A	*APVMA's Approach to the Use of International Data, Assessments, Standards and Decisions – Consultation Draft*

Australian Government

Australian Pesticides and Veterinary Medicines Authority

APRIL 2015

APVMA's Approach to the Use of International Data, Assessments, Standards and Decisions

CONSULTATION DRAFT

ISSN XXXXXX (electronic)
ISBN XXXXXX (electronic)

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1 EXECUTIVE SUMMARY

The Government's Industry Innovation and Competitiveness Agenda has set the guiding principle *that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is a good reason to do so.* All Commonwealth regulatory standards and risk assessment processes will be reviewed against this principle.

The APVMA has developed this document to articulate how international data, standards and assessments can be better utilised as part of the risk assessment processes that it is required to undertake as part of the approval of an active constituent, registration of a product, approval of a label or the reconsideration (review) of an existing agvet chemical.

These criteria provide general guidance, however the applicant may seek detailed advice relating to specific products and data requirements.

1.1 Use of International data

Any data generated according to the following international guidelines will be accepted by the APVMA if relevant to a specific product and application for registration:

- OECD test guidelines
- VICH guidelines
- FAO and WHO guidelines for data generation
- Test guidelines published by the USEPA, Canadian PMRA, EFSA for pesticide products, the EU Biocidal Products Regulations, the EMA for veterinary medicine products and USFDA

In addition, information on the APVMA website at http://apvma.gov.au/registrations-and-permits/data-guidelines specify other data guidelines that may be acceptable according to study and data type.

1.2 Use of Assessments prepared by overseas regulators and international organisations

Any assessments from the following sources will be accepted by the APVMA if relevant to a specific product and application, and provided the data supporting that assessment is made available to the APVMA:

- Hazard assessments published by JMPR, JMPS and JECFA (toxicology, residues assessments and chemical specifications)
- Unredacted hazard assessments conducted by EU Members states, EFSA, EMA USEPA, PMRA Canada, NZ EPA or NZ MPI, EMA, USFDA/CVM and FAO or WHO, with supporting data.
- Risk assessments conducted by FAO and WHO expert committees for international standard setting, for example JMPR and JECFA assessments.

- Risk assessments for products where the exposure assessment is comparable to that conducted by another regulator, for example home garden products, personal insect repellents, and other products that do not require an assessment of environmental risks or food safety risks.

The assessments can be used for approvals and registration, as well as to support any chemical review activity.

1.3 Use of International Standards

The APVMA uses the following standards on a routine basis:

- FAO standards and specifications for pesticide active constituents and associated products
- EP, BP and US P pharmacopeial standards for active and non-active constituents
- Internationally developed and endorsed standard methodologies for exposure assessment such as those used for worker safety and consumer safety.

1.4 Use of International Decisions

The APVMA will not accept the decisions of another regulator. However, data, assessments and standards that may contribute to a particular decision, will be utilised.

The APVMA will not automatically accept, without due consideration:

- Internationally generated MRLs.
- Internationally generated health-based guidance values such as acceptable daily intake (ADI) values and acute reference dose (ARfD) values.
- Exposure data generated from modelling.
- Risk mitigation measures of overseas regulators.
- Regulatory decisions of overseas regulators.
- Standards and guidelines that require specific consideration of Australian legislative criteria, environmental factors and different use patterns

Guidance will be provided to applicants that may wish to submit overseas assessments together with their application for registration in Australia or to support a chemical review. The APVMA encourages applicants to meet with the APVMA to discuss a new application and the use of international assessments and standards.

2 BACKGROUND

In the Australian Government's *Industry Innovation and Competitiveness Agenda 2014*, principles have been established to reduce the burden of regulation in various sectors. One of the principles adopted by the Government is *that if a system, service or product has been approved under a trusted international standard or risk assessment, Australian regulators should not impose any additional requirements unless it can be demonstrated that there is good reason to do so*. All Commonwealth Government regulatory standards and risk assessment processes will be reviewed against this principle.

3 INTRODUCTION

The APVMA is committed to minimising regulatory effort required to register agricultural and veterinary (agvet) products in Australia and to conduct reviews of existing chemicals by adopting international data guidelines and utilising overseas assessment materials and/or standards, unless there is a valid reason not to do so. The APVMA is also committed to reducing the amount of effort on the part of companies wishing to bring products to the Australian market, particularly those products identified as requiring low regulatory intervention.

