ACIL ALLEN CONSULTING

REPORT TO
DEPARTMENT OF AGRICULTURE AND WATER RESOURCES

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REVIEW OF INTERNATIONAL IP & REGISTRATION ARRANGEMENTS FOR THE REGULATION OF AGVET CHEMICALS

FINAL REPORT

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EXECUTIVE SUMMARY

This study has examined intellectual property (IP) settings and registration arrangements as they relate to agricultural and veterinary (agvet) chemical markets across selected OECD countries, including Australia. The purpose was to review the evidence and propose changes, where appropriate, to improve Australian agricultural producers' access (through registration by the Australian Pesticides and Veterinary Medicines Authority), to innovative agvet chemicals while also supporting access to generic agvet chemicals. Key insights from the study follow.

The overall conclusion is that Australia's IP and broad data protection settings are internationally competitive given the size of our market and should remain unchanged beyond maintaining international alignment. Efforts to improve Australian farmers' access to agvet chemicals through increased registrations would be better focussed on the registration process.

Agvet chemical markets

The major markets for agvet chemical products are North America and the EU. Both of these markets are home to major producers of agvet chemical products. Australia, by contrast, is a very small market on the other side of the world (less than 1.5 per cent of the world agvet chemical market). Australia's pesticide manufacturing industry is highly concentrated, with the top four manufacturers estimated to account for more than 97 per cent of total industry revenue in 2015-16. Nufarm is the largest, and is a generic chemical producer.

The small size of the Australian market means it can provide only limited returns to agvet chemical manufacturers. If Australia wants fast, or faster, access to agvet chemical products, it has to operate a regulatory regime that recognises this market reality. Therefore, Australian agvet chemical regulation needs to be internationally competitive in relation to costs, administrative hurdles, application processing time, intellectual property and data protection, and incentives. In several of these areas Australia's arrangements are internationally competitive.

The global market for agvet chemicals was dominated in the 1980s by patent-protected products. However, new patented active ingredient introductions have been declining since then because of increasing research and development costs and time and effort required to satisfy regulators. As active ingredient patents and data protection expired, the use of off-patent, or generic agvet chemical products, has grown significantly.

Australia, mirroring the global market, has also seen a dramatic increase in the supply of generic agvet chemical products over recent decades. However, as a comparatively small agvet chemical market, imports play a significant role in meeting Australian demand for pesticides. The situation for veterinary chemicals/pharmaceuticals is different. Given that Australia has many more manufacturers of veterinary products, imports only play a small role in meeting local demand in this area.

KEY FINDING ES 1 AN INTERNATIONALLY COMPETITIVE AGVET REGULATORY SYSTEM

In order for Australia's agriculture sector to be internationally competitive, fast access to agvet chemicals is essential. To achieve this, the relevant regulation needs to be internationally competitive in relation to costs, administrative hurdles, application processing time, intellectual property and data protection, and incentives. Overall, the analysis has found that Australia's arrangements are internationally competitive in several of these areas.

Intellectual property and data protection

Patents are a core feature of the market for agvet chemical products. Patent laws in Australia, the EU including the UK and Germany, the USA, Canada and New Zealand all provide standard patent terms of twenty years.

Patent term extensions are not available for agvet chemicals in Australia. They are available for human pharmaceuticals, however, the Productivity Commission has found that these arrangements have not proven effective.

Data protection is where regulators protect the data related to studies and tests undertaken to demonstrate the safety and efficacy of agvet chemicals. Data protection is meant to protect the property rights of the owners of new agvet chemicals. Data protection provisions differ across the selected countries. However, the data protection period for a new active ingredient is generally ten years.

Patents and regulatory data protection provide similar benefits for the manufacturers of original products, but are distinct from one another. Periods of regulatory data protection and patent terms may or may not run concurrently. Patents can be issued or expire independent of the approval status of the chemicals. Regulatory data protection periods generally commence when a chemical product is approved for use. Some chemicals have both patent and regulatory data protection simultaneously while others have just one or the other.

In Australia, springboarding became possible for agvet chemicals, and all other technologies, in 2012. This allows a generic manufacturer to seek and obtain regulatory approval of their generic version of a patented agvet chemical while the patent is still in force. Springboarding enables a generic manufacturer to launch their bioequivalent version of the agvet chemical onto the market as soon as the patent has expired.

Regulatory data protection arrangements in Australia, the USA, the EU, Canada and New Zealand are compared in **Table ES 1**.

KEY FINDING ES 2 AUSTRALIA'S AGVET IP AND DATA PROTECTION ARRANGEMENTS

Australia's agvet IP and data protection arrangements are generally appropriate and are comparable to, and competitive with those in the EU, the USA, Canada and New Zealand. There is no compelling case for change.

Confidential commercial information (CCI)

Information received with an application (for example, details provided in dossiers) is generally classified as sensitive — confidential commercial information. Countries use different definitions and approaches to managing confidential commercial information. There is some ambiguity in Australian legislation about the timing and the duration of managing such information by the APVMA.

CCI could be clarified in Australia, drawing on the practices in other countries:

— Define a list of categories of information which will be treated as CCI. These would include manufacturing processes and trade secrets.

— Define a second list of categories of information and data which will not be treated as CCI. This includes name and structure of active ingredients and test results. Again, other countries have already developed such lists.
— Allow a third category where an applicant may seek to have information or data not falling in the two areas defined above classified as CCI. The applicant would have to make a case for this categorisation. The APVMA would apply a set of criteria in deciding whether to accept the proposed classification, appealable through the Administrative Appeals Tribunal.

KEY FINDING ES 3 CLARIFYING CCI

There is a case for adopting an approach to defining CCI based on the approach used in some other countries where some information and data is automatically categorised as CCI and some categorised as not CCI.

Minor uses

Minor uses include agvet products needed for small specialist crops, and for small problems in large crops. Definitions of minor use vary across the countries reviewed.

What this study has found is that most countries rely on a mix of measures to encourage and facilitate approvals and / or permits for minor uses. The most successful approach is the US IR-4 program, which has been copied and adapted in other countries including Australia. This program provides support for the acquisition of data necessary to obtain regulatory approvals.

Liability issues have been identified in an OECD survey as being a barrier to the registration of minor uses. Canada has developed a solution to this issue by authorising the use of disclaimers on labels.

Most of the countries considered in this review offer low fees, reduced numbers of trials and expedited approval processes for minor uses.

Minor uses, whether for small crops or for small problems with large crops, are a challenge in most countries. Companies will not seek regulatory approval in a market where they are not going to get a satisfactory return on their investment. Australia's support of minor uses is predominantly through a small grants program. More could potentially be done.

KEY FINDING ES 4 INCENTIVES FOR MINOR USES

A mix of measures are needed to facilitate access to agvet chemical products for minor uses:

— The Government's program to assist the process of obtaining registration and permits for minor uses should continue
— Adopting the Canadian approach to limiting liability of manufacturers in relation to minor uses should be explored
— Minor use registration and permits should be fast-tracked by the APVMA.

Registration

Most of the selected countries have separate regulatory bodies for crop protection and animal medicines, while in Australia agvet chemical registrations are performed by a single agency, the Australian Pesticides and Veterinary Medicines Authority (APVMA).

The time taken by regulators to assess agvet proposals is of concern to agvet chemical companies because it delays their entry into the market and thus delays getting returns on their investments. The APVMA's official processing time limits are among the longest of the countries reviewed.

It is difficult to compare registration fees between countries because of the very different fee structures in use. However, Australian agvet chemical registration costs are broadly comparable with those in

North America and the EU. This is a problem because the small Australian market makes it more difficult for applicants to secure a return on the costs incurred in the Australian regulatory process.

This report includes a number of suggestions for improving the efficiency of the APVMA. In particular, making greater use of data and assessment by better-resourced overseas regulators would be a useful step. If the APVMA needs assurance that such reliance will be considered to have met the requirements of the legislation, then the legislation should be amended accordingly.

KEY FINDING ES 5 USING DATA AND ASSESSMENTS FROM OVERSEAS REGULATORS

There is scope for the APVMA to make greater use of data, analyses and assessments undertaken for / by trusted overseas regulators. This information should be requested from applicants and should be used to expedite Australian approval processes.

Regulatory reform

Overall, the study has established that there is a need for further agvet regulatory reform in Australia to ensure that our primary producers get faster access to new, innovative agvet products. These products are generally safer, more effective and better for the environment than their predecessors and will thereby improve the productivity, profitability and international competitiveness of Australian agriculture.

Although several initiatives—including consolidation of application categories, consideration of a greater use of modular assessment categories and reduction or elimination of application requirements for some minor applications—have been undertaken by the APVMA since an audit by ANAO (2006), consultations with the industry representatives for this project indicate that the APVMA not meeting statutory timeframes for assessments is still a major issue. Industry stakeholders have suggested that delays in the assessment process inhibit the ability of patent holders to realise a return on their R&D, which in turn threatens future flows of new agvet products into the Australian market.

The complexity and drafting of the agvet chemical legislation is, in itself, a significant barrier to providing Australian agricultural producers with timely access to innovative agvet chemicals and generic products. The team which prepared this report found the Act, Regulations and Code difficult to navigate and unnecessarily complex. Stakeholders are confused about the provisions of this legislation. There is a strong case for simplifying it and writing more of it in plain English. The legislation needs to be completely redrafted. The Federal Court judge in *Abbey v the APVMA* described it as a “legislative labyrinth that defies comprehension by mere mortals” and a “legislative morass”.

KEY FINDING ES 6 LEGISLATIVE REVIEW

The legislative review announced by the Deputy Prime Minister is urgently needed. The legislation and regulations urgently need to be simplified and rewritten.

TABLE ES 1 REGULATORY DATA PROTECTION COMPARISON FOR CROP PROTECTION PRODUCTS

Key components	Australia	New Zealand	EU	US	Canada
Protection period for a new active ingredient / constituent and associated formulated products not previously endorsed	10 years as of July 2014 under Section 34M of Agvet Code	10 years	10 years – plant protection products 13 years – low risk products 15 years -biocides	10 years exclusive use	10 years, 12 years with change in formulation
Protection period for previously endorsed or variations or new information	5 years as of July 2014	5 years for new variations	na	na	na
Extensions linked to minor use registrations	None	None	Additional 3 months for each minor use, up to 3 additional years (plant protection products). Up to 2 years (low risk products)	Up to 3 additional years (1 year for each three minor uses)	Up to 5 additional years. (1 year for each three minor uses)
Total potential protection period	10 years as of July 2014	10 years	10–13 years (plant protection products) 13–15 years (low risk protection products) 15 years (biocides)	10–13 years	10-15 years
Data compensation period – subsequent data to support / maintain registration of a new active ingredient to support re-evaluation	na	na	30 months (plant protection products) 5 years (review or renewal of biocides)	15 years compensable. Data with exclusive use protection are compensable for 5 years after exclusivity expires	12 years compensable
New legislation	New legislation took effect from July 2014. The interactions of various elements of the Agvet Code are complex relative to other countries.	New legislation took effect from November 2016 extending data protection periods for new actives and expanding scope to include variations to existing products, new products and reassessments	EC1107/2009 and 528/2012 test data are subject to compulsory sharing for both plant protection products and biocides. Agreement on costs may be reached through negotiation, arbitration or legal proceedings	na	na

SOURCE: VARIOUS SEE TABLE 3.1.

TABLE ES 2 REGULATORY DATA PROTECTION COMPARISON FOR VETERINARY CHEMICAL PRODUCTS

Key components	Australia	New Zealand	EU	USA	Canada
Protection period for a new active ingredient / constituent and associated formulated products not previously endorsed	10 years as of July 2014 under Section 34M of Agvet Code	10 years	10 years. One additional year (for already authorised product to other species, up to maximum of 18 years)	Depends on what type of exclusivity at issue. Orphan drug exclusivity for 7 years, new chemical entity exclusivity for 5 years, general antibiotic incentives now exclusivity for 5 years, new clinical investigation exclusivity for 3 years	8 years for innovative animal drugs
Protection period for previously endorsed or variations or new information	3 years as of July 2014	5 years	na	na	na
Extensions linked to minor use registrations	None	None	14 years for minor uses and 4 additional years for an extension to a minor use	Minor species or minor uses in a major species (MUMS) gets 7 years	
Total potential protection period	10 years as of July 2014	10 years	Maximum of 18 years for major and minor use	Depends on what type of exclusivity	8 years
Data compensation period – subsequent data to support / maintain registration of a new active ingredient to support re-evaluation	5 years exclusive use 8 years – data for a reconsideration of a registration (as of July 2014)		None	None	None

SOURCE: VARIOUS – SEE TABLE 3.2.

GLOSSARY OF TERMS

Active constituent	An active constituent is a substance that is primarily responsible for the biological or other effect identifying the goods as therapeutic goods.
ADUFA	*Animal Drug User Fee Act* (USA)
AGDUFA	*Animal Drug and Animal Generic Drug User Fee Reauthorization Act* (USA)
agvet	Agricultural and veterinary
Agvet Code	Schedule to the *Agriculture and Veterinary Chemicals Code Act 1994*
ANDA	Abbreviated New Drug Application (USA)
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARTG	Australian Register of Therapeutic Goods
AUSFTA	Australia-United States Free Trade Agreement
ACVM	*Agricultural Compounds and Veterinary Medicines* (New Zealand)
Bolar exemption	An exemption established after *Roche Products v. Bolar Pharmaceuticals* (US) which provides that it is not an act of infringement to make and test a patented drug solely for the purpose of developing and submitting information for regulatory approval. See also Springboarding
BVL	Federal Office of Consumer Protection and Food Safety (Germany)
CCI	Confidential commercial information
CETA	Canada-European Union Comprehensive Economic and Trade Agreement
CRD	Chemicals Regulation Division of the Health and Safety Executive (UK)
CVM	Centre for Veterinary Medicine (USA)
DAR	Data Assessment Report (EU)
DAWR	Department of Agriculture and Water Resources
DCI	Data call-in (USEPA)
DFAT	Department of Foreign Affairs and Trade
DoEE	Department of Environment and Energy (Australia)
EC	European Commission
EEA	European Economic Area
EFSA	European Food Safety Authority
EU	European Union
Evergreening	Legal, business and technological strategies used to extend patent life
FFDCA	*Federal Food, Drug and Cosmetic Act* (USA)
FIFRA	*Federal Insecticide, Fungicide and Rodenticide Act* (USA)
FQPA	*Food Quality Protections Act* (USA)

FSANZ	Food Standards Australia and New Zealand
FY	Fiscal year
Generic	Generic chemicals and medicines are copies of original products that generally have the same dosage, intended use, effects, side effects, route of administration, risks, safety, and strength as the original product
GJR	Global Joint Review
HSE	Health and Safety Executive (UK)
Infringement exemption	Patent law provisions that allow activities (e.g. research) which would otherwise be considered to be infringements (see Section 3.3.1)
IP	Intellectual Property
IPONZ	Intellectual Property Office New Zealand
MS	Member States
MPI	Ministry for Primary Industries (New Zealand)
MUMS	Minor Use / Minor Species (USA)
NAFTA	North American Free Trade Agreement
NHMRC	National Health and Medical Research Council
NRS	National Registration Scheme for Agriculture and Veterinary Chemicals (Australia)
NZEPA	New Zealand Environment Protection Authority
OCS	Office of Chemical Safety (Department of Health, Australia)
OECD	Organisation for Economic Cooperation and Development
OGTR	Office of the Gene Technology Regulator (Australia)
PC	Productivity Commission
PDS	Product data sheet (New Zealand)
OH&S	Occupational Health and Safety
PCPA	*Pest Control Products Act* (Canada)
PMRA	Pest Management and Regulatory Agency (Canada)
PPP	Plant protection products (Pesticides, EU)
PRIA	*Pesticide Registration Improvement Act* (USA)
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EU)
R&D	Research and Development
RMS	Rapporteur Member State (EU)
Safeners	Safeners are chemicals used in combination with herbicides to reduce the effect of the herbicide on crop plants
SPC	Supplementary Protection Certificates
Springboarding	A process that allows a generic manufacturer to seek and obtain regulatory approval of their generic version of a patented technology while the patent is still in force. See also Bolar exemption
TA	Technical Appraiser (New Zealand)
TCC	Technical Consultative Committee (New Zealand)
TGA	Therapeutic Goods Administration
TPP	Trans Pacific Partnership
UK	United Kingdom
US / USA	United States of America
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USFDA	United States Food and Drug Administration
USPTO	United States Patent and Trademark Office
VDD	Veterinary Drug Directorate (Canada)
WOT	Waiver of time (New Zealand)

1 INTRODUCTION

1.1 Background

Regulation of agricultural and veterinary chemicals (agvet chemicals) is essential to protect the health and safety of humans, animals and the environment from the potentially harmful effects of chemicals. However, poorly designed and implemented regulation impedes productivity, deters investment and undermines jobs and growth in the economy. For primary producers, poorly designed regulation can delay or prevent the introduction of innovative chemical products and increase costs. One recent report claims that some rural industries in Australia, including grains, are currently missing out on up to 50 per cent of the potential new technologies that are accessible to key competitors in Europe and the USA.[1]

This study has examined international and Australian intellectual property settings and registration arrangements as they relate to agvet chemical markets. The purpose has been to assess the evidence and propose changes to help improve Australian agricultural producers' access (through registration by the Australian Pesticides and Veterinary Medicines Authority) to innovative new agvet chemicals while also supporting prompt access to generic agvet chemicals.

This study should be viewed in the context of the Australian Government's wider objectives, and the need to balance both the upside and downside of allowing agvet chemicals to be introduced and used in agricultural production. This includes initiatives taken in recent years to improve the core legislation underpinning agvet chemicals, which includes:

- *Agriculture and Veterinary Chemicals Act* (Agvet Act)
- *Agriculture and Veterinary Chemicals (Administration) Act* (Agvet Administration Act)
- *Agriculture and Veterinary Chemicals Code Act* (the Schedule to this Act is the Agvet Code)
- *Agriculture and Veterinary Chemical Products (Collection of Levy) Act*

This legislation is a key element of Australia's regulatory framework for managing agvet chemicals, the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), which is a joint Commonwealth / State / Territory regime that provides a single Agvet Code for Australia.

Intellectual Property (IP) underpins the development of agvet chemicals intended for the Australian and international markets. One aim of patent protection is to ensure a return on investment for inventors.

[1] Rainbow R 2017, Delivery of Access to AgVet Chemicals Collaborative System – AgVet Collaborative Forum, report to the Rural Industries R&D Corporation, accessed on 18 July 2017 at https://rirdc.infoservices.com.au/items/17-019

Regulatory data protection pertaining to the testing of agvet chemical products for efficacy, safety and environmental impact is a key issue, and is considered by agvet companies to be potentially more important than the patent protection for newly developed products.

As the Productivity Commission has pointed out,[2] regulation should be fit-for purpose. It should be:

- **targeted** — the scope of the regulation (that is, who or what the regulation applies to) should be clear and appropriate for addressing the policy problem
- **evidence-based** — there should be an apparent and demonstrable connection between the content of the regulation and the regulatory objective
- **proportionate** — the burden imposed by the regulation on government agencies and the public should be proportionate to the regulatory outcome being sought.

This report examines a number of issues that relate directly to the Productivity Commission's points.

Companies manufacturing generic products do not incur the same research, development and commercialisation costs (although they may incur costs in developing manufacturing processes) as original patent holders. Whether companies manufacturing generics should be permitted to "free ride" on the data provided to the regulator by the original manufacturer as part of approval procedures is a matter of debate within a large body of literature and between policymakers. There are several issues here, one of which is minimising the cost of approval of generics and expediting their approval. Similar issues arise in relation to generic medicines for human consumption.

IP issues also arise in relation to trade agreements. For example, the *Agvet Administration Act* was amended to give effect to Australia's obligations under the Australia United States Free Trade Agreement (AUSFTA).

IP issues in Australia have been the subject of a number of studies and reports, of which a Productivity Commission report (2016)[3] is the most recent. The Productivity Commission report covers IP more generally and does not specifically address agvet chemicals. The key findings from the Productivity Commission report relevant to this study are provided in **Box 1.1**.

BOX 1.1 ISSUES RELATED TO AUSTRALIAN IP ARRANGEMENTS

Australia's IP arrangements fall short in many ways and improvement is needed across the spectrum of IP rights.

IP arrangements need to ensure that creators and inventors are rewarded for their efforts, but in doing so they must:

- foster creative endeavour and investment in IP that would not otherwise occur
- only provide the incentive needed to induce that additional investment or endeavour, and
- resist impeding follow–on innovation, competition and access to goods and services.

Australia's patent system grants exclusivity too readily, allowing a proliferation of low-quality patents, frustrating follow–on innovators and stymying competition.

- To raise patent quality, the Australian Government should increase the degree of invention required to receive a patent, abolish the failed innovation patent, reconfigure costly extensions of term for pharmaceutical patents, and better structure patent fees.

SOURCE: PRODUCTIVITY COMMISSION (2016), INTELLECTUAL PROPERTY ARRANGEMENTS, REPORT NO. 78, KEY POINTS, PAGE 2.

Various international organisations are active in relation to the regulation of agvet products. For example, the Organisation for Economic Cooperation and Development (OECD) has been active since the 1990s in relation to the efficacy and safe use of pesticides. In the early years of this work, there was a strong focus on mutual recognition and, in particular, mutual acceptance of data. A 1998 OECD report focussed on IP in relation to pesticide registration.[4] A 2014 OECD Guidance Document,

[2] Productivity Commission 2016, *Regulation of Australian Agriculture*, No. 79, 15 November 2016, p 89
[3] Productivity Commission 2016, *Intellectual Property Arrangements*, Report No. 78, September 2016
[4] OECD 1998, *OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration*, OECD Publishing, Paris

on regulatory incentives for registration of pesticide minor uses, is of particular relevance for this study.[5]

VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) is a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary product registration. Other countries including Australia are observers and have the opportunity to provide feedback on the technical data requirements. The role of VICH is to harmonise technical requirements for data necessary for the marketing authorisation of veterinary medicinal products. This is achieved by developing harmonised guidelines on the studies to be submitted in marketing authorisation applications. The VICH does not provide guidance on regulatory systems.

The VICH Outreach Forum is a recent development with the objective of providing a basis for wider international harmonisation of technical requirements, improving information exchange and raising awareness of VICH and VICH guidelines with non-VICH countries / regions.

In this context, the DAWR commissioned ACIL Allen Consulting (ACIL Allen) to undertake a review of international IP arrangements and registration processes for the regulation of agvet chemicals.

1.2 Objectives of the study

The objectives of this study are to produce a detailed report that:

- Proposes policy options to improve Australian agricultural producer's access, through registration by the APVMA, to innovative agvet chemicals while also supporting access to generic agvet chemicals. This is to include a robust and evidence-based analysis of policy options
- Includes supporting background and analysis, primarily based on desk-top research using national and international sources, as well as stakeholder consultations.
- In the context of the registration process for both new and generic agvet chemical products in Australia, the UK, EU, the USA, Canada and New Zealand,[6] documents and compares the supporting primary and subordinate IP legislation, including the provision and trade obligations around:
  - Patents
  - Data protection
  - The use and management of confidential commercial information by agvet regulatory bodies, and anything else important for understanding the intellectual property environment.
- Overviews the national registration arrangements for both new and generic agvet chemical products for the selected countries, including the costs and timeframes involved for applicants, protocols / protections on the use and management of confidential commercial information, references to overseas registration process, recent reforms and the direction of future reforms.
- For selected countries, explains the characteristics and unique features of the agvet chemical markets in which these regulators operate, including any market incentives / strategic behaviours fostered by IP settings, and how these have affected the registration rates of both new and generic agvet chemical product over recent years.
- For comparison purposes, reviews and provides a summary of the available literature on the registration arrangements and supporting IP schemes in those same set of countries for human therapeutic (pharmaceutical) products.
- Develops policy options that extend to considering changes to improve incentives to register agvet chemicals for minor uses.

