Australian Government

Australian Pesticides and Veterinary Medicines Authority

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

CONSULTATION DRAFT

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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 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.