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Agvet Chemicals – Market Drivers and Barriers

Department of Agriculture

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Contents

Glossary

Term	Description
ABARES	Australian Bureau of Agricultural and Resource Economics and Sciences
Active/s	Active constituent chemical/s (of a chemical product)
Agvet	Agricultural and veterinary
APVMA	Australian Pesticides and Veterinary Medicines Authority
CSIRO	Commonwealth Scientific and Industrial Research Organisation
The Department	Department of Agriculture
EPA	Environmental Protection Agency
EU	European Union
FAO	(United Nations) Food and Agriculture Organization
FHB	Fusarium head blight
FTE	Full time equivalent
Ha	Hectares
L	Litres
NZ MPI	New Zealand Ministry of Primary Industries
MRL	Maximum Residue Limit
NRS	National Registration Scheme for Agricultural and Veterinary Chemicals
NZ	New Zealand
OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management and Regulatory Agency
PRIA	Pesticides Registration Improvement Extension Act
R&D	Research and development
US	United States of America
UK	United Kingdom
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

Executive summary

Background

Agricultural chemicals and veterinary medicines ("agvet chemicals") are the primary way in which agricultural businesses manage pests, weeds and livestock diseases.

While agvet chemicals are critical to Australia's agricultural competitiveness, their use or misuse can pose a significant risk to human and animal health, and the environment. Their use in agricultural systems can also jeopardise international trade and market access, as Australia's trading partners have restrictions on the presence, above established concentrations, of certain chemical residues on agricultural imports. For these reasons, agvet chemicals are regulated in Australia, as they are in other comparable markets.

In Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent agency that is responsible for approving active constituent chemicals ("actives"), and the registration of agvet chemical products, including novel (newly developed) products. Once registered, agvet chemical products can be lawfully sold in Australia.

The scope of this study is limited to novel products, as lack of access to potentially useful new pest management solutions may put Australian farmers at a disadvantage to their international competitors.

The purpose of our engagement

The Department of Agriculture (the Department) engaged Deloitte to:

- Examine the full range of regulatory and non-regulatory drivers and barriers to the introduction of novel agvet chemicals to Australia;
- Identify the drivers and barriers with the most significant effect on novel chemical availability in Australia; and
- Investigate what additional changes, if any, the Australian Government could make to facilitate greater and/or timelier access to novel agvet chemicals, while maintaining protection for human and animal health, the environment and Australia's international trade interests. It is important to note that the Department of Agriculture has an ongoing program of legislative reform aimed at streamlining the enabling agvet chemical legislation and improving the efficiency of the approval and regulation of chemicals.

Barriers to and drivers of the introduction of novel agvet chemicals to Australia

Access to novel agvet chemicals in Australia is a function of both the demand for, and supply of, those products. The characteristics of the Australian market and its participants, and the properties of the chemicals themselves, can either be classed as *drivers* if they enhance access, or as *barriers* if they restrict access, to novel agvet chemicals.

Of the drivers we identify in the report, the most significant demand driver for novel agvet chemicals is **the relative advantage that they have over other products.** Relative advantage may take many forms – it could reflect a lack of resistance from pests, improved efficacy for treating specific pests or diseases, or cost-effectiveness. The most significant supply driver is the **potential returns** that chemical producers stand to make through the introduction of novel agvet chemicals into Australia.

Of the non-regulatory barriers, **the relatively small size and volatility of the Australian market are the most significant barriers restricting access to novel agvet chemicals.** Australia is a relatively small market for agvet chemicals, accounting for less than 5 per cent of the volume of agricultural chemical sales across countries in the Organisation for Economic Co-operation and Development (OECD). The small potential market size can reflect low planting areas or populations for some crop or animal species, or infrequency of certain pest or disease outbreaks in Australia. Australia's market is also volatile relative to other international jurisdictions, reflecting year-on-year variations caused by its highly variable climate and a greater exposure to international export markets. Thus Australia's small and volatile potential market for agvet chemicals is likely to be a factor in some chemical suppliers' decisions not to seek registration for certain products in Australia that they have registered overseas.

Another non-regulatory barrier is **high research and development (R&D) costs, which means that chemical producers prioritise the development of new agvet chemicals that treat pests and diseases with high global prevalence.** For novel agvet chemicals, the R&D phase requires a significant investment of time and resources. Some research suggests that the processes required to develop a new active constituent can take around 9 to 10 years, and cost approximately US$250 million. Suppliers recover these high costs by marketing products across multiple markets. This means that, in order to recover those costs and generate a positive return on investment in R&D, agvet chemical producers prioritise development of constituents and products that will treat pests and diseases with the highest global prevalence, rather than those that could treat pests and diseases that are significant in Australia but are less prevalent elsewhere.

Regulation of agvet chemicals also acts as a barrier to the market by actively restricting the actions of buyers and/or sellers. The time taken to register a product, as well as the statutory fee charged by regulatory bodies, are regulatory burdens which may influence the decision of chemical producers when deciding whether or not to register in individual countries. Additionally, restrictions placed on the use of agvet chemicals in Australia, although necessary, can act as barriers by limiting the broad usage of some agvet chemicals, effectively reducing the market size for that chemical.

As detailed by Pannell (1994), regulation of agvet chemicals is necessary in order to address a range of market failures that exist in pest and disease management. Because of this, regulation, in and of itself should not be viewed as a barrier. Moreover a comparison of Australia's regulatory system with that of the US, Canada and the EU shows that Australia is broadly in-line with other developed markets for agvet chemicals in terms of:

- The 'burden of proof' that the regulator places on manufacturers;
- The statutory fees charged for an assessment; and
- The length of time taken to assess applications to approve an active constituent and register an agvet chemical product.

Since these markets collectively account for a substantial share of the global agvet chemical sales, regulatory burdens are therefore unlikely to be a significant impediment to the introduction of novel products in Australia, versus other markets.

The Australian Government has made a number of reforms aimed at improving access to novel agvet chemicals. These reforms include:

- **Introducing crop groupings**
  Grouping indirectly **increases the size of the potential Australian market for some novel agricultural chemicals** by aggregating the potential demand of a wider array of growers than would otherwise be the case, and increasing potential returns to the suppliers of agvet chemicals.

- **Allowing information from trusted international regulators to support APVMA decisions**
  Since 2015, applicants have been able to request that the APVMA use the standards, data and assessments of other international organisations and regulators. Using these assessments can **reduce the time taken, reduce information-gathering costs and lower statutory fees** for registering an agvet chemical.

- **Participating in joint reviews**
  The APVMA participates in joint reviews, where multiple international regulatory authorities collaborate to review a single application. Assessment work is split amongst review partners. Joint reviews can increase access to novel agvet chemicals primarily by **reducing the cost of registering a product in multiple jurisdictions for registrants.**

Our recommendations

The findings presented in this report suggest that the small size and volatility of Australia's agvet chemical market are the most significant barriers to entry for novel agvet chemicals. There are few (if any) levers available to the government that could significantly address this, though the government has undertaken a range of reforms that have indirectly ameliorated these barriers to some degree. Addressing the other barriers identified in this report is unlikely to have as significant an impact in improving access to novel agvet chemicals as increasing the size of the Australian market.

In considering future policy options for increasing the availability of novel agvet chemicals, the government should explore ways to further leverage Australia's reputation in agvet chemical regulation to drive cooperative partnerships with neighbouring agricultural markets with similar farming conditions and pest, weed and disease issues. This would likely make Australia an attractive market in which to seek registration of novel agvet chemicals.

However, any change in the status quo would require a detailed assessment of costs, benefits and risks of proposed options. This would include carefully assessing the risks that any proposed option would pose to human and animal health, the environment and international trade, as well as Australia's unique environment and agricultural production systems.

1 Report Background

This chapter provides context for the report by discussing the important role that agricultural chemicals and veterinary medicines play in Australian agriculture, the risks they present and the need for balanced regulation.

1.1 Agvet chemicals are important for Australia's agricultural competitiveness

Agricultural chemicals and veterinary medicines ("agvet chemicals") are the primary way in which agricultural businesses manage pests, weeds and diseases.

Agvet chemicals are critical to Australia's agricultural competitiveness. Deloitte Access Economics (2018) found that agricultural chemicals applied predominantly to crops contribute around $2.3 billion and over 9,200 full time equivalent (FTE) jobs to the Australian economy. Australia's veterinary medicines industry is also of significant importance to Australia's livestock industries. ACIL Allen (2018) reported the industry contributed 9,900 FTE jobs and $2.7 billion to the Australian economy.

For a detailed overview of the Australian agvet chemicals market, see Appendix A.

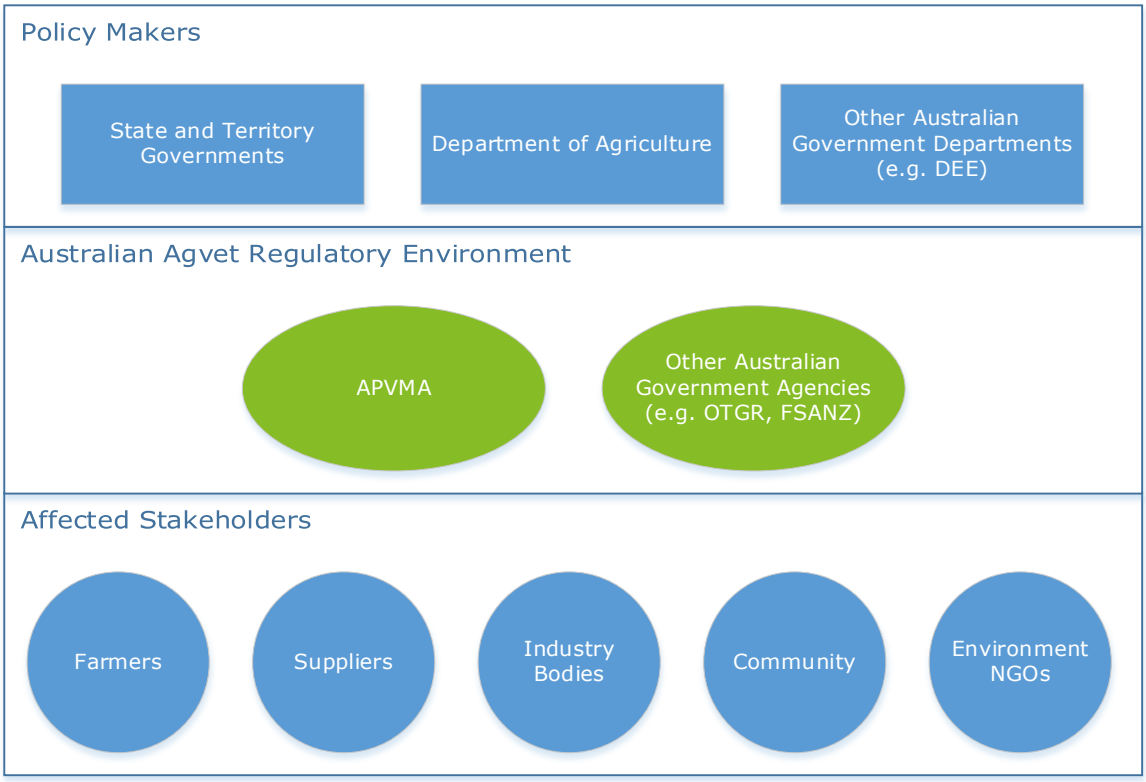
1.2 Agvet chemicals pose risks and require regulation

Agvet chemicals, while important to maintaining Australia's agricultural competitiveness, can pose a significant risk to human and animal health, and the environment. This is because, by design, agvet chemicals interrupt or otherwise affect the biological and chemical processes of plants and animals. They can also disrupt international trade and market access, as Australia's trading partners have restrictions on the presence above established concentrations of certain chemical residues on agricultural imports. A recent example of a trade disruption was Japan's rejection of Australian barley, after detecting a residue violation for the pesticide *azoxystrobin* in a 2018 shipment (Asada and Sturmer 2018).

In order to mitigate these risks, the Australian Government (in partnership with the states and territories) regulates the supply of agvet chemicals through the National Registration System for Agricultural and Veterinary Chemicals (NRS). The NRS is partly administered by the APVMA, which sits within the portfolio of the Minister for Agriculture (Department of Agriculture 2015a). Among the APVMA's roles and responsibilities is the approval of novel active constituent chemicals ("actives") and the registration of agvet chemical products.

In addition to its cooperative relationship with the state and territory governments, the APVMA works with a range of other Australian and international organisations in approving agvet chemicals and registering agvet chemical products (see Figure 1.1).

Figure 1.1: The Australian agvet chemical environment



1.3 Purpose of this report

The Australian regulatory system has undergone several recent reviews, and reforms, aimed at improving the balance between the regulatory burden it imposes and the risks agvet chemicals pose to human and animal health, the environment and trade (Productivity Commission 2016). This followed the Australian Government's commitment to undertake reforms in the Agricultural Competitiveness White Paper (Australian Government 2015). The Department has also consulted on and implemented a number of reforms, which are further detailed in Appendix B.

During these consultations, one of the concerns raised by stakeholders is that Australian users of agvet chemicals cannot readily access the novel products that are available in overseas markets, due to the time, costs and/or requirements (that is the 'barriers') associated with registering these products in Australia with the APVMA.

