



**Australian Government**  
**Department of Agriculture  
and Water Resources**

Ref: MS18-002013

Committee Secretary  
Senate Rural and Regional Affairs and Transport References Committee  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Secretary

The Department of Agriculture and Water Resources welcomes the opportunity to provide the attached submission to the inquiry into the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

I trust that the information in this submission will assist the committee with its inquiry.

Should the committee require any further information about this submission, the department's contact officer is Julie Gaglia, Assistant Secretary of the Agvet Chemicals branch in the Agvet Chemicals, Fisheries and Forestry division

Yours sincerely

Cindy Briscoe  
Deputy Secretary  
Department of Agriculture and Water Resources

2 November 2018

# **Inquiry into the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)**

## **Submission by the Australian Government Department of Agriculture and Water Resources**

On 16 October 2018, the Senate referred the following matters to the Senate Rural and Regional Affairs and Transport References Committee (the committee) for inquiry and report by 1 February 2019:

The independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA) with particular reference to:

- a) the responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators
- b) the funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making
- c) the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals
- d) the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products
- e) the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner
- f) any other related matters.

## **Introduction**

Australians need access to safe and effective agricultural and veterinary (agvet) chemicals. They protect crops, livestock, and domestic pets; safeguard the environment from invasive weeds and pests; and meet consumer needs for things such as household insecticides. Agvet chemicals have brought long-term benefits to Australian agriculture by supporting increased productivity, better quality produce, and agricultural industries that are more competitive. Agvet chemicals will play an important part in helping the sector achieve the \$60 billion worth of farm production forecast by ABARES<sup>1</sup> for 2018-19.

The intent of many agvet chemicals is to kill a target pest so, in this sense, they are intrinsically hazardous (at least to the target). While there is value in these chemicals for Australian agriculture and communities, this is not at the expense of all else. It is important to preserve the integrity of the strong safeguards built into the regulation of agvet chemicals.

Australia has a long history of considering both the hazards posed by a chemical and the mechanisms for its safe use in determining whether to allow access to the Australian market. In 1995, the Australian Government, the state governments and the Northern Territory Government, consolidated the individual approaches in place in each jurisdiction into a single national framework, bringing consistency and efficiency to the agricultural and chemical manufacturing sectors.

### **a) the responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators**

Robust, evidence-based regulatory systems for agvet chemicals allow for the reconsideration of earlier decisions as science progresses and identifies new relevant information. Australia, like other comparable regulators in Canada, the United States of America (USA), New Zealand and the European Union (EU), has a formal legislated process for reviewing agvet chemicals.

The Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) details this process (commonly referred to as a chemical review). It provides that the Australian Pesticides and Veterinary Medicines Authority (APVMA) may at any time reconsider:

- the approval of an active constituent (the substance that is primarily responsible for a product's biological or other effect)
- the registration of a chemical product (a formulation containing one or more active constituents)
- the approval of a label for containers of a chemical product.

The APVMA may also invite any person through a public invitation notice to propose active constituents, chemical products, or labels for chemical reconsideration. A person proposing a chemical/product or label for reconsideration must submit reasons (based on the statutory criteria of safety; efficacy; trade; labelling; or a subset determined by the APVMA) for the proposal.

In commencing a chemical reconsideration, the APVMA must prepare a work plan which is published on its website. The plan must state, amongst other things, the date the reconsideration will commence, the timeframe proposed to complete it, the matters the APVMA is considering, persons it proposes to inform, and the dates it will inform them. The plan must also include expected dates for information requests and opportunities to contribute to the reconsideration for holders of approvals and registrations and other persons.

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<sup>1</sup> ABARES Agricultural Commodities: September 2018.

Once the APVMA has established the work plan, it must review and update it at least annually, regardless of whether it has commenced the chemical reconsideration. Where the APVMA publishes notices or invitations to contribute, or makes regulatory decisions, it must include these dates in the work plan.

For active constituents to remain approved, i.e. accessible to the Australian market, they must continue to meet the safety criteria. For chemical products to remain registered, they must continue to meet the safety, efficacy, and labelling criteria. For labels of containers of chemical products to remain approved, they must continue to meet the labelling criteria. In conducting a chemical reconsideration of an active constituent, chemical product, and/or label, the APVMA can consider all or parts of any of the criteria. This provides the APVMA with the ability to target a reconsideration to only those matters where concern may exist. This provides for efficiency in process and clarity in scope to both government and industry.