1.3 Our approach

The approach used by ACIL Allen to meet the study objectives has included a review of Australian and international literature in relation to agvet chemical IP frameworks, registration processes and registration arrangements in order to identify policy options to improve Australian agricultural producer

[5] OECD 2014, *Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses*, OECD Publishing, Paris

[6] Germany was originally go be included in this study but very little information on German IP and registration processes is available in English. Germany closely follows the EU procedures, which are discussed in some detail.

access to both innovative and generic agvet chemical products. The literature identified through this review is footnoted in the relevant chapters.

Industry consultations (a list of organisations consulted for this project are provided in Appendix A) also supported the in-depth documentary review of the Australian and selected overseas regulatory systems and processes. Key considerations included:

- Are the characteristics and features of agvet chemical markets inhibiting the timely access to agvet chemicals by Australian agricultural producers?
- How do the Australian agvet product registration arrangements differ from other countries (UK, EU, the USA, Canada and New Zealand)?
- Are Australian registration arrangements effective and efficient in providing timely access to agvet chemical products for Australian agricultural producers?
- Are the nature of agvet chemical registration processes and related IP frameworks causing inefficiencies in timely access to agvet chemical products for Australian agricultural producers?
- Is minor use an issue for the Australian agricultural industry?
  - Which overseas minor use incentives could deliver and improve the timely access to agvet chemical products for Australian agricultural producers?
- How do Australia's veterinary medicine registration arrangements and supporting IP schemes differ from human pharmaceuticals?
  - Are these differences affecting the timely access of agvet chemical products to Australian agricultural producers?

1.4 Structure of the report

The structure of the report follows the terms of reference or key objectives of the study.

Chapter 2 explains the characteristics and unique features of the agvet chemical markets in major countries.

Chapter 3 documents and compares primary and subordinate IP legislation and data protection (including confidential commercial information) in Australia, the EU, the UK, USA, Canada and New Zealand in the agvet chemical context.

Chapter 4 outlines the national registration arrangements for both new and generic agvet chemical products for the same selected countries.

Chapter 5 examines the time and costs of agvet chemical product registration for the same selected countries.

Chapter 6 discusses issues related to minor use in agvet chemical products.

Chapter 7 compares IP arrangements for veterinary medicines and human pharmaceuticals.

Chapter 8 provides findings and insights to improve Australian agricultural producers' timely access to agvet chemicals at the lowest possible cost.

2 CHARACTERISTICS AND FEATURES OF AGVET CHEMICAL MARKETS

Agvet chemicals play an important role in crop production, public health, environmental protection and animal welfare. They comprise a broad range of substances including insecticides, herbicides, fungicides, rodenticides, parasiticides, vaccines and antibiotics.

As at February 2017, the APVMA was reported as having registered over 13,000 products and chemicals for over 900 businesses, individuals and organisations.[7] Nearly 75 per cent of these registrations related to agricultural chemicals, with the remaining 25 per cent for veterinary chemicals.

This chapter provides some information on the characteristics and unique features of the agvet chemical markets in Australia and some selected countries, as well as globally. It details the context within which Australia's regulator operates, including the types of market incentives / strategic behaviours fostered by IP settings and how these settings have influenced the rates of registration for both new and generic agvet chemical products in recent years.

2.1 Key features of agvet chemical markets

The agvet chemical markets in the world are influenced by complex legislative and regulatory regimes underpinned by producer, environmental, and animal and human safety protection objectives, the supply of agvet chemicals (mainly from the Asia, North American and European zones) and derived demand for agvet chemicals from the primary agricultural producers.

In general, innovative agvet chemical producers are:

- highly concentrated and exert monopoly or oligopoly market power
- global in nature with international operations and plants in numerous countries
- more likely to incur significant R&D costs, and
- dynamic and may release new products with the same active ingredient and / or different formulations (e.g. to address the development of resistance to chemicals).

The supply elasticities for generic and patented products are impacted by national regulations. Agvet products face specific regulations and complex IP laws and data exclusivity arrangements in most developed countries. (**Box 2.1** explains the concept of data protection / exclusivity**)**. Original product manufacturers also face increased pressures from generic products, and are constantly seeking greater protection of their early-stage investments in developing and commercialising products. These factors have contributed to a decline a number of new active ingredients introduced in to the market.

Agvet product consumers operate in highly competitive and volatile product markets and are price takers in their product markets.

[7] ANAO 2017, Pesticide and Veterinary Medicine Regulatory Reform, Australian Pesticides and Veterinary Medicines Authority, ANAO Report no. 56 2016-17.

BOX 2.1 DATA PROTECTION AND EXCLUSIVITY

Data exclusivity applies to the use of data submitted to support an application for regulatory approval of a new agvet product. Internationally, the terms data protection and data exclusivity are used interchangeably. Australia's Agvet Code does not use the term exclusivity. The Productivity Commission has adopted the following definition:

Data protection, sometimes referred to as data exclusivity, describes the period in which a follow-on (generic) manufacturer is prohibited from seeking approval based on the originator's data. The regulator cannot commence its assessment of the biosimilar based on a reliance on the earlier data until this period expires.

SOURCE: PRODUCTIVITY COMMISSION (2016) INTELLECTUAL PROPERTY ARRANGEMENTS – DRAFT REPORT

Agvet chemicals are a significant component of user cost structures and, as a result primary producers are sensitive to agvet chemical prices. When generic products enter the market they can be significantly less expensive than the original patented product. For example, some US studies have shown that a generic herbicide can be 56 per cent less expensive than the original branded product.[8]

The combination of the market power of agvet chemical producers, the competitive nature of agricultural producers, and the impact of regulation create a complex and unique dynamic within agvet chemical markets. In these circumstances, agvet chemical legislation would appear to be a significant factor.

Which entities undertake agvet chemical R&D and where they conduct the research is another significant influence on the Australian and global agvet chemical market. Research related to the discovery of new molecules and active ingredients or constituents tends to be undertaken either in the USA or Europe. Formulation and packaging development is more widespread, and often located in or near final markets where local data is required for regulatory approvals.

2.1.1 Global production

The major players in the global pesticides manufacturing industry are multinational chemical companies which typically offer a diverse range of chemical-based products. While R&D activities tend to be limited to a few countries, chemical synthesis and product formulation occurs in numerous locations, often reflecting the existence of import tariffs on finished products, freight-saving advantages, the regulatory environment and / or the need to adapt the product to the local market.

Total sales for the global crop-protection and non-crop chemicals industry now exceed A$80 billion.[9] Top global players include:

- Bayer CropScience
- Syngenta AG
- BASF SE
- Dow AgroSciences
- DuPont, and
- Sumitomo Chemicals.

Factors shaping the agvet chemical industry in recent years include the rise of generic companies, the move towards outsourcing and the rationalisation of product portfolios, which are associated with industry consolidation and globalisation. The industry is characterised by a high level of globalisation, which looks set to continue.

[8] See http://www.nebraskafarmer.com/crop-protection/comparing-generic-vs-name-brand-pesticides accessed on 20 August 2017
[9] IBISWorld Report 2016a, C1832, Pesticide Manufacturing in Australia, July 2016

The veterinary pharmaceutical manufacturing industry forms part of a global industry dominated by various global research-based pharmaceutical companies that manufacture and / or supply animal health products to markets across the globe. Many of these global entities operate within Australia, either at the manufacturing or the wholesaling level (IBISWorld Report 2016b), including:

- Virbac
- Zoetis
- Eli Lilly and Company
- Bayer
- Merial
- Boehringer Ingelheim Vetmedica, and
- Merck.

At the manufacturing level, four of the top six players (Virbac, Zoetis, MSD Animal Health and Bayer) are subsidiaries of the top global giants, with these four accounting for just under 80 per cent of industry sales in Australia.

However, in contrast to human health pharmaceuticals where international trade plays a dominant role both for imports and exports, international trade within the Australian *veterinary* pharmaceutical manufacturing industry accounts for less than 10 per cent of domestic demand. This is in spite of the need to import active ingredients to produce a finished product. Due to the relatively small size of the Australian industry, global parent companies tend to conduct primary manufacturing activities, such as synthesising active ingredients, offshore. Those products are imported into Australia and used by local manufacturers to finish the product and package it for distribution. In view of these variables, the veterinary product industry is considered to display a moderate level of industry globalisation.

Worldwide, there appears to be an increase in toll manufacturing, where all or parts of the manufacture of an agvet chemical is contracted to another party. China is emerging as a major toll manufacturer.

2.1.2 The cost of bringing a new active ingredient to the market

A number of factors contributed to the decline of active ingredient introductions. Among them is the cost of bringing a new product to market.

The expenditure necessary for the discovery, research and development of a new crop protection product, based on a survey of five major companies, is provided by Phillips McDougall (2016)[10] and is shown in **Figure 2.1**. The overall costs of discovery, research and development of a new crop protection product increased by 88.2 per cent in nominal terms over the past 20 years in US dollars. US inflation has risen by 55.4 per cent during the same period,[11] indicating in real terms that costs have increased by 32.8 per cent over the past 20 years.

- Registration costs from incorporating extra studies required to satisfy EU and US regulators rose from 6 per cent in 2000 to 12 per cent in 2010-14 (nominal terms) of overall costs of discovery and development of new crop protection products.
- The greatest rise was seen in the costs of satisfying environmental chemistry regulatory requirements, which were shown to have risen by 45.8 per cent in nominal terms. It is likely that this increase was due to a rise in environmental safety data required by regulatory bodies. For example, in the EU, more than 100 specific tests are required on physical and chemical properties, analytical methods, toxicity and metabolism studies, residues, environmental and eco-toxicological studies.[12]
- The largest single cost in the development cycle continues to be field trials, which account for 30.1 per cent in nominal terms in 2010-14 of overall development costs of an active ingredient, having increased from 20 per cent in 1995.
- Overall costs of new product research rose by 30.6 per cent from US$72 million per product in 1995 to US$94 million in 2000, but declined slightly to US$85 million in 2005-08. This has been attributed to cost savings due to greater efficiency from high throughput screening, combinatorial chemistry and

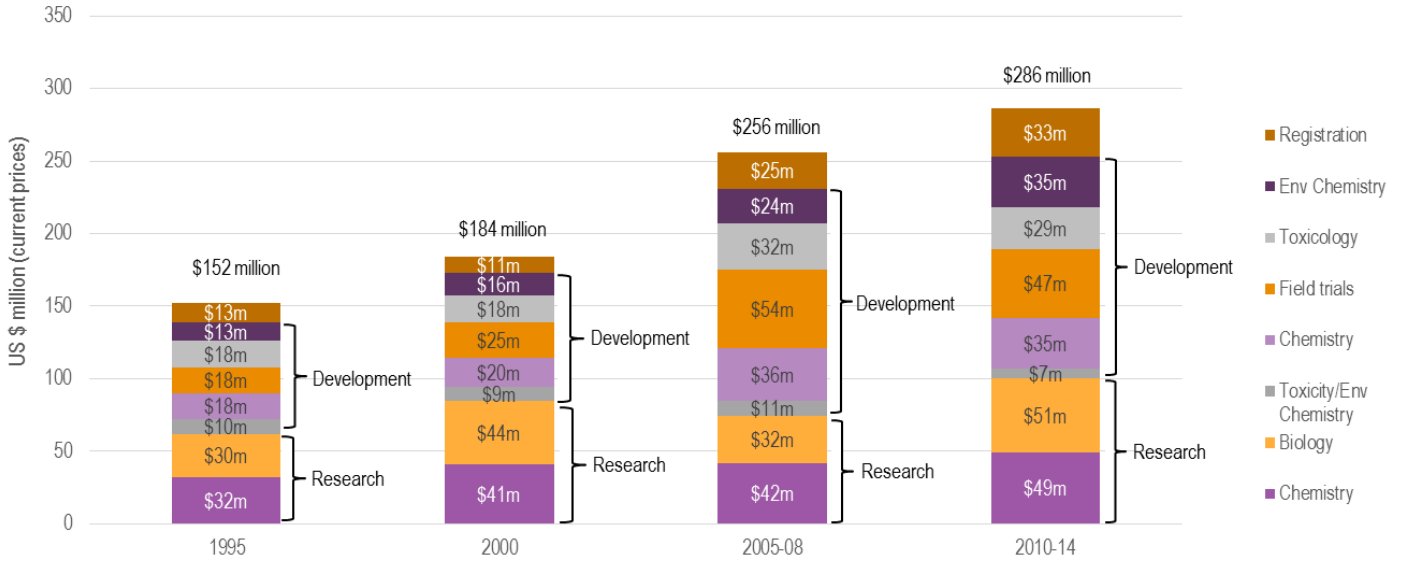
[10] See http://191hmt1pr08amfq62276etw2.wpengine.netdna-cdn.com/wp-content/uploads/2016/04/Phillips-McDougall-Final-Report_4.6.16.pdf accessed on 20 August 2017

[11] Estimate based on the World Bank Data.

[12] European Crop Protection, Registering Plant Protection Products in the EU, November 2012.

genomics. Between 2005-08 and 2010-14 the cost of research of a new agrochemical rose by 25.9 per cent to US$107 million, somewhat greater than the general rate of US inflation.

FIGURE 2.1 DISCOVERY AND DEVELOPMENT COSTS OF NEW CROP PROTECTION PRODUCTS (CURRENT PRICES), 1995, 2000, 2005-08 AND 2010-14



Note: The companies included in the survey were: BASF, Bayer, Dow, DuPont and Syngenta. Category chemistry comes under research phase and under development phase. Research chemistry costs include synthesis and formulation. Development chemistry costs include scale-up of manufacture and formulation. Biology costs include glasshouse efficacy testing and small plot trials. Research toxicology includes mammalian acute, mammalian sub chronic and environmental. Development toxicology includes chronic mammalian and environmental.

SOURCE: Phillips McDougall 2016, The cost of new agrochemical product discovery, development and registration in 1995, 2000, 2005-08 and 2010 to 2014

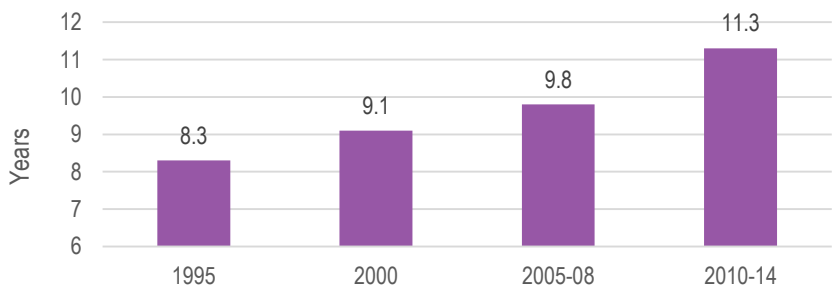
These survey findings are consistent with the outcomes of consultations undertaken for this project. Stakeholders generally agreed with the above analysis.

2.1.3 Product discovery and development lead time

While both costs and the number of developmental leads have steadily increased, the survey results from Phillips McDougall also demonstrate that the average lead time between the first synthesis of a new crop protection molecule and its subsequent commercial introduction has increased as shown in **Figure 2.2**. This increase reflects both greater complexity in the data requirements of regulatory bodies and the time and effort required to satisfy regulators.

A number of stakeholders have noted during consultations that the Australian market is one-tenth the size of the US market but has a regulatory system that can impose similar costs on companies.

FIGURE 2.2 PRODUCT DISCOVERY AND DEVELOPMENT LEAD TIME, 1995 – 2010-14



Note: Number of years between the first synthesis and the first sale of the product

SOURCE:: Phillips McDougall 2016, The cost of new agrochemical product discovery, development and registration in 1995, 2000, 2005-08 and 2010 to 2014

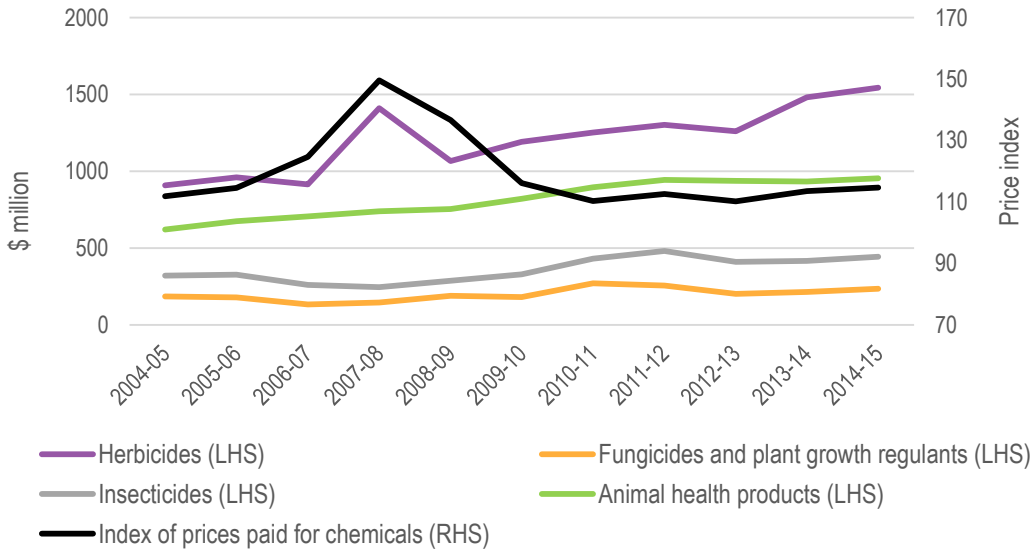
2.2 Australian market

2.2.1 Sales and prices of agvet chemicals in Australia

Global sales of plant protection and non-crop agrochemicals were US$63.2 billion in 2014[13] (currently approximately A$83.3 billion). This does not include veterinary chemicals.

The size of the agricultural and veterinary chemicals market in Australia in 2014-15 was A$3.2 billion (**Figure 2.3**).[14] The Australian market size increased by 56 per cent over the past ten years at an average annual growth rate of 4.6 per cent in nominal terms.

FIGURE 2.3 AUSTRALIAN SALES AND PRICES OF AGRICULTURAL CHEMICALS, BY PRODUCT TYPE (NOMINAL PRICES), 2004-05 –2014-15



SOURCE: DEPARTMENT OF AGRICULTURE AND WATER RESOURCES, AGRICULTURAL COMMODITY STATISTICS, 2016

The data indicate that from the period 2004-05 to 2014-15 the sales of herbicides has increased at an annual average growth rate of 5.5 per cent, insecticides at an annual average growth rate of 3.3 per cent, and animal health products at an annual average growth rate of 4.4 per cent, while the use of fungicides / plant growth regulators increased at an annual average growth rate of only 2.5 per cent.

An index of prices paid for chemicals increased only by 2 per cent—an annual average growth rate of 0.24 per cent. The major chemical used in Australia is glyphosate. Glyphosate is the main ingredient in many knockdown herbicides, used to kill the majority of annual and perennial plants.

In the absence of a more detailed analysis of agvet chemical price trends, it is difficult to understand the key factors influencing agvet chemical price changes. **Figure 2.3** is based on composite indices developed by DAWR.

In an ideal world, it would be preferable to separate regulatory costs from other factors that impact on agvet chemical prices. The Australian agvet chemical market is relatively small on a global scale, comprising less than 2 per cent of the global distribution of agricultural and veterinary chemicals. The importation of chemical products and active constituents is significant, with sources such as China and India featuring strongly in terms of active constituent manufacturing. For this reason, movements in

[13] Phillips McDougall 2017, The Global Agrochemical Market Trends by crop, 11th China International Forum on Development of Pesticide Industry, Shanghai, February 2017.

[14] Department of Agriculture and Water Resources (2016), Agricultural Commodity Statistics 2016, http://www.agriculture.gov.au/abares/publications/display?url=http://143.188.17.20/anrdl/DAFFService/display.php%3Ffid%3Dpb_agcstd9abcc0022016_Sn9Dg.xml accessed on 20 August 2017.

global chemical pricing can have a significant effect on prices in Australia.[15] This makes it difficult to separate out the cost of regulation on the price of agvet chemicals in Australia.

2.2.2 Size of the Australian industry and major players

Background

Globally, the agricultural sector is the major consumer of pesticides. In Australia the sector is thought to account for approximately 80 per cent of national pesticide consumption. Also known as crop protection products, pesticides are used to protect plants and crops from the damage caused by weeds, insects and disease. Pesticides are applied at various stages of the production process: in the seeding stage, to harvested produce or during processing, and / or during packaging and transportation. As a result, pesticides play an essential role in increasing the efficiency of Australian agriculture. Households and professional pest control services also use pest control chemicals.

Herbicides, fungicides and insecticides are common forms of pesticides, with these three groupings accounting for over 86 per cent of all product sales. Other products, such as plant growth regulators, soil fumigants, vertebrate poison and various other agricultural and pastoral chemicals, account for the remainder of industry. The vast majority of pesticides are consumed by wheat and other crop producers, including those involved in cereal grains, coarse grains, pulses and oilseeds. [16,17]

Industry consultations undertaken for this report have indicated that the Australian market in agvet products is approaching $4 billion per annum of which crops comprise $2.8 billion. Nufarm Ltd is the only manufacturer of active ingredients for agricultural chemical products in Australia. Other agricultural chemical companies import active ingredients and formulate here. However, veterinary active constituents are routinely manufactured in Australia (e.g. vaccines).

In this report, we have used IBISWorld data which includes the veterinary pharmaceutical manufacturing industry as a small segment of the general Australian pharmaceutical sector. The industry develops and manufactures animal health products, including veterinary medicines, vaccines, and other biological and medicinal feed additives. The industry is geared towards two main segments:

- food-producing animals (including cattle, pigs, poultry and sheep), and
- companion animals (including cats and dogs).

The veterinary pharmaceutical manufacturing industry accounts for just over 5.5 per cent of the Australian pharmaceutical sector.[18] The largest product segment for the industry is parasiticides. Other key segments include antibiotics, immunotherapy products, and nutritional and metabolism products.

Major players

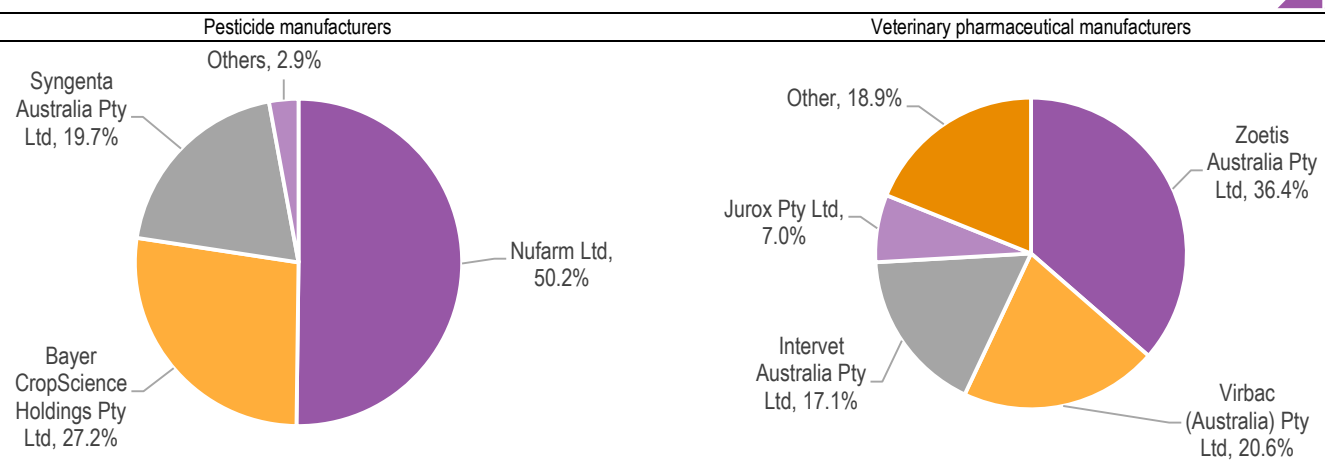
Industry concentration in pesticide manufacturing is considered high in Australia, with the top four players estimated to account for over 97 per cent of total industry revenue in 2015-16. The Australian trend is in line with the global crop protection industry, where six major companies supply over 75 per cent of the global market. [19,20]. Herbicides, fungicides and insecticides are common forms of pesticides, with these three groupings account for over 85 per cent of all product sales.