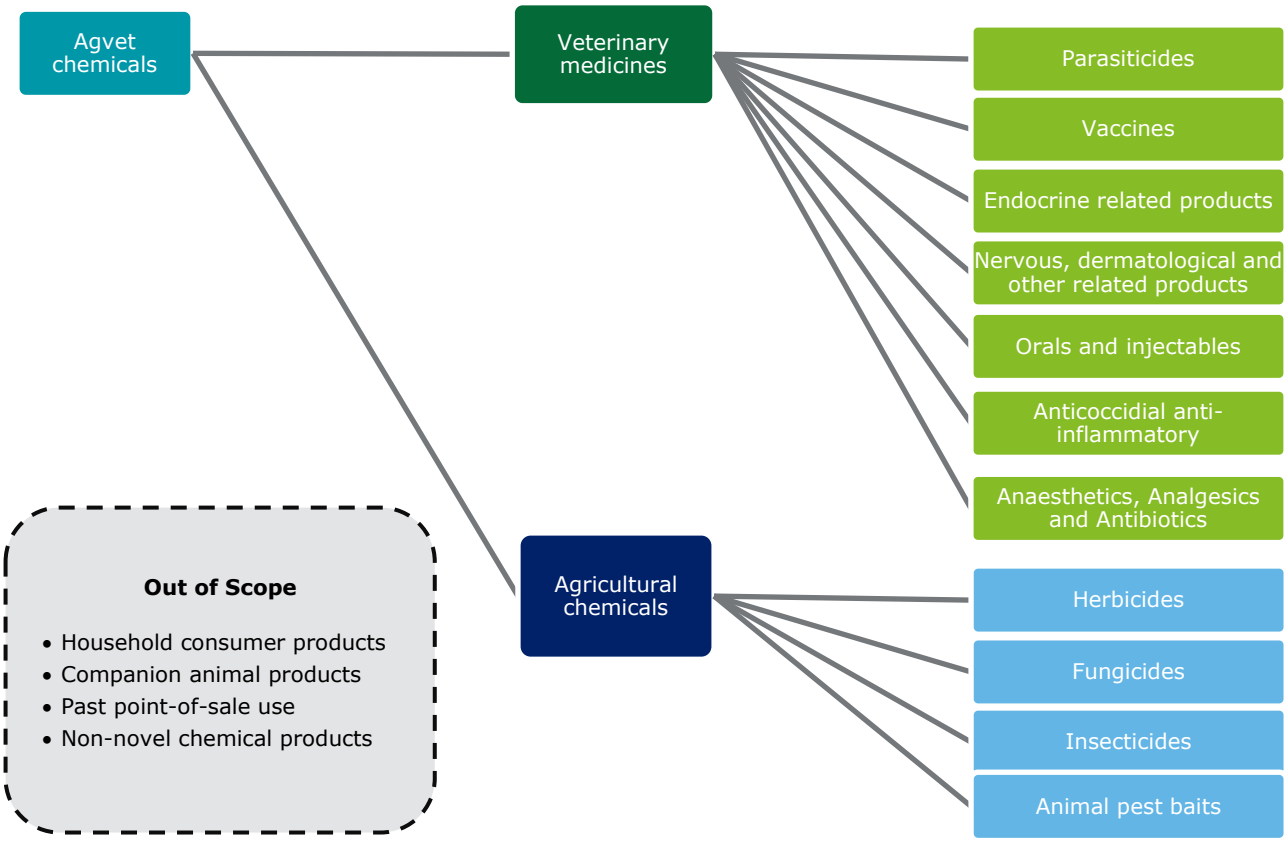
In order to further understand and potentially address these concerns, the Department engaged Deloitte to:

- Identify and examine the full range of regulatory and non-regulatory drivers and barriers to the introduction of novel agvet chemicals to the Australian market. This includes novel products that contain novel actives that require approval by the APVMA, or novel uses for products that contain actives that the APVMA has previously approved.
- Investigate what additional changes, if any, the Australian Government could make to facilitate greater and/or timelier access to novel agvet chemicals, while maintaining protection for human and animal health, the environment and Australia's international trade interests.

1.4 Scope

The scope of this report is limited to agvet chemicals used in agricultural industries, which includes products that support crop and plant production (agricultural chemicals) or livestock production (veterinary medicines). Products used in other sectors such as for household consumption or local government use, are considered out of scope, as are products for animals other than livestock, such as dogs, cats and other companion animals. For the purpose of this report, agvet chemicals have been defined and categorised in Figure 1.2.

Figure 1.2: Hierarchy of terms used in this report (non-exhaustive)



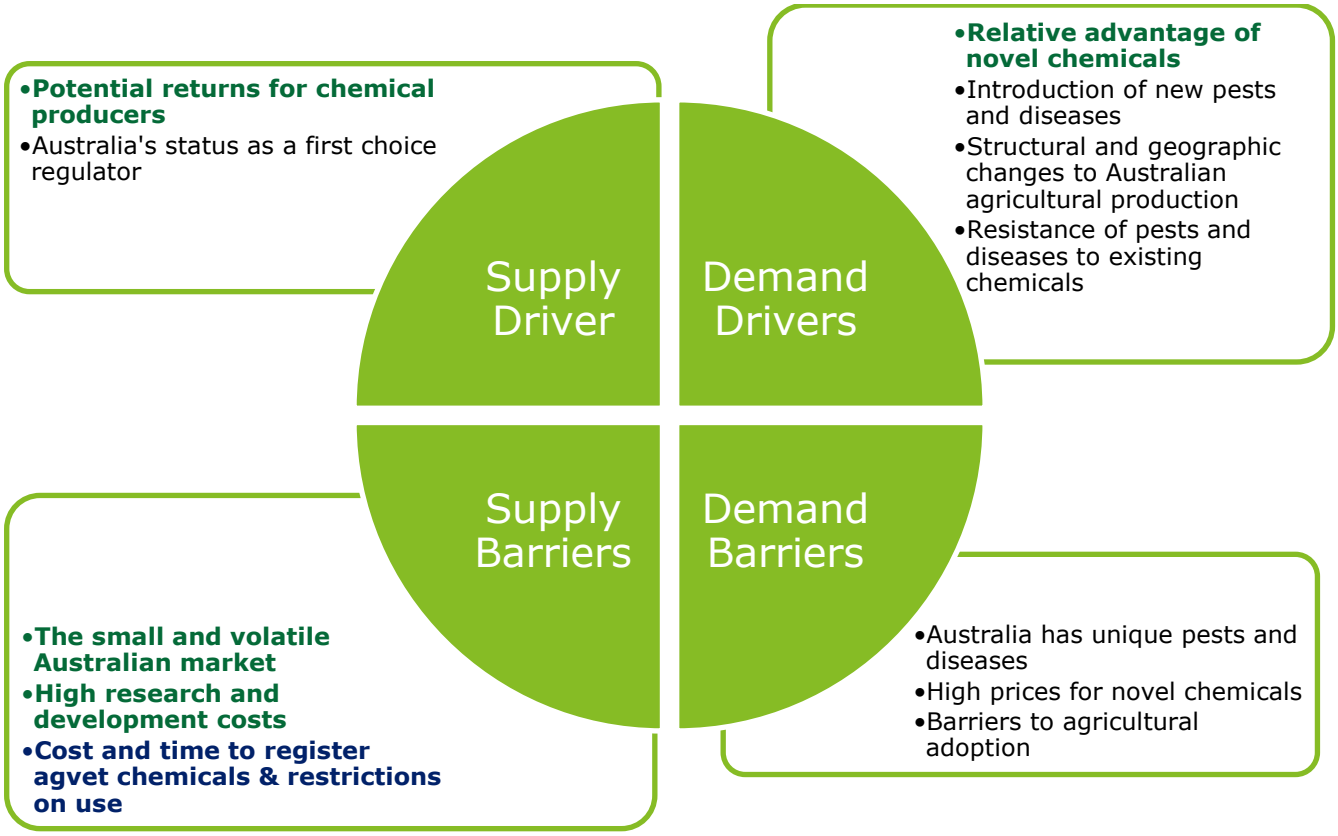
2 Priority agvet chemical market barriers and drivers

This chapter outlines the priority barriers to and drivers of demand and supply for novel agvet chemicals in Australia.

Access to novel agvet chemical products in Australia is influenced by a range of supply and demand factors relating to the market, its participants and/or the properties of the chemicals themselves. These factors can be grouped into 'barriers' – those aspects that restrict or prevent supply or demand – or 'drivers' – those aspects of the market that support demand or supply.

This report identifies 12 broad categories of barriers and drivers, which are summarised in Figure 2.1. Of these, this chapter describes the five 'priority' barriers and drivers that appear to have the most significant impact on access to novel agvet chemicals in Australia (bolded green and blue in Figure 2.1), and those that the Australian Government is reasonably able to influence through policy decisions or regulatory reforms (bolded blue). The remaining barriers and drivers identified through this review are described in more detail in Appendix C.

Figure 2.1: Novel agvet chemicals market drivers and barrier



2.1 Barriers

The three priority barriers to novel agvet chemical access in Australia are:

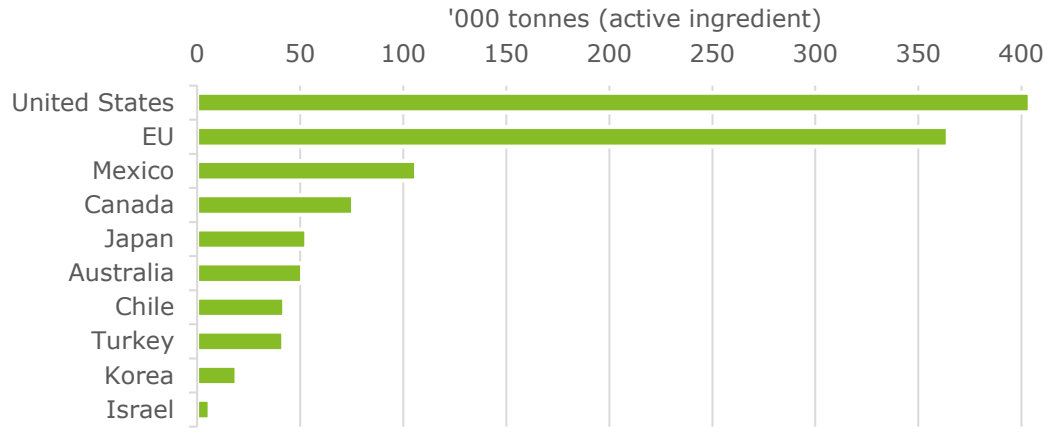
- The relatively small size and volatility of the Australian market (supply barrier)
- High research and development costs to develop new agvet chemicals (supply barrier)
- Cost and time to register agvet chemicals (supply barrier)

Of these, the most significant barrier is the small size and volatility of the Australian market, which distinguishes Australia from most other markets, especially those with whom Australia competes to supply agricultural commodities for international trade. By comparison, the other two priority barriers apply to most other major markets for agvet chemicals. As such, Australia's small and volatile market for agvet chemicals (discussed in section 2.1.1) is likely to be a significant factor in some chemical suppliers' decisions to register products in some markets, but not in Australia.

2.1.1 The relatively small size and volatility of the Australian market

Australia is a relatively small market for agvet chemicals. According to the OECD, Australia accounts for less than 5 per cent of the volume of agricultural chemical sales across its member states (OECD 2019). Sales in Australia are dwarfed by those in the US and EU (although the EU is treated as a single market, some active constituents and products do require both EU and national-level authorisation), which are each around seven times that of Australia (Figure 2.2). This is largely because Australia accounts for a small share of global cropping. Australia's share of the global value of crops was estimated at just 1.0 per cent in 2016 (FAO 2019).

Figure 2.2: Annual agricultural chemicals sales '000 tonnes of active ingredient, top 10 regions.



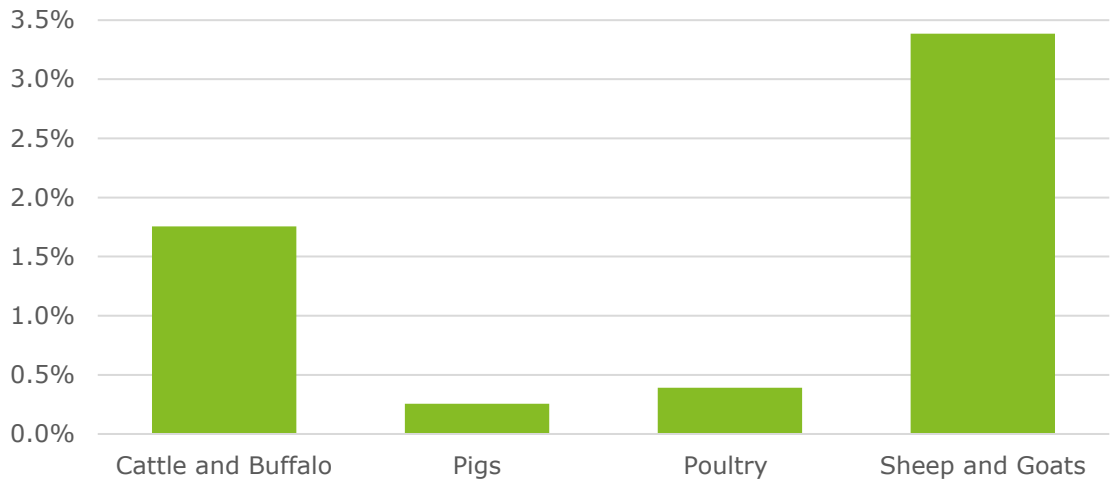
Source: OECD (2019)

Australia also accounts for a small proportion of global livestock production (Figure 2.3) with just 3.5 per cent of the world's ovine (sheep and goat) population and 1.7 per cent of the bovine (cattle and buffalo) population. Australia's pig and poultry animals make up less than 0.5 per cent of the world total (FAO 2019). This indicates Australia is also a small market for veterinary medicines.

Within livestock classes in Australia, species typically differ by area, which can further reduce the potential market size for some veterinary medicines. Similarly, pest and disease pressures can differ between northern and southern Australia, or between high rainfall and semi-arid regions. This means that some parts of Australia will have specific demands for veterinary medicines (OIE 2019a, 2019b). For example, differences in treatments may be required within breeds grown in different regions, such as *bos indicus* cattle in northern Australia and *bos taurus* cattle in southern regions. *Bos indicus* cattle are more likely to be treated with

hormone growth promotants than *bos taurus* cattle (MLA 2011).

Figure 2.3 Australian share of global livestock population by species



Source: FAO (2019)

The small size of the market limits the potential returns that chemical producers can generate from registering and subsequently selling novel agvet chemical products in Australia (Gregg et al. 2010). A survey of veterinary medicine manufacturers found that the most negative aspect of the Australian market was judged to be its size, with 88 per cent of respondents indicating that sales were low at less than US$100 million per annum (HealthforAnimals 2016). This is illustrated for agricultural chemical products and suppliers in Box 1 (details in Appendix D), which contains estimates of potential annual sales of selected agvet chemicals that are not registered in Australia, but are registered in the US.

Box 1 Assessing the impact of market size on agvet chemicals not registered in Australia

In order to assess the impact that market size has had on manufacturers' decisions, Deloitte has calculated the potential market size of three agricultural chemicals that are not registered in Australia but are registered in the US. The details of this analysis are outlined in Appendix D.