The APVMA may require the holders of approvals or registrations that are subject to the chemical reconsideration to supply information necessary to inform the reconsideration, and conduct trials or experiments, the results of which are relevant to the APVMA decision process. The APVMA must prescribe a time for compliance by holders with the requirement.

In coming to a decision in chemical reconsideration, the APVMA must have regard to:

- the information given to it in response to notices or invitation for comment
- the results of trials it required holders to conduct
- information it has received independent of the chemical reconsideration that would suggest one or more of the safety, efficacy, trade or labelling criteria may not be met
- any other information it deems necessary.

In finalising its decision in a chemical reconsideration, the APVMA must, if it is not satisfied that statutory criteria relevant to the reconsideration are met, consider what changes to the approval or registration could be made that would allow the criteria to be met. In reaching this conclusion, the APVMA can only have regard to the information presented in the reconsideration process or as the result of response by the registrants to the proposed decision.

If a variation of the approval or registration would not result in it meeting the statutory criteria, the APVMA must suspend or cancel the approval or registration. Withdrawal from the marketplace and cessation of use must occur no later than one year from the date of the decision.

These processes and the scientific rigour for reconsiderations are consistent with comparable international regulators. These regulators also identify the scope of the work, seek input from industry and the wider public and then consider these responses against the statutory criteria set for their jurisdiction. In 2014, the Australian Government amended the agvet legislation to improve the transparency of chemical reconsideration and provide certainty for completion dates. These amendments were in response to community expectations for access to safe and effective chemical pest management options and reflective of international regulatory models. These amendments did not affect the rigour of APVMA assessment.

Some international regulators (i.e. EU and the USA) conduct systematic periodic reviews of part or all of their chemical inventories. This can be in addition to, or in place of, processes to consider new information for chemical products. These periodic reviews can represent a re-evaluation from first principles against contemporary standards, or target information that addresses new regulatory standards introduced since initial registration. These periodic reviews represent different triggers for regulatory consideration from the Australian approach, but are comparable in their assessment rigour once evaluation has commenced.

These periodic reviews have, because of the costs to industry in addressing them, resulted in the withdrawal of some chemical products from the market in the absence of identifiable concerns for

human, animal or environmental health. Periodic reviews of chemical products overseas that pose potential adverse health concerns, where an equivalent risk exists within Australia for the use patterns (as measured against the statutory criteria of safety, efficacy, trade and labelling), can be addressed through the APVMA chemical reconsiderations process to ensure they continue to meet the safety criteria.

**b) the funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making**

The APVMA funding arrangements comply with the Australian Government Charging Framework, which applies to all non-corporate Commonwealth entities and selected corporate Commonwealth entities, as defined under the *Public Governance, Performance and Accountability Act 2013*. The regulatory activities performed by the APVMA are subject to the Australian Government Cost Recovery Guidelines, which set out the overarching framework under which government entities design, implement and review regulatory charging activities.

Cost recovery measures improve the transparency of the costs of sound management of chemicals and preserve the integrity of those management systems thereby ensuring they maintain adequate resourcing to protect human, animal and environmental health and Australia's interests as an agricultural exporter. This arrangement also applies to the regulation of human therapeutics by the Therapeutic Goods Administration (TGA) in the Australian Government Department of Health. As for the TGA, the APVMA's funding arrangements do not affect the independence of its scientific decision-making - stipulated in the Agvet legislation - and Australian consumers can be confident of the safety of the chemicals regulated by the APVMA.

All comparable international regulators also charge the regulated entity for access to the chemicals market in that country. Charging mechanisms vary between countries, with some (such as the USA) charging the entire fee up-front, whereas the APVMA charges 40 per cent of the regulatory costs of registering a chemical as an up-front fee and recovers the remaining costs from a levy on subsequent product sales. The purpose of this arrangement is to encourage innovation and competition and to improve consumer access to affordable chemicals by ensuring equitable access to the chemicals market for the producers of generic variants.