Major pesticide manufacturers and veterinary pharmaceutical manufacturers in Australia and their market share in terms of revenue in 2015-16 are summarised in **Figure 2.4**.[21] The figure shows that Nufarm Ltd was the largest pesticide manufacturer in Australia in 2015-16, with a total market share of 50.2 per cent. In second place was Bayer CropScience Holdings Pty Ltd which had a market share of

[15] Parliament of Australia 2009, Pricing and supply arrangements in the Australian global fertilizer market, http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Former_Committees/agric/completed_inquiries/2008-10/fertiliser/report/index accessed on 20 August 2017.
[16] IBISWorld Industry Report C1832, Pesticide Manufacturing in Australia, July 2016.
[17] These data are based on a variety of surveys, which can lead to measurement errors. It has been assumed that these surveys are unbiased— that is, all companies have the same probability of being over or under represented.
[18] IBISWorld Industry Report C1842, Veterinary Pharmaceutical Manufacturing in Australia, December 2016.
[19] IBISWorld Industry Report C1832, Pesticide Manufacturing in Australia, July 2016.
[20] IBISWorld Industry Report C1842, Veterinary Pharmaceutical Manufacturing in Australia, December 2016.
[21] Pool and spa chemicals are highly prolific from a product registration perspective and they are excluded from this data.

27.2 per cent. The third largest third largest pesticide manufacturer in Australia is Syngenta Crop Protection Pty Ltd, which had a market share of 19.7 per cent.

FIGURE 2.4 MAJOR AGVET CHEMICAL MANUFACTURERS IN AUSTRALIA AND THEIR MARKET SHARE IN TERMS OF REVENUE, 2015-16



SOURCE: IBISWORLD REPORT 2016A, C1832, PESTICIDE MANUFACTURING IN AUSTRALIA, JULY 2016 AND IBISWORLD REPORT 2016B, C1842, VETERINARY PHARMACEUTICAL MANUFACTURING IN AUSTRALIA, DECEMBER 2016

Nufarm Ltd is an Australian-based global company that manufactures and markets agricultural crop-protection products and seed technologies. The group operates in Australasia, Asia, Europe and the Americas and holds over 2,700 product registrations in 100 countries. The company manufactures crop protection and weed-control products, with a focus on off-patent chemicals used in herbicides, insecticides and fungicides. Nufarm Ltd addresses some non-patented proprietary or generic segments of the crop protection market. It is a large generic manufacturing company and the largest player in Australia's generic crop protection market. It is larger than the next biggest two innovative manufacturers combined.

Zoetis Australia Pty Ltd is the largest veterinary pharmaceutical manufacturer in Australia, with a market share of 36.4 per cent in 2015-16. This is followed by Virbac (Australia) Pty Ltd (20.6 per cent), Intervet Australia Pty Ltd (17.1 per cent) and Jurox Pty Ltd (7 per cent).

Zoetis is involved in the global development, manufacturing and marketing of veterinary medicines and vaccines for companion animals and livestock. The company has 28 manufacturing facilities across 11 countries, producing 300 product lines. Globally, Zoetis employs 9,000 people, with 1,050 involved in R&D activities. The company's Australian operations account for roughly 3 per cent of total group revenue.

2.2.3 Cost structure

A key feature of agvet chemical markets is that prices are inelastic—that is, demand for pesticides is not usually price sensitive. This reflects the fact that pesticides are traditionally a significant component of total farm cash outlays (4.3 per cent of total farm cash costs).

The average cost structure of agvet chemical producers in Australia is provided in **Figure 2.5**. Active ingredient purchases constitutes a major share of their cost structure, 67 per cent for pesticide manufacturing and 56 per cent for veterinary pharmaceutical manufacturing.

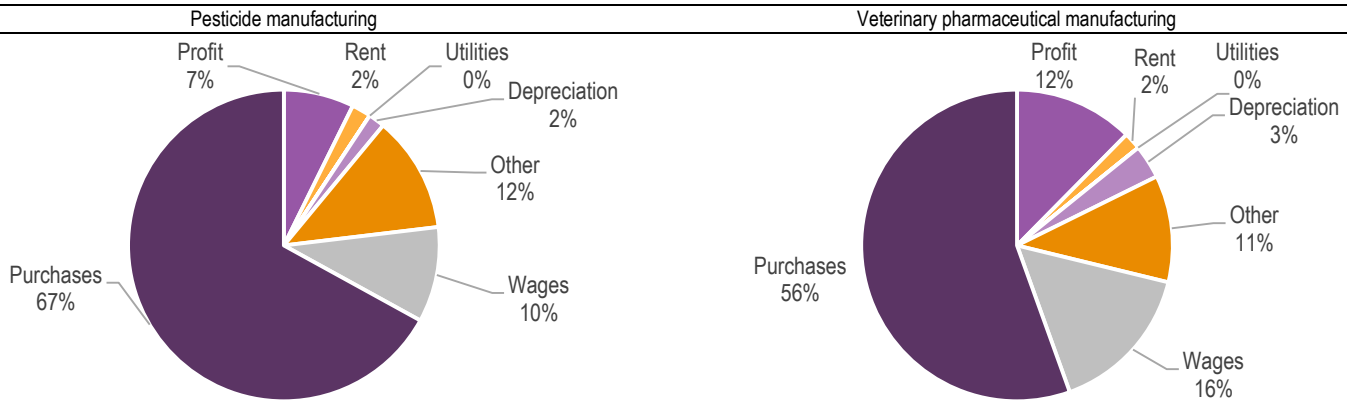
2.2.4 Australian demand for agvet chemicals

Australian pesticide manufacturing

The Australian pesticide manufacturing industry is predominantly oriented towards the domestic market, with exports accounting for around 15 per cent of industry revenue. At the same time, imports play an important role in meeting domestic demand needs (see **Table 2.1**). This gives rise to a significant trade imbalance. In 2015-16 the Australian pesticide manufacturing industry trade deficit

was an estimated A$614 million, nearly double that of one decade earlier, as the trade gap continues to widen.

FIGURE 2.5 COST STRUCTURE, 2015-16



NOTE: THESE FIGURES DO NOT INCLUDE POOL AND SPA CHEMICALS.

SOURCE: IBISWORLD REPORT (2016A) C1832, PESTICIDE MANUFACTURING IN AUSTRALIA, JULY 2016 AND IBISWORLD REPORT (2016B) C1842, VETERINARY PHARMACEUTICAL MANUFACTURING IN AUSTRALIA, DECEMBER 2016

In 2007-08, 33 per cent of domestic pesticide demand was met by imports. This increased to 46 per cent in 2015-16. These data show that imports play a significant role in Australian pesticide consumption. Since nearly half of the domestic consumption comes from imports, there is a strong policy rationale for fast access to products that have already been approved by a comparable overseas regulator.

Australian veterinary pharmaceutical manufacturing

This section discusses Australian *veterinary pharmaceutical manufacturing* rather than chemical manufacturing. This is because of the availability of IBISWorld data. The Australian veterinary pharmaceutical manufacturing industry is predominantly oriented towards the domestic market, with exports accounting for around 4 per cent of industry revenue. Unlike pesticides, imports play a small role in meeting domestic demand needs (see **Table 2.2**). Though small, this manufacturing gives rise to only a small trade imbalance. In 2015-16 the Australian veterinary pharmaceutical manufacturing industry trade deficit was estimated at $28.9 million—it was $0.9 million a decade ago.

TABLE 2.1 AUSTRALIAN PESTICIDE MANUFACTURING INDUSTRY, 2007-08 – 2015-16

Year	Revenue	Industry gross value-add	Exports	Imports	Domestic demand	Trade balance
	$ million	$ million	$ million	$ million	$ million	$ million
2007-08	982.9	209.9	98.9	439.8	1,323.8	-340.9
2008-09	1,112.1	233.3	131.1	481.4	1,462.4	-350.3
2009-10	1,140.8	211.2	102.0	456.5	1,495.3	-354.5
2010-11	1,100.4	231.1	111.7	622.3	1,611.0	-510.6
2011-12	1,001.8	226.6	115.8	559.7	1,445.7	-443.9
2012-13	1,024.7	219.8	131.3	582.4	1,475.8	-451.1
2013-14	1,039.7	193.5	118.5	771.7	1,692.9	-653.2
2014-15	1,061.4	216.1	154.0	751.1	1,658.5	-597.1
2015-16	1,076.2	205.6	164.3	778.3	1,690.2	-614.0

SOURCE: IBISWORLD REPORT 2016A, C1832, PESTICIDE MANUFACTURING IN AUSTRALIA, JULY 2016

TABLE 2.2 AUSTRALIAN VETERINARY PHARMACEUTICAL MANUFACTURING, 2007-08 – 2015-16

Year	Revenue	Industry gross value-add	Exports	Imports	Domestic demand	Trade balance
	$ million	$ million	$ million	$ million	$ million	$ million
2007-08	501.3	172.6	19.2	20.1	502.2	-0.9
2008-09	495.5	157.8	19.2	20.4	496.7	-1.2
2009-10	495.0	146.3	19.7	20.9	496.2	-1.2
2010-11	403.1	127.4	17.8	37.2	422.5	-19.4
2011-12	437.9	150.4	19.9	44.4	462.4	-24.5
2012-13	457.9	182.2	20.6	39.7	477.0	-19.1
2013-14	496.3	164.4	21.2	44.8	519.9	-23.6
2014-15	558.5	177.7	21.5	52.3	589.3	-30.8
2015-16	576.2	182.7	25.1	54.0	605.1	-28.9

SOURCE: IBISWORLD REPORT 2016B, C1832, VETERINARY MANUFACTURING IN AUSTRALIA, JULY 2016

In 2007-08, 4 per cent of veterinary pharmaceutical demand was met by imports. This increased to 9 per cent in 2015-16. This indicates that imports play a limited role in Australian veterinary pharmaceutical consumption.

For veterinary pharmaceutical products, the Australian market tends to make extensive use of products that are imported in a ready-to-use form through 'toll' manufacturing arrangements. Toll manufacture is where all or parts of the manufacture of veterinary medicines is contracted to another party. For example, an Australian company with specialised inputs, equipment and expertise can produce a veterinary medicine from materials supplied by the parent organisation. Toll manufacturers are also called contract manufacturers. The APVMA licences veterinary chemical manufacturers, consistent with global best practice.

2.2.5 Patents filed in Australia

IP Australia data, provided in **Table 2.3**, shows that Australian applicants are minor patent owners of class A01 - Agriculture, forestry, animal husbandry, hunting, trapping and fishing. Of the 17 Australian patents owned by Australian based companies:

- 12 patents are by Nufarm Australia Ltd
- 3 patents are by Jurox Pty Ltd
- 1 patent is by Syngenta Seeds Pty Ltd
- 1 patent is by Virbac (Australia) Pty Ltd

The data indicates that Australian firms (some are clearly subsidiaries of multinationals) have only one per cent of Australian agvet patents in force. German and US companies dominate patents filed in Australia.

2.2.6 Generic plant protection products in Australia

The growth in the availability of generic chemical plant protection products in Australia is shown in **Table 2.4**. There has been a rapid increase in the supply of a number of generic agricultural chemical products between 2004 and 2017 in Australia.

In the past, the agvet chemical industry was dominated by patent-protected solutions. But as active ingredients have aged out of their patents, the use off-patent products has grown significantly. For example, in 2012, there were 305 plant protection chemicals with glyphosate as the active ingredient. Now the number has reached 545,[22] an increase of 78 per cent within a span of five years.

[22] Based on advice from the APVMA, 2017.

TABLE 2.3 PATENT APPLICATIONS FILED / GRANTED BY IP AUSTRALIA 2000-16 BY COUNTRY

Country	A01	Other	Total	A01 as per cent of total
Australia	**17**	14	31	55
Belgium	27	36	63	43
Canada	1	24	25	4
Switzerland	202	143	345	59
China	0	1	1	0
Germany	676	937	1,613	42
Denmark	1	79	80	1
Spain	0	2	2	0
Finland	0	12	12	0
France	18	33	51	35
UK	72	37	109	66
Italy	0	2	2	0
Japan	124	636	760	16
Netherlands	17	122	139	12
Norway	0	1	1	0
New Zealand	1	12	13	8
USA	438	1,026	1,464	30
Total	**1,594**	**3,117**	**4,711**	**34**

SOURCE: WEBSTER, E, PERSONAL COMMUNICATION BASED ON IP AUSTRALIA DATA

As the generic product share of agvet markets grows, companies are gaining a comparative advantage by introducing new formulations or mixtures of already patented active ingredients, in particular when a chemical ingredient is at the end of its patent life. This product differentiation strategy appears common amongst both primary registrants and generic manufacturers.

TABLE 2.4 NUMBER OF REGISTERED GENERIC PLANT PROTECTION PRODUCTS IN AUSTRALIA, 2004, 2012, 2017

Active ingredient	2017	2012	2004
Herbicides			
glyphosate	545	305	131
paraquat	124	50	17
quizalofop-P-ethyl	46	27	10
triasulfuron	41	33	22
clodinafop	33	27	1
propyzamide	68	32	9
Insecticides			
imidacloprid	273	108	17
abamectin	177	31	15
pirimicarb	30	11	3
bifenthrin	274	142	50
alpha-cypermethrin	96	58	30

Active ingredient	2017	2012	2004
Fungicides			
azoxystrobin	70	12	3
tebuconazole	117	38	7
iprodione	70	47	19
phosphorous acid	70	34	24
propiconazole	97	51	16
Plant Growth Regulators			
ethephon	50	26	16
paclobutrazol	34	22	10
mepiquat-chloride	1	23	19
Gibberellic acid	32	19	11
Total in sample	2248	1096	430

SOURCE:INFOPEST, HTTP://WEBSVR.INFOPEST.COM.AU/SEARCHJS ACCESSED ON 20 AUGUST 2017

New patented active ingredient introductions have been declining for several decades. They peaked in the mid-1980s and have subsequently declined, with an average introduction of 12.7 per year in the 1990s, 10.3 in the 2000s and 7.3 per year in 2010s.[23]

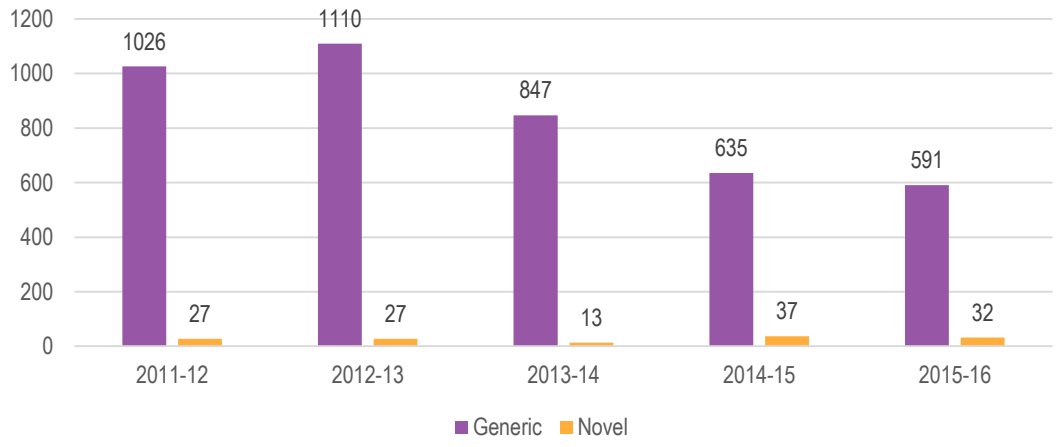
The development pipeline is also shrinking for new active ingredients, with around half as many active ingredients in development in 2013 industry-wide as there were just over a decade earlier.[24]

With fewer new active ingredients being introduced, the use of off-patent products has grown to meet the global demand for agvet chemicals.

2.2.7 Number of agvet products registered in Australia

The number of agvet products registered each year for the last five years in Australia are shown in **Figure 2.6**. The numbers of generic agvet chemicals registered in Australia has declined from 1110 in 2012-13 to 591 in 2015-16. On average, 27 novel agvet chemicals have been registered each year in Australia since 2011-12.

FIGURE 2.6 NUMBER OF AGVET CHEMICAL PRODUCTS REGISTERED IN AUSTRALIA, 2011-12 TO 2015-16



Note: For simplicity, the APVMA application items 1-4 are considered as novel and items 5-10 are considered as generic.

SOURCE: BASED ON ADVICE FROM DAWR, JULY 2017

[23] Phillips McDougall 2013, Crop Protection Market Trends, Industry Presentation 2013.
[24] Phillips McDougall 2015, The Development of the Agrochemical Market in Europe, March 2015.

2.3 UK market

The UK pesticide and other agrochemical manufacturing industry is predominantly oriented towards the export market, with exports accounting for around 97 per cent of industry revenue. At the same time, imports play an important role in meeting domestic demand (see **Table 2.5**).

TABLE 2.5 UK PESTICIDE AND OTHER AGROCHEMICAL MANUFACTURING INDUSTRY, 2007-08 – 2015-16

Year	Revenue	Industry gross value-add	Exports	Imports	Domestic demand	Trade balance
	£ million	£ million	£ million	£ million	£ million	£ million
2007-08	933.0	185.4	672.0	489.7	750.7	182.3
2008-09	954.3	189.7	809.8	595.3	739.8	214.5
2009-10	1,085.0	210.7	906.9	525.9	704.0	381.0
2010-11	913.7	179.4	908.0	575.4	581.1	332.6
2011-12	1,087.3	196.2	1,022.7	624.5	689.1	398.2
2012-13	1,151.1	218.6	997.1	660.3	814.3	336.8
2013-14	1,211.4	220.8	1,049.3	629.6	791.7	419.7
2014-15	1,167.0	216.1	1,072.2	629.3	724.1	442.9
2015-16	1,151.3	220.1	1,121.7	631.1	660.7	490.6

SOURCE: IBISWORLD REPORT 2016C, C20.200, PESTICIDE AND OTHER AGROCHEMICAL MANUFACTURING IN THE UK, OCTOBER 2016

The major players in plant protection in terms of sales revenue in the UK are Nufarm UK Limited (12.7 per cent) and Syngenta UK Limited (12.6 per cent). The UK Market is relatively less concentrated than the other countries studied in this report. Nufarm UK is the subsidiary of the Australian Nufarm, manufacturing and marketing generic crop-protection products.

Syngenta UK Limited is the British subsidiary of Syngenta AG, a Basel-based multinational specialist chemical company. Syngenta AG was formed in November 2000 following the merger of the global agribusinesses of Novartis (Novartis Agribusiness) and AstraZeneca (Zeneca Agrochemicals). Since then, Syngenta AG has grown to become a leading player in both the global crop protection and the high-value commercial seeds markets. Other companies include BASF plc, estimated market share of 4.4 per cent and Croda Europe Ltd with an estimated market share of 2.2 per cent.[25]

2.4 US market

The global market for crop protection products is echoed by the US market, with the top five players accounting for 77 per cent of market share.

- Syngenta AG (24.6 per cent)
- The Dow Chemical Company (22.3 per cent)
- Monsanto (11.8 per cent)
- Bayer AG (10.8 per cent), and
- E.I du Pont de Nemours and Company (7.6 per cent).

Syngenta operates in three segments — integrated crop protection, seeds and global lawn and garden care. The crop protection segment is involved in the discovery, development, manufacturing and marketing of a range of pesticides designed to improve crop yields and food quality.

Monsanto is US-based and produces two main herbicide products — Roundup and Harness. Monsanto's main product was threatened at the start of 2015, as Roundup's patent covering its active ingredient expired in the USA. The consequences of this are still unclear. Roundup has been the

[25] IBISWorld Industry Report 2016C, C20.200 Pesticide and Other Agrochemical Manufacturing in the UK. October 2016.

company's best performing brand, with various extensions being introduced, including Roundup WeatherMax.

IBISWorld expects that Monsanto will experience increasing competition in the years to come, as generic substitutes to Roundup are introduced to the market. Nonetheless, the company still has many patents which remain active on glyphosate formulations and production processes.

Generic products are gradually becoming an important source of competition as the patents on earlier discoveries expire. It is likely that over the next five years, about 80 per cent of crop protection chemicals will not be patented, creating a new competitive basis for the industry.[26]

The US pesticide manufacturing industry is predominantly oriented towards the US domestic market, with exports accounting for around 23 per cent of industry revenue. At the same time, imports play a limited role in meeting domestic demand needs in the USA (see **Table 2.6**).

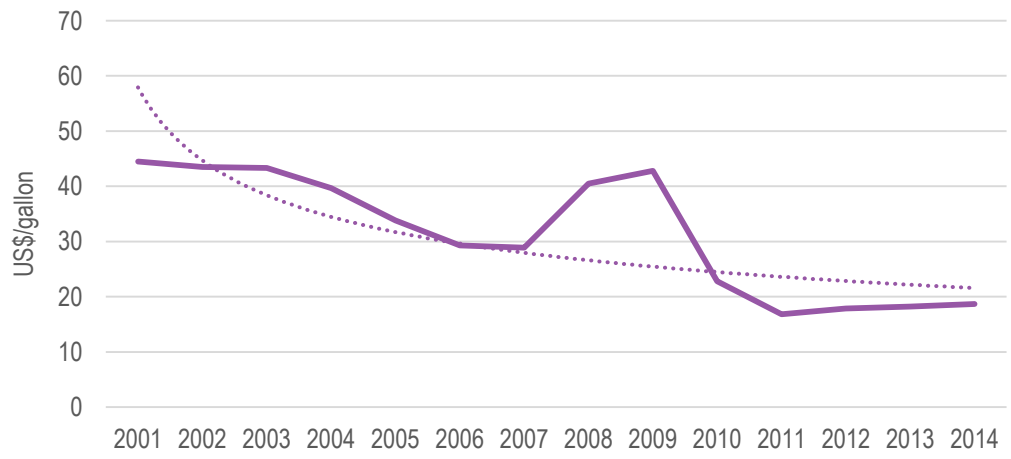
TABLE 2.6 US PESTICIDE MANUFACTURING INDUSTRY, 2008–16

Year	Revenue	Industry gross value-add	Exports	Imports	Domestic demand	Trade balance
	US$ million	US$ million	US$ million	US$ million	US$ million	US$ million
2008	15,012	1,645	2,839	952	13,124	1,888
2009	13,800	1,924	2,505	844	12,139	1,661
2010	12,460	2,012	3,065	842	10,237	2,223
2011	12,784	2,613	3,268	1,045	10,561	2,223
2012	16,385	3,565	3,564	1,022	13,843	2,542
2013	18,935	4,271	4,026	1,230	16,139	2,796
2014	16,612	4,199	4,201	1,275	13,686	2,926
2015	15,400	3,633	3,639	1,403	13,164	2,237
2016	15,599	3,224	3,553	1,482	13,528	2,072

SOURCE: IBISWORLD REPORT 2016C, C20.200, PESTICIDE AND OTHER AGROCHEMICAL MANUFACTURING IN THE UK, OCTOBER 2016

An average US Roundup price is provided in **Figure 2.7**. This shows that there is considerable price volatility within the US market alone. There is also a general downward trend as the Roundup patents expire.

FIGURE 2.7 AVERAGE US ROUNDUP PRICE US$ / GALLON, 2001-14



SOURCE: USDA NATIONAL AGRICULTURAL AND STATISTICAL SERVICES, ACCESSED ON 12 JULY 2017

[26] IBISWorld Industry Report 2017, 32532 Pesticide Manufacturing in the US, June 2017.

2.5 Canadian market

The pesticide manufacturing industry in Canada has a very low level of market share concentration. This is mainly the result of a highly fragmented industry, composed mostly of smaller companies and owner operators. Major global pesticide companies have vast operations in the USA and a significant proportion (65 per cent) of Canadian domestic demand is met by imports from the USA (see **Table 2.7**). Thus there are no major Canadian players in the industry.