Table 2.1 summarises the findings of this analysis. It demonstrates that the potential market size for each product is significantly higher in the US than it is in Australia. This indicates that potential returns on those products (which is the primary supply driver) are lower in Australia than they are in the US.

Because registering a product comes at a cost - industry has estimated that it costs up to $400,000 to satisfy the efficacy requirements alone to register a novel agvet chemical (Department of Agriculture 2015b) - it would be inherently more difficult to generate a positive return in Australia. Australia's small market size means that it is more challenging to generate a positive return on investment in Australia for products such as Elumin and SHIELDEX 400SC, which have an estimated potential market size of less than $1 million per year.

Table 2.1: Estimated revenue of agricultural chemical products available in the US, but not Australia (in US$/yr.)

Manufacturer	Product	Group	Treated crop(s)	Estimated potential annual market size (US$m)	
				United States	Australia
Summit Agro	SHIELDEX 400SC	Herbicide	Maize	$111.70	$0.20
BASF	Caramba	Fungicide	Cereals, soybeans, sugarbeet	$1,072.60	$411.10
Valent	Elumin	Herbicide	Cucurbits	$4.40	$0.40

In contrast, BASF's Caramba appears to have a relatively large potential market in Australia at $411 million per annum. This is because the product is applied to a broad grouping of cereal crops (namely wheat, barley and oats) that are grown throughout Australia. However, Caramba was developed to treat Fusarium head blight (FHB). This disease is not common in Australia, occurring in atypical 'wet years', or when conditions are warm and humid (Thompson 2013). As such, the impacts of FHB are largely limited to Australia's northern grains regions (i.e. northern NSW and Queensland), which collectively account for around 10 per cent of the total cereal cropping area in Australia (ABARES 2018c; GRDC 2014). The constrained effects of FHB are highlighted in Table 2.2, with the disease developing in Australian on average in just 3.1 per cent of years, and in 2.7 per cent of area planted to barley.

Table 2.2: Proportion of years and barley area where Fusarium head blight developed in Australian regions

Proportion (%) of:	Northern	Southern	Western	Australia
Years	15.3	0	5.4	3.1
Area	8.6	0	6.8	2.7

Source: GRDC (2009)

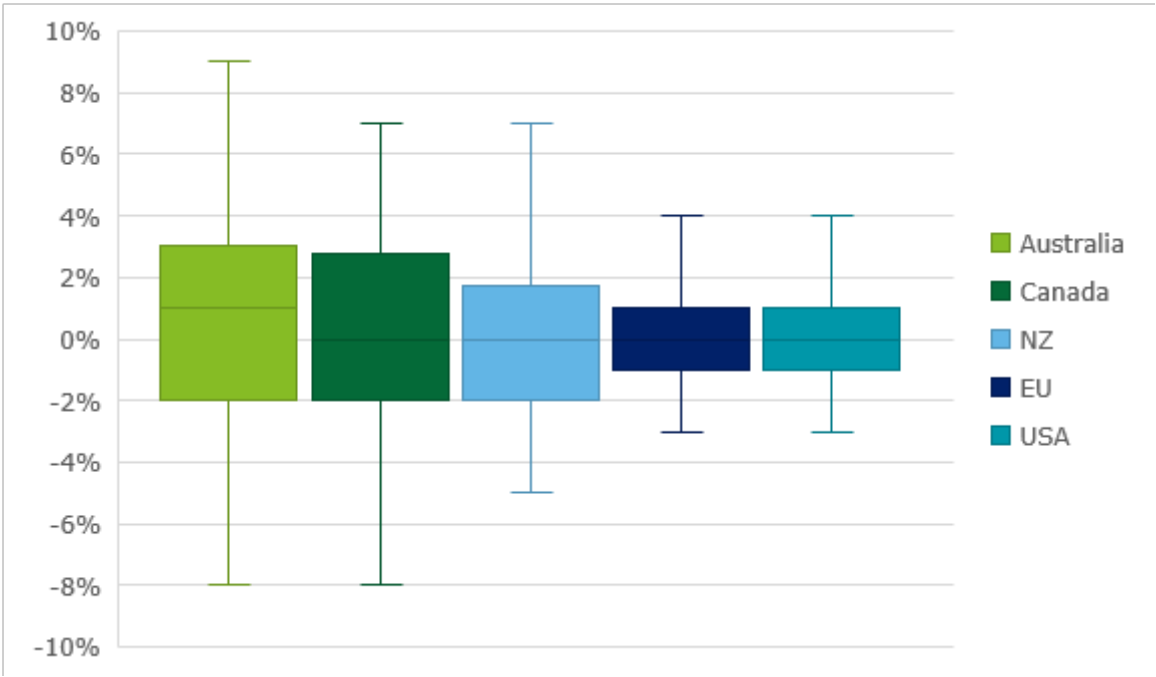
Estimates presented in Table 2.1 assume individual chemicals are able to capture the entire market once registered in Australia. However, this is unlikely to be the case as novel chemicals would most likely have to compete with already established products in the market. For example, BASF's Caramba (used to treat Fusarium head blight), if registered, would enter a market where Bayer's Prosaro 420SC is already registered in Australia to treat FHB (Tonneson 2017). As such the estimated potential market size presented in Table 2.1 should be treated as an upper bound indicator and it is likely that it over-estimates the potential revenue for a particular agvet chemical, with the size of the market likely smaller than reported.

In summary, the primary reason that these three products have not been registered in Australia is likely to be the limited expected return on investment that results from Australia's small market size.

In addition to being small, the Australian market for agricultural inputs is relatively volatile. Australian agriculture is subject to more revenue variability than other developed markets for agvet chemicals. This is because of Australia's highly variable climate (with lower mean rainfall and higher variation in rainfall), and exposure to volatile export markets (ABARES n.d.). This not only affects dryland agriculture, it also affects the reliability of water sources for irrigated agriculture. During 'bad' years when crop plantings and/or profitability are low, expenditure on agvet chemicals is also likely to be lower than it would be during 'good' years.

Figure 2.4 depicts annual variation in the total value of agricultural production for selected countries between 1960 and 2017. Deviations below trend in Australia are significantly larger in magnitude than other markets for agvet chemicals. As a result, agricultural incomes, and hence expenditure on inputs (or agvet chemical revenue from manufacturers' point of view), are relatively more variable and risky.

Figure 2.4: Variation in the value of agricultural production, selected markets 1960 to 2017

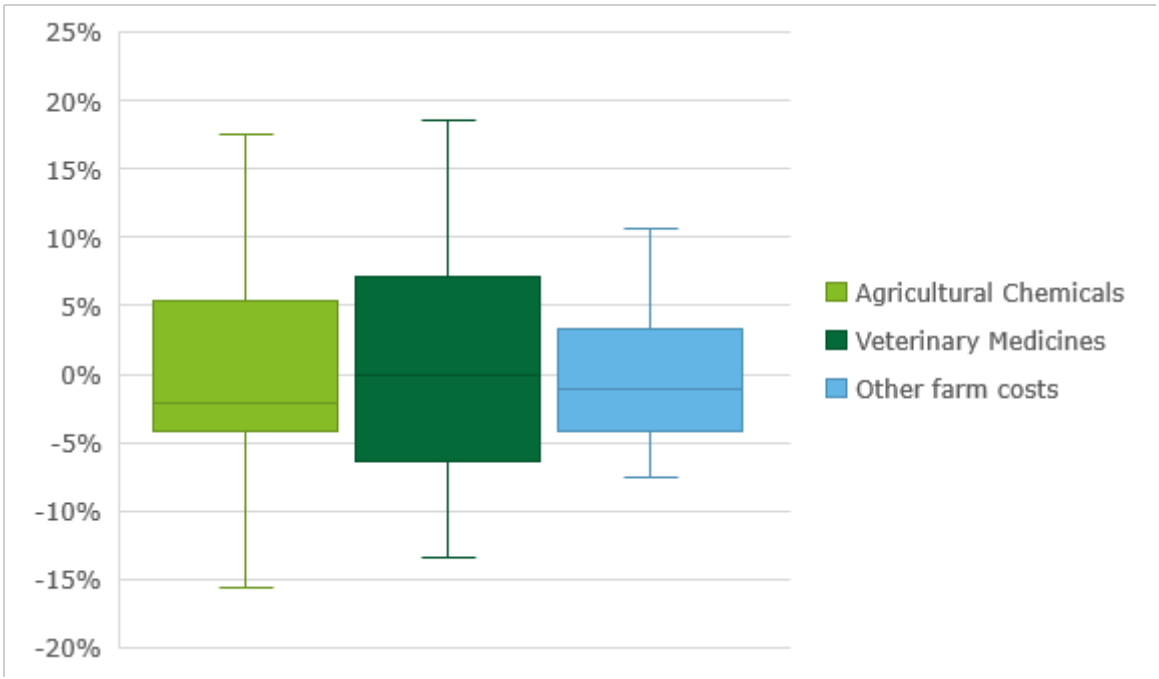


Source: FAO (2019)

Note: Deviation from trend is calculated by taking the percentage difference between actual agricultural production and the trend-adjusted average. Trends are estimated using a Hodrick-Prescott smoothing filter.

Inter-year variability in production and revenue can cause expenditure on inputs to vary significantly from one year to the next. This is demonstrated in Figure 2.5, which shows how expenditure on agricultural chemicals, veterinary medicines and all other farm costs deviate from their trend-adjusted averages. It shows that deviations from trend for agvet chemicals appear more negatively skewed than other farm costs. This means that farmers are more likely to significantly reduce their expenditure on agvet chemicals in any given year, relative to other farm expenditure items.

Figure 2.5: Variation in annual farm costs from the trend-adjusted average, Australia, 1990 to 2017



Source: ABARES (2018c)
Note: Deviation from trend is calculated by taking the percentage difference between actual farm costs and the trend adjusted average. Trends are estimated using a Hodrick-Prescott smoothing filter.

2.1.2 High research and development costs to create agvet chemicals

For novel agvet chemicals, the R&D phase requires significant investment of time and resources. As such, R&D in a novel agvet chemical is seen as an investment with higher risk, as well as a high potential return (Gregg et al. 2010). It includes the cost of running laboratory facilities for speculative or targeted chemical synthesis, analysis and formulation development, followed by biological screening against representative pest and weed species in glasshouses to discover 'lead' candidates which need further investigation to arrive at a few potential candidates for development. Preliminary toxicity, stability and manufacturing cost consideration, and field trials for biological efficacy under realistic conditions result in rejection of most of these candidates within two to three years of effort.

In order to produce a successful active ingredient, around 160,000 chemicals must be initially synthesised. From this, only a few are eligible to be developed, with ultimately only a single prospect registered. These processes take place in R&D sites globally, over a period of around nine to 10 years, and at a cost of around US$250 million (Whitford et al. 2006). R&D costs account for the majority of costs (around 90 per cent) in initially getting the product to market, and is estimated to account for 5 per cent of future revenue (McDougall 2016). It should also be noted that, once a product has been developed, these costs can be recovered through global sales of that product (across multiple jurisdictions), rather than just through a single market.

Table 2.3: Number of different chemicals synthesised in the process of producing a successful active ingredient

Phase	1995	2000	2005–08	2010–14
Research	52,500	139,429	140,000	159,574
Development	4	2	1.3	1.5
Registration	1	1	1	1

Source: McDougall (2016)

The cost and time to get a chemical to market have been increasing. Compared to the mid-1990s, the number of chemicals synthesised to successfully develop an active ingredient has increased three-fold (see Table 2.3), with the time between first synthesis and first sale of a novel chemical expanding from 8 years 4 months to 11 years 4 months (Whitford et al. 2006).

R&D costs in bringing a novel chemical to market (excluding registration fees) also increased during this period by around 80 per cent (McDougall 2016). Most of this increase was in the development phase where costs expanded 118 per cent to an average of US$146 million. Higher development costs were largely driven by environmental chemistry testing and field trials, with manufacturers required to do increasingly numerous and complex testing of possible chemicals. These trials are undertaken in part to satisfy regulatory requirements to achieve registration in specific countries. Field trials are also undertaken to satisfy corporate liability requirements, as manufacturers increasingly consider the potential for legal challenges, negative publicity or brand damage (Whitford et al. 2006). Such risk reduction measures are similar to efforts to pre-empt future regulatory changes and uncertainty, further described in section 2.1.3.

Research costs associated with bringing a novel chemical to market increased by 50 per cent over the same period to an average of US$107 million. This increase was driven by higher expenditure on chemistry screening and synthesis which accounts for around 90 per cent of research costs. The increase in research costs, while large, is comparatively small next to the increase in development costs and the number of chemicals synthesised for each marketed active ingredient. This reflects recent improvements in research methodology, for example high throughput screening and combinatorial chemical synthesis — which allows manufacturers to synthesise larger numbers of molecules — and the use of genomics, which has facilitated the discovery of potential sites of activity within target organisms in addition to new actives (McDougall 2016).

2.1.3 Cost and time to register agvet chemicals

Preparing for registration with the APVMA is a complex process that takes considerable time, resources, and expertise. Manufacturers are required to gather and submit detailed data and information to the APVMA that demonstrates the efficacy and safety of their product (APVMA 2014a). However, this is not a uniquely Australian barrier: the 'burden of proof' placed on manufacturers by Australia's regulatory system is broadly in-line with that of other jurisdictions, suggesting that it is unlikely to be a significant impediment to the introduction of novel products in Australia, versus other countries (See Box 2).

The burden of proof required of manufacturers depends on the type of chemical and the complexity of the application. In support of chemical safety assessments, the APVMA requires (for example):

- Physical/chemical properties and methods to generate data e.g. water solubility
- Detailed description of manufacturing processes (to assess potential presence of toxic substances)
- Identification of potential impurities

The process involves a number of stakeholders including registration authorities, manufacturers and various public interest groups as public concerns grow over the health and environmental effects of chemicals in general. Between 2010 and 2014, total global registration costs were estimated to be around US$30 million on average for successful agricultural chemical products (McDougall 2016). Registration costs, incorporating extra studies required to satisfy EU and US regulators, rose by 32 per cent between the periods 2005–2008 and 2010–2014.

Ongoing and likely future changes to regulatory requirements can also create uncertainty and complexity for the industry. One study in the European Union found that companies can over-assure by conducting more

studies than needed to pre-empt possible future regulatory requirements (Carroll 2016). Similar research has not been undertaken in Australia.