The PricewaterhouseCoopers (PwC October 2017) review of the APVMA's cost recovery arrangements identified that the authority's financial position is deteriorating and cannot be sustained if expenditure and cost recovery pressures are not addressed. The APVMA has recently commenced a comprehensive review of its cost recovery implementation statement to reassess the entirety of the APVMA's regulatory activities to ensure that the fees and charges associated with them appropriately reflect the costs of those activities and the administrative infrastructure that supports them.

**c) the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals**

**The National Registration Scheme**

The National Registration Scheme for Agricultural and Veterinary Chemicals (NRS) is the regulatory framework for managing agvet chemicals in Australia. The NRS is a partnership between the Commonwealth and state and territory governments, with a shared division of responsibilities.

The Australian Government, the states and the Northern Territory signed the intergovernmental agreement (IGA) establishing the NRS in 1995. Under the IGA, the Commonwealth assumed responsibilities for regulating agvet chemicals up to the point of sale. The states and territories retained responsibility for controlling the use of chemicals after supply (commonly called ‘control of use’). The Australian Capital Territory became a party to an updated and extended IGA in 2013 that incorporated further policy principles for the harmonisation of control of use regulation.

The table below lists the enabling Australian Government legislation.

<b>Legislation</b>	<b>Purpose</b>
<i>Agricultural and Veterinary Chemicals (Administration) Act 1992</i>	Establishes the APVMA as an independent statutory authority responsible for the regulation and control of agvet chemicals in Australia up to the point of sale. Sets out the APVMA roles and responsibilities.
<i>Agricultural and Veterinary Chemicals Code Act 1994</i>	Enables the APVMA to: evaluate, approve or register and review active constituents and agvet products; issue permits; license the manufacture of chemical products; and conduct compliance and enforcement activities with respect to the Agvet Code.
<i>Agricultural and Veterinary Chemicals Act 1994</i>	Enables the Agvet Code to have effect and provides that the Agvet Code is to apply as a law of the participating jurisdictions.
<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994</i>	Contains measures that allow for the assessment and collection of levies in regard to agvet products registered for use in Australia.
<i>Agricultural and Veterinary Chemicals (Administration) Regulations 1995</i>	Prescribes the fees for export certificates and the form of search warrant to be used when there is a suspected offence in relation to the importation, manufacture or exportation of agvet chemicals.
<i>Agricultural and Veterinary Chemicals Regulations 1999</i>	Prescribes functions that enable the Director of Public Prosecutions of the Commonwealth to bring prosecutions and proceedings for offences against the Agvet Code or the Agvet Regulations.
<i>Agricultural and Veterinary Chemicals Code Regulations 1995</i>	Prescribes detailed provisions of the Agvet Code.
<i>Agricultural and Veterinary Chemical Products (Collection of Levy) Regulations 1995</i>	Prescribes the state laws under which an agvet product is registered under the <i>Collection of Levy Act 1994</i> and specifies the rate of levy applicable.

Additionally, a number of legislative instruments provide clarity on the operations of the APVMA.

The states and territories have enacted mirror legislation, consistent with the arrangements set out in the *Agricultural and Veterinary Chemicals Act 1994*, to establish the single national supply framework.

### **Minister for Agriculture and Water Resources**

The Minister for Agriculture and Water Resources is responsible for the appointment of the Chief Executive Officer of the APVMA. In specific instances, the minister may give directions to the APVMA. However, the direction may only relate to policies set between the Australian Government and the governments of one or more of the states or territories, such as those contained in the IGA. The scope of the direction is also limited to ensuring the APVMA complies with the relevant policy.

The legislation that governs the APVMA does not provide for the Australian Minister for Agriculture and Water Resources, or any other Commonwealth or state or territory minister, to play a role in the decision-making process of the APVMA with respect to the registration or review of chemicals.

### **Australian Government Department of Agriculture and Water Resources**

The Australian Government Department of Agriculture and Water Resources (the department) manages the legislation under which the supply components of the NRS operates. Each state and territory has unique legislation addressing their control of use responsibilities under the NRS. The department provides general oversight of the Australian Government's agvet chemical policy and advises the Australian Minister for Agriculture and Water Resources on matters concerning the regulation of agvet chemicals and strategic aspects of chemical management in Australia.