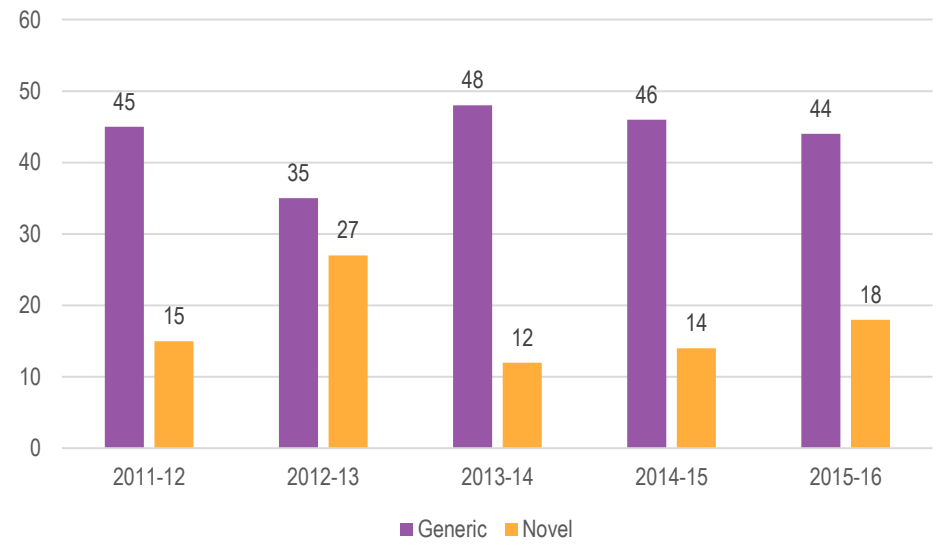
TABLE 2.7 CANADIAN PESTICIDE MANUFACTURING INDUSTRY, 2008–16

Year	Revenue	Industry gross value-add	Exports	Imports	Domestic demand	Trade balance
	C$ million	C$ million	C$ million	C$ million	C$ million	C$ million
2008	965.3	303.5	106.9	1,262.9	2,121.3	-1,156.0
2009	1,115.8	250.1	120.3	1,466.0	2,461.5	-1,345.7
2010	975.3	238.8	102.6	1,198.1	2,070.8	-1,095.5
2011	960.8	140.9	81.5	1,059.1	1,938.4	-977.6
2012	1,068.2	170.6	84.9	1,210.1	2,193.4	-1,125.2
2013	1,125.3	210.3	67.1	1,585.5	2,643.7	-1,518.4
2014	1,147.7	216.9	83.6	1,686.9	2,751.0	-1,603.3
2015	1,086.0	232.2	114.8	1,635.6	2,606.8	-1,520.8
2016	1,076.9	253.9	113.9	1,599.3	2,562.3	-1,485.4

SOURCE: IBISWORLD REPORT 2016C, C20.200, PESTICIDE AND OTHER AGROCHEMICAL MANUFACTURING IN THE UK, OCTOBER 2016

A number of plant protection products registered in Canada are provided in Figure 2.8. In 2015-16, 44 generic products, including 27 technical or manufacturing products and 17 end-use products and 18 novel products were registered in Canada.

FIGURE 2.8 NUMBER OF PLANT PROTECTION PRODUCTS REGISTERED IN CANADA, 2011-12 TO 2015-16



SOURCE: PEST MANAGEMENT REGULATORY AGENCY, ANNUAL REPORT 2016-16 AND PREVIOUS ISSUES.

The Canadian pesticide market is about 3 per cent of the size of the US market. Canadian firms in this sector tend to be subsidiaries of US or European multinationals. These companies are generally

vertically integrated. However, the formulation process has been increasingly tendered out to specialised large-scale low-cost formulators.[27]

Canada's pesticide market is not large by world standards. Canada's large acreage crops use only modest amounts of pesticides. Regulation in Canada is reported to be slower than the USA and involves higher costs. Surveys of Canadian and US pesticide prices have found some significant differences—for some products the prices were higher in Canada, while for others the prices were higher in the USA.[28] In the past, Canadian farmers have felt disadvantaged by the smaller number of new product registrations in Canada relative to the USA. This has been a particular problem for minor uses.

In seeking to understand pesticide markets, there are lessons that can be learned from some unique Canadian work that does not appear to have been replicated elsewhere. Reports by McEwan and colleagues in the late 1990s suggested that there are many factors that can influence Canadian pesticide prices including health of the agricultural economy, regulation and standards, advanced marketing and advertising campaigns, effectiveness and crops safety. McEwan and Deen examined pesticide availability in Canada, and Canada's position in the North American pesticide industry in terms of market size, types of crops grown and overall pricing strategies.

In relation to pesticide pricing, McEwan and Deen[29] compared Canada and Australia. Even though this analysis was undertaken twenty years ago, much of it appears to be relevant to Australia today. McEwan and Deen concluded that Canadian and Australian pesticide markets are different in terms of climate, crop mix, and the size of the domestic market. However, they are similar from the perspective that they both represent relatively small pesticide markets and grow extensive crops (i.e. low yielding crops, with limited crop price subsidisation). The report considered that pesticide pricing was therefore probably similar in the two jurisdictions. McEwan and Deen concluded that:

The authors of this report felt the major crop markets did have strong price competition over time. When manufacturers are introducing a new product, detailed market analysis is performed to position the product relative to other competitive products. The Canadian pesticide industry is highly segmented and firms try to differentiate themselves in the market place by competing on service, crop safety, effectiveness and etc. There is no difference in programs or pricing setting schemes in the different regions of Canada. Much of the flexibility in price that occurs at the distributor and retail level is function of local demand and the ability to take advantage of manufacturer programs.

McEwan K and Deen B 1997, A review of agricultural pesticide pricing and availability in Canada, p70

McEwan and Deen referenced a 1993 Australian Prices Surveillance Authority (PSA) report which compared international pesticide pricing and showed substantial differences across countries and products. The conclusion reached by the PSA was that individual country markets are in effect largely insulated one from the other even though free trade may exist. As a result, the Australian farm chemical industry at a global level was not considered to be a competitive industry with respect to prices. While Australian firms did compete, the majority of their products were sufficiently differentiated for firms to be able to be price makers, not price takers. Such differentiation could occur from a natural source (resistance, seasonal factors) or from value added delivery systems. The final conclusion of the PSA was that pesticide pricing is not cost based but "determined according to what the market will bear, given the high proportion of costs accounted for by the active ingredient."

Most of the McEwan and Deen (and the PSA) views appear to continue to be true even though Australia's IP and data protection arrangements have undergone a number of changes in the intervening period. Australia's high level of agricultural chemical imports means that we are now a price-taker.

[27] McEwan K and Deen B 1997, A review of agricultural pesticide pricing and availability in Canada, December 31 1997

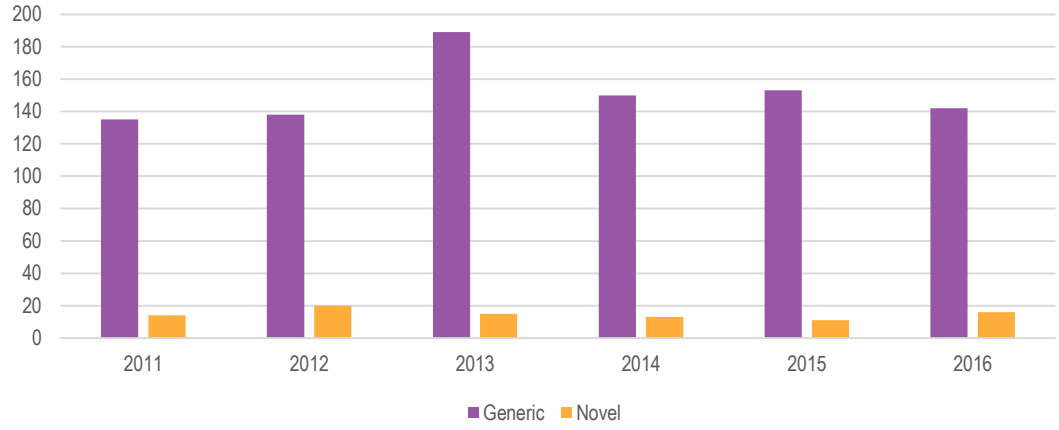
[28] McEwan K 1997, A comparison of farm input prices- Ontario versus Great Lake States, Ridgetown College, University of Guelph, and Smith VH and Johnson JB 2004, Agricultural Chemical Prices in Canada and the United States: A Case Study of Alberta and Montana, Agricultural Marketing Policy Paper No. 4, December 2004 (Revised)

[29] McEwan K and Deen B 1997, Op cit.

2.6 New Zealand market

The number of agvet products registered each year for the last five years in New Zealand are shown in **Figure 2.9**. On average, 150 generic and 14 novel agvet chemicals were registered in New Zealand since 2011. This is unpublished data provided by the New Zealand authorities. Similar information is not generally available for other countries.

FIGURE 2.9 NUMBER OF AGVET CHEMICAL PRODUCTS REGISTERED IN NEW ZEALAND, 2011–2016



SOURCE: PERSONAL COMMUNICATION WITH NZ MPI, RECEIVED ON 15 JUNE 2017

2.7 The Australian market in context

In regulating agvet chemical products, Australia needs to ensure that:

- original product manufacturers are encouraged to register their products in Australia and at an early stage in product life cycles
- generic manufacturers are provided with the opportunity to enter the Australian market soon after patent protection for the original product has lapsed.

There are several possible indicators of how well Australia is striking this balance. Two indicators are:

- The numbers of new agvet and generic products registered in Australia compared with numbers registered in other countries in the same year is a broad indicator of the level of activity in relation to these two categories. This does not necessarily compare registration of the same products. However, a product-by-product comparison would be difficult (it would need information on the active ingredients) and time consuming, and may not yield better information.
- A comparison of the ratios of generic to new agvet products registered annually is a broad indicator of how well Australia is faring in the registration of generics.

A simple comparison of crop protection products registered in Australia and Canada is provided below in **Table 2.8**.

On average over the past five years, the number of novel plant protection chemicals registered in the two countries was similar, that is around seven products in each country. However, the number of generic plant protection products registered with their respective agencies was significantly different.

In Australia, on average over 700 generic plant protection products were registered with the APVMA each year. On the other hand, on average only 44 generic plant protection products were registered annually with Canada's PMRA.

TABLE 2.8 A COMPARISON OF PLANT PROTECTION PRODUCT REGISTRATIONS, AUSTRALIA AND CANADA, 2011-16

	Australia		Canada	
	Generic	Novel	Generic	Novel
2011-12	914	13	45	15
2012-13	1006	22	35	27
2013-14	689	8	48	12
2014-15	493	15	46	14
2015-16	498	27	44	18
Average	***720***	***17***	***44***	***17***

SOURCE: APVMA AND PMRA

2.8 Conclusions

The world market for agvet chemicals is dominated by a small number of large multinational corporations based in North America and Europe. Nufarm Ltd is the largest agvet chemical company in Australia. The Australian agvet chemical market is very small (less than 1.5 per cent of the world market). The total domestic demand in the USA and Australia for plant protection products in 2016 was A$17.8 billion and A$1.7 billion respectively. Thus the small size of the Australian market means that, in general, it can provide only limited returns to agvet chemical manufacturers.

Australia needs timely access to innovative agvet chemical products, which are generally better than older products. However, as a recent report has noted:

> *With a general decline in productivity growth and changes to external factors in managing weed, pest and disease risk, Australia more than ever requires access to new and safer pesticide and veterinary medicines. The plant and animal industries are all facing significant emerging biosecurity threats and being impacted on by pesticide resistance. Australia is no longer on the global priority list for pesticide and veterinary medicine commercialisation as it was 20 years ago.*
>
> *Rainbow R 2017, Delivery of Access to AgVet chemicals collaborative system – AgVet Collaborative Forum, accessed on 17 July 2017 at https://rirdc.infoservices.com.au/items/17-019*

Factors which influence the prices of agvet chemicals in Australia are complex. They include the ability of the consumer to pay / market demand, the price of oil, the extent to which there is competition between different products serving similar purposes, and the availability of generics. For major plant protection products, the market for generics in Australia appears to grow quickly once patent and / or data protection expires (see **Table 2.4**).

The veterinary product market in Australia has some characteristics which are different to those of the agricultural chemical market—principally that there are more manufacturers of veterinary products and imports play a less important role.

For plant protection products, Australian agricultural producers seem to have better access to generic agvet chemicals than their Canadian counterparts. The numbers of novel agvet chemical products being registered in each country are about the same.

3 AGVET CHEMICAL PRODUCT IP AND DATA PROTECTION

This chapter summarises the various IP arrangements for agricultural chemical products and veterinary chemicals in Australia, the EU including the UK and Germany, the USA, Canada and New Zealand.

3.1 Context

In order for a chemical plant protection product to be authorised for sale, a registration dossier has to be assembled to demonstrate safety and efficacy to the satisfaction of government regulators across major developed economies.

The registration dossier contains many components that are also covered by mainly five forms of intellectual property rights.[30]

- The **patent** usually covers the invention, which can be the active substance and the formulated products but also in some cases the manufacturing process, and these are described briefly in the registration dossier.
  - Patents involve disclosure and annual payment by country and are time limited.
  - In Australia, the EU and North America (USA and Canada), patents for agvet chemicals are typically of 20 years duration from filing. In Europe this can be extended by up to a further 5 years if the registration process delays market entry. Such extensions are not available outside the EU. Patent filing and agvet chemical registrations are different and unrelated processes in Australia.
- **Trade secrets** are found in the confidential business information section of the registration dossier and are typically the manufacturing process if not patented, the technical specification of the active ingredient and formulated product and any specific analytical methods that could betray the manufacturing process by extrapolation from individual impurities. Trade secrets are not registered and applies where there are reasonable grounds for believing that the information has been and can continue to be kept secret.
- The **trademark** is used to protect the brand name of the formulated product, and there is a current vogue for branding the active ingredient. Trademark fees are paid every five or ten years depending on the jurisdiction (Australian fees are paid every ten years). Protection can be perpetual provided fees are paid and the mark is in active use. Related to trademarks is the protection of invented names for agvet and pharmaceutical products. A proposed name of a new pharmaceutical that could confuse consumers with an existing product will not be approved.
- **Copyright** protects the chemical plant protection product label and, like a trade secret, is not registered. However there is an enhanced system in the USA that involves an initial one-off payment.

[30] Carroll MJ 2016, The importance of regulatory data protection or exclusive use and other forms of intellectual property rights in the crop protection industry, *Pest Management Science*. 72(9):1631-1637.

Finally, there is **regulatory data protection.** Regulatory authorities protect the data related to studies and tests that are undertaken to demonstrate safety and efficacy of the agvet chemicals. '**Data protection'** is a general term used in the literature. It is known as '**limitation on use'** in Australia, or '**data exclusive use'** or **'data exclusivity'** in the USA.

Patents are a core feature of the market for agvet products. Patent laws in Australia, the EU including the UK and Germany, the USA, Canada and New Zealand all provide standard patent terms of twenty years.

Patents and regulatory data protection provide similar benefits for the manufacturers of original products, but are distinct from one another. Periods of regulatory data protection and patent terms may or may not run concurrently. Patents can be issued or expire at any time regardless of the approval status of the chemicals. Regulatory data protection periods generally commence when a chemical product is approved for use. Some chemicals have both patent and regulatory data protection simultaneously while others have just one or the other.

A key aim of regulatory data protection is to protect the property rights[31] of the owner of the new agvet chemicals.

The extent to which agvet chemical companies rely on patents as opposed to data protection is not known. Consultations for this project suggest that the latter is of some considerable importance. Given a patent life of twenty years, it is likely that applicants to the APVMA still have some years before their patent(s) expire.

3.2 Patent protection in selected countries

3.2.1 Australia

The *Patents Act 1990* provides for patents with a standard term of twenty years. Under amendments passed in 1998, the term of a patent can be extended for human pharmaceuticals. However such extensions are not available for agvet chemicals.

Pharmaceutical patent extensions

The holder of a patent for a human pharmaceutical may apply for extension of patent term if the following conditions are satisfied:

— One or more pharmaceutical substances per se must be disclosed in the specification of the patent and in substance fall within the scope of the claim or claims of that specification

— The goods containing, or consisting of, the substance must be included in the Australian Register of Therapeutic Goods (ARTG), and

— There has to be a period of at least five years between the date of the patent and the first regulatory approval date for the substance.

An application for an extension of term must be made within six months of either the date the patent was granted or the date of commencement of the first inclusion of a product containing the patented substance in the ARTG, whichever is the later. The length of the extension is calculated by subtracting five years from the period between the commencement of the patent and the date of the first regulatory approval of the substance. The maximum extension is five years.

Where an extension of term is granted, the legislation provides that the exclusive rights of the patentee during the term of the extension are not considered to have been infringed if another person exploits the pharmaceutical substance for a purpose other than a therapeutic use.

The 2004 Australia-US Free Trade Agreement (AUSFTA) includes a provision requiring that "with respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process." This does not apply to agvet chemical products.

[31] This property is the testing and trial data

A review of the Australian pharmaceutical patents system[32] examined Australia's pharmaceutical patent extension provisions and recommended alternative approaches to meeting the stated policy objectives. This recommendation has not been accepted by the Government.

The Productivity Commission reported on Intellectual Property Arrangements in 2016.[33] The Commission noted that extensions of term for human pharmaceuticals are capped at an effective market life of 15 years. These arrangements were intended to attract pharmaceutical research and development investment to Australia and to improve incentives for innovation by providing an effective market life for pharmaceuticals more in line with other technologies. The Productivity Commission found that these arrangements have had little effect on innovation in Australia and describes the hoped-for benefits as "largely illusory". It found that "poor targeting means that more than half of new chemical entities approved for sale in Australia enjoy an extension in patent term, and consumers and governments face higher prices for medicines". The implication would appear to be that better targeting might have produced more useful results.

In the Productivity Commission's view, rather than compensating firms for being slow to introduce drugs to the Australian market, extensions should only be allowed where the actions of the regulator result in an *unreasonable* delay. It suggested that the one year timeframe set by Government for the Therapeutic Goods Administration would be a reasonable processing period, with extensions granted only where the time taken by the regulator exceeds this period. The Australian Government responded to the Productivity Commission report in August 2017. The Government noted the Productivity Commission's recommendation on reforming extensions of patent terms for pharmaceuticals and will discuss ways to improve arrangements with the sector.

3.2.2 The European Union

Standard patents in EU countries are granted for twenty years either by the relevant national agency or by the European Patent Office.[34] In these countries and three European Economic Area (EEA) countries,[35] supplementary protection certificates (see **Box 3.1**) are available that extend the protections of patents for medicinal and plant protection products to cover the period needed for regulatory approval of the product, typically for a maximum of five years.[36]

Infringement exemption arrangements[37] differ between European countries. Research exemptions do not have a common basis in European law.[38] As a result there are no uniform rules regarding this exemption in the EU.

Article 10(6) of EU Directive 2001/83/EC authorises the Bolar exemption for conducting "necessary studies and trials". There are significant differences in how different EU member countries have implemented this Directive.

3.2.3 The United Kingdom

Patent protection for agvet products in the UK closely follow the provisions of the European Union, with a standard patent term of twenty years. The UK has implemented the European Union provisions for extending the protection of patents for these products through SPCs.[39]

[32] Harris T, Nicol D, Gruen N 2014, Pharmaceutical Patents Review Report 2013.
[33] Productivity Commission 2016, Intellectual Property Arrangements, Report No 78, September 2016.
[34] Patent Protection in the EU, European Commission, accessed on 16 June 2017 at http://ec.europa.eu/growth/industry/intellectual-property/patents/.htm
[35] The EEA countries are Iceland, Liechtenstein and Norway
[36] Supplementary Protection Certificates for Pharmaceutical and Plant Protection Products, European Commission, accessed on 16 June 2017 at http://ec.europa.eu/growth/industry/intellectual-property/patents/supplementary-protection-certificates/index_en.htm
[37] Patent law provisions that allow activities (e.g. research) which would otherwise be considered to be infringements
[38] Kupecz A, Roox K, Dekoninck C, Schertenleib D, Stief M, Sanna F, Orsingher M, Miralles E, Molina E, Crosse T, Gilbert M, James W, 2015, Safe harbors in Europe: an upgrade on the research and Bolar exemptions to patent infringement, Nature Biotechnology, 33, 7(710-715)
[39] Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992, SI 1992/3091, accessed on 16 June 2016 at http://www.legislation.gov.uk/uksi/1992/3091/made
Patents (Supplementary Protection Certificate for Plant Protection Products) Regulations 1996, SI 1996/3120, accessed on 16 June 2017 at http://www.legislation.gov.uk/uksi/1996/3120/made
Patents (Compulsory Licensing and Supplementary Protection Certificates) Regulations 2007, SI 2007/3293, accessed on 16 June 2017 at http://www.legislation.gov.uk/uksi/2007/3293/made

BOX 3.1 EUROPEAN UNION SUPPLEMENTARY PROTECTION CERTIFICATE

Regulation No. 469/2009 Concerning the Supplementary Protection Certificate for Medicinal Products[40] (including products to treat animals) applies to any product that has already been protected by a patent in a Member State and is subject to an authorisation procedure before it is placed on the market.[41]

Regulation (EC) No. 1610/96[42] governs the creation of an SPC for plant protection products. Any product that is protected by a patent in a Member State and is subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure under Directive 91/414/EEC,9 or an equivalent provision of national law, may be the subject of an SPC. Plant protection products are defined as "active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user" and intended to:

- protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;
- influence the life processes of plants, other than as a nutrient (e.g. growth regulators)
- preserve plant products, and not be subject to special Council or Commission provisions
- destroy undesirable plants, or
- destroy parts of plants, check or prevent undesirable growth of plants.

Chemicals, micro-organisms and viruses are included.

An application for an SPC for a medicinal or a plant protection product must be filed with the relevant national agency in the Member State that granted the patent and where the authorisation was obtained. The conditions for applying for an SPC for a medicinal or plant protection product are the same. The applicant must:

- Have a valid patent
- Have valid authorisation to place the product on the market
- Show that the product has not already been the subject of a certificate, and
- Show that the marketing authorisation is the first authorisation to place the product on the market as a medicinal product or a plant protection product.

An SPC grants the same rights, limitations, and obligations as those conferred by a patent, except that the protection extends only to the product covered by the authorisation to place the product on the market. An application for an SPC must be filed within six months of the date the product was authorised to be marketed. If the authorisation to place the product on the market is granted before the patent is granted, the application for a certificate must be filed within six months of the date on which the patent is granted. An application to extend the duration of a certificate that has been already granted must be filed no later than two years before the expiration of the certificate.

The duration of an SPC commences at the end of the term of the basic patent and extends for a period equal to the period that elapsed between the date on which the application for a basic patent was filed and the date the product was first authorised to be placed on the European Community market, reduced by a period of five years. The duration of an SPC may not exceed five years from the date on which it takes effect. Any provisional first marketing authorisation is taken into account only if it is directly followed by a definitive authorisation of the same product.

SOURCE: ACIL ALLEN CONSULTING ADAPTED FROM EUROPEAN COMMISSION AND OTHER SOURCES

The purpose of the SPCs is to compensate patent holders for delays caused through UK regulatory processes. In order to be eligible for an SPC, the individual must have:

- a valid UK patent that protects either the active ingredient, the process to obtain the active ingredient, or an application of the active ingredient, and

[40] Regulation (EC) No. 469/2009 of the European Parliament and of the Council of May 6, 2009 Concerning the Supplementary Protection Certificate for Medicinal Products (Codified version), 2009 O.J. (L 152) 1, accessed on 16 June 2017 at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:pdf

[41] The relevant Directive for veterinary products is Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, 2001 O.J. (L 311) 1, accessed on 16 June 2017 at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0082&from=EN

[42] Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 Concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, 1996 O.J. (L 198) 30, accessed on 16 June 2017 at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31991L0414&from=EN

— a marketing authorisation that allows the active ingredient to be placed on the UK market as a pharmaceutical or plant protection product.