By increasing the use of international assessments and standards, the APVMA can facilitate more timely access by Australian consumers to safe and effective agvet chemicals. It will also streamline the Australian regulatory system by harmonising requirements, to the extent possible, with comparable overseas regulators while maintaining the quality of regulatory decisions by the APVMA.

However, there are unique differences with the Australian regulatory system that must be taken into account. The National Registration Scheme is a partnership between the federal Department of Agriculture and state and territory regulators, be they agriculture, health or environment. Roles and responsibilities for monitoring and validation of the APVMA's approvals and registrations lie jointly with the states and territories, as well as with the food regulator, Food Standards Australia New Zealand (FSANZ). This establishes the Australian regulatory environment and provides a point of comparison (as well as understanding of differences) between the APVMA and other like overseas regulators and the national regulatory environment within which they operate.

Australia's natural environment is unique in a number of ways. Australia possesses a range of reserves, national parks, threatened species and heritage areas that must be protected. Pest and disease pressures in Australia can be quite different to those in other countries. For example, plagues of locusts and mice and other pests are not prevalent in the European union (EU) or North America and require specific chemical access and control measures as well as environmental considerations. Australia's climate and soils means that farming systems are different to those that exist overseas, therefore different use practices of chemicals must be accounted for as part of the decision-making process.

Australia is one of only two countries (the other is New Zealand) where the impact of agvet chemicals on international trade is considered by their respective regulatory agencies. This is due to the longstanding history of primary production and food exports of both nations. The interplay between this Australian requirement and international assessments and guidelines must be carefully considered, alongside the expectations of major export industries and their activities, while still maintaining a primary focus on health and environmental considerations.

This document explains the APVMA's approach to the use of:

- International data
- International risk assessments
- International guidelines and standards
- International decisions

4 EXISTING INTERNATIONAL AGREEMENTS

The Australian government is a signatory to a number of international conventions and agreements, through the Organisation for Economic Cooperation and Development (OECD), the Codex Alimentarius Commission (Codex) and the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

These agreements promote harmonisation of data guidelines, scientific assessment methods and international standards. They also promote the sharing of assessments between member governments. Elements of these agreements are also prescribed in APVMA legislation (the Agvet Codes), such as international standards that the APVMA will accept for an active constituent in a chemical product

The APVMA is an active participant in these forums and regularly updates its data requirements, standards and guidelines to align with international developments. The focus of these organisations is briefly outlined below.

4.1 OECD Vision and a global approach to the regulation of agricultural pesticides

Australia is aligned with other OECD partners in harmonising the regulatory system for agricultural pesticides by using or sharing risk assessments to make independent regulatory decisions at a national level. This involves global coordination of data packages by chemical manufacturers to maximise work-sharing opportunities, the development of harmonised data requirements that are accepted by all OECD governments, and collaboration to ensure that outcomes afford a high level of protection to human health and the environment.

4.2 The Codex Alimentarius Commission (CAC or Codex)

The Codex Alimentarius Commission envisages a world afforded the highest attainable level of consumer protection including food safety and quality. The Commission develops internationally-agreed standards such as Maximum Residue Limits (MRLs) and health-based guidance values for use in domestic regulation and international trade in food that are based on scientific principles and that fulfil the objectives of consumer health protection and fair practices of food trade. The main principles of Codex are:

- Decision making should be based on sound scientific evidence using principles and policies established by expert UN technical bodies, such as the Joint WHO/FAO Meeting on Pesticide Residues (JMPR).
- Sound regulatory frameworks are promoted to ensure that the safety of foods entering international trade conform to national requirements.
- International harmonisation is to be based on Codex standards, guidelines and recommendations.

4.3 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)

This body establishes and implements harmonised technical requirements for the registration of veterinary medicinal products in the VICH regions, which meet high quality, safety and efficacy standards and minimise the use of test animals and costs of product development.

5 INTERNATIONAL DATA

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 only 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.

6 OVERSEAS AND INTERNATIONAL RISK ASSESSMENTS

Definitions:

- **Hazard assessment**: an assessment of the data related to the inherent toxicity of an active constituent and/or formulated product
- **Exposure assessment**: an assessment of the likely exposure of humans and environmental organisms that takes into account how the chemical product is to be used, the type and formulation of the product, and the crops or animals to be treated
- **Chemical Risk Assessment = Hazard assessment + Exposure assessment**

Risk assessments comprise a hazard assessment and an exposure assessment.