Scientific tests are also continually improving due to technological advancements and increasing scientific knowledge – providing greater precision, detection and assessment. Improved hazard prediction methods, hazard reduction measures and the broadening scope of relevant scientific knowledge have also contributed to changes and improvements in the registration process.

Box 2 Comparing agvet chemical regulations across jurisdictions

Countries around the world regulate agvet chemicals in different ways. This includes variations in limits for agricultural chemical residues on food, product registration requirements, and use restrictions.

The European Union, with its emphasis on the *hazard* presented by agvet chemicals (before *risk* is considered), is widely understood as the most burdensome international framework for agvet chemicals (McDougall 2016). This is because a risk based system takes into account the likely real-world exposures of people and the environment to a hazard. The EU system is also more complicated. In the EU, registration of actives is undertaken centrally, while products have to be separately registered in an EU member state to enter the market.

At the other end of the spectrum is New Zealand, which seems on the surface to take a more streamlined approach to elements of its agvet chemical regulation. Applicants seeking to register novel agricultural chemicals submit an application to the Ministry of Primary Industries (MPI) to secure their data protection and then to the Environment Protection Authority (EPA) and each agency performs its part of the evaluation; MPI assesses residues, chemistry, manufacture, efficacy and trade implications and EPA assesses toxicity and environmental impacts. Both agencies accept applications in the form of a regulatory assessment. Generally applications provide MPI with assessments conducted by an external assessor, either one who is accredited by the regulator, or another suitably qualified person (whose qualifications must be demonstrated to the regulator). The EPA has a statutory timeframe of 100 working days, but "time-waiver" (where the "clock" stops) can apply with the applicant's consent (and in certain circumstances without their consent) meaning the elapsed time taken for an assessment can be longer that the statutory timeframes imply. The 100 days starts when the EPA formally accepts the application. MPI has a statutory timeframe of 40 days, or seven days after the EPA finishes its assessment (for those applications that go to the EPA). Most veterinary medicines don't require a separate EPA assessment because it has group standards that cover the risks posed by those chemicals. Applications for agricultural chemicals that are the same or closely similar to a product that has already been approved can be approved via a rapid route. Third party assessors may charge around $150 to $250 per hour to complete a regulatory assessment and can finalise simple ones in around one week.

New Zealand's system appears to be the most streamlined of all the systems examined, particularly for veterinary medicines and generic agricultural chemicals. However, it is unclear if the registration process would be much quicker or cheaper for novel agricultural chemical products, given the likelihood that they would require a more complex efficacy assessment and a full toxicological assessment by the EPA.

Overall, there is evidence to suggest that the costs and time of Australian novel product registrations are broadly similar to those in other countries. Moreover, in a recent review of the APVMA's assessment performance, the Reason Group found the APVMA faces similar challenges as other international regulatory bodies (Reason Group 2017). The process through which agricultural chemicals are registered in most jurisdictions broadly encompasses three processes (veterinary medicines are also assessed for animal welfare effects). These are:

- agronomical performance,
- human toxicology and
- environmental toxicology

These processes are broadly similar across countries, with evidence to establish safety criteria for the US, EU, Australia and New Zealand all related to:

- Physical and chemical properties
- Stability
- Manufacturing process
- Toxicology

- Batch analysis results.

The main difference across countries is the relative weights attributed to each of these aspects for registration.

Another important difference is that, in Australia (like New Zealand), the trade impacts of agvet chemicals are considered as part of the product registration process. This reflects the export orientation of Australia's agricultural sectors. Additionally, In New Zealand, if the risks of a product are not negligible, both MPI and EPA conduct a benefits test that requires applicants to demonstrate that the risks of their product are outweighed by its benefits.

Appendix E contains a summary of the criteria that agvet chemical regulators assess in Australia, NZ, Canada, the US and the EU.

In all comparable regulatory systems, in addition to the provision of supporting data and information, applicants pay statutory fees to the regulator, adding to the cost of registration. Application fees and assessment periods also vary depending on the complexity of the chemistry submitted for assessment. In Australia, fees can be broadly grouped into three categories:

- **Approval of an active constituent in a chemical product** and **registration of the associated chemical product** — costed at 18 months and $96,135 (increases to 25 months if additional information or clarification of submitted information is required)
- **Approval of an active constituent** — ranges from 7 months and $3,155 to 14 months and $30,550, depending on the assessment requirements.
- **Registration of a chemical product containing an approved active constituent** and **approval of the product label** — ranges between 2 months and $1,595 and 18 months and $64,620, depending on the assessment requirements and the similarity of the proposed product to existing chemicals (a modular fee and timeline structure is applied if the assessment requirements is less than full).

The APVMA's statutory fees are set according to cost recovery principles, with fees calculated to pay for the resources required to assess and register agvet chemicals only. A comparison of Australia's regulatory system with that of the US, Canada, UK and the EU shows that Australia is broadly in-line with comparable overseas markets in terms of the statutory fees charged for an assessment and the length of time taken to assess applications. Since these markets collectively account for a substantial share of global agvet chemical sales, time and costs are also unlikely to present a significant impediment to the introduction of novel products in Australia, versus other countries (Box 3).

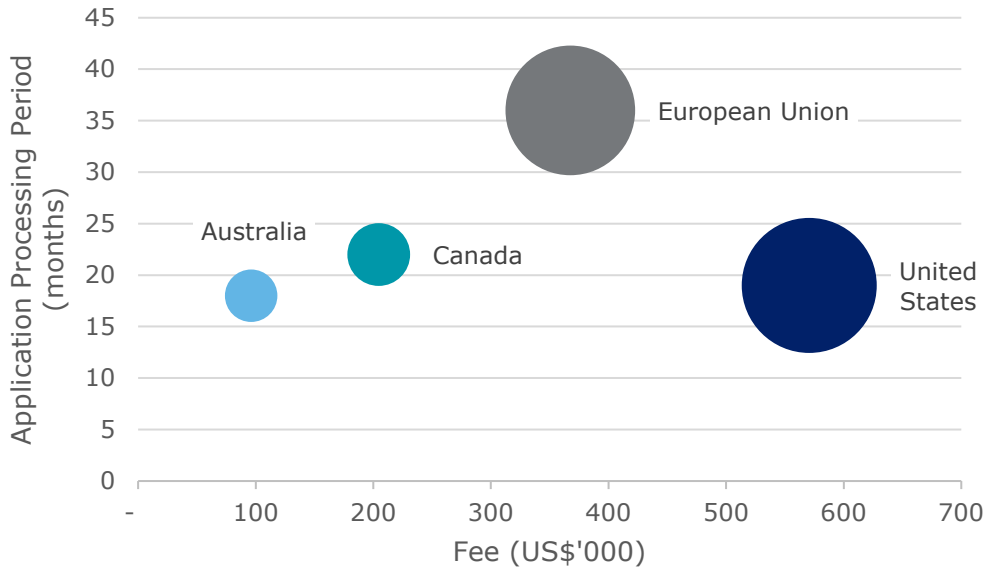
Furthermore, there is, evidence to suggest that statutory fees (globally) represent a small proportion of the overall registration cost to manufacturers, and are therefore not a significant barrier. McConnell (2016) noted that "Statutory registration fees represent only a small proportion of the overall registration process [for a manufacturer]" (McDougall 2016).

Box 3 Comparing statutory fees and application times across countries

Statutory fees and periods of time taken to complete applications differ widely across countries. This mainly reflects the different regulatory systems and the environments they operate in. Comparisons across countries are also difficult due to the multitude of pathways that are available in each country for registering novel agvet chemicals. In Australia alone there are more than 15 ways to register a novel active and/or product (See Appendix F).

Despite these differences in regulatory approaches, the costs and time frames imposed by Australia's regulatory system compare favourably. This is illustrated in Figure 2.6, which shows statutory fees and application processing periods for the approval of an active constituent and registration of the associated chemical product in Australia, Canada, the United Kingdom and the United States. Application times frames in Australia are around half those in the UK, while Australian application fees are around a third of those in the United States.

Figure 2.7: Indicative registration costs and time, selected countries



Source: APVMA; US EPA; Canada PMRA; OECD
Note: Bubble size reflects the size of that region's market for agricultural chemicals. Fees and Application processing periods in the United Kingdom are used as a proxy for the European Union; Bubble size indicates estimated tonnes of active ingredient sold in individual markets between 2012 and 2016 for herbicides, insecticides and fungicides

2.2 Drivers

The two priority drivers for novel agvet chemical access in Australia are:

- The relative advantage of novel agvet chemicals (demand driver)
- Potential returns for chemical manufacturers (supply driver)

In a relative sense, it is difficult to determine which of these factors is more important than the other, since they are inextricably linked. Australian agricultural producers will only demand a novel chemistry if it offers a relative advantage over an existing agvet chemical product or pest/disease management strategy. Manufacturers will only generate a positive return on registering and supplying a product in Australia if there is sufficient demand for that product.

Each driver is described in more detail in the following sections.

2.2.1 The relative advantage of novel agvet chemicals

Agricultural producers will only adopt new technologies or management practices if they provide them with some relative advantage over their existing systems. The causal link between relative advantage and adoption of a new technology or management practice has been widely discussed in the international literature (see for example Casell et al (1994) or Kuehne et al (2017).

The relative advantage of a novel agvet chemical compared to existing chemicals (or other strategies) can be shown through a range of factors, including:

- increased revenue resulting from reductions in yield losses
- reduced uncertainty or risk as targeted pests and diseases are treated with improved efficiency
- lower environmental impacts
- reduced risk to animal or human health
- lower costs through reduced application rates, and
- reduced resistance, compared to other commonly used pesticides or medicines.

The relationship between novel chemistries and their relative advantage has been identified as a driving factor in adoption. This includes a recent report by ABARES which found new control methods were the most important means of improving the management of pests or weeds (Stenekes et al 2017). Similar results were reported by the Australian Competition and Consumer Commission (ACCC), which found surveyed farmers value a novel chemical for the benefits it provides, within a 10 per cent price premium (ACCC 2016).

2.2.2 Potential returns for chemical manufacturers

The principal driver for the supply of agvet chemicals is the potential return to chemical manufacturers (Gregg et al. 2010). New products must capture a percentage of the market and remain competitive for many years, which is why so much attention is focused on consumer and market information, and the awareness of a product. An active generally requires large/broad markets that can support sizeable sales and a substantial global sales force to serve the target markets. This is especially important since the cash flow for a new agricultural chemical can be negative for many years following its launch – often 10 or more years (Sparks and Lorsbach 2016).

Consideration of potential profit is applicable throughout the product development stage, including research, development, manufacturing and registration (Whitford et al. 2006). Agricultural chemical manufacturers must develop products that will generate a return on their investment, and it is important that the profit potential of an active and the resulting product be determined early in the discovery process. Losses can subsequently be limited if an active is deemed to not be promising or profitable early in its R&D.

3 Recommendations

This chapter suggests areas in which the government should focus future reforms to best target its work in facilitating access to novel agvet chemicals.

3.1 Findings

This report investigated how access to novel agvet chemicals might be improved by analysing the market and its regulatory and non-regulatory drivers and barriers. While multiple aspects of the market were found to significantly affect access, three supply barriers were discussed in detail due to their relative importance: (1) the size and volatility of the Australian market, (2) the high R&D costs associated with novel agvet chemicals, and (3) the cost and time required to register novel agvet chemicals in Australia.

The small size and volatility of the Australian market was found to be the most significant barrier that restricts access to novel agvet chemicals. This is mainly because Australia accounts for a very small proportion of global agricultural production and is compounded by a relatively variable climate – which drives sharp changes in input expenditure between years. Because it is a small and volatile market, it is difficult for chemical manufacturers, particularly smaller manufacturers, to generate a return on their investment in Australia. In addition, the high R&D costs associated with developing a new product for market means that chemical producers prioritise new agvet chemicals that treat pests and diseases with high global prevalence, which are not always highly prevalent in Australia.

While it is difficult to compare international regulatory systems, regulation of agvet chemicals in Australia was broadly in-line with comparable overseas markets; in terms of the burden of proof placed on manufacturers, the statutory fees charged by the APVMA and registration time frames. However, the time taken to register a product, as well as the statutory fees, are regulatory burdens that may influence producers' decisions, particularly when assessing these costs against the lower potential returns of the small Australian market.

3.2 Recommendations

There are few (if any) levers that government can or should activate to address the most significant barrier identified as part of this report — the small size and volatility of the market in Australia (as outlined in chapter 2). The Department of Agriculture has an ongoing program of legislative reform aimed at streamlining the enabling agvet chemical legislation and improving the efficiency of the approval and regulation of chemicals. Any future reforms by the government – as part of the ongoing legislative reform program, or otherwise – should be prioritised based on their potential to offset the size of the Australian market. This might include for example exploring ways to further develop cooperative partnerships with other agricultural markets or leveraging Australia's strong international reputation in agvet chemical regulation — which would likely make Australia a more attractive market in which to seek registration of novel agvet chemicals.

Regulation of agvet chemicals by government is necessary. Because of the central role of government, options to address other barriers identified in this report focus on improving regulation. These options are described in Appendix B and have to a large extent previously been examined by the government. Compared to and because of the unattractive size of the Australian market to some chemical manufacturers, addressing these other barriers is unlikely to have as significant an impact on improving access to novel agvet chemicals. It is also important to note that options that would reduce regulatory burden may have unintended consequences, including for example reducing the attractiveness of the market to manufacturers. This may ultimately reduce the supply of novel agvet chemicals to Australia.

For these reasons, any future changes to the status quo should give significant consideration to the size of the Australian market, as well as the costs, benefits and risks of proposed options — this includes assessing proposals in more detail in a Regulatory Impact Analysis (or similar).

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Appendix A Agvet Chemicals in Australia

This section describes the Australian markets for agricultural chemicals and veterinary medicines, and discusses the current status and major trends.