The date of the marketing authorisation that first placed the active ingredient on the UK market is the starting date for any SPC. This authorisation can be from a regulatory agency elsewhere in the EU / EEA.

The maximum period for which an SPC may be granted in the UK is fifteen years from the date of the first authorisation in the EU, or five years from the date on which the SPC takes effect, whichever occurs first. In the UK, an SPC covers only the active ingredient and the additional protection applies only in the UK.

3.2.4 Germany

The *German Patent Act* also closely follows the provisions of the European Union as described above, with a standard patent term of twenty years from the date the application is filed. Germany also provides SPCs for agvet products. An English translation of the *German Patent Act* is available[43] but other relevant national documentation is available only in German.

The statutory basis for the experimental use exemption can be found in s.60(5)(b) of the Patents Act. This exemption need not be driven by purely scientific interest.

3.2.5 The United States of America

The standard "utility patent" term in the USA is twenty years. For applications filed on or after 8 June 1995, the *Uruguay Round Agreements Act* provides that the term of a patent (other than a design patent) begins on the date the patent issues and ends on the date that is twenty years after the application for the patent was filed in the USA or, if the application contains a specific reference to an earlier filed application or applications, twenty years from the filing date of the earliest of such application(s).

The term of utility patents can be adjusted for delays within the US Patent and Trademark Office (USPTO).[44] Utility patents issued for applications lodged after 29 May 2000 are eligible for adjustment under 35 U.S.C. 154(b) and 37 CFR 1.702-1.705. Patent term extensions are also available under 35 U.S.C. 156 for pre-market regulatory review. These are separate from USPTO delay extensions and are added to them.

The right to a patent term extension based on time lost to regulatory review arises from the *Drug Price Competition and Patent Term Restoration Act of 1984*, (known as the Hatch-Waxman Act). This Act eliminated two distortions to the normal patent term arising from the requirement that certain products must receive pre-market regulatory approval:

— The first distortion was the loss of patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency

— The second distortion occurs after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive USFDA approval before patent expiration.

The provisions of 35 U.S.C. 156 were designed to create new incentives for research and development of certain products subject to pre-market government approval by a regulatory agency. This statute enables the owners of patents on certain products including animal drugs, and veterinary biological products to restore to the terms of those patents some of the time lost while awaiting pre-market government approval from a regulatory agency. The rights derived from extension of the patent term are defined in 35 U.S.C. 156(b) and are a right (i.e. not subject to a claim-by-claim basis).

In exchange for extension of the patent term, Congress legislatively overruled *Roche Products v. Bolar Pharmaceuticals* and provided that it is not an act of infringement, for example, to make and test

[43] Unofficial English translation available at http://www.gesetze-im-internet.de/englisch_patg/patent_act__patent gesetz__patg_.pdf accessed on 20 August 2017.
[44] See https://www.uspto.gov/web/offices/pac/mpep/s2701.html accessed on 20 August 2017.

a patented drug solely for the purpose of developing and submitting information for an Abbreviated New Drug Application (ANDA).[45]

On November 1988, 35 U.S.C. 156 was amended, to add animal drugs and veterinary biologics to the list of products that can form the basis of patent term extension. Animal drug products manufactured primarily through biotechnology are excluded from the provisions of patent term extension.

On 3 December 1993, *35* U.S.C. 156 was further amended to provide for interim extension of a patent where a product covered by the patent was expected to be approved, but not until after the original expiration date of the patent.

An application for the extension of the term of a patent under 35 U.S.C. 156 must be submitted by the owner of the patent within a sixty-day period beginning on the date the product received permission for commercial marketing. Details of the calculation of the sixty-day period were clarified by the *America Invents Act*.

The USPTO initially determines whether the application is formally complete and whether the patent is eligible for extension. The Director of the USPTO notifies the Secretary of Agriculture or the Secretary of Health and Human Services of the submission of an application for extension of patent term which complies with requirements within sixty days, and the Secretary determines the length of the applicable regulatory review period and notifies the Director of the determination. If the Director determines that the patent is eligible for extension, the Director calculates the length of extension for which the patent is eligible and issues an appropriate Certificate of Extension.

It should be noted that:

- Under US patent law there is an option for the patentee to take a patent term extension for a food producing animal indication even if a companion animal indication is approved first. This is only for the first approved use. No such extensions exists for human pharmaceutical patents.
- Genetically engineered animal drugs are excluded from patent term restoration in the USA. There is no such exclusion in the case of human therapeutics.
- Genetically engineered animal drugs are excluded from safe harbour provisions in the USA. There is no such exclusion in the case of human therapeutics.
- In general, a second patent term restoration for same active ingredient is prohibited in the USA for animal drugs and but there is no prohibitions for human drugs
- Unlike human drugs, there is no paediatric exclusivity for animal drugs in the USA
- Orphan drug status—for rare diseases—can be obtained under the *US Orphan Drug Act*, where the holder is entitled to several specified benefits. This does not extend to animal drugs. However, animal drugs meeting certain criteria have the possibility to obtain so called Minor Use / Minor Species (MUMS) designation, which provides seven years exclusivity for that indication.

3.2.6 Canada

Canada provides standard patent terms of 20 years from the date on which a patent is filed. Canada does not provide patent term extensions for pharmaceutical or agvet products. However Canada has recently signed an agreement (CETA) with the EU which provides for such extensions ("restoration") in the future, for patent term extensions of two years for qualifying pharmaceutical products.

3.2.7 New Zealand

The standard term of a New Zealand patent is twenty years. On 11 July 2016, the New Zealand Ministry of Business, Innovation and Employment released a consultation document seeking feedback on proposed regulations to implement the patent term extension provisions in the Trans-Pacific Partnership (TPP) Agreement Amendment Bill. The Bill received Royal Assent on 21 November 2016 but will only come into force when / if the TPP is ratified by sufficient countries. It amends the New Zealand *Patents Act 2013* to provide for patent term extensions for pharmaceuticals (but not agvet products):

[45] See Donald O. Beers *et al* 2013, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, Eighth Edition, Wolters Kluwer Law & Business, 2013, 4.05 for a discussion of the Hatch-Waxman Act and infringement litigation.

— Unreasonable delays in patent grant, and
— Unreasonable curtailment of the effective patent term as a result of the Medsafe approval process.

The proposed regulations mainly relate to procedural matters, including:

— The manner in which requests for extension of term must be made
— The information that must be provided (in addition to that required by the TPPA Bill) with requests for an extension
— Time limits for requesting an extension, and
— Procedures by which third parties can oppose the grant of extensions of term for unreasonable curtailment, including the time limits by which such oppositions must be made.

The Bill provides for regulations to be made setting out time periods to be disregarded when determining whether there have been unreasonable delays in grant of a patent. These disregarded periods will be ignored when deciding whether there has been unreasonable delay.[46]

The extension for delays at IP New Zealand would be available for all patents, no matter what the subject matter. However it appears that it will be very difficult to get this type of extension in New Zealand. This is partly because the Intellectual Property Office of New Zealand (IPONZ) is currently very quick to examine patent applications. In addition, under the present proposals for how the extension would be calculated, any periods of time during examination that are outside the direction or control of IPONZ will be discounted from the extension calculation.

The extension for delays in Medsafe approvals is only available for pharmaceutical patents. However, the proposals for calculation of the extension are very different to those used in Australia. The calculation will be based on compensating for delays by the regulatory body (i.e. Medsafe) in processing the marketing approval, rather than the overall length of time for a pharmaceutical to get to market.

An extension will only be available if marketing approval is allowed after the patent is granted and it takes more than three years between the date marketing approvals is applied for and the date it is granted (or five years for the pharmaceutical substance produced by the use of recombinant DNA technology). Any time during the marketing approval process which is considered outside the direction or control of the regulator can also be disregarded for the purposes of calculating the extension. For example, if the applicant is asked by the regulator for more information, the time it takes for that information to be supplied will likely not be included in the calculation.

The length of the extension will be the shortest of:

— The length of time it takes to get marketing approval over the 3 or 5 years (minus time periods outside the control of the regulator, or
— The time between grant of the patent and obtaining marketing approval, or two years.

3.3 IP-related provisions

There are some IP-related provisions that vary between countries. Beyond general patent protection of twenty years, some chemical products, particularly pharmaceuticals, are subject to specific arrangements. Areas of difference include:

— Exclusivity over the test data (data exclusivity or regulatory data protection).
— Patent extension of term provisions (called patent restoration period in the USA), extending the time beyond 20 years patent term to restore patent life lost during the regulator's review of new chemical products. Sometimes this includes clinical trials phases.
— Market exclusivity — some companies use the patent system strategically to extend their period of market exclusivity. This practice of incremental patenting is known as "evergreening". On the other hand, some generic manufacturing companies, or the original manufacturer with a generic version of the patented product, seek regulatory approval for a generic version of a patented technology whilst the patent is still in force. This practice is known as "springboarding".

[46] MBIE, not dated, accessed on 20 May 2017 at http://www.mbie.govt.nz/info-services/business/intellectual-property/tpp-intellectual-property-chapter/consultation-on-proposed-patent-term-extension-regulations

3.3.1 Evergreening

Evergreening is an informal term used to describe the ways in which patent owners can use the law and related regulatory processes to extend their rent-earning IP rights particularly over highly profitable chemicals and drugs.

Evergreening refers to the strategy of obtaining multiple patents that cover different aspects of the same product, typically by obtaining patents on improved versions of existing products.

The overall impact of evergreening on the agricultural sector is a loss to the economic productivity and capacity of the agricultural sector.

3.3.2 Springboarding

A patent confers on a patentee the right to prevent others from using the patented invention during the patent term, although patentees may license its use to other parties. Ordinarily, a patent will be infringed by another person making, using or selling the invention without authority. Springboarding provides an exemption from infringement, for uses of a patented invention that are reasonably related to seeking regulatory approval.

Springboarding allows a generic manufacturer to seek and obtain regulatory approval of their generic version of a patented technology, whilst the patent is still in force. Springboarding enables generic manufacturers to rapidly launch their bioequivalent version of the drug onto the market as soon as the patent has expired. Without springboarding, any use of the subject matter of the patent while it is in force would constitute a patent infringement. Hence, without the ability to springboard, it could be any number of years before the necessary data can be generated to enable a generic version to enter the market. These types of provisions are commonly known as “Bolar exceptions” or “clinical trial exceptions” in the USA and Canada.

In Australia the *Intellectual Property Laws Amendment Bill 2006*, passed by the House of Representatives on 22 June 2006[47] made significant changes to the provisions in the *Australian Patents Act* relating to springboarding for human pharmaceuticals. Before 2006, springboarding was only possible in Australia in relation to pharmaceuticals protected by a patent for which an extension of term had been granted for up to five years (taking the total period of protection from twenty years up to a maximum of twenty-five years). That is, the subject matter of the patent could only be used during the extension period.

The 2006 changes were made to address the impact that the previous provisions had on the ability of generic companies based in Australia to competitively enter the Australian human pharmaceutical market, particularly in comparison to the IP provisions in the USA, Canada and New Zealand and later in Europe. One of the aims of the 2006 legislation was to encourage the production of generics in Australia. Due to a series of eligibility criteria, including the fact that the extension of term was only up to five years if the patentee experienced significant delay in attaining regulatory approval, the superseded springboarding provisions were only applicable to a relatively limited number of pharmaceuticals.

In 2012, major changes were made to Australia’s patent system with the passage of the *IP Laws Amendment (Raising the Bar) Act 2012*. The *Raising the Bar Act* addresses six key areas, two of which are of relevance here:

- Raising the quality of granted patents: the new standards are more closely aligned with international standards, giving innovators more certainty when applying in Australia and other jurisdictions, and
- Providing free access to patented inventions for regulatory approvals and research to ensure that experimentation and approval for generic manufacturers is not delayed or negatively impacted by patents.

Thus in 2012 springboarding became possible for all technologies, including agvet chemicals. It is important to note that there has been no change to the five year period of data protection for pharmaceutical patents in Australia, where the pharmaceutical patentee is entitled to five years of data protection on clinical data submitted to the regulatory authorities. That is, in the data protection period

[47] See http://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r2536 accessed on 16 June 2017.

generic competitors are still unable to use, without the consent of the originator, previously undisclosed safety and efficacy test data and information.

Both Australia and New Zealand allow springboarding for a pharmaceutical patent and provide five year data protection periods. The USA on the other hand, provides data exclusivity for five years for new pharmaceutical entities, three years for new indications and twelve years for biologic products (consisting of four years data protection, and eight years of exclusivity on biologics).

More analysis of springboarding can be found in Section 7.4.

3.4 Regulatory data protection in selected countries

3.4.1 Australia

In Australia, the pathways for commercialisation of agvet chemical products involves obtaining regulatory and marketing approval based on proof of safety, quality and efficacy. The APVMA is responsible for the regulation of agvet chemical products up to the point of sale. Australia's states and territories are responsible for regulating agvet chemical use after the point of sale.

For agvet chemical products, up to 10 years data protection is provided in relation to an application to register a new active constituent (i.e. an active constituent that was not a previously endorsed active constituent at the time of registration), or a product containing a new active constituent, where that product has been accepted for evaluation before the active ingredient had been approved:

- **five years** in relation to the approval to register another *agricultural* chemical product based on an approved active, or registration variations in relation to such a product, such as labelling
- **three years** in relation to the approval to register another *veterinary* chemical product, or registration variations in relation to a veterinary chemical product, such as labelling.

The period of data protection commences from the date on which the new product is registered. The effect is that generic competitors are blocked for the period of protection from using an innovator company's data in support of their own application for approval of an equivalent product.

In relation to human pharmaceuticals, the Productivity Commission [48] noted that confidential data submitted in support of regulatory approval processes are protected for a period of five years and that pharmaceutical companies had pressed the Australian Government to extend the duration of data protection. The companies view data protection as an insurance policy to guard against what they see as inadequate patent protection. The Productivity Commission found little evidence to support this complaint. Even if isolated cases could be verified, extending protection to a broad class of products to address exceptional cases would represent a blunt and costly response.

In consultations for this report, the Productivity Commission has suggested that using data protection as a proxy for patent protection has drawbacks. Beyond the obvious absence of disclosure of information to promote further innovation, data protection lacks other important balances that apply to patents. Data protection arises automatically and cannot be challenged in court.

3.4.2 The European Union

The EU adopted new pharmaceutical legislation under Directive 2004/27/EC on 31 March 2004 and introduced a new data exclusivity system for original medicines. The new system introduces a period of data exclusivity of eight years (protecting against filing of a generic application), and then an additional two year marketing exclusivity provision (protecting against marketing of the generic). This effective 10-year exclusivity period can be extended by an additional one year if, during the first eight of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies. This is referred to as the 8+2+1 formula and is applicable in all EU and EEA Member States for innovative products for which applications for marketing authorisation have been sought since October / November 2005. Article 14.11 of Regulation 726/2004[49] applies to products submitted for

[48] Productivity Commission 2016, *Intellectual Property Arrangements*, Report No 78, September 2016.
[49] See http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf accessed on 16 June 2017.

approval via the Centralised Authorisation Procedure. Article 10.1 & 10.5 of Directive 2001/83[50] applies to products submitted for approval via the Mutual Recognition Procedure, National Approval Procedure or Decentralised Approval Procedure.

For the protection of innovative products for which the marketing authorisation was submitted to national authorities before 30 October 2005, the Member States could choose between a period of data exclusivity (protecting against filing of a generic application) of ten years, six years, or six years but limited to the duration of the patent protecting the product.[51] Products approved by the European Medicines Agency and European Commission under the centralised procedure on the basis of an application for marketing authorisation submitted before 20 November 2005 benefit from ten years of data exclusivity (protecting against filing of a generic application). Ten years of data exclusivity provides protection against generic competition for a period equal to ten years plus the review time needed to approve the generic product.

3.4.3 The United States

In the USA, under the Hatch-Waxman legislation, generic manufacturers were given the benefit of earlier market entry possibilities in exchange for pioneer companies able to retrieve some of the years of valuable patent life lost due to the regulatory approval process. Basically, data exclusivity is available for five or 12 years. Data exclusivity is provided under the *Federal Food, Drug, and Cosmetic Act*, Section 505 [21 U.S.C. 355] (c) (3)(F) subject to numerous very complex conditions, and the *Public Health Service Act*, Section 351 (42 U.S.C. 262) (k)(7) which provides data exclusivity for reference products, again under a complex set of conditions. For more information see International Federation of Pharmaceutical Manufacturers and Associations (FPMA).[52]

3.4.4 Canada

The amendments to Section C.08.004.1 of the Food and Drug Regulations ("Regulations") are intended to provide new drugs with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. An additional six month period of data protection is available for innovative drugs that have been the subject of clinical trials designed and conducted for the purpose of increasing the knowledge of the behaviour of the drug in paediatric populations.

The amendments were intended to clarify and effectively implement Canada's North American Free Trade Agreement (NAFTA) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) obligations with respect to the protection of undisclosed test or other data necessary to determine the safety and effectiveness of a pharmaceutical or agricultural product which utilises a new chemical entity.[53]

This legislation places conditions on manufacturers who seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug. They may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug for six years after the first notice of compliance was issued. Further the relevant Minister cannot approve that submission or supplement and cannot issue a notice of compliance in respect of the new drug within a period of eight years after the first notice of compliance was issued. This period may be extended to eight years and six months if the product is for use in clinical trials relevant to paediatric conditions. These arrangements do not apply if the innovative drug is not being marketed in Canada. They also do not apply if the innovator consents to a subsequent manufacturer seeking approvals

[50] See http://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf accessed on 16 June 2017.

[51] Belgium, France, Germany, Italy, Luxembourg, the Netherlands, Sweden and the UK chose a general ten-year data exclusivity period. The other Member States chose for six years (sometimes limited to patent life). Despite the 6-year period adopted by Spain in its domestic law in 1993, it operates a special, separate administrative arrangement whereby a "generic pharmaceutical specialty" will not generally be granted authorisation until 10 years have elapsed since authorisation of the original, innovative product in Spain, or when the drug is authorised as a generic in an EU country where product patent protection for the active principle could have been obtained.

[52] International Federation of Pharmaceutical Manufacturers and Associations 2011, Data exclusivity: Encouraging development of new medicines, accessed on 16 June 2017 at https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity__En_Web.pdf

[53] Canadian Government 2006, Regulatory Impact Analysis Statement, accessed on 16 June 2017 at http://www.wipo.int/edocs/lexdocs/laws/en/ca/ca052en.pdf

before the end of the six year period, and to some other arrangements with the subsequent manufacturer.

Under Canada's *Pest Control Products Act* the Pest Management Regulatory Agency handles data protection in accordance with regulations which came into force in June 2010. Data submitted to support an application to register a pesticide or amend an existing registration are categorised as having either:

- **Exclusive Protection Status**: Data provided in support of the initial application to register a new active ingredient or to add minor uses to the registration are protected for ten years from the date of initial registration, with up to five years of additional protection for all registered uses if minor uses are added to the registration.
- **Compensable Protection Status**: Data that are used to support registration applications and amendments but not subject to exclusive use protection can be used by other applicants as long as those applicants compensate the initial registrant. Compensable protection requirements apply for twelve years.
- **Generic Status**: Once the period of exclusive use or the compensable period for protected data lapses, the data become generic and can be used or relied on by applicants without consent or payment of compensation.

A 2014 review[54] of these arrangements found that most stakeholder representatives from grower groups, innovative companies and generics companies supported the overall approach and design of the data protection program, and saw no need for a fundamental re-design. At the same time, many stakeholders noted that the current design and delivery of a number of key process elements was limiting the timeliness and predictability of the data protection program, and inhibiting the rate at which companies were seeking to register generic products. The report had a particular focus on compensation arrangements, some of which are not of particular relevance to Australia. The response to this report[55] by Health Canada accepted most of the review recommendations.

3.4.5 New Zealand

Under the *New Zealand Medicines Act 1981*, data exclusivity is provided for five years.

3.5 Confidential commercial information in selected countries

The terms "confidential information", "commercial confidentiality" and similar terms are little used in regulation of agvet chemicals in other countries:

3.5.1 Australia

Details on confidential commercial information (CCI) in Australia are provided in **Box 3.2**. Consultations undertaken for this report suggest that there is confusion about what data and information is to be treated as CCI in Australia and how this classification relates to other APVMA data protection provisions.

3.5.2 The European Union

The EMA is required[56] to:

"give the widest possible access to the documents carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as regarding the

[54] Intersol 2014, Recommendations: Administering the Data Protection Program for Pesticides in Canada, 20 November, 2014, available from Health Canada on request.

[55] Health Canada 2016, accessed on 4 August 2017 at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/corporate-plans-reports/pest-management-regulatory-agency-response-intersol-group-ltd-report-recommendations-administering-data-protection-program-pesticides.html

[56] EC COM(2014) 558 final 2014/0257 (COD) accessed on 2 August 2017 at https://ec.europa.eu/health//sites/health/files/files/veterinary/vet_2014-09/regulation/reg_part1_en.pdf

protection of personal data, or the protection of commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001".

The 2001 Regulation referred to in the quotation above relates to public access to European Parliament, Council and Commission documents.[57] While test data submitted to the EMA is protected, such data will not normally be considered to be commercially confidential.

BOX 3.2 CONFIDENTIAL COMMERCIAL INFORMATION IN AUSTRALIA

Section 162 of the Agvet Code prohibits the APVMA (or any member of its staff) from disclosing confidential commercial information. Confidential commercial information in relation to an active constituent or a chemical product is defined in section 3 of the Agvet Code to mean:

- a trade secret relating to the active constituent or chemical product or other information about them that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed; or
- information that concerns the lawful commercial or financial affairs of a person, organisation or undertaking and relates to the manufacture, distribution or supply of the active constituent or chemical product that if disclosed could unreasonably affect the owner of the information in an adverse manner.

The definition of confidential commercial information under the Agvet Code does not include information associated with making a permit application, if the use proposed in the application is for minor or emergency use and includes the information prescribed by regulation 3C of the Agvet Code Regulations.

The APVMA takes reasonable precautions to ensure that its staff does not release or enable access to classified information by unauthorised people.

Separate to the concept of information being confidential commercial information, some information associated with applications to the APVMA attracts protection under the Agvet Code:

- Information where use is restricted under limits on use of the information under Division 4A of Part 2 of the Agvet Code ('limits on use of the information')
- Information where use is restricted under Part 3 of the Agvet Code ('protected information')
- Information where use is restricted under Part 7B of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*
- Information protected by section 14B.

Any one piece of information can be covered by more than one set of restrictions. The documents or samples provided to the APVMA for any purpose under the Agvet Code do, by section 169 of the Agvet Code, become the property of the APVMA including information from any application that has been refused or withdrawn. Despite this, the information may remain confidential commercial information indefinitely.

SOURCE: APVMA, HTTPS://APVMA.GOV.AU/NODE/581 ACCESSED ON 16 JUNE 2017

The EMA in association with the Heads of Medicines Agencies (in the EU) has provided guidance on the identification of CCI.[58] This guidance is that:

CCI means that the section contains commercially confidential information and therefore, as a main rule, cannot be released (the corresponding section of the CTD has to be redacted). For the purpose of this guidance document, 'commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information (HMA/EMA recommendations on transparency approved in November 2010).

Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation (EMA/484118/2010)).

The document also sets out additional principles to be applied for the redaction of CCI after approval of a marketing authorisation application. The general principle regarding quality and manufacturing

[57] EC Regulation 726/2004 of 31 March 2004

[58] EMA/MMA 2012, HMA/EMA Guidance document on the identification of commercially confidential information and personal data with the structure of marketing authorisation (MA) application – release of information after the granting of a marketing authorisation, accessed on 4 August 2017 at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf

information is that detailed information is commercially confidential but general information should be disclosed.