Hazard assessments look at the intrinsic properties of the active constituent and/or product itself (all the possible adverse effects it may cause), without any knowledge or understanding of the use of or exposure to the formulated product. The exposure assessment is based on how the formulated product is used and impacts of the use on worker safety, residues in food, and impacts on the environment as well as non-target species. Exposure assessments take into account local or national differences based on population composition, dietary exposure, agronomic practices or environmental conditions.

The APVMA has accepted hazard assessments from trusted overseas regulators in the past and will continue to do so. Highly regarded international hazard assessments on human toxicology and chemical residues in food are published by expert technical committees of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) of the United Nations, namely the JMPR and the Joint Expert Committee on Food Additives and Veterinary Drug Residues (JECFA). These assessments are based on the Codex guiding principles.

The APVMA may accept international exposure assessments where the label and use instructions are similar to those proposed for registration in Australia. For example, house and garden products such as fly sprays, pesticides used in the garden, cat and dog flea treatments and personal insect repellents. It is advised to check with the APVMA prior to making an application to confirm whether such international assessments will be accepted.

Common methodologies such as surrogate databases (e.g. AHED/PHED[1]; USEPA re-entry calculators) or modelling (e.g. EUROPOEM, USEPA Re-entry calculator[2]) are used for worker safety assessments in the US and EU and are also used in Australia.

In all cases, the APVMA will require the applicant to submit a full data package and provide unredacted assessments to support the application. In addition, the applicant should provide any adverse experience reports from the country of registration associated with the product and any relevant new information that became available after the international assessment report was completed.

[1] Agricultural/Pesticide Handlers Exposure Database;
[2] Pesticide Operator Exposure Model

The APVMA will conduct a critical assessment of any reports provided from overseas regulators to account for any differences between the Australian and other national regulatory systems and determine the degree of similarity between the overseas registered product and that proposed for registration in Australia.

The applicant is responsible for sourcing and providing any assessment reports from overseas regulators that they wish to include with their application for registration.

6.1 Global Joint Reviews

The APVMA, through the OECD *Vision of a global approach to the regulation of agricultural pesticides*, is involved in the global joint review program with the US, Canada and some EU member states, as well as non-OECD observer members such as Brazil and China. In this program, a chemical manufacturer provides one data package to all regulators at one time and the assessment work is split amongst the review partners. In this way assessments are shared and harmonised hazard assessments are produced. The manufacturer then receives registration in a number of countries within a specified and predictable time period. This program only applies to approval of new active constituents in pesticide products.

7 INTERNATIONAL STANDARDS AND GUIDELINES

Definitions:

- **Standards:** the term 'standards' can mean a number of things. It may refer to standards for data generation, such as Good Laboratory Practice, or standards for active constituents, or health standards, Maximum Residue Limits (MRLs) or standard methodologies for assessment, environmental standards such as pesticide levels in ground water.

- **Guidelines:** the term 'guideline' is very broad and is taken to mean any document that provides guidance of some form. For example there are guidelines on how to make an application, guidelines on legislative processes. A guideline may provide guidance for study design, data generation and interpretation. Guidelines are not requirements, however the two terms are often confused and used interchangeably.

The APVMA is actively involved in international standard setting and adopts, where appropriate, international standards. This is namely through government participation in a number of international conventions and committees.

Standards may be used for data generation, which form the basis of regulatory guidelines and requirements. Standards for active constituents such as pharmacopoeial standards or FAO specifications are accepted internationally and prescribed in APVMA legislation. The APVMA will accept data generated according to OECD, VICH, or Codex guidelines and adopt guidance developed by these organisations. The APVMA will accept data generated according to US, Canada and EU guidelines, as these are, to a large extent, aligned or harmonised with OECD, VICH or Codex.

7.1 When international standards may not be used

There are some circumstances where the APVMA will not automatically adopt another countries or international standard, for example in relation to MRLs or where considerations relating to our environment or farming systems must be taken into account in decision making.

The APVMA will clearly identify, on a case-by-case basis, why a particular standard or guideline will not be accepted. These reasons will be included in an assessment document as well as being published on the APVMA website.

Applicants are advised to check with the APVMA that a relevant international standard or guideline will be accepted prior to proceeding with their application.

Where the APVMA is yet to make a determination on a particular standard or guideline, it will make its best endeavours to provide advice in a timely manner as to the likely acceptance of that standard or guideline.

7.2 Maximum Residue Limits (MRLs)

Definition:

- **Maximum Residue Limit (MRL):** the maximum concentration of a residue resulting from the registered use of an agricultural or veterinary chemical which is legally permitted or recognised as acceptable to be present in or on a food, agricultural commodity or animal feed.

