



**Australian Government**  

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**Australian Pesticides and  
Veterinary Medicines Authority**



## **International engagement strategy**

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## Foreword

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates the supply of safe and effective agricultural and veterinary (agvet) chemicals in Australia. Robust risk assessment methods are used to scientifically evaluate new and existing agricultural chemicals and veterinary medicines. Through efficient and effective regulation, we ensure the appropriate protections for human health and safety, animals and the environment, while supporting international trade.

The APVMA international engagement strategy sets out the APVMA's approach to enhancing existing and building new global partnerships with agvet chemical regulators, and scientific expert groups to achieve and support whole-of-government, legislative and business objectives.

As a relatively small market for agvet chemicals, effective partnerships with other regulators provide the best opportunity for safe and effective chemicals to be available in Australia when they are needed. They also provide opportunities to enhance the capability and skills of APVMA staff through participation in international activities and sharing knowledge.

Australia operates a well-regarded chemical registration system and has potential to contribute to the capability and capacity of other regulators in the region – something that is important given the increasing international trade in agvet chemicals and the number of trade agreements with regional nations. There is ongoing recognition of the quality of Australian assessments, with regulated entities seeking to share the Australian evaluation with other key regulators in support of registration.

The APVMA, already participates in, and often leads, a variety of international initiatives. This strategy outlines how the APVMA will build on that experience to ensure it is well positioned to take advantage of the opportunities presented by better international cooperation and alignment.

The APVMA's international engagement strategy establishes our priorities for 2022–26, supports the strategies in the corporate plan and the principles in the Regulator Performance Guide.

## Introduction

This strategy describes how the APVMA will enhance its international connections to fulfil its role of protecting the health and safety of people, animals, the environment, trade and agricultural and livestock industries, and ensuring the availability of effective products, through regulation of pesticides and veterinary medicines.

The APVMA engages in a range of international activities related to regulation and risk analysis of agvet chemicals. Global cooperative activities, such as global joint reviews of pesticides and veterinary medicines and the use of other national assessments to aid in decision-making in relation to approvals and registrations, build our understanding the regulatory practices of our key partner regulators and work for continual development of, and alignment with, international best practice.

Recognition of other national processes for good manufacturing practice audits, and the facilitation of export of agvet chemicals through the provision of export certificates are other benefits of international engagement.

Regional engagement and training on compliance, risk assessment and registration processes and engaging in data sharing, assists in promoting international best practice throughout the region. Regular communication with regulatory counterparts in other countries allows greater information sharing, an enhancement of scientific skills and the ability to better predict emerging issues.

The APVMA participates in international expert committees, conferences and working groups. We take a leadership role in the development of international best-practice in relation to agvet chemical risk assessment and regulation. We promote the use of evidence-informed decision making and a risk-based approach to the management of agvet chemicals, and the development of international standards for the national interest.

## Strategic initiatives

For the period 2022–26, the APVMA has 3 key focus areas for its international engagement efforts. We seek to develop and enhance our:

1. collaboration with international regulators, including to share information, identify trends and solve regulatory issues in both pre and post market settings
2. ability to influence international risk-based approaches and best practice, and contribute to the development of relevant international standards and guidelines
3. efficient assessment processes and reduced regulatory burden, by participating in global work sharing arrangements and using international or overseas assessments.

By committing to these focus areas, we will build APVMA's capability in risk analysis, contributing to the continued effective operation of the National Registration Scheme. The APVMA remains confident our contribution is of value for Australia and its farming community, APVMA staff, and our international colleagues in agvet chemical regulation.

### **Collaboration with international regulators, including to share information, identify trends and solve regulatory issues in both pre and post market settings**

The APVMA is committed to strengthening effective relationships with other national agvet chemical regulators. Sharing expertise, information and intelligence is critical to ensure our regulatory framework is modern and consistent with global best practice. We also have a role in supporting the development of regulatory capability in our region.

When we have trusted relationships with other regulators, we can be more efficient and reduce regulatory burden on industry, for example by increasing the use of global joint reviews, and recognition of manufacturing licensing schemes and audit arrangements. We are also able to support other Australian Government work, for example, in biosecurity and management of pest and disease incursions.