The final qualitative formulation (composition) of the authorised product is not commercially confidential. Information on the structure of the active substance is not commercially confidential. However, detailed information concerning the particulars of studies regarding polymorphism and particle size are treated as confidential. In regard to impurities and degradation products, qualitative and quantitative information is regarded as confidential unless disclosure is necessary for public health reasons. A general description of the types of test methods used and the appropriateness of the specification is not commercially confidential.

For more detailed information, see the EMA / HMA reference cited above. This is a forty page document with tables indicating what can be released at the time of marketing approval and what should be treated at CCI.

3.5.3 The United States

CCI in relation to USFDA regulation is governed by a number of Federal Regulations. For example, the regulations relating to confidentiality of data and information in an "Index File" for new animal drugs for minor use and minor species are summarised in **Box 3.3**. Similar rules apply to other veterinary products. Information *not* normally available to the public includes:

- Manufacturing methods or processes, including quality control procedures
- Production, sales, distribution, and similar data and information, and
- Quantitative or semi-quantitative formulas.

BOX 3.3 CONFIDENTIAL COMMERCIAL INFORMATION IN THE USA

The following data and information in the index file are normally available for public disclosure:[59]

- All safety and effectiveness data and information previously disclosed to the public.
- A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the index file.
- A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information (defined in section 20.61).
- Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of the following:
  - Names and any information that would identify the person using the product.
  - Names and any information that would identify any third party involved with the report, such as a veterinarian.
- A list of all active ingredients and any inactive ingredients previously disclosed to the public (as defined in section 20.81).
- An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in section 20.61.
- All correspondence and written summaries of oral discussions relating to the index file, in accordance with the provisions of Part 20.

SOURCE: USFDA

The USFDA defines trade secrets and commercial information which is privileged or confidential[60] in Section 20.61.

[59] Title 21--Food and Drugs Chapter I—Food and Drug Administration, Subchapter E--Animal drugs, feeds, and related products, Part 516 -- new animal drugs for minor use and minor species, Subpart C--Index of Legally Marketed Unapproved New Animal Drugs for Minor Species, accessed on 2 August 2017 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=516.171

[60] Title 21--Food and drugs chapter I--Food and Drug Administration, Subchapter A – General, Part 20 public information, accessed on 2 August 2017 at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=20&showFR=1&subpartNode=21:1.0.1.1.16.4

— A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

— Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the US Freedom of Information Act. Any such designation will expire 10 years after the records were submitted to the Government.

3.5.4 Canada

Health Canada's guidance document[61] on Master Files (information relating to proposals) uses the term Confidential Business Information, defined as business information:

— that is not publicly available

— in respect of which the person has taken measures that are reasonable in the circumstances to ensure that it remains not publicly available, and

— that has actual or potential economic value to the person or their competitors because it is not publicly available and its disclosure would result in a material financial loss to the person or a material financial gain to their competitors.

Master Files are divided in the "Applicant's Part" and the "Restricted Part". The Restricted Part contains the information that the Master File Holder regards as confidential. There are various circumstances in which Confidential Business Information may be disclosed. These are set out in another guidance document.[62]

3.5.5 New Zealand

Section 23B of the Medicines Act[63] addresses protection of confidential supporting information (CSI) about innovative medicines. In summary, where the Minister receives an innovative medicine application and confidential supporting information, the Minister, *during the protected period* (emphasis added) in relation to that confidential supporting information:

— has to take reasonable steps to ensure that that confidential supporting information is kept confidential, and

— cannot use that confidential supporting information for the purposes of determining whether to grant any other application.

Protection under section 23B does not apply to certain disclosures of the information for administrative purposes, disclosure with the consent of the applicant, or disclosure considered necessary to protect the health or safety of members of the public

3.6 Conclusions

A summary of the approach of different jurisdictions to regulatory data protection are provided in **Table 3.1** and **Table 3.2**.

[61] Health Canada 2017, Guidance document - Master Files - Procedures and Administrative Requirements, accessed on 4 August 2017 at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/mf-guide-ld-fm-eng.pdf

[62] Health Canada 2017, Guidance Document - Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the Food and Drugs Act, accessed on 4 August 2017 at https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/request-disclosure-confidential-business-information/disclosure-confidential-business-information/guidance.html

[63] New Zealand Government 2017, Medicines Act 1981, accessed on 4 August 2017 at http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55085.html

The countries examined in this report all provide standard twenty-year patents for agvet chemicals. Where they differ is in the provision of extensions to compensate for market time lost to regulatory procedures. In Europe, these extensions do not formally extend a patent term, but are provided through supplementary protection certificates (SPCs). SPCs are the subject of an EU Directive, and are implemented in individual countries. Their duration can be fifteen years from the date of the first authorisation in the EU or five years from the day that the SPC is to take effect, whichever is the lesser. There is an application process to obtain an SPC.

In the USA, extensions of patent term are available for delays in the USPTO. Broadly, further extensions can be added under the *Hatch-Waxman Act*. Veterinary products have an entitlement to an extension for delays by a regulatory agency. Generics are provided with an extension because they are not able to prepare to enter the market prior to the expiry of a patent. Up until now, Canada has not provided patent extensions for pharmaceutical or agvet products but will shortly provide extension of two to five years for qualifying pharmaceutical (but not agvet) products. New Zealand is moving to provide extensions for pharmaceutical (but not agvet) products. Australia does not provide extensions for agvet products.

TABLE 3.1 REGULATORY DATA PROTECTION COMPARISON FOR CROP PROTECTION PRODUCTS

Key components	Australia	New Zealand	EU	USA	Canada
Protection period for a new active ingredient / constituent and associated formulated products not previously endorsed	10 years as of July 2014 under Section 34M of Agvet Code	10 years	10 years – plant protection products 13 years – low risk products 15 years -biocides	10 years exclusive use	10 years, 12 years with change in formulation
Protection period for previously endorsed or variations or new information	5 years as of July 2014	5 years	na	na	na
Extensions linked to minor use registrations	None	None	Additional 3 months for each minor use, up to 3 additional years (plant protection products). Up to 2 years (low risk products)	Up to 3 additional years (1 year for each three minor uses)	Up to 5 additional years. (1 year for each three minor uses)
Total potential protection period	10 years as of July 2014	10 years	10–13 years (plant protection products) 13–15 years (low risk protection products) 15 years (biocides)	10–13 years	10-15 years
Data compensation period – subsequent data to support / maintain registration of a new active ingredient to support re-evaluation			30 months (plant protection products) 5 years (review or renewal of biocides)	15 years compensable. Data with exclusive use protection are compensable for 5 years after exclusivity expires	12 years compensable
New legislation	New legislation took effect from July 2014. The interactions of various elements of the Agvet Code are complex relative to other countries	Legislation was amended in late 2016	EC1107/2009 and 528/2012 test data are subject to compulsory sharing for both plant protection products and biocides. Agreement on costs may be reached through negotiation, arbitration or legal proceedings	na	na

NOTE: NA = NOT APPLICABLE
SOURCE: BASED ON AGVET CODE (2016), NZ MINISTRY OF PRIMARY INDUSTRIES, CARROLL M J (2016), THE IMPORTANCE OF REGULATORY DATA PROTECTION OR EXCLUSIVE USE AND OTHER FORMS OF IP RIGHTS IN THE CROP PROTECTION INDUSTRY, PAGE 1637.

TABLE 3.2 REGULATORY DATA PROTECTION COMPARISON FOR VETERINARY CHEMICAL PRODUCTS

Key components	Australia	New Zealand	EU	USA	Canada
Protection period for a new active ingredient / constituent and associated formulated products not previously endorsed	10 years as of July 2014 under Section 34M of Agvet Code	10 years	10 years. 1 additional year (for already authorised product to other species, up to maximum of 18 years)	Depends on what type of exclusivity at issue. Orphan drug exclusivity for 7 years, new chemical entity exclusivity for 5 years, general antibiotic incentives now exclusivity for 5 years, new clinical investigation exclusivity for 3 years	8 years for innovative animal drugs
Protection period for previously endorsed or variations or new information	3 years as of July 2014	5 years	na	na	na
Extensions linked to minor use registrations	None	None	14 years for minor use species and 4 additional years for an extension to a minor species	Minor species or minor uses in a major species (MUMS) gets 7 years	
Total potential protection period	10 years as of July 2014	10 years	Maximum of 18 years for major and minor species	Depends on what type of exclusivity	8 years
Data compensation period – subsequent data to support / maintain registration of a new active ingredient to support re-evaluation	5 years exclusive use 8 years – data for a reconsideration of a registration (as of July 2014)		None	None	None

NOTE: NA = NOT APPLICABLE

SOURCE: BASED ON AGVET CODE (2016), NZ MINISTRY OF PRIMARY INDUSTRIES, EUROPEAN COMMISSION (2014), REGULATION OF THE EUROPEAN PARLIAMENTARY AND OF THE COUNCIL ON VETERINARY MEDICINAL PRODUCTS (2014/0257 (COD), FDA 2017, CANADIAN MINISTRY OF HEALTH (2017), FUDENACE DOCUMENT, DATA PROTECTION UNDER C.08.004.1 OF THE FOOD AND DRUG REGULATIONS.

Given that IP Australia is efficient in processing patent applications, the only grounds for an extension for agvet chemicals in Australia would arise from regulatory delays by other agencies. However as the Productivity Commission has noted, patent extensions (whether formal or in the form of SPCs), do not appear to be an appropriate way to address slow regulatory processes. They create distortions and are costly to consumers.[64]

With respect to CCI, there is merit in clarifying what data and information is to be treated as CCI in the Australian context. Overseas models can assist with this.

Differences in IP related provisions between the human and veterinary pharmaceuticals are discussed in Chapter 7.

[64] Productivity Commission 2016 Op cit.

4 AGVET CHEMICAL PRODUCT REGISTRATION PROCESSES

This chapter documents the processes required by regulators in Australia, the EU, the UK, USA, Canada and New Zealand for agvet chemical product registrations.

Governments in Australia and around the world intervene in the workings of their economies for a variety of reasons including to address market failures. As the Productivity Commission has noted,[65] there are potentially several sources of chemical-related market failures. Market failures essentially arise because allowing parties to act solely in their own private interest may not lead to the best possible outcome. Some general sources of chemical-related market failure are:

- externalities — for example, when chemicals discharged from a farm cause pollution and / or health problems for farm workers or downstream
- information failures — individuals may lack the expertise and or information to make fully informed decisions about the use of, or disposal of chemicals
- public good — measures that protect human health and the environment can be underprovided by the private sector because 'free riders' cannot be excluded from enjoying the benefits, and therefore sufficient returns cannot be captured by those providing them to justify their investment.

The presence of one or more of these market failures may suggest that there is a case for government intervention in the form of chemical market regulation. However, the presence of a market failure alone does not necessarily provide all the grounds for government intervention; as intervention in the agvet chemical market must be more cost effective and ultimately improve community wellbeing to a level that exceeds a government's decision not to regulate the market. These are the basic economic principles that all effective government agencies involved in the regulation of agvet chemicals should adhere to.

Table 4.1 lists the government regulatory authorities that oversee the registration of agvet chemicals and the scope of regulatory activities they are afforded. The table shows that some countries have separate regulatory bodies for crop protection and animal medicines, while in others including Australia, agvet chemical registrations are performed by a single agency.

[65] Productivity Commission 2008, Chemicals and Plastics Regulation, Research Report, Melbourne, accessed on 16 June 2017 at. http://www.pc.gov.au/inquiries/completed/chemicals-plastics/report/chemicals-plastics-regulation.pdf

TABLE 4.1 GOVERNMENT AGVET CHEMICAL REGULATION

Country	Authority name	Scope and recent changes in legislations
Australia	Australian Pesticides and Veterinary Medicines Authority (APVMA)	Both crop protection products and veterinary chemicals the APVMA is responsible for up to the point of sale. It is an independent statutory regulator, established in 1993 under the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Cwlth).
EU	Standing Committee for Food Chain and Animal Health European Food Safety Authority (EFSA)	A large body of EU legislation regulates the marketing and use of plant protection products and their residues in food. A dual system is in place, under which EFSA evaluates active substances used in plant protection products while Member States evaluate and authorise the products at national level. Plant protection products are principally regulated by framework Regulation (EC) No 1107/2009.
	European Medicines Agency (EMA)	The EMA is responsible for the scientific evaluation of *centralised marketing authorisation applications*. Once granted by the EC, the centralised marketing authorisation is valid in all EU Member States, Iceland, Norway and Liechtenstein. Regulation of veterinary products is subject to Directive 2001/82/EC. Changes occurred on 10 September 2014 when the EC adopted proposals on veterinary medicinal products and medicated feed. These aim to increase the availability of veterinary medicinal products; reduce administrative burden; stimulate competitiveness and innovation; Improve the functioning of the internal market; and address the public health risk of antimicrobial resistance.
UK	The Chemicals Regulation Division (CRD) in the Health and Safety Executive (HSE)	The CRD is responsible for the regulation of biocides, pesticides, detergents, chemicals covered by REACH and for compliance with the Classification, Labelling and Packaging (CLP) Regulation.
	Veterinary Medicines Directorate (VMD)	Veterinary medicines regulation provides legislative requirements concerning the manufacture, classification, supply, marketing and use of veterinary medicines. Additionally, there are a range of EU regulatory controls that also apply to veterinary medicinal products including controls on safety, licensing and monitoring.
Germany	Federal Office of Consumer Protection and Food Safety (BVL)	The BVL manages German legislation that implements to EU agvet Directives. BVL is responsible for both agricultural and veterinary chemicals. These chemicals are regulated in accordance with EU Directives. Producers and distributors of plant protection products are legally obliged to report sales and exports to the BVL. BVL also regulates veterinary products under the Medicines Act (*Arzneimittelgesetz*), which applies to medicinal products for humans and animals.[66]
USA	US Environmental Protection Agency (USEPA)	The USEPA registers pesticides under the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA). The *Federal Food, Drug and Cosmetic Act* (FFDCA) establishes tolerances (maximum legally permissible levels) for pesticide residues in food. The *Food Quality Protection Act* (FQPA) of 1996 requires that a pesticide possess a reasonably certainty of creating no harm. The *Pesticide Registration Improvement Act* of 2003, 2007 and *Extensions Act* of 2012 (PRIA) amended FIFRA and FFDCA. These Acts provide shorter decision review periods for reduced risk applications. The *Endangered Species Act* (ESA) requires the chemicals will not jeopardize the continued existence of any listed species.
	US Food and Drug Administration (USFDA)	The USFDA's Center for Veterinary Medicine (CVM) is responsible for regulation of veterinary products. It does not regulate animal vaccines—these are the responsibility of the US Department of Agriculture. It also does not cover some flea and tick products for animals, which are the responsibility of the USEPA. CVM issues guidance documents in accordance with the USFDA's good guidance practices regulations (21 CFR 10.115) published in the Federal Register on 19 September 2000 (65 FR 5646). New guidance currently under development can be found on the CVM website.[67]

[66] BVL not dated, accessed on 16 July 2017 at http://www.bvl.bund.de/EN/05_Veterinary_Drugs/veterinary_node.html;jsessionid=7E6A0CA57D1DF385D3A261990D336E88.1_cid332)

[67] CVM not dated, accessed on 16 July 2017 at https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042451.htm

Country	Authority name	Scope and recent changes in legislations
Canada	Pest Management and Regulatory Agency (PMRA)	Separate agencies are responsible for the regulation of crop protection products and animal medicines. PMRA is responsible for administering *The Pest Control Products Act* (PCPA) on behalf of the Minister of Health. The PCPA regulates the products used for the control of pests. The PCPA came into force on 28 June 2006. The PMRA must also take into account other Acts, such as the *Pesticide Residue Compensation Act* (PRCA) and the *Food and Drugs Act*, which have an impact on pest management. In addition, the PMRA relies on the *Agriculture and Agri-Food Administrative Monetary Penalties Act* as an enforcement tool for the PCPA.
	Veterinary Drug Directorate (VDD)	The VDD evaluates and monitors the safety, quality and effectiveness, sets standards and promotes the prudent use of veterinary drugs administered to food-producing and companion animals. VDD applies the Canadian Food and Drug Regulations under the authority of the *Food and Drugs Act*. Canada currently has an Interim Notification Program (INP) for low risk veterinary health products. This is a temporary measure pending the new veterinary drug framework to improve (simplify) the regulation of these products. It provides a Notification Number if certain conditions have been met. The Notification is valid for one year and can be renewed using a simplified procedure.[68]
New Zealand	Ministry for Primary Industries (MPI) NZ Environmental Protection Authority (NZEPA)	MPI administers the *Agricultural Compounds and Veterinary Medicines Act* 1997 (ACVM Act), while the NZEPA administers the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The ACVM Act focuses on agricultural compounds, while the HSNO Act covers agricultural compounds it covers a wider range of other compounds such as industrial chemicals. The ACVM Act covers risks to agricultural security, trade, animal welfare and public health, while the HSNO Act covers risks to health and safety and the environment. Registration of an agricultural compound trade name product under the ACVM Act is subject to it having an approval under the HSNO Act. Both Veterinary medicines and agricultural chemicals require approval under the ACVM Act. The NZEPA introduced some new requirements for labels, safety data sheets and packaging of pesticides from 2015.[69] New requirements for anti-fouling paints have been introduced in 2017.[70]

SOURCE: VARIOUS SOURCES

4.1 Australian registration processes

Agvet chemical products are regulated under the National Registration Scheme (NRS)—a partnership between the Commonwealth, state and territory governments in Australia. Under the NRS, the Australian Pesticides and Veterinary Medicines Authority (APVMA) undertakes the assessment, registration and regulation of agvet chemical products up to the point of supply, while states and territories are responsible for regulating agvet chemical use after supply.

4.1.1 Institutional arrangements

The NRS is a partnership between the Commonwealth, state and territory governments underpinned by an intergovernmental agreement (IGA). Under the agreement, state and territory governments conferred their power to regulate the supply of agvet chemicals to the Commonwealth, and adopted a template Agricultural and Veterinary Chemicals Code (Agvet Code). The responsibility for regulating the use of agvet chemicals after supply remains with the state and territory governments.

[68] VDD not dated, accessed on 16 July 2017 at https://www.lrvhp.ca/public/documents/view/overview
[69] NZEPA undated, New requirements for labels, safety data sheets and packaging accessed on 4 August 2017 at http://www.epa.govt.nz/Publications/OPC_manufacturers_and_importers.pdf
[70] NZEPA 2017, New requirements for manufacturers and importers of anti-fouling paints, accessed on 4 August 2017 at http://www.epa.govt.nz/Publications/Antifouling_manufacturers_and_importers.pdf

The APVMA is a statutory authority within the portfolio of the Commonwealth Minister for Agriculture and Water Resources. It derives its powers from the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and related legislation. Its functions include (among others) to:

- assess the suitability for supply in Australia of chemical products, active constituents for proposed or existing chemical products, and labels for containers for chemical products
- provide information to governments about approved active constituents, registered products, and approved labels
- fund a program to ensure compliance
- evaluate the effects of the use of chemicals in states and territories, and
- facilitate the introduction of uniform national standards on controlling the use of chemicals.

4.1.2 Funding

APVMA operates on a cost-recovery basis and is principally funded via a levy imposed on sales of registered agvet products[71] as well as application and annual registration fees. APVMA also collects licensing fees from manufacturers of veterinary medicines.

In 2015-16, total APVMA revenue amounted to $30.6 million, of which $16.7 million, or approximately 55 per cent, came through the sales levy.[72] APVMA expenditure in 2015-16 was $33.9 million.

4.1.3 Assessment and registration of new products

The APVMA assesses a chemical or product on its potential impact on human and animal health, the environment, and trade as well as on its efficacy. Some assessments are performed within APVMA and may include consultation with other agencies. This can include Food Standards Australia New Zealand (FSANZ) in relation to dietary exposure and the Office of Gene Technology Regulator (OGTR) where a product contains a genetically modified organism. Some assessments are undertaken by external private sector scientific reviewers contracted by the APVMA. Some environmental assessments are also undertaken by the Department of the Environment and Energy (DoEE), including advice on risk-management strategies to mitigate environmental risks.

On completion of the evaluation, if the APVMA is satisfied that the product is safe, effective, will not adversely impact on trade and that the label contains adequate instructions, it will approve the application.

The APVMA may put conditions on the manufacture and supply of the product. For example, it can require the product to be supplied in a container of a particular kind. Elements of the product label also have to be approved by the APVMA. Product labels are predominantly based on managing the *risks* of the product, although some *hazard* information may also be included. Matters that are approved by the APVMA and are required to be included on labels include:

- circumstances in which the product should be used and how it should be used
- approved times and frequency of product use
- withholding period after use of the product
- re-entry period after use of the product
- disposal of the product and its container when they are no longer required, and
- safe handling of the product and first aid in the event of an accident caused by the handling of the product.

4.1.4 Permits

In addition to registering agvet products, the APVMA can, in some circumstances, issue permits for using an unregistered agvet product, or authorising the use of a registered product in a manner that is contrary to the registration conditions.

[71] The levy applies to individual products and is tiered on the basis of the value of the sales.
[72] See https://apvma.gov.au/sites/default/files/docs/apvma-2015-16-ar.pdf accessed on 20 August 2017.

Various types of permits are approved by the APVMA. They are:[73]

- **Minor use permit** — for uses where no relevant registered products or use patterns exist because registering the use pattern would not produce an economic return (issues related to minor use are discussed in Chapter 6).
- **Emergency use permit** — supports primary producers during emergencies or impending emergencies, such as outbreaks of pests and diseases, by allowing the use of a chemical product or an active constituent if there is a genuine belief that the use is required because of the emergency.
- **Research permit** — assists in the development, through experiments, of new uses for products. Note that the APVMA does not issue permits to enable market research.
- **Veterinary manufacturing permit** — may be issued to authorise the carrying out of a step (or steps) of manufacture of veterinary product/s, that would otherwise be an offence or a contravention of a civil penalty provision set out in the Agvet Code, in relation to manufacture and licensing. This type of permit may only be issued for exceptional circumstances, where compliance with the APVMA's Manufacturing Principles can be demonstrated, and is restricted to a maximum period of 90 days.
- **Miscellaneous permit** — may be issued for a circumstance not covered by the other permits (for example, a permit to possess or supply an unregistered chemical product for export; to oversticker an approved label; to supply specific batches of a registered product that do not comply with the product specifications; to supply a registered product with an unapproved label; or to extend the shelf life of a batch.

4.1.5 Assessment of existing chemicals and products

When the NRS was introduced in 1995, the APVMA assumed responsibility for over 5,000 agvet products that were registered under prior state and territory arrangements. The APVMA is also responsible for re-assessing previously approved chemicals and products as necessary. Chemical reviews occur on triggers other than age of registration. Reviews decide whether the product is safe, requires reformulating, requires restrictions on conditions of use, or whether it should be suspended, cancelled or withdrawn from the market.[74]

4.1.6 Interface with other national schemes

Selected outcomes arising from APVMA assessments serve as inputs into other national schemes:

- When the APVMA sets a maximum residue limit in food, it also incorporates this limit into the Food Standards Code which is administered by Food Standards Australia New Zealand (FSANZ).
- As part of the APVMA assessment, a product may also be scheduled as a poison. This involves reference to the National Drugs and Poisons Schedule Committee. It is understood that, while pharmaceutical companies can submit papers directly to this Committee, agvet companies can only do this through the APVMA. The scheduling process is a potential source of delay.

4.1.7 Interface with state regulators

The APVMA cooperates with state and territory governments in monitoring and enforcing compliance with the Agvet Code provisions. While the scope of the APVMA's role under the NRS does not extend to controlling product use, controlling product use is part of state and territory responsibility under the NRS. The conditions of use specified by the APVMA during product registration form part of the state and territory control-of-use regimes.