The current IGA requires all signatories to consult with all other parties to the agreement on changes to agvet chemicals legislation and regulation. Formal consultation occurs through the Harmonised Agvet Chemicals Control of Use Task Group (HACCUT), formerly the Agvet Chemicals Task Group. The HACCUT oversees the implementation of reforms to agvet chemicals and control of use regulation, and identifies areas for future reform. Membership of the HACCUT comprises representatives from each state and territory, the Australian Government and New Zealand. The HACCUT directly reports to the Agriculture Senior Officials' Committee (AGSOC) and, through AGSOC, to the Agriculture Ministers' Forum (AGMIN). The Australian Minister for Agriculture and Water Resources chairs the AGMIN, the membership of which comprises Australian, state, territory and New Zealand government ministers with responsibility for primary industries. The role of AGMIN is to enable cross-jurisdictional cooperative and coordinated approaches to matters of national and trans-Tasman interest.

Additionally, the department undertakes monitoring of agvet chemical and environmental contaminant residues in food commodities through the National Residue Survey programs (the survey) and publishes the annual survey results. The survey's programs include random, targeted and compliance monitoring of agvet chemical residues and environmental contaminants in selected animal and plant products. These activities help identify compliance issues that may trigger follow-up action by state and territory regulators, or a review of approved uses or label instructions by the APVMA.

The department manages Australia's import and export obligations under two international agreements relating to the trade of certain hazardous chemicals: the "Stockholm Convention on Persistent Organic Pollutants" and the "Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade". The department fulfils the conventions' obligations via a permit system administered under the following regulations:

- The Agricultural and Veterinary Chemicals (Administration) Regulations 1995 establish import and export controls on chemicals that are subject to the Stockholm Convention, and export controls on chemicals subject to the Rotterdam Convention when these chemicals are used as pesticides. No import controls are required for chemicals subject to the Rotterdam Convention as importation is already regulated under the NRS.

- The Customs (Prohibited Exports) Regulations 1958 put in place export controls at the Australian border on the Stockholm and Rotterdam chemicals whether or not the chemicals are used as pesticides.
- The Customs (Prohibited Imports) Regulations 1956 introduce import controls on the Stockholm chemicals whether or not the chemicals are used as pesticides.

### **The Australian Pesticides and Veterinary Medicines Authority (APVMA)**

The APVMA, as an independent statutory authority, undertakes the Australian Government's responsibilities under the NRS. The APVMA is a portfolio agency of the Minister for Agriculture and Water Resources. The APVMA evaluates the use (including manufacture and supply) of chemicals to ensure the protection of the health and safety of people, animals, crops and the environment, and to protect Australia's international trade in agricultural commodities.

The APVMA regulates agvet chemicals by:

- approving active constituents and registering agvet chemical products
- reconsidering active constituents and agvet chemical products when new scientific information emerges that suggests a change in the risks to human health, the environment, animal or crop safety, or trade
- administering a permit scheme that allows for the legal use of chemicals in ways contrary to the label instructions, or for the limited use of unregistered chemicals (permits are subject to the same safety, efficacy and trade criteria as active constituents and chemical products)
- licensing the manufacture of chemical products (currently restricted to veterinary chemical products)
- conducting compliance and enforcement activities associated with the sale, supply, import, export, manufacture, labelling, packaging, storage and advertising of agvet products and active constituents
- enforcing compliance with the Agvet Code in partnership with law enforcement, the judiciary, and Australian, state and territory government agencies.

The APVMA routinely draws on the specialist advice of Australian, state and territory government agencies for particular aspects of the evaluation, approval, registration, reconsideration and permit issuance processes. The APVMA may seek specialist expertise from:

- the Australian Government Department of the Environment and Energy in relation to the environmental impact of agvet chemicals
- the Australian Government Department of Health on relevant matters relating to human health, including Poisons Scheduling Committee, Food Standards Australia New Zealand (FSANZ) and The Office of the Gene Technology Regulator (OGTR).
- the state and territory departments with responsibility for agriculture or primary industries about the quality, efficacy and safety of agvet chemical uses, in particular in relation to applications for a permit approval.