The agricultural chemicals market

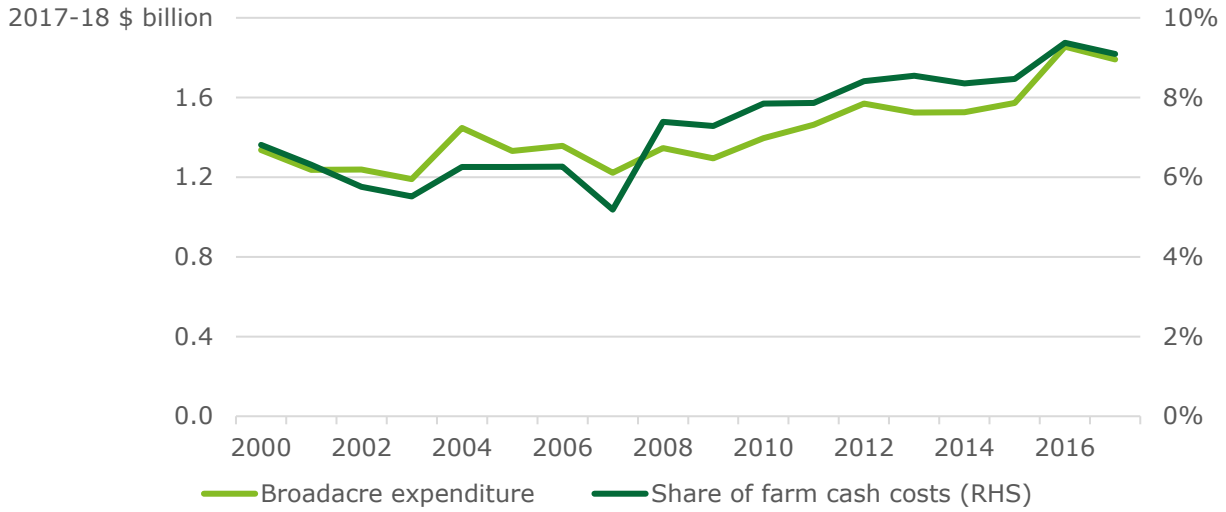
This sub-section profiles the Australian market for agricultural chemicals, not just novel ones.

The use of agricultural chemicals is rising

In 2017, the estimated total Australian broadacre farm expenditure on agricultural chemicals was $1.8 billion (ABARES 2018c). Annual farm expenditure on agricultural chemicals has increased by around 45 per cent (in real terms) since the early 2000s and has risen faster than other farm costs (Figure A.1). In 2017, expenditure on crop and pasture chemicals accounted for 9 per cent of non-capital on-farm costs for broadacre farms, up from around 6 per cent in the early 2000s.

It is unclear whether the increase in expenditure on Australian agricultural chemicals has been driven by an increase in use, prices or a combination of the two. Price indices for agricultural chemicals are reported as rising in the order of 10 per cent during this period, suggesting at least some of the increase is attributable to higher use (ABARES 2018b). However, with Australia's cropping area declining by around 4 per cent between 2000 and 2017 (FAO 2019), any increase in the use of agricultural chemicals would reflect higher application rates.

Figure A.1: Australian broadacre farm expenditure on agricultural chemicals and share of cash costs



Source: ABARES (2018c)

Local production confined to generic products

Production of agricultural chemicals in Australia is dominated by two large multinational corporations (IBISWorld Australia 2018b): Bayer CropScience Pty Ltd. ("Bayer") and Nufarm Ltd ("Nufarm"). Both companies have significant global footprints and their combined share of the Australian market is close to 90 per cent by revenue. While agricultural chemicals are their primary source of revenue in Australia, both companies are increasingly diversified. In their Australian operations, both Bayer and Nufarm formulate mostly generic products from imported actives (IBISWorld Australia 2018b).

Very few novel agvet chemicals are developed and commercialised in Australia (Gregg et al. 2010). According to the APVMA, just seven novel products were developed in Australia between 2000 and 2016 (see Table A.1). Greg et al (2010), later found that most were only partially developed in Australia, with products adapted (to Australian conditions) from technologies previously commercialised overseas by improving formulation methods and selecting strains.

Table A.1: Novel pest management products developed in Australia

Product	**Active ingredient**	**Notes**
Vivus	*Helicoverpa* nuclear polyhedrosis virus	Registered in 2002 for control of *Helicoverpa armigera*. An Australian strain selection of a pathogen previously developed for control of American *Helicoverpa* species
Green guard	*Metarhizium anisopliae*	Registered in 2007 in Australia for control of grasshoppers and locusts. Other strains of the pathogen have been developed overseas for a range of pests
1080	Sodium fluoroacetate	Developed by the Western Australian Agriculture Protection Board for fox and wild dog control in the 1950s, but previously used for rodent control in the USA
Beat-a-bug	Garlic/ chilli/ pyrethrum/ piperonyl butoxide mix	Ingredients known as botanical pesticides or synergists for many years, although the mixture is novel
Dryacide	Amorphous silica	Registered as a stored grain protectant in Australia in 2001, but previously registered for the same purpose in the USA in 1998
Vapormate	Ethyl formate	Registered as a stored grain protectant in Australia in 2006, but previously registered for the same purpose in India in 1996
Achieve	Tralkoxydim	Registered as a herbicide in Australia in 2006, but previously registered for the same purpose in the USA in 2006

Note: developed in Australia includes adapting products developed overseas.

Source: (Gregg et al. 2010)

In 2018-19, revenue for manufacturers of agricultural chemicals in Australia is forecast to be around $1 billion (IBISWorld Australia 2018b). Growth in revenue has been volatile in recent years, influenced by climatic conditions. Unfavourable weather conditions, including droughts and floods, can significantly reduce crop plantings, which flows through to less demand for pesticides. Australia experienced one of the driest autumns on record in 2018, resulting in a poor winter crop season and an associated fall in demand for agricultural chemical products (IBISWorld Australia 2018b).

Significant merger and acquisition activity has occurred in recent years. This includes Nufarm consolidating operations into its Laverton Plant, and Bayer CropScience divesting its Horsham wheat and oilseeds breeding centre to BASF in August 2018, as part of Bayer's merger with Monsanto.

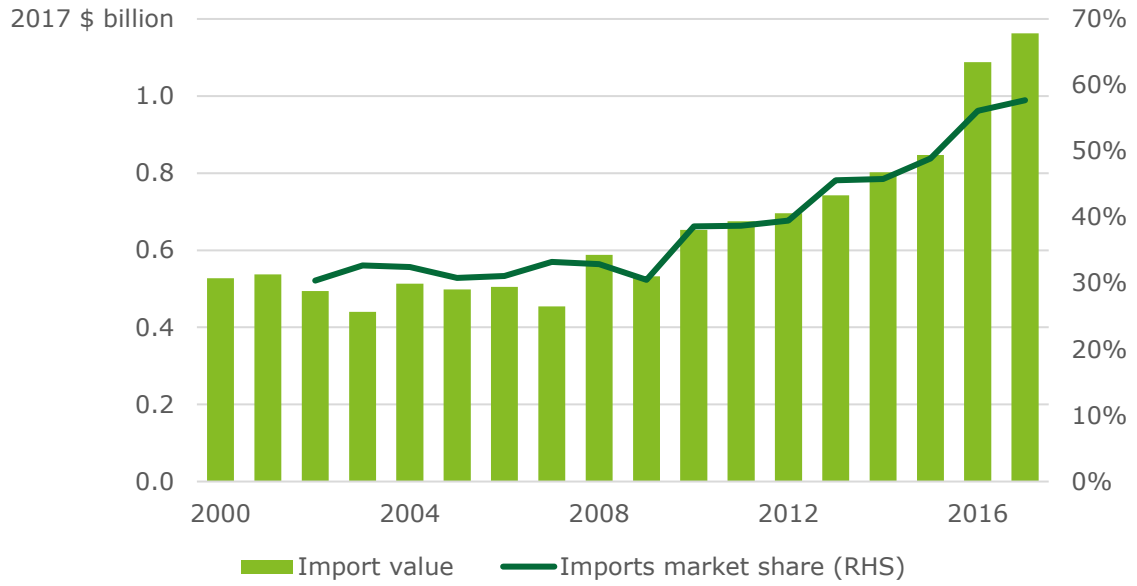
Other companies include Accensi, BASF, Syngenta and DowDuPont. Locally, DowDuPont formulates and distributes a range of herbicides, fungicides, insecticides and nematicides that target the grain and specialty crop sectors. DowDuPont also carries out part of its agricultural chemical research and development (R&D) activities in Australia, focusing on materials for herbicides and fungicides. It has operated a joint venture with the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to develop compounds for new agricultural chemicals for over a decade.

Imports account for an increasing share of the market
In 2017, agricultural chemical imports were valued at just under US$1.2 billion (Figure A.2). Imports account for 59 per cent of the Australian market for agricultural chemicals. This share has been rising – up from around 33 per cent a decade ago (IBISWorld Australia 2018b).

The increase in imports reflects rising cost pressures faced by manufacturing in Australia and increasingly competitive pricing of overseas suppliers. Manufacturers in Australia are outsourcing an increasing proportion of production or have left and set up international operations (IBISWorld Australia 2018b).

Imports historically consisted mostly of active constituents, with manufacturers in Australia formulating products in Australia. However the reduction in local manufacturing and the rise of imports has resulted in imports consisting increasingly of formulated products (IBISWorld Australia 2018b). China, the United States, New Zealand and Malaysia supply over 70 per cent of all imported product (United Nations 2019).

Figure A.2: Value of Australian agricultural chemicals imports and imports' market share



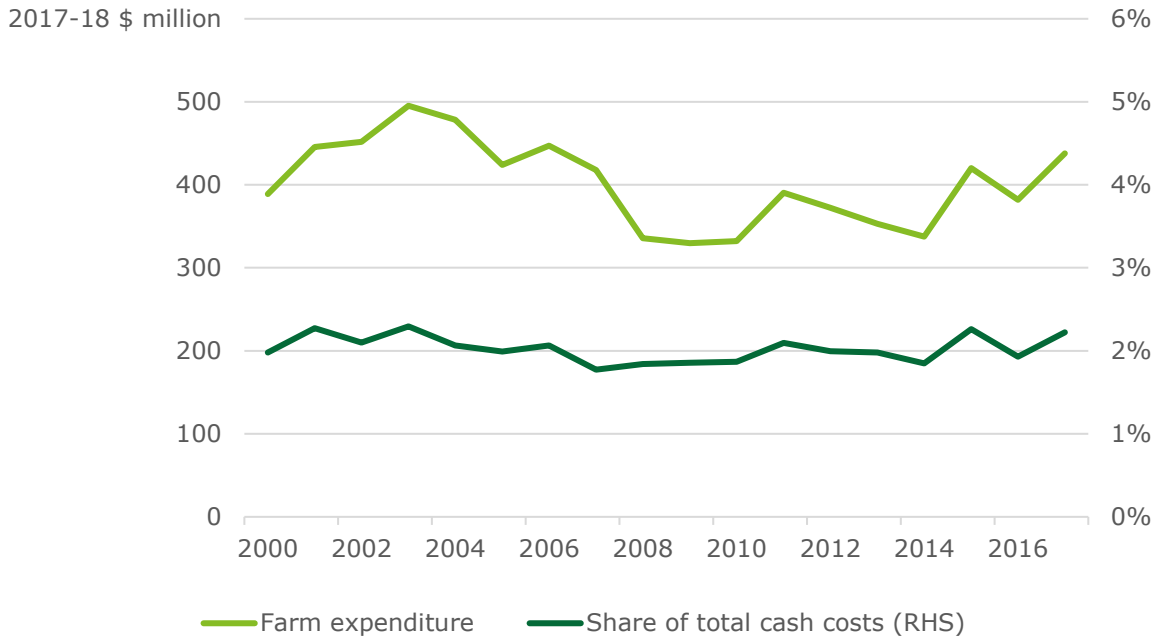
Source: United Nations (2019); IBISWorld Australia (2018b)

The veterinary medicines market

This sub-section profiles the Australian market for veterinary medicines, not just novel ones.

Livestock numbers drive Australia's veterinary medicines market
Australian broadacre farm expenditure on veterinary medicines totalled $438 million in 2017 (ABARES 2018c). Since 2000, veterinary medicines expenditure has fluctuated between $300 million and $500 million (Figure A.3). This has been driven largely by changes in Australian livestock numbers, with veterinary medicines remaining at a steady share of total costs (2 per cent).

Figure A.3: Veterinary medicine expenditure by Australian farms, and share of total farm costs



Source: ABARES (2018c)

Veterinary medicines in Australia dominated by parasiticides
Data sourced from Animal Medicines Australia indicates that the Australian market for veterinary medicines is dominated by parasiticides, which accounted for 33 per cent of livestock veterinary medicine sales value in 2015-16 (ACIL Allen Consulting 2018). This was followed by vaccines (29 per cent). This broadly aligns with that reported by the APVMA (APVMA 2019a), although the scope of the APVMA's data is broader and includes companion animals. In discussing the market for veterinary medicines in Australia, the remainder of the statistics in this section are inclusive of companion animal products (due to a lack of disaggregated data).

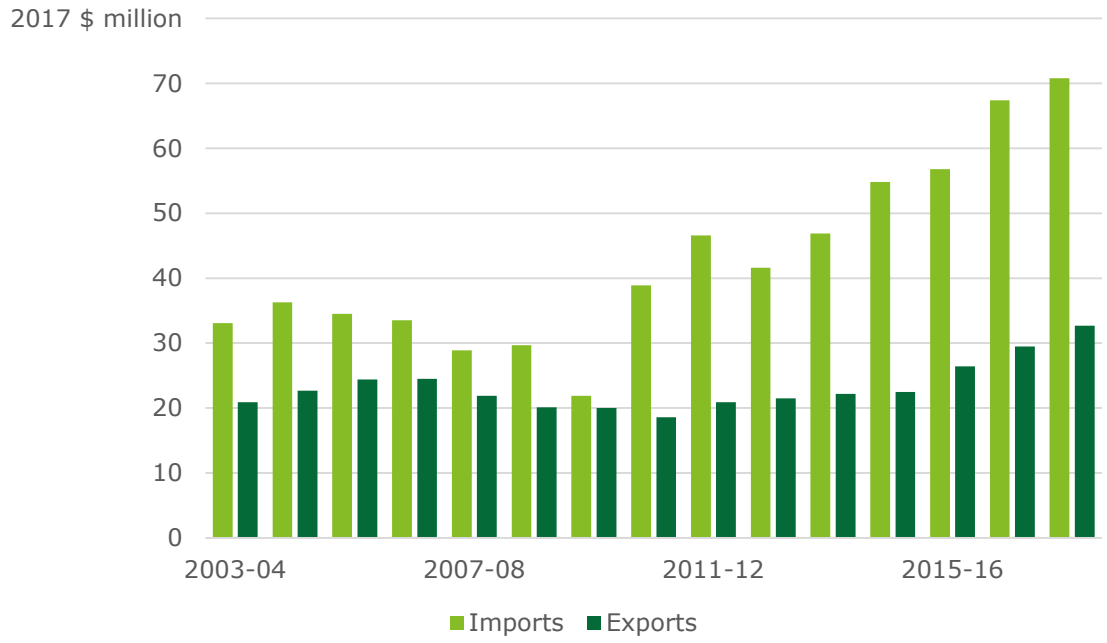
Secondary manufacturing dominates veterinary medicine production in Australia
Very little primary manufacturing of veterinary medicines occurs in Australia, with secondary manufacturing, the formulation or packaging of imported actives, dominant (IBISworld Australia 2018a). Veterinary medicines manufacturing in Australia is dominated by three global companies: Zoetis Australia, Intervet Australia and Virbac (Australia). Collectively these three firms account for around 75 per cent of the market. Jurox is the only Australian-owned and operated firm and has a market share of around 7.5 per cent (IBISworld Australia 2018a).