4.1.8 The agvet chemical registration process

Anyone who wishes to supply agvet chemicals for the first time in Australia must apply to the APVMA to register the product or seek a permit and obtain approval for particular content for labels attached to product containers before the products can be supplied, sold, distributed and used in Australia. A diagram illustrating the product registration process is provided in **Figure 4.1**.

[73] See https://apvma.gov.au/node/612 accessed on 20 August 2017.
[74] See https://apvma.gov.au/node/10971 accessed on 20 August 2017.

The clarification of applicant's registration requirement is the first step in the registration process. APVMA approvals are required from the applicants on:

- A new active ingredient
- A new chemical product that also contains an approved active constituent
- A new product that also contains an approved active constituent
- Variation to an existing product registration, label approval or active constituent approval
- The addition of a name of chemical product that is to appear on an approved label
- A listed product that complies with an APVMA standard
- Submission of timeshift application[75]
- Application for a permit
- Renewal of a registration
- Application to change identifying information for the holder or nominated agent
- Application for technical assessment
- Application for manufacture assessment

The steps outlined in **Figure 4.1** vary depending on the type of registration requirements. While the figure suggests that some of the assessment steps take place in parallel it appears from feedback gained during consultations that this is not always the case.

Data generation for new active ingredients / products

Registration of a new agvet chemical product requires submission of a comprehensive dossier by the applicant. The dossier includes data on the product that is potentially valuable to the applicant's competitors. Legal protection is afforded on this data, preventing a potential competitor from using the information to register a generic version of the agvet chemical for a period of 10 years for new active ingredient.

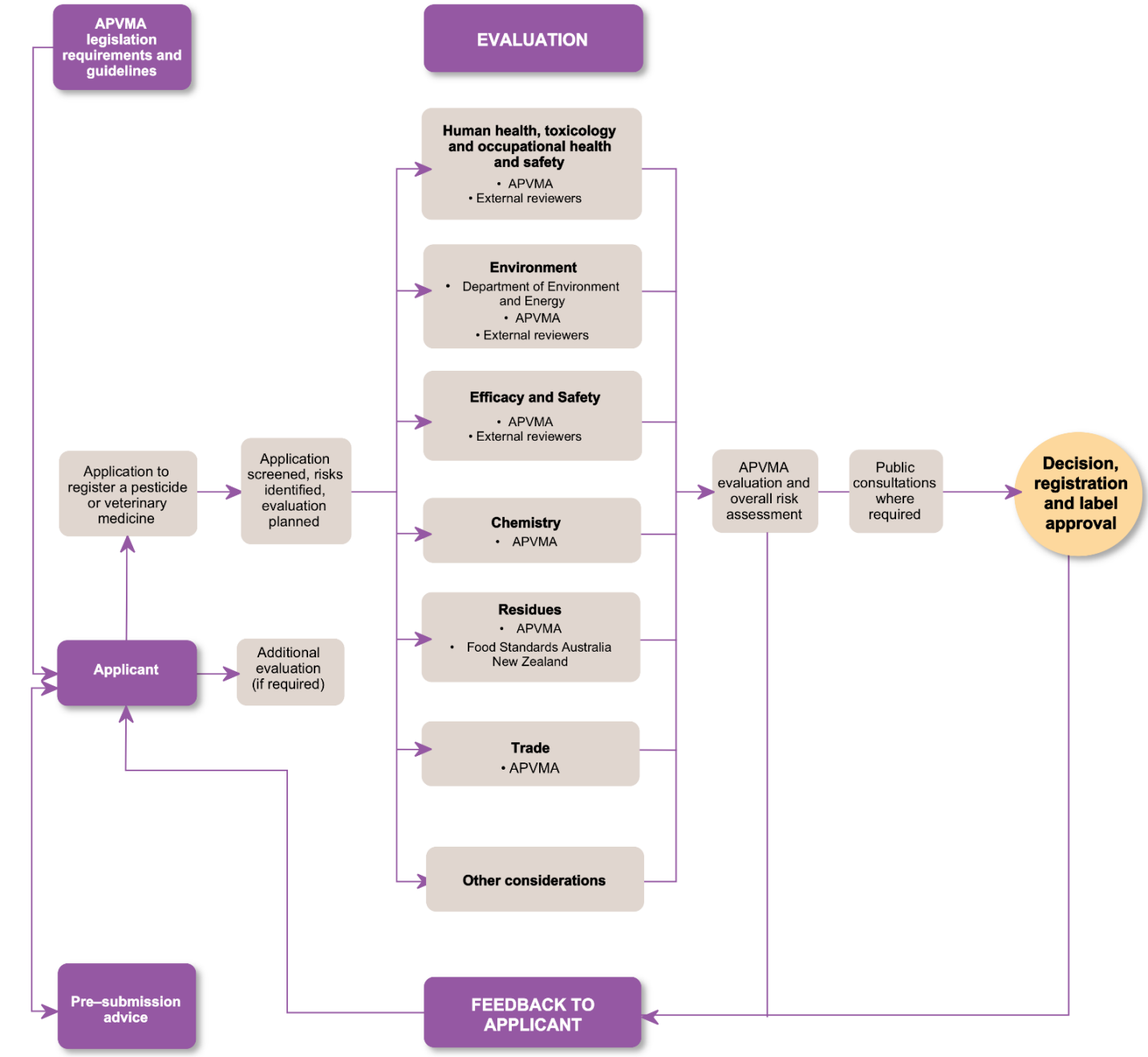
Australia's agvet legislation allows the APVMA to consider data on the new product that has been generated overseas provided the proposed use patterns for the agvet chemical are comparable to those proposed for Australia. At the same time as the APVMA considers overseas generated data, it may also require locally generated confirmatory data. Most of the Australian data is related to residues, environmental impact and efficacy. Registrants and the APVMA make additional use of overseas generated data for agvet chemical registration through the Global Joint Review (GJR) process.[76] Data provided by the registrant must be sufficient for the APVMA to assess:

- Chemistry and manufacture
- Toxicology
- Metabolism and kinetics
- Residues
- Trade aspects (i.e. product residues will not breach requirements set by recipients of Australia's agricultural exports)
- Occupational Health and Safety (OH&S)

[75] The Agvet Code Regulations define a timeshift application to mean an application that is 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 and will by agreement of the applicant and the APVMA, be assessed in accordance with assessment periods set out in a project plan for the application agreed to by the applicant and the APVMA. See https://apvma.gov.au/definition-of-terms/t .

[76] A global joint review is the concurrent evaluation of a new pesticide or variations to a registered pesticide product through a globally coordinated system of evaluations, peer reviews and report sharing. Countries take lead roles in the hazard assessments of proposed pesticides, and their reports are peer-reviewed by other participating countries. These reports are shared and used as the basis for each country's own risk assessment and decision-making, which may require the provision of data reflecting regional conditions and use patterns. The global joint review process does not extend to evaluation of efficacy and where required each country undertakes its own independent evaluation. The OECD has established the framework for conducting the reviews in the Guidance document on the planning and implementation of joint reviews of pesticides.

FIGURE 4.1 APVMA REGISTRATION PROCESS IN AUSTRALIA



SOURCE: APVMA

- Product quality, which covers the ability of products to consistently meet assessed specifications; the design and management of the production plant and its quality control procedures; and the products storage stability so that its quality is maintained throughout its life span
- Efficacy and safety (i.e. scientific evidence exists for the activity claimed by the agricultural chemical or veterinary medicine)
- Human and animal health and safety, including OH&S for those working with the product (such as farmers, contract sprayers, and veterinarians), the welfare of the animals that receive it (in the case of veterinary medicines) and the consumers of the resultant food or fibre, and
- Environmental safety, that there will be no adverse impacts on the natural environment from either direct use or product residues.

The *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* included a number of reforms aimed at improving this process, including that efficacy and trade aspects do not need to be considered if they are not relevant.

Preliminary assessment

All applications are assessed by the APVMA to ensure that they appear to contain the required supporting data and information. Registrants or applicants are advised of any data deficiencies after the initial, administrative, technical and preliminary assessment.

Evaluation

Evaluation is completed by the APVMA's scientific staff with advice from other organisations including the DoEE; FSANZ; the Office of the Gene Technology Regulator (OGTR); the National Health and Medical Research Council (NHMRC) and the Department of Agriculture and Water Resources Biosecurity Services as appropriate.

Public consultations

To ensure that new innovative products will not negatively impact on the export of Australian produce the APVMA also seeks advice from relevant industry bodies and the public. To inform the public that a new innovative product is being considered for registration, the APVMA posts notices in the relevant Commonwealth Government Gazette.

Finalisation and approval

Registration is based on a rigorous and independent evaluation of scientific information related to the safety and efficacy of a new product or active ingredient. As reported in Chapter 2, a majority of APVMA registrations are generic versions of previously assessed products. The APVMA grants registration if the evaluation of a product has shown that it is not likely to be harmful to target crops or animals, users, consumers and the environment. The evaluation also has to be satisfied that the product is suitably formulated, and that its label contains adequate instructions for safe and effective use. The APVMA also assesses whether using the product may unduly prejudice trade.

The costs of registrations and approvals are generally recovered through a combination of application fees and a levy, with most of the costs recovered through the levy. The Australian Government, states and territories agreed when establishing the NRS that the costs of assessing applications should be collected in two parts: An average 40 per cent of the assessment costs is charged as an upfront application fee and the balance of revenue required to fund the APVMA's costs is covered by a levy based on the annual value of sales. The policy intent is to ensure that the application fee to assess and register new and innovative products is not a disincentive to bringing them to market, particularly for small businesses, niche products and chemical products that have a low value of sales. This approach also acts as a balancing factor to buffer the APVMA budget against changes in application volumes and sales values.

Protected information

Under the Agvet Code protected information is defined as information or results given to the APVMA as required in relation to reconsideration. The protection period for this information begins when the information is first given to the APVMA in relation to a reconsideration and ends eight years after the APVMA makes its decision on the reconsideration.

4.1.9 Limits on use

Limits on use of information by the APVMA is afforded to applicants / registrants in recognition of the cost of agvet chemical development and the cost of generating data to facilitate chemical registration. Other countries use different terminology for this, such as data protection. Regulatory data protection (or limits on use) is different from CCI. The CCI provisions limit the *disclosure* of information and it is indefinite.

Under the Agvet Code 34G, the APVMA must not use the following information to assess or make a decision on an application made under section 10 or 27:

— Information given to the APVMA in connection with another application made under section 10 or 27 by the applicant for the other application; and information given under section 161.

The APVMA must not use the following information to vary relevant particulars or conditions under section 26C or 29A or reconsider an approval or registration under Division 4 of Part 2:

— Information given to the APVMA in connection with an application made under section 10 or 27 by the applicant for the application; and information given under section 161.

There are some exceptions to the general rules under the public interest considerations and consent to the use of information. Limitation periods for certain information given in connection with an application made under Section 10 or 27 and Section 161 of the Agvet Code are provided in **Table 4.2**.

TABLE 4.2 LIMITATION PERIODS

	The limitation period for:	ends	after
1	information: (a) given in connection with an application under section 10 for approval of an active constituent (for a proposed or existing chemical product) that was not a previously endorsed active constituent on the commencement of this Division; and (b) relied on to approve the active constituent	10 years	the constituent is approved.
2	information: (a) given in connection with an application made under section 10 for:(i) registration of a chemical product at least one of whose active constituents was not a previously endorsed active constituent when the application passed preliminary assessment; or (ii) approval of a label for a container for a chemical product at least one of whose active constituents was not a previously endorsed active constituent when the application passed preliminary assessment; and (b) relied on to register the product or approve the label	10 years	the product or label, as required, is registered or approved.
3	information: (a) given in connection with an application (except one covered by item 2 above) made under section 10 for: (i) registration of an agricultural chemical product; or (ii) approval of a label for a container for an agricultural chemical product; and (b) relied on to register the product or approve the label	5 years	the product or label, as required, is registered or approved.
4	information: (a) given in connection with an application (except one covered by item 2 above) made under section 10 for: (i) registration of a veterinary chemical product; or (ii) approval of a label for a container for a veterinary chemical product; and (b) relied on to register the product or approve the label	3 years	the product or label, as required, is registered or approved.
5	information: (a) given in connection with an application made under section 27 for variation of the relevant particulars or conditions of: (i) the registration of an agricultural chemical product; or (ii) the approval of a label for a container for an agricultural chemical product; and (b) relied on to vary the relevant particulars or conditions	5 years	the relevant particulars or conditions are varied.
6	information: (a) given in connection with an application made under section 27 for variation of the relevant particulars or conditions of: (i) the registration of a veterinary chemical product; or (ii) the approval of a label for a container for a veterinary chemical product; and (b) relied on to vary the relevant particulars or conditions	3 years	the relevant particulars or conditions are varied.
7	information given under section 161 in connection with an agricultural chemical product	5 years	the information is given.
8	information given under section 161 in connection with a veterinary chemical product	3 years	the information is given.

SOURCE: AGRICULTURAL AND VETERINARY CHEMICALS CODE ACT 1994, NO 47, COMPILATION NO. 29. COMPILATION DATE 21 OCTOBER 2016.

Section 10 of the Agvet Code indicates a person may apply to the APVMA for approval of an active constituent for a proposed or existing chemical product; or for registration of a chemical product; or for approval of a label for containers for a chemical product. The application must meet the application requirements; and for an active constituent or chemical product — must include proposed instructions for use of the constituent or product.

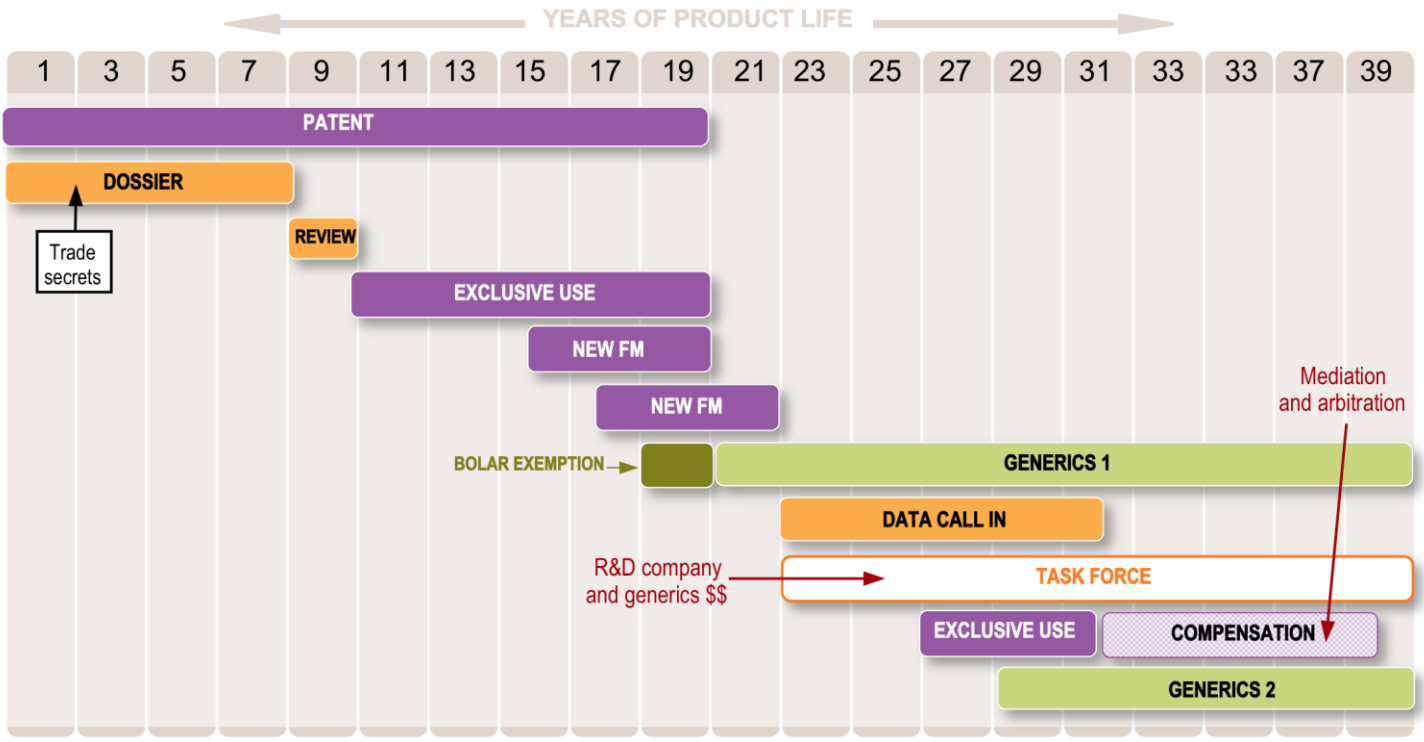
Section 27 of the Agvet Code indicates the holder may apply to the APVMA for variation of the relevant particulars or conditions of the approval of an active constituent; or the registration of a chemical product; or the approval of a label for containers for a chemical product. A person may, with the consent of the holder, apply to the APVMA for variation of the relevant particulars or conditions of the registration of a chemical product; or the approval of a label for containers for a chemical product.

Section 161 of the Agvet Code relates to notification of new information to APVMA. If the holder of the approval of an active constituent for a proposed or existing chemical product or the registration of a chemical product; or the holder of a permit in relation to an active constituent for a proposed or existing chemical product or in relation to a chemical product; becomes aware of any relevant information in relation to the constituent or in relation to the product or of any of its constituents, the holder must, as soon as the holder becomes aware of the information, give that information to the APVMA.

The limitation periods for certain information given in connection with an application for agricultural chemicals and veterinary chemicals vary in Australia as noted in **Table 4.2**. The limitation period for active constituent information for both agricultural and veterinary chemical products is 10 years after the constituent is approved or the product or label, as appropriate, is registered or approved. For any variations or new information, the limitation periods for agricultural chemicals is 5 years and veterinary chemicals is 3 years.

Figure 4.2 shows a schematic representation of the Australian registration process for agvet products with various IP related aspects.

FIGURE 4.2 AUSTRALIAN REGISTRATION PROCESS WITH IP RELATED PROVISIONS



NOTE: APVMA has advised that the data call in and taskforce is hypothetical and not routine practice. Chemical review is a risk-based activity that only occurs as risks are identified that require regulatory intervention.
SOURCE: Carroll MJ 2016, The importance of regulatory data protection or exclusive use and other forms of IP rights in the crop protection industry, p 1634.

Agvet chemical manufacturers may seek, on commercial terms, to access information that is being submitted by other companies in respect of an agvet chemical review by the APVMA. In other countries, the term used to describe this arrangement is 'compensation'. The Agvet Code includes provisions for APVMA involvement in this process.

4.2 European Union registration processes

4.2.1 Plant protection products

Regulation (EC) No 1107/2009 is the legislation concerning the placing of plant protection products (PPPs) on the market in the European Union. PPPs (also referred to as 'pesticides') are products in the form in which they are supplied to the user, consisting of, or containing active substances, safeners[77] or synergists. This regulation applies to users other than in agvet.

A zonal system of authorisation operates in the European Union, with member countries divided into three zones; North, Central and South. Member States may assess applications on behalf of other countries in their zone and sometimes on behalf of all zones.

Applicants, Member States, the European Commission and the European Food Safety Authority (EFSA) can be involved in the process of authorisation. There are different types of application that can be submitted depending on the intended use of the PPP, the Member State(s) for which the PPP is required and the regulatory status of any existing authorisations.

The procedure for an approval of active ingredient is slightly different to renewal of approval. Approval generally involves following steps:[78]

- The applicant submits a dossier to a Member State of his choice (the Rapporteur Member State, RMS). The format of the dossier is established in accordance with the advisory committee procedures
- Within 45 days RMS acknowledges receipt of the dossier and check whether the dossier is complete
- Where elements are missing in the dossier, the RMS requests the applicant to complete the dossier within 3 months
- Where at the end of this period the missing elements are not submitted, the application is inadmissible
- Where the dossier is considered admissible, the RMS notifies the applicant, the other Member States, the Commission and EFSA on the admissibility of the application and start assessing the active ingredient or substance.
- The applicant immediately forwards the dossier to the other Member States, the Commission and EFSA
- EFSA makes the summary dossier available to the public
- Within 12 months of the notification of admissibility, the RMS prepares a Draft Assessment Report (DAR), assessing whether the active ingredient or substance can be expected to meet the approval criteria
- Where the criteria with regard to CMR classification are not satisfied, the DAR is limited to those parts of the assessment
- The DAR is submitted to the Commission and EFSA
- Where the RMS needs additional information, there is a maximum of six months in which the applicant must submit the additional information; the Commission and EFSA have to be informed of this
- The format of the DAR is established in accordance with the advisory comitology procedure
- The EFSA peer review comprises the following steps:
  - Commenting
  - Consideration of the comments
  - Expert meetings (optional)
  - Drafting of the EFSA conclusion
- EFSA circulates the DAR to the applicant and the other Member States within 30 days
- Where relevant EFSA asks the applicant to circulate an updated dossier to the Member States, the Commission and EFSA
- EFSA makes the DAR available to the public

[77] Safeners are chemicals used in combination with herbicides to reduce the effect of the herbicide on crop plants.
[78] See https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_efsa-proc.pdf accessed on 20 August 2017.

- A period of 60 days is allowed for submission of comments (from the applicant, Member States and the public)
- EFSA also comments on the DAR
- The comments are collated in a "reporting table"
- The applicant is given the opportunity to react on the comments
- The RMS is invited to address all comments
- EFSA determines the way forward in respect of each of the comments (point closed, point to be further considered by the RMS, point to be scheduled in an expert meeting, additional information requested)
- Where EFSA needs additional information it sets a period of a maximum of 90 days for the applicant to submit it to the Member States, the Commission and EFSA
- The need for additional information is discussed in a teleconference between EFSA / COM / RMS
- The RMS assesses the additional information within 60 days
- The period for the adoption of the EFSA conclusion is extended where the time needed to submit and assess the additional information
- Where appropriate, EFSA organises a consultation of experts, including experts from the RMS
- On the basis of the reporting table EFSA decides which points need to be discussed in an expert consultation
- These points are transferred to an evaluation table
- The evaluation table is further completed throughout the peer review process (further input from the RMS where relevant, outcome of the discussions during the expert consultation, final EFSA position on each issue)
- The discussions during the meeting are documented in detail in a discussion table
- EFSA adopts a conclusion within 120 days after the commenting period on whether the active ingredient. can be expected to meet the approval criteria
- This period is extended to 150 days in case an expert consultation takes place
- Before adopting the conclusion, EFSA circulates the draft to the Member States for a written consultation
- The Member States' comments are collated in a table; for each comment, EFSA indicates in the table how the comment was addressed
- the EFSA conclusion refers to Background Documents A and B; Background Document A is the DAR and any addenda to it; Background Document B is the compilation of all documents generated during the peer review process (reporting, evaluation and discussion tables)
- EFSA reaches a conclusion and the Background Documents A and B are made available on its website, and
- Within six months of receiving the conclusion the Commission presents a review report and a draft regulation on approval or non-approval of the active ingredient to the Standing Committee.

European Union new active substance approval timelines (including additional information request and expert consultation) are provided in **Figure 4.3**.

Figure 4.4 shows the schematic representation of the EU registration process for chemical plant protection products with IP related provisions.