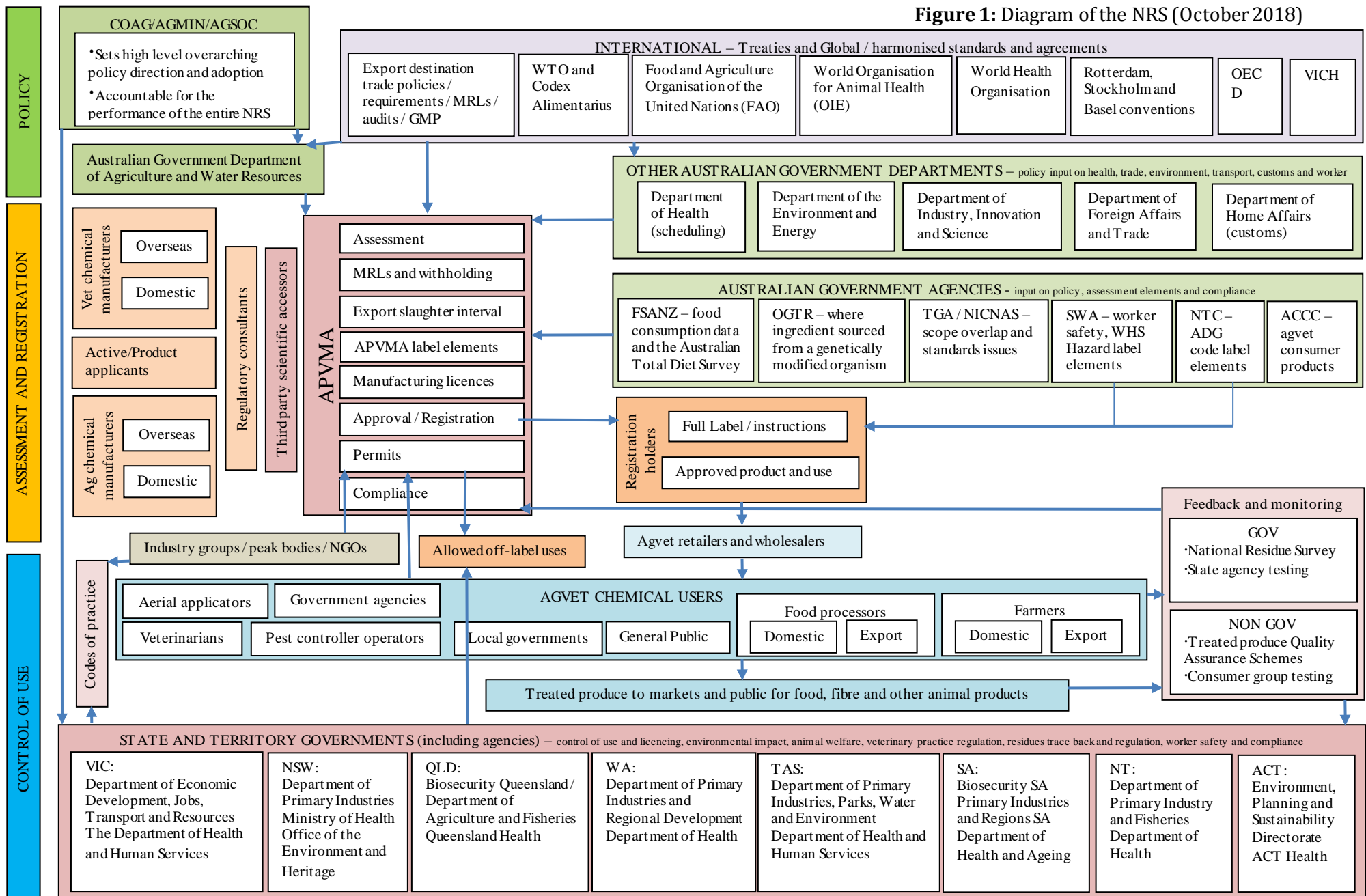
### **States and territories**

The states and territories are responsible for regulating and managing the use of agvet chemical products after sale. States and territories are responsible for:

- ensuring that agvet chemicals are lawfully used, according to the directions for use set by the APVMA
- training requirements for licensing and use of higher risk products
- licensing of professional operators
- monitoring and auditing of licence compliance and chemical residues in produce and the environment
- investigations into, and resulting enforcement/compliance actions from, these matters.

Some states have these responsibilities spread across more than one agency, including departments with responsibility for primary industries, agriculture, environment or health.

Figure 1 represents the key stakeholders, at the national and state and territory levels, involved in the regulation of agvet chemicals, from manufacture through to supply and use of a product.