As with the agricultural chemicals, the market for veterinary medicines in Australia is influenced by climatic conditions. In the decade prior to 2010, Australian agriculture was subject to an extended period of below average seasonal conditions. During this period, veterinary medicines industry revenue contracted annually by around 1 per cent as livestock numbers contracted and farm incomes and expenditure shrunk (IBISworld Australia 2018).

Imports are rising but continue to account for a small share of the market
In 2017-18, Australia imported around $100 million of veterinary pharmaceutical and medicinal products (IBISworld Australia 2018a). Most imports arrive from the United States and European countries such as the Netherlands and Spain, which are major pharmaceutical producing nations. The majority of these are active compounds for use in secondary manufacturing, with final product imports being a relatively small share of the market, accounting for just 10.5 per cent of domestic demand (IBISworld Australia 2018a). Despite this, final products have reportedly been rising as a share of total imports (IBISworld Australia 2018a). The value of Australian vaccine imports has doubled in real terms in the last decade (Figure A.4).

Australia is also an exporter of veterinary medicines, however the value of exports is smaller than imports at $33 million (IBISworld Australia 2018a). Major export markets include New Zealand, Iran, the United Kingdom and the Netherlands.

Figure A.4: Value of Australian veterinary vaccine imports and exports, 2017 $ million



Source: IBISworld Australia (2018a)

Appendix B Examined and implemented policy options

This appendix describes policy options identified as part of this project that have the potential to improve access to novel agvet chemicals. These options have been previously examined by the Department, some of which have been implemented in various forms.

Previously implemented policy options

This section outlines options that the Australian government has previously implemented that have ameliorated the effect of Australia's small market size.

Crop grouping

In submitting evidence in support of an application for registration with the APVMA, manufacturers have historically only been able to submit individual residue studies for each crop treatable by the chemical. Crops can, however, now be grouped according to similarities in botanical and morphological characteristics, as well as agronomic production practices — crop groups can also contain smaller and more closely related crop subgroups. This is known as 'crop grouping', a practice recently established (in late 2018) by the APVMA to enable it to recognise data generated in a subset of crops and extrapolate it to other related crops within that same crop group, with little or no additional data (or assessment) required. In practice, where registration or a permit has been granted for representative crops, automatic extension or approval would be granted to all other crops within the group (and possibly across other groups) with little or no additional data or streamlined data.

Crop grouping is a common practice among international regulators and is used to streamline the establishment of data guidelines and regulatory risk assessments. The concept was first introduced into the US in the early 1970s. In the US, crop grouping is used to set tolerances for both major and minor crops and has become an increasingly relevant mechanism because of the rapid development of global food crop markets and international trade (USDA NIFA 2006).

Crop grouping has been recently introduced into Australia

As part of the Australian Government's commitment to improve access to agricultural and veterinary chemicals, the APVMA has introduced crop grouping for the purpose of agvet chemical registration in Australia. The Australian system is based on extrapolation, similar to the EU system. Here, the mechanism identifies the key crops for which data may then be used to support registration in other related crops. For example, apple, pear, and quince may be extrapolated to persimmon (APVMA 2018a, 2019b).

Australia also participates in the International Crop Grouping Consulting Committee — which works to revise and harmonise crop groupings at the international level. Additionally, the Department has provided a grant of $130,000 to the APVMA to establish an official Australian list of crop groupings and develop associated guidelines.

Use of crop groupings offsets some of the effects of Australia's small market

While only recently introduced, and depending on the industry's uptake of this registration option, grouping crops indirectly increases the size of the potential Australian market for novel agvet chemicals. It does so by relaxing restrictions on the crops that chemicals can be applied to. This has the potential to increase the potential market size of products for producers looking to register a novel agvet chemical in the Australian market, since the number of uses could be extended beyond a single crop type.

Grouping crops could also result in lower registration costs for applicants looking to register a product for multiple uses. Extending the registration for a single crop to a group of similar crops maximises the use of data generated from testing on any individual crop. In the US for example, crop groupings allow for around 10 new uses for a single residue study. Prior to the introduction of crop groupings, one residue study would result in only one new use (US NIFA 2006). This is demonstrated in US *Crop Group table 15 - Cereal Grains Group* (US

Government n.d., 41), which shows that corn (*Zea mays*), rice (*Oryza sativa*), sorghum (milo) (*Sorghum* spp.) and wheat (*Triticum* spp.) can be used as representative crops for the rest of the 'cereal grains' crop group which also includes:

- Barley (*Hordeum* spp.)
- Buckwheat (*Fagopyrum esculentum*)
- Millet, pearl (*Pennisetum glaucum*)
- Millet, proso (*Panicum milliaceum*)
- Oats (*Avena* spp.)
- Popcorn (*Zea mays* var. *everta*)
- Rye (*Secale cereale*)
- Teosinte (*Euchlaena mexicana*)
- Triticale (*Triticum-Secale* hybrids)
- Wild rice (*Zizania aquatica*)

The APVMA relies on international evidence in support of its decisions

In 2015 the APVMA released its policy on the use of international data, guidelines and standards that applicants would submit for review (APVMA 2015). The policy states that, although it will not adopt the decisions of another regulator, it will use the standards, data and assessments of other international organisations and regulators in making its own decision. In 2017-18, the APVMA used international data and assessments from other regulators to inform the decision on 28 product applications (APVMA 2018b).

Broadly, the policy outlines that the APVMA will accept data and information in support of overseas applications, but not the application itself or the resulting outcome. 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 pharmacopoeial standards.
- Internationally developed and endorsed standard methodologies for exposure assessment such as those used for worker safety and consumer safety.

Accepting the standards, data and assessments of other international organisations and regulators could reduce the time taken to register an agvet chemical, as well as reduce information-gathering costs and lower the statutory fees paid by the applicant.

Australian Government takes part in International Joint Reviews

The Australian Government also participates in International Joint Reviews of Agvet Chemicals (joint reviews), where the regulatory authorities of multiple countries collaborate to review a single application. The assessment work is split amongst the review partners. In this way, assessments are shared and harmonised hazard assessments are produced. Once approved, the chemical becomes registered in a number of countries within a specified and predictable time period. Australia completed its first global joint review of a pesticide dossier in 2007 (APVMA 2018c, 2016). In 2016, the APVMA approved *Metcam* – an animal health drug - alongside Canada and New Zealand.

Australia is harmonising its regulatory system with international regulators

Australia already participates in a range of international programs that promote harmonisation and regulatory convergence. For example, Australia participates in the OECD Working Group on Pesticides (APVMA 2017), and has observer status on the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) program. Through participation in these programs, the Australian regulatory system is aligned in assessing agvet chemicals through assessing efficacy data (VICH) and testing of chemicals (OECD guidelines).

Other policy options

This section outlines other policy options identified that have previously been examined by the Department, but which haven't been implemented. These options would not affect the most significant barrier identified as part of this report — the size of the Australian market — for which there are few (if any) levers available to the government. This section considers how each of the options could influence the priority drivers and barriers, as well as the benefits, costs and risks associated with them.

Optional submission of mandatory efficacy assessments to APVMA

For most agricultural inputs (such as capital equipment and fertiliser), farmers are left to make their own determination on the relative efficacy of products. However, in the case of agvet chemicals, manufacturers are required to submit evidence to the APVMA that a product will work to its stated purpose and efficacy. The APVMA then makes an assessment of that evidence, and must be satisfied that the chemical will be effective for its stated purpose for the product to be registered in Australia.

Efficacy assessments are common across international regulatory systems for agvet chemicals. However, not all countries require the submission of supporting data with their applications. In the United States for example, manufacturers are not required to submit evidence to support efficacy, rather they are required to possess it should the regulator wish to assess it in the future.

Adopting a similar approach in Australia to that in the United States may reduce the quantity of information assessed by the APVMA. This could reduce the time and cost to register agvet chemicals in Australia and improve access to novel agvet chemicals by making registration more attractive.

Proposed option

One policy option is to remove the requirement for applicants to submit evidence of efficacy to the APVMA, unless:

- It is required to satisfy safety considerations; or
- The applicant chooses to submit evidence of efficacy for the APVMA to consider.

Under this policy option, chemical manufacturers would still be required to collect and retain evidence which supports the efficacy of their products. However this evidence would not be required to be submitted in support of an application made to the APVMA. Instead, chemical manufacturers would need to 'hold' efficacy evidence so that it may be assessed by the APVMA should it request it at any point after registration. This option is modelled after the approach currently adopted in the United States.

Benefits of this approach

Making efficacy assessments optional could reduce the cost and time to register agvet chemicals by reducing the scope of assessment undertaken by the APVMA. In the absence of efficacy, only evidence in support of safety and trade would need to be assessed by the APVMA. This has two potential effects: firstly, optional submission of mandatory efficacy assessment data may result in faster application assessment periods and secondly, it could reduce the resources required by the APVMA for individual applications. Because the APVMA's application fees are set according to cost recovery principals, this may lower APVMA's statutory fees.

This option would be likely to apply to more agricultural chemicals applications than veterinary medicines. This is because animal medicines that are not efficacious may put animal health and welfare at increased risk. In cases such as these, it is important that those medicines are efficacious. For many agricultural chemical products, however, relaxing the efficacy criteria would not necessarily compromise safety if used according the label instructions.

Costs and risks associated with this approach

One of the primary risks in removing the requirement for manufactures to submit evidence of efficacy is that it would increase the risk of an ineffective chemical being registered. This would likely impose costs on other parties (particularly the users of the chemical) or on the general public. Stakeholders have previously noted that agricultural producers may lack the resources to pursue compensation for exaggerated efficacy. However, as already stated, this is also true of many products, which do not have protections beyond the usual protections provided by Australian consumer law and the ACCC and contract/commercial law, while businesses are protected under Consumer Law for purchases of goods and services under $40,000. Furthermore, industry bodies and Rural Research and Development Corporations (RDCs) play a role in trialling new products and

informing farmers of their outcomes. This information would also be disseminated through grower groups and agronomists. This means that non-performing products would probably be identified swiftly.

Not requiring the APVMA to assess efficacy would also remove a safety net for Australian farmers and a trusted source of information that signals whether a product is efficacious. However, as noted earlier, this support is not available for most other farm inputs, nor is it a mechanism used by other industries. Outside of agvet chemicals, the government allows market signals, rather than regulation, to provide product efficacy information to its users. It is also important to note that the safety net provided by the APVMA is a driver of demand for novel agvet chemicals. Agricultural producers would possibly have weaker demand for a given product if they knew less about its performance in managing pests and diseases. Instead, producers may favour established management practices. Because of this, allowing for optional efficacy assessments by the APVMA may ultimately reduce the supply of novel agvet chemicals as manufacturers face weaker demand in the Australian market.

There are also positive externalities associated with the treatment of a pest or disease. Ensuring the efficacy of a novel agvet chemical before it is approved for use could prove to be a critical factor in preventing the spread of a pest or disease. In circumstances such as this, it would be in the public interest for the APVMA to have assessed the efficacy of any agvet chemicals used to manage or prevent an outbreak. However, it is important to note that (under this policy option) optional assessments of efficacy would not apply to chemicals used for treating outbreaks that would affect human health (e.g. Hendra Virus). For products that address those pests and diseases (such as mosquitos and rats), applicants would be required to submit evidence of efficacy, which the APVMA would assess to be satisfied the product meets safety criteria.

There is also a risk that this reform may compromise Australia's strong global reputation for agvet chemical regulation. There is evidence that this strong reputation is a driver of supply. Some manufacturers have indicated that Australian registration of their products aided their registrations in other jurisdictions (See the driver "Australia is viewed as a first choice regulator and this drives the supply of agvet chemicals" in Appendix C for further details) (Gregg et al. 2010). Registration of a chemical in Australia (as well as the UK and United States) has, in some instances, been sufficient for foreign governments to allow it to be sold (Gregg et al. 2010). This is, in part, because Australia's regulatory system is focussed on the safety and efficacy of individual chemicals.

Allowing external third parties to make assessments against the standards set by the APVMA
Currently, by default, agvet chemical manufacturers only use the APVMA to assess products or actives before they are registered or approved in Australia because of the form in which the APVMA accepts applications. This approach is common in most other comparable jurisdictions although some jurisdictions have separate entities to assess agricultural chemicals and veterinary medicines. New Zealand is the only comparable jurisdiction where the regulatory body largely does not undertake assessment of agvet chemicals (unless requested to do so by the applicant), instead it reviews assessments made by third party assessors. This model of assessment is common in Australian markets outside agvet chemicals, including for example the building and construction sector.

In New Zealand, the Ministry for Primary Industries (MPI) administers the Agricultural Compounds and Veterinary Medicines Act 1997 which focuses on agvet chemicals. The MPI works with the NZ EPA, who administers the Hazardous Substances and New Organisms Act (1996) which covers a wider range of chemicals and their risks to health, safety and the environment. Prior to submitting an application to the NZ MPI, prospective applicants must have their chemical product assessed by a suitably qualified person. This approach means chemical manufacturers generally engage independent third parties to draft assessments of their data packs, which leaves the New Zealand regulator with more of a peer review role.

The APVMA already outsources elements of its technical assessments to third party external assessors who are experts in the fields of human health, environment, efficacy and target animal and crop safety risk assessment (these assessors are used for applications lodged with the APVMA). The APVMA has also conducted a pilot project, allowing applicants to engage third party external assessors to conduct a pre-application assessment of efficacy and target animal and crop safety. Under the pilot, assessors are engaged directly by applicants, rather than by the APVMA.