MRLs are legal standards for food and are country specific. They correspond to registered label directions for use of a chemical product in a food producing situation for pest and disease control under Australian conditions. Part of the exposure assessment for setting MRLs involves an estimate of exposure of the chemical residues in food to children and the general population, which is based on residues data, Australian consumption patterns and data collected for Australian consumers. Directions for use are not the same in other countries and the exposure assessment is based on national consumption patterns making MRLs different internationally.

MRLs are used by state and territory regulators as a measure of whether a chemical product is being used correctly in accordance with label directions. If residues tested in any product are below the MRL, the food can be legally sold and is safe for consumers.

The APVMA will not automatically adopt MRLs from overseas countries. However, the underlying residues data that support the overseas MRLs can be useful, particularly in cases where it supplements Australian generated data. This approach assists in reducing the amount of field trial work that needs to be conducted under Australian conditions of use of any chemical product.

8 OVERSEAS REGULATORY DECISIONS

Definition

- **Decision:** A regulatory decision is prescribed by the relevant legislation of the regulatory agency or authority. It comprises various forms of approval or authorisation (active constituent, formulated product, label instructions, registration), conditions of registration which may include any reporting or monitoring provisions, safety directions and restrictions, or compliance provisions. Conditions of registration and approval relate to standards (new or existing) that are put in place at the time of approval and registration.

The APVMA will not accept a decision from an overseas regulator as the sole justification for registering or cancelling a product or active constituent approval because risk management around use of a product may incorporate unique national legislative framework, regulatory environment and government policy elements. Nevertheless, the existence of an international decision may support an application, provided appropriate data and scientific argument demonstrate that the factors underpinning that decision are comparable and relevant to Australian use situations and meet Australian requirements.

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 by overseas regulators that may neither be appropriate nor relevant in Australia, or be able to be automatically applied to uses in Australia. For example, if conditions were placed on herbicides used in the EU, these may 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 of 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.

In summary, decisions of one regulator cannot be adopted or accepted, without considerable knowledge of the legislative basis, post-market compliance and surveillance programs and reporting requirements of other like

regulators. 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. It is important to note that the APVMA reserves its right to request information or data to adequately assess the quality, safety and efficacy of any agvet product.

8.1 Proprietary Information, Confidential Commercial Information and Data Protection or Exclusivity

Australia is a signatory to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). The TRIPS Agreement sets out the minimum requirements for intellectual property protection for WTO Member states, including for protection of secret, commercially valuable information. Australia complies with the TRIPS Agreement.

Data generated in overseas countries (international data) that is provided to the APVMA in the course of assessing applications will be handled by the APVMA in accordance with Australian law. The APVMA's legislation contains data protection provisions which protect certain data for defined time-periods, and also places restrictions on the use and disclosure by the APVMA of commercially confidential information.

When an applicant requests consideration of an overseas or international assessment, the data supporting the assessment must be provided for the applicant to gain (or retain) commercial value of that data and to prove proprietary ownership of the data. This is a requirement that applies across all OECD member governments.

9 SUMMARY

In summary, the APVMA will accept:

- Data generated internationally according to OECD, VICH, USEPA, EU, FAO and WHO guidelines for specific studies to support assessments.
- Unredacted hazard assessments conducted by EU Members states, EFSA, EMA USEPA, PMRA Canada, NZ EPA or NZ MPI, EMA, FAO or WHO, with supporting data.
- Risk assessments for products where the exposure assessment is comparable to that conducted by another regulator, for example home garden products and personal insect repellents, possibly other products that do not require an assessment of environmental risks or food safety risks.
- International standards for active constituents such as FAO standards and pharmacopeial standards
- Internationally developed and endorsed standard methodologies for exposure assessment such as those used for worker safety and consumer safety.

The APVMA will not automatically accept, without due consideration:

- Internationally generated MRLs.
- Internationally generated health-based guidance values such as acceptable daily intake (ADI) values and acute reference dose (ARfD) values.
- Exposure data generated from modelling.
- Risk mitigation measures of overseas regulators.
- Regulatory decisions of overseas regulators.
- Standards and guidelines that require specific consideration of Australian legislative criteria, environmental factors and different use patterns

The APVMA will provide regular guidance to applicants that may wish to provide overseas assessments together with their application for registration in Australia. The APVMA encourages applicants to meet with the APVMA to discuss a new application and the use of international assessments and standards.