**d) the need to ensure Australia's farmers have timely access to safe, environmentally sustainable and productivity enhancing products**

The department is working with the APVMA and other stakeholders to implement the government's commitment under the 2015 Agricultural Competitiveness White Paper to streamline the regulation of agvet chemicals. The 2016–17 budget included a \$17.1 million measure over four years to achieve this goal. Improved access to agvet chemical products will improve farmer competitiveness while ensuring human and environmental protection.

**Legislative Reform**

The department and the APVMA have worked with stakeholders to identify priority issues, potential legislative and regulatory changes, and operating policies.

The Senate is currently considering the Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill (the Operational Efficiency Bill). It includes measures to streamline reporting by industry, support the APVMA's operations and clarify legislative ambiguities that are creating inefficiencies in regulatory processes.

The Operational Efficiency Bill in part simplifies reporting chemical volume requirements, encouraging compliance through reduced reporting costs for industry. The information will continue to be available for our international reporting obligations and policy development needs.

To perform its role as a regulator the APVMA has to rely on information provided to it by applicants. The Operational Efficiency Bill also broadens the suite of sanctions available to the APVMA for dealing with any false or misleading information.

The government amendments to the Operational Efficiency Bill will establish a five person skills-based governance board to assist in strengthening the APVMA's governance arrangements and enhance the independence of the agency.

The Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (the Streamlining Bill) was introduced into the House of Representatives on 18 October 2018. The Streamlining Bill supports improved access to safe and effective chemical products and reduced costs associated with their registration.

The Streamlining Bill measures intend to free up the time of the APVMA's assessors so they can focus on more complex assessments, such as chemical reconsiderations (commonly called chemical reviews).

The Streamlining Bill also provides for incentives for registration holders to include certain uses of chemical products on labels that they would not ordinarily register. Based on the experience of these incentives overseas, this could encourage companies to register chemical products for more minor uses (i.e. emerging specialty crops) where the cost of registering the use would not otherwise be viable. This could have significant benefits to Australian farmers through improved access.

A range of regulation and subordinate legislation is also being considered to further improve the regulatory environment and chemical access, and assist the APVMA and industry. The amendments under consideration include:

- extending the range of applications that can be assessed as 'timeshift' applications, to provide more flexibility for the APVMA and applicants to plan and assess complex applications
- provide for greater use of disallowable ministerial orders in agvet legislation so the government can be more responsive to agvet chemical issues

- declare certain lower risk products to not be agvet chemical products where sufficient surety of public and environmental safety is provided through other chemical regulatory schemes, allowing APVMA resources to be directed to products of higher concern
- other amendments to support the changes to primary legislation, following royal assent.

#### Improved access to chemicals program

The Australian Government has also committed \$14.3 million over six years from 2014–15 to improve farmers' access to safe and appropriate agvet chemicals to control pests and diseases. This includes funding for the Improved Access to Agricultural and Veterinary Chemicals grants program. The grants program assists rural Research and Development Corporations in generating data required to support applications to the APVMA. This program helps growers gain access to the agvet chemicals to address a minor use need.

The first three rounds of grants provided a total of 126 grants worth \$5.9 million. A fourth and fifth round of grants worth up to \$2 million each will be awarded in 2018–19 and 2019–20.

In the first two years of the program, the grants have contributed to 25 permits and the inclusion of two additional uses on an existing product label, providing improved access for Australian producers. The grant projects are expected to be completed in three to five years from commencement; therefore, the number of permits generated and additional uses approved on labels will increase significantly in coming years.

The \$14.3 million government commitment also supported APVMA projects to:

- establish an Australian list of crops with similar botanical and other characteristics, and reference crops. This will allow data generated in certain key crops to also apply to other similar crops, reducing the regulatory costs for many new uses.
- examine minor use permits that may be suitable for listing on product labels without further data.

#### International minor use programs

The Australian Government's commitment to improving agvet chemical access also supports participation in international minor use programs such as the US Inter-Regional Research Project Number 4, the Canadian Biopesticides and Minor Use Pesticides Priorities Workshops and Global Minor Use Summit. Participation in these fora is important to inform Australia's minor use regulatory approach and leverage global resources to improve chemical access for our growers.

#### e) the impact of the APVMA's relocation on its capability to undertake chemical reviews in a timely manner

The department has no comments to make on this.

#### f) any other related matters

The department has no comments to make on this.