Proposed option

One policy option considered here is for the Australian regulatory system to adopt partially or in full, the New Zealand approach. Under this approach, third parties would be used to assess applications for novel agvet chemicals, based on standards detailed by the APVMA. Third party assessment of a novel agvet chemical would be undertaken prior to the application submission to the APVMA, with the APVMA reducing its role in assessments to one of review.

Benefits of this approach

The primary benefit of this approach would be to provide applicants with more control over data assessment timeframes and costs. The provision of assessments by third party providers prior to submission of the application to the APVMA may allow chemical companies to better manage their timelines for registration. For example, applicants would have the option to submit data for assessment as it becomes available, or pay third party assessors to undertake an assessment with greater speed at a higher cost.

This approach is likely to increase the efficiency of application processing for the APVMA, causing a reduction in application processing periods. Ultimately this may make novel products available to agricultural businesses sooner than otherwise would be the case. This approach could also reduce the resources required of the APVMA in assessing and registering novel agvet chemicals.

Costs and risks associated with this approach

The cost of this approach is likely to differ across stakeholders. The Australian Government, for example, could incur significant initial costs in transitioning to this approach if there was a requirement to set up an accreditation scheme prior to accepting third party assessments, and changes to existing governance and processes would also involve costs.

Since the burden of proof (in terms of data requirements and criteria) would be unchanged under this proposed option, the cost to manufacturers should be broadly similar to those of the current system. Furthermore, lower registration fees with the APVMA would probably be partially or fully offset by the costs incurred in using third party assessors. It is also possible that registration costs would increase – which was a concern highlighted by at least one stakeholder, who requested pricing of applications to be monitored if this approach was adopted.

Under this proposed option, there may be a greater risk of unsafe or inefficacious chemicals being registered than would otherwise be the case. The APVMA currently effectively manages the risk of fraudulent data, however additional safeguards may be required should a third party assessor option be adopted. The APVMA would need a mechanism to ensure that third party assessors supported the continued integrity of the system. This might include for example an accreditation scheme where third party assessors are audited — such as in the building and construction industry.

There is also potential for this option to compromise Australia's strong global reputation for agvet chemical regulation which is underpinned by the independent regulator's assessment of scientific evidence in support of efficacy and safety. Introducing an option for third parties to undertake the assessment of evidence in support of an application would diminish the regulator's role and this may weaken reputation of the Australian system. Because the strength of the current system is a driver of supply for novel agvet chemicals — with manufactures seeking registration in Australia to facilitate approval in other markets — weakening the system's reputation may in fact reduce the supply of novel agvet chemicals.

Appendix C Other identified novel agvet chemical drivers and barriers

This appendix lists the seven drivers and barriers that are considered to be outside of the five priority categories. These barriers and drivers were considered to have a limited impact on access to novel agvet chemicals in Australia, relative to those described in Chapter 2. Furthermore, the Australian Government would not be able to reasonably influence these drivers and barriers through policy changes or regulatory reforms.

Barriers

Australian demand is restricted by its unique pests and diseases

Agricultural producers in Australia may require different agvet chemicals from those in other parts of the world (Deloitte Access Economics 2018). Australia's geographical isolation and island status and rigorous quarantine and biosecurity systems limit the establishment of overseas pests and diseases and a number of pests and diseases are endemic only to Australia such as Queensland Fruit Fly (*Bactrocera tryoni*) (QDAF 2013). This restricts demand for some novel chemicals that are used in (or being developed for) other parts of the world, since they would not be necessary or appropriate for use in Australia (Deloitte Access Economics 2018).

Producer demand for novel products can be restricted by high prices

Price is a key consideration for farmers choosing agvet chemicals, as they trade-off between affordability and efficacy. Limitation periods allow manufacturers to recover the R&D costs incurred in getting an innovative product to market by providing market exclusivity. Limitation periods last for a specified time, currently ten years post-approval for agricultural chemical actives and products in Australia, and act to restrict competition in the supply of that specific chemical or product. They allow manufacturers to increase the sale price above the marginal cost of production, yielding higher returns than would otherwise be possible (Timmermann 2014).

There are several examples of the mark-up in agricultural chemical pricing that market exclusivity brings during limitation periods. For example, the price of *deltamethrin* halved to US$220/kg, and the price of *glyphosate* fell from around US$7.3/kg to US$2.7/kg, when the limitation period for each of those chemicals expired in 2000.

There is also evidence to suggest that novel chemistries are becoming increasingly expensive to commercialise due to the complexity of developing new molecules with more specific toxicological requirements and reduced environmental risks (Sparks and Lorsbach 2016). Simple molecules such as DDT and organophosphorus insecticides, which cost US$1/kg, have been substituted by more complex and expensive molecules which cost US$200/kg.

Conservative decision making limits adoption of innovations in agriculture

Demand for novel chemistries can also be a result of decisions made by agricultural producers to incorporate innovations into their production systems. Decisions to adopt new technologies or management practices are themselves determined by a range of case-specific socio-economic factors relevant to the producer, their production system and their environment.

In Australia, the main barriers to adoption often include financial capacity and, anecdotally, aversion to risk, as well as any characteristics that leave the agvet chemical at a disadvantage to existing management practices.

Agricultural producers will not adopt new technologies or management practices if they do not have appropriate *financial capacity*. Trialling and integrating innovative pest and disease management approaches into production systems requires financial assets, access to credit and an ability to incur costs and potential losses (Nossal and Lim 2011). Agricultural producers will therefore not trial or adopt new agvet chemicals unless they have the financial capacity to replace or modify existing management practices with new ones.

Financial capacity is particularly important in Australia due to the determining influence of the variable climate. Seasonal conditions in Australia are directly correlated with farm incomes and input use. Droughts for example are correlated with low crop yields and reduced use of agricultural chemicals, as well as reductions in livestock numbers and consequently lower demand for veterinary medicines (IBISWorld Australia 2018a).

Risk aversion is a general preference for a sure thing rather than a gamble with the same statistically expected value. Empirical evidence indicates that farmers most commonly lean towards risk aversion, although individual preference profiles vary widely (Feder and Umali 1993; R. K. Lindner 1987; Lindner, et al 1982; Kuehne et al. 2017). Because of this, agricultural producers can be less willing to adopt new technologies or management practices due to the perceived risk that it may not improve their production system. Risk aversion therefore acts as a barrier to demand for novel chemicals as producers prefer established chemistries.

Even in instances where agricultural producers are willing and able to adopt new chemistries, their decision to adopt novel agvet chemicals may be influenced by the *requirements of export markets*, since around 70 per cent of Australian agricultural production is exported (ABARES 2018a). Access to international markets is affected by a range of technical barriers to trade, with many countries setting restrictions on input uses, including Maximum Residue Limits (MRL) (see Table A.2 in Appendix A for examples) or outright bans (e.g. EU ban on hormone growth promotant chemicals).

Producers who wish to service specific markets must adhere to the product-specific thresholds declared by individual countries. This may prevent some producers from adopting the use of a novel chemistry, if its use potentially risks the eligibility of the treated commodity to be sold in target markets.

Table C.1: Permitted chemicals for use on wheat post-harvest and applicable Maximum Residue Limits (in mg/kg), 2018–19

Chemical	Codex	China	India	Indonesia	Japan	South Korea	Taiwan	Thailand
Chlorpyrifos-methyl	3.0	5.0		10.0	10.0	3.0	5.0	3.0
Dichlorvos	7.0	0.1	1.0	7.0	0.2	7.0	0.02	0.2
Fenitrothion	6.0	5.0	0.01	na	10.0	0.2	0.5	6.0
Pirimiphos-methyl	7.0	5.0	5.0	na	1.0	5.0	5.0	7.0
Deltamethrin	2.0	0.2	0.5	na	1.0	0.1	1.0	2.0
Methoprene	10.0	na	na	na	5.0	5.0	2.0	10.0
Piperonyl butoxide	30.0	30.0	na	na	24.0	0.05	15.0	30.0
Pyrethrins	0.3	na	na	na	3.0	3.0	0.3	0.3
Spinosad	1.0	1.0	na	na	2.0	1.0	1.0	1.0 na
Carbaryl	2.0	na	1.5	2.0	na	2.0	0.02	2.0
Bromide ion	50.0	na	na	na	50.0	na	na	na
Phosphine	0.1	0.05	na	na	0.1	0.1	0.1	0.1
Sulfuryl flouride	0.05	0.1	na	na	0.1	0.08	na	0.05
Methyl bromide	na	5.0	25.0	na	na	50.0	na	50.0

Note: Codex (Codex Alimentarius Commission) is the international body responsible for developing food standards and guidelines for protecting the health of the consumers and ensuring fair trade practices in the food trade. Codex sets international MRLs.

Source: Grain Trade Australia (2018)

Drivers

Demand for novel agvet chemicals is driven by the emergence of new pests and diseases

The introduction or emergence of new pests and diseases is a strong driver of demand for novel agvet chemicals. New pests and diseases can arrive in Australia in a variety of ways, including through climate change (e.g. the geographic spread of livestock virus vectors due to global warming), spontaneous emergence or mutation, or via a breach in Australian biosecurity (e.g. though rapidly increasing containerised trade and domestic and international travel movements) (Wittmann, et al 2001; Horticulture Australia 2012).

In the last three years, at least three highly destructive exotic pests and diseases — white spot disease, tomato potato psyllid and Russian wheat aphid — have been detected in Australia. These pests and diseases were on the national radar of priority, but still managed to enter Australia via unknown pathways (Horticulture Australia 2012).

Any new pest or disease will require consideration of how best to manage the threat. Existing technologies or practices may be sufficient. However novel approaches, including specialised chemistries, may also be required. In some instances, actives already approved for use in Australia may not supress the introduced pest or disease efficiently or effectively, so new actives or products are needed.

Structural and geographic changes to agricultural production shift demand for agvet chemicals

Demand for novel agvet chemicals can be driven by changes in agricultural production patterns. This includes both the introduction of new agricultural commodities into Australia (e.g. saffron into Tasmania) and the geographic shift of existing production (e.g. expansion of cattle into northern Australia), as well as the commercialisation of native products (e.g. Kakadu plum, native pepper and seaweeds).

Structural change in Australian agriculture can result in pests and diseases being co-located with production in ways that may not have previously occurred. Treating these pests and diseases may require consideration of new and innovative management practices, with novel chemistries a possible solution.

The link between land use change and pesticide use is demonstrated in a recent report by Urruty et al. (2016) which showed shifts in France between crop types had a significant impact on pesticide use, while large scale land use changes (such as converting grassland to arable land) had a commensurately larger impact on total pesticide use.

Australia is viewed as a first choice regulator and this drives the supply of agvet chemicals
Australia has a robust and independent system for regulating the agvet chemical market. This acts as a driver of supply with manufacturers registering their products in Australia to aid their registrations in other countries.

Registration of chemicals in Australia (as well as the UK and United States) has been deemed sufficient for use in other countries. (Gregg et al. 2010) for example, in discussing insecticides reports:

> *"MOOV® is now sold in Asia and the Middle East because its Australian registration, and early discussions in potential markets for Magnet® in south-east Asia have also indicated the value of Australian registration".*

This is in part because Australia's regulatory system is focussed on the safety and efficacy of individual chemicals. It also reflects Australia's low country and sovereign risk more generally. This is demonstrated through a range of international measures, including the World Bank's index of government effectiveness. This index measures perceptions of the quality of public services, the quality of the civil service and the degree of its independence from political pressures, the quality of policy formulation and implementation, and the credibility of the government's commitment to such policies. Of 193 countries, Australia ranks 17th (World Bank 2017).

Increased resistance to existing agvet chemicals drives demand for novel chemistries
Resistance describes the reduced susceptibility of a pest or disease to a treatment regimen that had previously been effective. Over time, pest species develop pesticide resistance via natural selection, with the most resistant pests surviving treatment and passing on their heritable traits to the next generation.

Resistance is a global phenomenon, although it has been most heavily concentrated where agvet chemical use is greatest, namely the United States, the European Union, Canada and Australia (Australian Herbicide Resistance Initiative 2014). Global herbicide resistance cases have increased from negligible levels in the late 1950s (when pesticides were first commercially available) to around 500 cases of resistance in 2019 (Heap 2019). In Australia, around 90 weeds are reportedly resistant to herbicides, with the first case — Rigid Ryegrass in Western Australian — reported in 1982 (Gill 1995).

As a pest or disease population becomes increasingly resistant to existing treatment regimens, agricultural producers, manufacturers and scientists look to alternative management strategies. This includes the discovery of new biochemical pathways to combat and reduce populations and coverage of pests or disease. An example is an insecticidal neurotoxic venom peptide developed from the venom of an Australian tarantula (Hardy 2014b, 2014a). Changes to agricultural practices, such as encouraging crop rotation to curb the spread of weed seeds, are another approach being encouraged to fight pest and disease resistance (Borel 2018).

Appendix D Estimated Revenues of Agricultural Chemical Products

This section details the estimation presented in Section 2.1.1 of potential market size in Australia for selected chemicals that have not been registered with the APVMA.

First, we identified chemicals that have been registered overseas but not in Australia. A large number of agvet chemicals were found to satisfy this criteria, principally found via Zheng (2016; 2017; 2018) and Xie (2015). Table D.1 lists those chemicals registered in the United States but not in Australia, that were identified.