Sharing intelligence is vital to ensuring the protection Australia's trade and the health and safety of people, animals and the environment. International regulatory networks allow us to identify post-market issues and improve our compliance capabilities, for example by contributing to the fight against illegal international trade in counterfeit chemicals.

The quality of our relationships with international regulators will underpin our success in these areas.

The APVMA has active working relationships with many overseas regulators as well as being strongly connected to other regulators through our work at Organisation for Economic Co-operation and Development (OECD), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), Joint Meeting on Pesticide Residues (JMPR), the Codex Alimentarius Commission (CODEX) and other international fora. We will continue to build these relationships to our mutual benefit and identify gaps where greater communication and collaboration is needed.

In addition to formal and informal networks and fora, the APVMA has several Memorandums of Understanding with regulators in other countries which define our approach to sharing information between countries. We will continue to develop opportunities for further formal relationships with overseas counterparts.

## **Ability to influence international risk-based approaches and best practice, and contribute to the development of relevant international standards and guidelines**

The APVMA is actively involved in the development of international best practise in risk-based regulatory assessment of agvet chemicals and international standard setting. We adopt international standards whenever appropriate. This is facilitated through participation in international conventions, expert committees and agreements, such as OECD, WHO, CODEX, the Food and Agriculture Organization (FAO) and VICH.

The importance of trade and access to export markets for Australian agricultural producers means that international factors as well as domestic factors are critical in considering the future influences on the management of agvet chemicals in Australia. As such, it is essential that we are involved in these conversations and decisions at the international level.

Many of our people are acknowledged internationally for their expertise and are regularly called upon to take leadership roles or participate in international fora. We are involved in government-only fora, combined government-industry fora and some staff attend in an individual capacity as subject matter experts.

In addition to being directly involved in international expert meetings, the APVMA supports international work of other Australian Government agencies by providing relevant expertise, for example, in Australia's contributions to international chemical conventions.

Preparation for and attendance at international meetings can be resource intensive, however by prioritising our engagement, the APVMA can ensure our contributions are valuable and warranted. Hybrid and virtual conferences throughout the COVID-19 pandemic have provided positive lessons in virtual participation in international fora, and we will continue to take advantage of this meeting format whenever appropriate.

## **Efficient assessment processes and reduced regulatory burden, by using international or overseas assessments and participating in global work sharing arrangements**

By leveraging the trusted relationships, knowledge and expertise gained through our activities under the previous two focus areas, the APVMA is able to reduce duplication of effort by increasing the use of other national and international assessments and through participation in work-sharing arrangements.

### **Participation in global work sharing and joint reviews**

The APVMA collaborates internationally to assess specific applications through global joint reviews. This is where an application for approval or registration is made simultaneously to the APVMA and one or more overseas regulatory authority. Each agency takes responsibility for part of the assessment (for example, human health or chemistry and manufacture), and shares their assessment with the other agencies for peer review.

Although each agency makes its own national decision based on its legislative framework, work-sharing between regulatory authorities offers opportunities to make more efficient and effective use of the specialist and expert resources needed to evaluate the data supporting each risk area.

International work-sharing and global joint review arrangements are established on a case-by-case basis, with the agreement of the product sponsor/registrant.

Work-sharing of applications simultaneously made to several countries takes into account additional local information or data guidelines, for example local environmental assessment or efficacy assessments.

Increased use of international standards relating to manufacturing licensing arrangements will also benefit Australian veterinary manufacturers.

### **Using international and other national assessments**

Where a product or active constituent has already been assessed outside Australia, the APVMA can use relevant assessments from trusted overseas regulators and international bodies to support its own decision making processes. While the APVMA must make decisions based on Australian legislative requirements, when overseas assessments are available, APVMA officers will use these to the extent possible.

By increasing the use of these assessments, the APVMA can facilitate more timely access to safe and effective agvet chemicals by Australian users, while reducing regulatory burden on applicants.

To recognise that the use of existing high-quality assessments can reduce the APVMA's assessment workload while maintaining the quality and independence of our regulatory decisions, the APVMA is committed to passing time savings on to applicants whenever possible and will negotiate provision of formal cost and time savings through the next cost recovery implementation statement.