Table D.1 Selected chemicals registered in the United States but not Australia

Manufacturer	Product	Active Ingredient	Group	Treated crop(s)
Dow AgroSciences	Loyant	Rinskor	Herbicides	Rice
Bayer CropScience	COPeO Prime	Fluopyram	Nematicides	Cotton
Dow AgroSciences	N/A	Meptyldinocap	Fungicides	Grapes
DSM	Zivion P	Natamycin	Fungicides	Pineapples
SePRO	Brake	Fluridone	Herbicides	Cotton
Helm Agro	Helm Sulfentrazone 4F	Sulfentrazone	Herbicides	Sunflowers, soybeans, tobacco, tomatoes and strawberries
Helm Agro	Sheridan 25WG	Chlorimuron	Herbicides	Soybeans, peanuts and non-crop areas
Gowan	Magister	Fenazaquin	Insecticides	Almonds, cherries, Christmas trees, non-bearing tree fruits and nuts
Dupont	Lumisena™	Oxathiapiprolin	Seed treatments	Soybeans and sunflowers

For chemicals registered in the US but not in Australia, we then looked to find information that would allow an estimation of the market size in the country of registration. For each country of registration, we searched for data on the following use and purchase statistics:

- Indicative farm gate prices
- Average application rates
- Average applications per annum
- Area of applicable crops
- Average annual area treated

Only three chemicals were found to have publically available data information that would inform each of the use and purchase statistics. These three chemicals are all registered in the United States:

- Summit Agro's SHIELDEX 400SC
- BASF's Caramba
- Valent's Elumin

None of these chemicals is registered by the APVMA, a number of assumptions are required to estimate potential annual revenue in Australia. US data was assumed to be directly applicable to Australia for:

- Indicative farm gate prices
- Average application rates
- Average applications per annum

Average annual area treated was also based on information from the US National Agricultural Statistics Service (NASS). However, values differ slightly between Australia and the US for Caramba and Elumin. This is because these two products are for use on groups of agricultural commodities, cereals, soybeans and sugar beets (Caramba) and Cucurbits (Elumin). Within these commodity groups, average treatable area rates differ considerably, with the treatable area of watermelon around five times that of squash. Because Australia and the US plant different areas of watermelon and squash, the weighted average of the commodity group differs between Australia and the United States.

Finally, the area of applicable crops was obtained for Australia and the US from UN FAO's FAOstat database – which reports annual cropping areas in hectares for a range of countries.

Indicative revenue assumes the chemical is able to capture the entire market once registered in Australia. However, this is unlikely to be the case. Many novel chemicals would have to compete with already established products in the market. For example, BASF's Caramba (used to treat Fusarium head blight), if registered would enter a market where Bayer's Prosaro 420SC is already established (Tonneson 2017). As such estimated potential market share over estimates the potential revenue for a particular agvet chemical and should be treated as an upper bound indicator.

Summit Agro's SHIELDEX 400SC

In 2017 Summit Agro US launched SHIELDEX 400SC (SHIELDEX) in the US (Summit Agro USA n.d.). SHIELDEX is a post-emergent contact herbicide designed for use on corn. Its active ingredient is Tolpyralate, which controls weeds by inhibiting HPPD (pigment synthesis) biochemical process. (Summit Agro USA 2014) The product can be used in the US on field corn, seed corn, sweet corn and popcorn (Summit Agro USA 2014). SHIELDEX is not currently registered in Australia.

Table D.2 Estimated annual market revenue for Summit Agro's *SHIELDEX 400SC*

Steps	**Units**	**United States**	**Australia**
Application rate	L/ha	0.0859	*0.0859*
Applications per year	No.	1.07	*1.07*
Annual application rate (Application rate X Applications per year)	**L/year**	**0.0919**	**0.0919**
Average harvested area of corn (5 years to 2017)	ha	34,057,660	62,327
Treated area per cent of area planted	per cent	10	*10*
Applied area (Average harvested area X per cent of planted area treated)	**ha**	**3,405,766**	**6,046**
Annual volume of agvet chemical applied (applied area X annual application rate)	**L**	**312,990**	**556**
Sale price	US$/L	$357	$357
Indicative revenue (Annual volume of agvet chemical applied X sale price)	**US$m/year**	**$111.7**	**$0.2**

Sources: Summit Agro USA (2014); USDA NASS (2019); FAO (2019); Pestrong (2019a)

Note: application rates, applications per year, treated area and sale price are assumed to be equivalent in Australia and the United States.

BASF Caramba

In 2014 BASF released Caramba. Caramba is a fungicide for use on cereals crops, soybeans and sugarbeet. Its active ingredient is metconazole, it is registered in the US but not Australia.

Table D.3 Estimated annual market revenue for BASF's Caramba

Steps	Units	United States	Australia
Application rate	L/ha	0.877	0.877
Applications per year	no.	1.06	1.06
Annual application rate (Application rate X Applications per year)	**L/year**	**0.928**	**0.928**
Average harvested area (5 years to 2017)	ha	439,352,920	86,923,135
Treated area per cent of area planted	per cent	5.9	11.4
Applied area (Average harvested area X per cent of planted area treated)	**ha**	**25,740,550**	**9,865,917**
Annual volume of agvet chemical applied (applied area X annual application rate)	**L**	**23,898,659**	**9,159,952**
Sale price	US$/L	$44.88	$44.88
Indicative revenue (Annual volume of agvet chemical applied X sale price)	**US$m/year**	**$1,072.6**	**$411.1**

Sources: BASF (n.d.); USDA NASS (2019); FAO (2019); Cropwatch (2017)

Note: application rates and sale price are assumed to be equivalent in Australia and the United States. Applications per year and treated area are also assumed to be equivalent at the individual crop level, but values differ when aggregated across broader crop groupings.

Valent Elumin

In 2014 Valent released Elumin in the United States. Elumin is a thiazole carboxamide fungicide for use on watermelons, squash and other cucurbits. Its active ingredient is ethaboxam, which controls foliar and soil borne disease.

Table D.4 Estimated annual market revenue for Valent's Elumin

Steps	Units	United States	Australia
Application rate	L/ha	0.585	0.585
Applications per year	no.	2.11	2.23
Annual application rate (Application rate X Applications per year)	**L/year**	**1.234**	**1.304**
Average harvested area (5 years to 2017)	ha	161,500	15,329
Treated area per cent of area planted	per cent	18.05	16.12
Applied area (Average harvested area X per cent of planted area treated)	**ha**	**29,145**	**2,471**
Annual volume of agvet chemical applied (applied area X annual application rate)	**L**	**35,965**	**3,222**
Sale price	US$/L	$121.52	$121.52
Indicative revenue (Annual volume of agvet chemical applied X sale price)	**US$m/year**	**$4.4**	**$0.4**

Sources: Valent (2017); USDA NASS (2019); FAO (2019); Pestrong (2019b)

Note: application rates and sale price are assumed to be equivalent in Australia and the United States. Applications per year and treated area are also assumed to be equivalent at the individual crop level, but values differ when aggregated across broader crop groupings.

Appendix E International evaluation criteria comparison

This appendix presents criteria against which agvet chemical regulators in Australia, NZ, Canada, the US and the EU assess agricultural chemicals and veterinary medicines.

Table E.1 Agricultural chemical registration criteria by country

	Efficacy	Distribution	Hazard	Exposure	Trade implications
AUS	Effective if it would achieve one of effects listed	Droplet size classification subject to extra regulation	Toxicity posed by chemical /potential harm	Amount of contact with hazard	Meets criteria if use does/would not prejudice trade between Australia & other countries
CAN	Efficacy assessments are part of testing if chemicals provide demonstrated benefit/value	Bridging trials needed to show product is evenly distributed	Approved when there is reasonable certainty there will be no harm to health/environment	Dynamic Risk Assessment to estimate human exposure over single day vs. lifetime - estimates from residue level & food consumption	na
EU	Overall improvement of yield or quality	na	Assesses extent of direct or indirect harm to human or animal health	Exposure not part of process – shift from risk-based approach to hazard-based	na
NZ	Efficacy standards complemented by criteria regarding crop tolerance & pest resistance	No explicit mention of how distribution plays into evaluation – dietary exposure forms basis for measurement	na	na	Information & technical data required regarding any possible impact on trade from use
US	Efficacy requirements – data submitted as part of application	Implicit – testing of intensity	'EPA must evaluate both hazard and exposure' – will identify adverse effects on health/environment as part of testing process	Duration, intensity, frequency, number of exposures	na

Sources: Australian Government (2014); APVMA (n.d.; 2014b; 2018d); US EPA (2018, 2017); NZ MPI (2014); PMRA (2003b, 2003a); Government of Canada (2019); den Hoed (2007)

Table E.2 Veterinary Chemical Registration criteria by country

	Efficacy	Animal welfare	Trade implications
AUS	Effective if it would achieve one of effects listed	'is not/would not be likely to have unintended effect that is harmful to animals'	Meets criteria if use does/would not prejudice trade between Australia & other countries
CAN	Monitors effectiveness of vet medicine – 'pure, potent, safe & efficacious'	'works to protect animal health' (more explicit discussion of human consumption of animal products)	na
EU	Guidelines on efficacy pre-market authorisation application	Target animal safety evaluation for submission of product application	na
NZ	Risks to animal welfare & national productivity as result of lack of efficacy – included in submission	Potential risks must be discussed in submission (apparent trade-off between efficacy and welfare?*)	Same as agricultural chemcials
US	Animal drug must be proven effective before approval (2nd criteria)	Safety as primary criterion e.g. ensuring medicines are made under sanitary conditions before animal can consume	na

Sources: Canadian Food Inspection Agency (2019); VDD (2019); EMA (2008, n.d); NZ MPI (2015); US FDA (2018); APVMA (2018e)

Appendix F International registration time and statutory fees

The following table details the various application types, and each application's indicative assessment period and fee required to be registered in the relevant country.

Table F.1 International registration times and statutory fees for selected registration types and countries

Application type	Australia	New Zealand[A]	United States[B]	United Kingdom	Canada
	Assessment period (fees in local currency)				
Approval of an **active** constituent contained in a chemical product, **registration** of the associated chemical product and approval of the product **labe**l requiring a **full assessmen**t of the active constituent and product	18 months ($96,135)	2 months (NZ$2,000-$5,000)	14-24 months (US$182,000 - $627,500)	30-42 months (~£197,600)	22 months (~ CA$194,535)
Approval of an **active** constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring **less than full assessment** of the active constituent and product	Modular assessment period and fee	2 months (NZ$2,000-$5,000*)	14-24 months (US$182,000 - $627,500)	30-42 Months (~£197,600)	na (~ CA$194,535)
Registration of a chemical product containing **an approved active** constituent, and **approval of the product** label, if there is **no registered chemical product** containing the active constituent and a **full assessment** of the product is required	18 months ($64,620)	2 months (NZ$3,000 - $4,000)	16- 21 months (US$191,144-264,000)	na	na (~ CA$152,950)
Registration of a chemical product containing an **approved active** constituent, and approval of the product label, if there **is a registered chemica**l product containing the active constituent and a **full assessment** of the product is required and there are **no relevant maximum residue** limits and poison schedule classification is required	18 months ($36,675)	3 months[C] (NZ$3,150 - $4,150[C])	10-15 months (US$26,500 - $66,000)	na	na (~ CA$152,950)
Registration of a chemical product containing an **approved active** constituent, and approval of the product label, if the product is **similar to a registered** chemical product and chemistry and manufacture, **efficacy** or target species **safety data is the only data** required to demonstrate the similarity of the product to the registered chemical product	8 months ($4,870)	2 months (NZ$2,000-$3,000)	4 months (US$1,500 - $1,900)	na	na (~ CA$152,950)

Application type	Australia	New Zealand[A]	United States[B]	United Kingdom	Canada
	Assessment period (fees in local currency)				
Registration of a chemical product containing an **approved active** constituent, and approval of the product label, if the product is **closely simila**r to a registered chemical product and **efficacy and safety data are not** required to demonstrate the similarity of the product to the registered **chemical product and chemistry and manufacture data are required**	8 months ($4,290)	2 months (NZ$2,000-$3,000)	7 months (US$5,300)	na	na (~ CA$152,950)
Registration of a chemical product containing an **approved active** constituent, and approval of the product label, if the product is **closely similar** to a registered chemical product and **efficacy and safety data are not** required to demonstrate the similarity of the product to the registered chemical product and **chemistry and manufacture data are not required**	3 months ($1,755)	2 months (NZ$2,000-$3,000)	na	na	na
Registration of a chemical product containing an **approved active** constituent, and approval of the product label, if the chemical product is the **same as a registered** chemical product and the product is to be registered with **a different name**	3 months ($1,655)	2 months (NZ$700 - $900)	na	na	na
Registration of a **listed chemical** product and approval of a product label where the product and label comply with an **established standard** that has been approved in accordance with section 8U of the code	2 months ($1,595)	2 months (NZ$2,000-$3,000)	na	na	na
Registration of a chemical product containing an **approved active** constituent (or an active constituent for which the APVMA has received an application for approval) and approval of the product label for **all situations other than those described** in items 3 to 9	Modular assessment period and fee	2 months (NZ$3,000 - $4,000)	10-15 months (US$26,500 -66,000)	na	na
Application for **approval of a labe**l for **containers** for a **registered chemica**l product	Modular assessment period and fee	na	na	na	na
Approval of an **active** constituent requiring a **full assessment**	14 months ($30,550)	2 months (NZ$2,000-5,000)	na	30-42 Months (~£197,600)	na (~ CA$194,535)
Approval of an active constituent requiring **less than a full assessment** but requiring a **toxicological** assessment	9 months ($18,805)	2 months (NZ$2,000-5,000)	na	na	na (~ CA$194,535)
Approval of an **active** constituent requiring **less than a full assessment** but **not requiring a toxicological** assessment	7 months ($3,155)	2 months (NZ$2,000-$5,000)	na	na	na (~ CA$117,211-194,535)

Application type	Australia	New Zealand[A]	United States[B]	United Kingdom	Canada
	Assessment period (fees in local currency)				
Approval or registration under section 10 of the code **requiring assessment of a technical** nature (other than of the kinds described in any of items 1 to 10, 15, 16 or 17)	Modular assessment period and fee	2 months (NZ$2,000-$5,000)	na	na	na
Timeshift application for approval of an active constituent that is **not a previously endorsed active** constituent or registration of a chemical product containing an active constituent that is not an active constituent contained in any other registered chemical product	Modular assessment period and fee	na	na	na	na

Note: **A** New Zealand's allowance of third party, independent assessors by registrants means that prices quoted by the Ministry for Primary Industries is only for their review and subsequent approval of assessments conducted by independent assessors. An additional fee is paid to the independent assessors, as required. **B** fees are for 2016–17; **C** indicates values reflect before poison analysis; na refers to not applicable.

Limitation of our work

General use restriction
This report is prepared solely for the use of the Department of Agriculture. This report is not intended to and should not be used or relied upon by anyone else and we accept no duty of care to any other person or entity. The report has been prepared for the purpose of reporting to the Department of Agriculture on the market drivers and barriers for the introduction of innovative agvet chemicals into the Australian market. You should not refer to or use our name or the report for any other purpose.

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