Key elements in the EU registration process in relation to patents and data protection include:

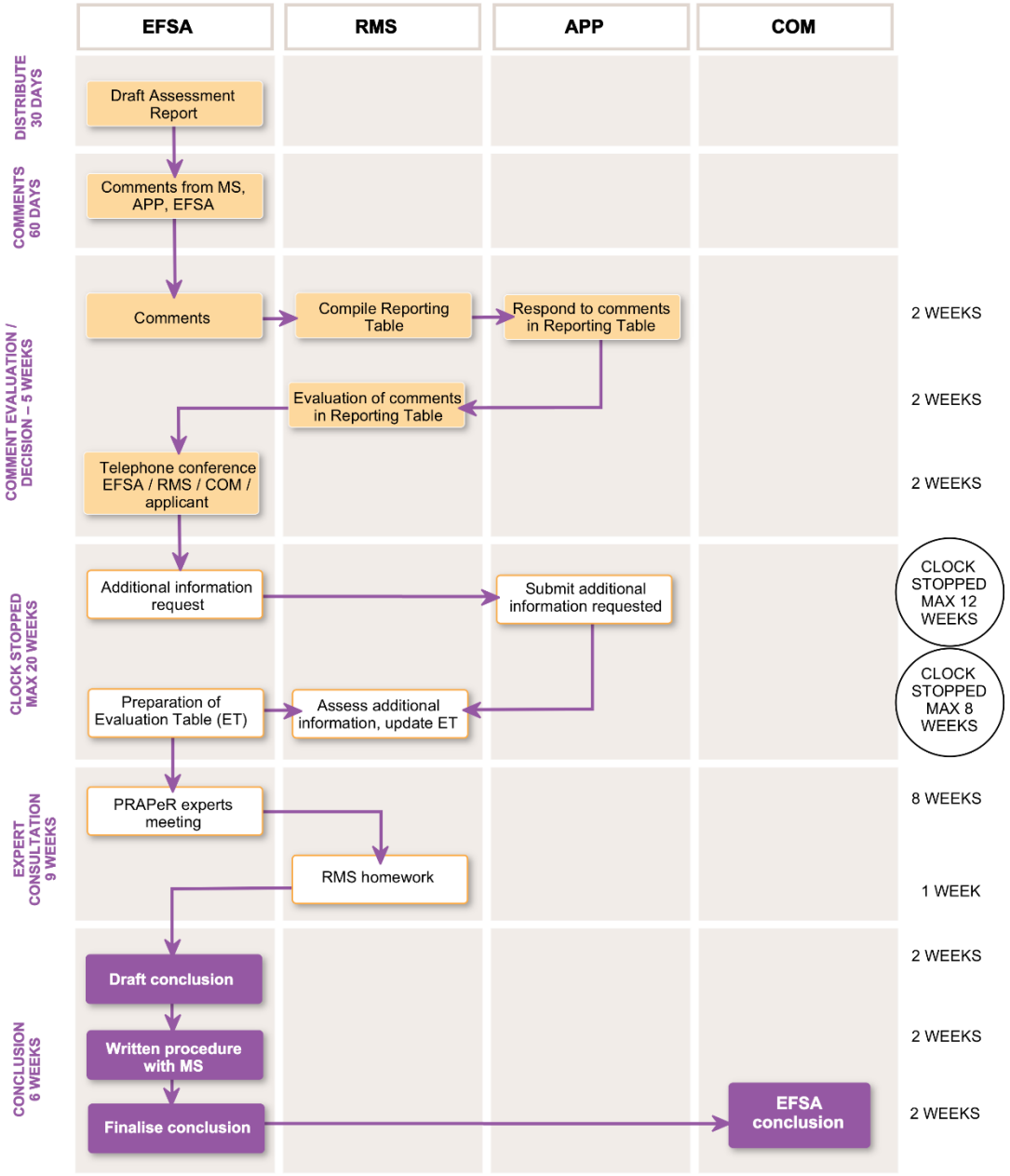
- A 20 year patent protection in EU can be supplemented by up to a further 5 years through the use of supplementary protection certificates (SPCs) if market entry has been significantly delayed by the registration process.[79]
- Once the chemical plant protection product is authorised at Member State level, 10 years of regulatory data protection or exclusive use is granted in relation to that particular Member State. A further three

[79] Mattaar H 2016, *Vademecum 2016*, 3rd edition. Pappas and Associates, Brussels, Belgium, pp. 5–16.

years maximum, exclusive use is possible if 12 minor uses are developed and authorised. This can extend the data exclusivity period past the patent expiry date.

— The Bolar exemption[80] allows companies other than the inventing company to develop their registration dossiers during the last couple of years of the patent or SPC, and eventually other manufacturers with generic versions of the original product enter the market.

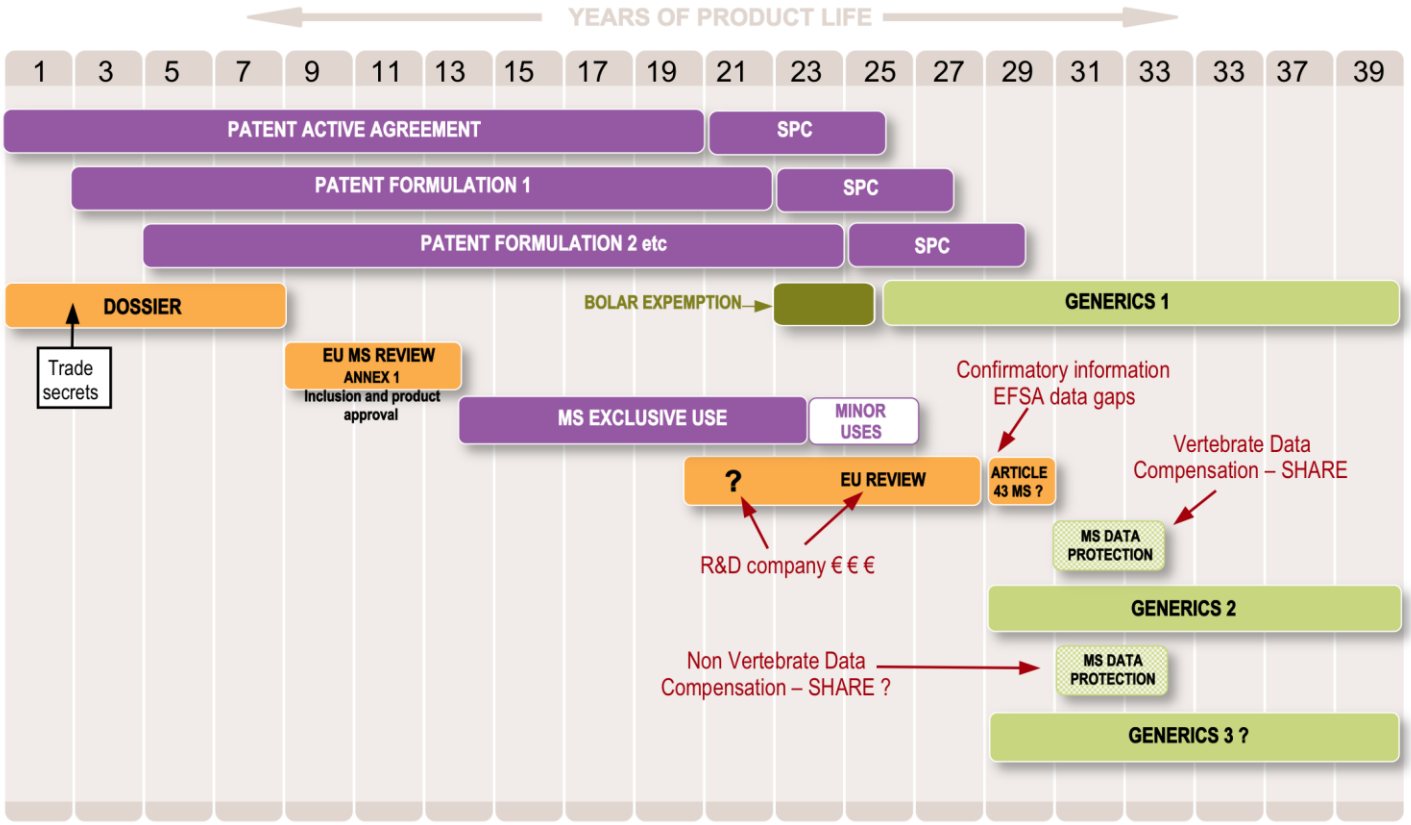
FIGURE 4.3 EU NEW ACTIVE SUBSTANCE APPROVAL PROCEDURE



SOURCE: EFSA 2011, REGULATION (EC) NO 1107/2009

[80] A Bolar exemption is an exception to the exclusive right granted by a patent, permitting use of patented products in experiments for the purpose of obtaining regulatory approval.

FIGURE 4.4 EU REGISTRATION PROCESS WITH DATA PROTECTION AND OTHER IP PROVISIONS



SOURCE: CARROLL MJ 2016, THE IMPORTANCE OF REGULATORY DATA PROTECTION OR EXCLUSIVE USE AND OTHER FORMS OF IP RIGHTS IN THE CROP PROTECTION INDUSTRY, PAGE 1634.

As the author of the above flow charts has noted:

Before patent expiry, the originating company must prepare for regulatory review, which is usually expensive if it is related to patent and takes an uncertain time as the exact requirements of the review are not specified by the regulator. From the regulator's point of view, this is a rational decision because not all parts of the regulatory risk assessment have reached scientific consensus and so it is difficult for the regulator to specify in advance what the review should consider. The problem for the registration holder is that they must effectively guess what the regulator may require, and this leads to overcompensation in that perhaps more studies are carried out than are eventually necessary. Not only is this expensive, it may lead to further complexity as studies may not resolve regulatory questions completely, leading to further studies and more expense. Generic registration holders may not have taken part in the review, and although this means they have not spent any money, there is great uncertainty about how their product authorisations will be dealt with at Member State product review. However, task forces are formed in Europe between the primary and secondary manufacturers to defend active ingredients that have been off-patent for several years. If the review is successful and the active substance is reapproved, then the data necessary for the regulatory decision will be protected for a period of 30 months from reregistration of the first product containing the active substance under review, when each Member State re-authorises the product. Vertebrate data necessary for the review regulatory decision must be shared (reportedly for ethical reasons), with compensation payable to the data generator, but there is no forced sharing of non-vertebrate data. This can lead to a lot of confusion and the possibility of duplication of studies and the resulting multiple data endpoints, which can cause chaos for the regulatory risk assessment.

Carroll M. J 2016, The importance of regulatory data protection or exclusive use and other forms of intellectual property rights in the crop protection industry, Pest Management Science 2016, 72. p 1632

4.2.2 Veterinary chemical products

The registration process for veterinary chemical products has its origins in the 1965 EC Medicines Directive, which laid down the criteria of safety, quality and efficacy. In 1981 two EC Directives were published with the intention of improving and harmonising the registration process for medicinal products within the European Union. These were later extended to include vaccines and homeopathic medicines. In the 1990s, controls were further harmonised and tightened with the introduction of legislation covering residues in food, a centralised registration procedure and the rules for Good Manufacturing Practice. In 2004, the legislation was amended to increase the efficiency of the procedures, particularly taking into account the 10 new Member States that joined the EU on 1 May 2004, and would therefore have to apply the legislation.

The EU system offers three different pathways for authorisation of veterinary medicine. The centralised procedure allows the marketing of a medicine on the basis of a single EU-wide assessment and marketing authorisation which is valid throughout the EU. Veterinary pharmaceutical companies submit a single authorisation application to the European Medicines Agency (EMA). The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) then carries out a scientific assessment of the application and gives a recommendation to the European Commission on whether or not to grant a marketing authorisation. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States. The use of the centrally authorised procedure is compulsory for most innovative medicines, including medicines for rare diseases.

The majority of medicines authorised in the EU do not fall within the scope of the centralised procedure but are authorised by national competent authorities (NCAs) in the Member States. When a company wants to authorise a medicine in several Member States, it can use one of the following procedures:[81]

- The decentralised procedure applies where companies can apply for the simultaneous authorisation of a medicine in more than one EU Member State if it has not yet been authorised in any EU country and does not fall within the scope of the centralised procedure
- The mutual-recognition procedure allows for companies that have a medicine authorised in one EU Member State to apply for this authorisation to be recognised in other EU countries. This process allows Member States to rely on each other's scientific assessments. Rules and requirements applicable to pharmaceuticals in the EU are the same, irrespective of the authorisation route for a medicine.

The EU has established a two-tier registration system for the approval of active substances and authorisation of formulated products.

Since 2009, the EU has moved from a risk based approach to chemical regulation, to a hazard based approach. Under a risk based approach, the risk from a chemical that is toxic can be mitigated through conditions of use, packaging and formulation. Under the hazard based approach if an assessed chemical exceeds a hazard trigger for a property such as persistence, bio accumulation or toxicity it is deemed unacceptable and will be either withdrawn or not registered, irrespective of the risk mitigation measures that could be deployed.

4.3 UK registration processes

4.3.1 Plant protection products

The process and standards required to obtain product authorisations are set out in EU legislation (Regulation (EC) No. 1107/2009 and associated guidance). This legislation applies in all EU Member States. However, national legislation is needed to underpin its operation and to provide for fees and charges. These provisions were implemented by the following legislation in UK:[82]

- Plant Protection Products Regulations 2011
- Plant Protection Products Regulations (Northern Ireland) 2011

[81] See http://www.ema.europa.eu/docs/en_GB/document_library/Leaflet/2014/08/WC500171674.pdf accessed on 20 August 2017

[82] See http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/general/introduction-to-active-substance-approval.htm accessed on 20 August 2017.

— Plant Protection Products (Fees and Charges) Regulations 2011

4.3.2 Veterinary products

There are four pathways to get a market authorisation for new veterinary medicines in the UK.[83] These pathways determine the procedures, processes and timelines used in processing an application for a new market authorisation. Once granted, the authorisation will be nationally authorised, centrally authorised, or mutually recognised.

— **National** — a product that has been assessed and approved on a national basis only, i.e. there has been no interaction with other EU Member States.

— **Centralised** — a centrally authorised product is one that has been assessed and approved on a community level involving all EU Member States. A pan-European authorisation is issued by the European Commission (EC) permitting the marketing, sale and supply of the product in all EU member states including the UK. The EMA organises the process of evaluation using scientific expertise from all EU Member States. If a positive opinion is given by the EMA after a product has been evaluated, it is sent to the EC. If the EC also has a favourable opinion, it makes a formal decision to authorise the product and grants a single market access that is valid in all EU Member States. While the EC will usually endorse a positive opinion, it has the right to reject it. Although the VMD does not issue market authorisation for products authorised by the centralised procedure, the outcome is the same: the product is authorised for use in the UK. The centralised procedure is compulsory for some products and optional for others. Some products are not eligible for the centralised procedure.

— **Mutual Recognition** — a mutually recognised product is one that has been assessed and approved on a European level involving at least two EU Member States that is, it has been evaluated via the mutual recognition or decentralised procedure. The mutual recognition procedure (MRP) is a European authorisation route resulting in a mutually recognised product. Mutual recognition must be used when a product is already authorised in at least one EU Member State on a national basis

— **Decentralised approval** takes place when a product is not already authorised in any EU Member State and the registrants obtain authorisation in several Member States.

Market authorisation for generics is different from new innovative veterinary products. Market authorisation for generics arises when the applicant refers to the safety and efficacy aspects of a data package submitted in support of an already authorised veterinary medicine, which is referred to as the reference product. In addition to a full quality data package, applicants must provide an environmental risk assessment for the product and a user risk assessment. The type of user risk assessment provided depends on the degree of similarity between the generic and reference products. For generics of injectable products the submission of injection site residues data are necessary, unless a biowaiver exempts the application from the need for residues studies. Applicants must demonstrate that the generic product is bioequivalent to the reference product, unless they are exempt from doing so under the bioequivalence guidelines.

The reference product must have been authorised in accordance with the EU Directive for at least 10 years before the generic product can be placed on the market. For applications for generic products, which are based on reference products authorised after October 2005, the application can be submitted after eight years of authorisation, but the generic product cannot be marketed until the 10 year data protection period has expired.

In some cases the data protection period for the reference product may be extended to 13 years. For products indicated for the treatment of bees and fish the protection period of the reference product is automatically 13 years.

4.4 US registration processes

4.4.1 Plant protection products

The process of registering a pesticide in USA requires the USEPA to examine:

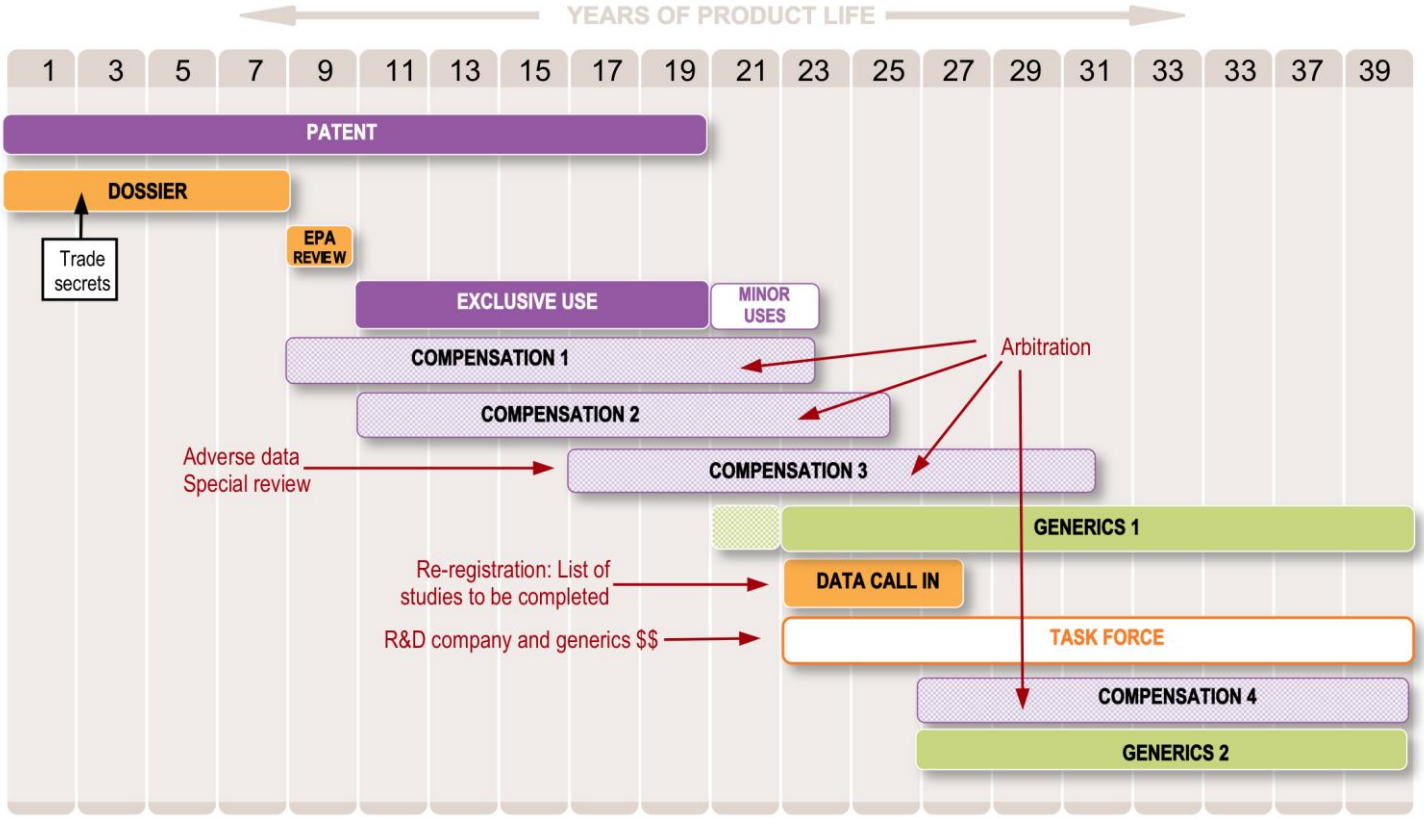
[83] See https://www.gov.uk/guidance/marketing-authorisations-for-veterinary-medicines#authorisation-routes accessed on 20 August 2017.

— the ingredients of the pesticide
— the particular site or crop where it is to be used
— the amount, frequency, and timing of its use, and
— storage and disposal practices.

In evaluating a pesticide registration application, the USEPA assesses a wide variety of potential human health and environmental effects associated with use of the product.

Figure 4.5 shows a schematic representation of the US registration process for chemical plant protection products. The following section draws on a recent paper by Carroll.[84]

FIGURE 4.5 US REGISTRATION PROCESS FOR PLANT PROTECTION PRODUCTS



SOURCE: CARROLL MJ 2016, THE IMPORTANCE OF REGULATORY DATA PROTECTION OR EXCLUSIVE USE AND OTHER FORMS OF IP RIGHTS IN THE CROP PROTECTION INDUSTRY, PAGE 1634.

In contrast to the EU, there is no provision for supplementary patent protection, but the 10 year exclusive use period for regulatory data protection is the same as in the EU and starts at first registration. Minor use registrations can extend the exclusive use period in the USA in a similar fashion to the EU. In addition, all data on submission are compensable in that they have a value that must be paid by another party seeking access to the data. This period of compensation lasts for 15 years from data submission.

Any data required by the USEPA or data that would change the risk assessment made by the USEPA are compensable and, if submitted at different times, trigger separate compensable 15 year periods.

There is no Bolar exemption in the USA, and so it is not possible to generate regulatory data towards the end of the patent period as is possible in the EU.

Generic products eventually arrive after patent and exclusive use periods have expired or compensation has been paid to the data owner. The review process in the USA is quite different from

[84] Carroll MJ 2016, The importance of regulatory data protection or exclusive use and other forms of IP rights in the crop protection industry, Pest Management Science, 72:9, pp 1631-1637, September 2016

the EU, in that the USEPA specifies what studies are required using a data call-in (DCI) system. The USEPA specifies the studies required and the protocols to be followed, and allows enough time for studies to be completed. The registration holder may not like the final list of requirements, but at least there is some form of contract between regulator and registration holder. If there are multiple registration holders, acceptance of the review DCI allows those registration holders to stay in the market. Non-compliance with the review DCI means that the registration holder will eventually have the approval cancelled. Multiple registration holders form task forces to share costs and avoid multiple studies for the same regulatory endpoint. Once data are submitted in the review to comply with the DCI, the data are compensable for 15 years from the date of submission.

If further companies wish to enter the market post-patent and after the regulatory data protection exclusive use period has expired, they must pay compensation for access. Thus, after the first 10 year period of regulatory data protection / exclusive use, all further access to data is determined by ability of would-be generic manufacturers to pay compensation.

This approach avoids the relative complexity and uncertainty of the EU system, where sequential periods of regulatory data protection exclusive use detract from an efficient regulatory process. A final but important point is that, in order to obtain approvals on the basis of compensating data holders, the compensating company need only offer to pay. Thus, registrations can be granted and compensation may well end up being decided in the courts or through extended periods of mediation and arbitration.

4.4.2 Veterinary chemical products

The USFDA employs a number of new animal drug application procedures.[85] A guidance document[86] describes the type of information that the Food and Drug Administration's Center for Veterinary Medicine (CVM) recommends sponsors provide to address the human food safety of new animal drugs used in food-producing animals.

The human food safety evaluation of new animal drugs used in food-producing animals helps ensure that food derived from treated animals is safe for human consumption. Sponsors are required to furnish to CVM scientific data or information necessary to demonstrate that residues of the new animal drug in the edible tissues of treated animals are safe (see section 512(b)(1) of the *Federal Food, Drug, and Cosmetic Act* (the FDFDCA)). In general, studies conducted to provide this information must be conducted in accordance with USFDA's Good Laboratory Practice regulations. See Title 21, Code of Federal Regulations, Part 58 (21 CFR 58).

The USFDA conducts a human food safety assessment of new animal drugs for use in food-producing animals through hazard identification, hazard characterization and mitigation to reduce human exposure to residues in food derived from treated animals. The CVM has developed a guidance document to inform sponsors of the scientific data and / or information that may provide an acceptable basis to determine that the residue of a new animal drug in or on food, when consumed, presents a reasonable certainty of no harm to humans.

This guidance document describes a recommended approach for providing human food safety scientific data and / or information. The CVM acknowledges that alternate approaches also may be appropriate and encourages sponsors to discuss with CVM whether an alternate approach may be appropriate for specific new animal drugs. An overview of the overall process for the human food safety evaluation of new animal drugs used in food-producing animals includes:

- Determining an acceptable daily intake
- Calculating safe concentrations
- Assignment of a tolerance
- Calculation of a withdrawal period and a milk discard time, and
- Evaluation of carcinogenic compounds.

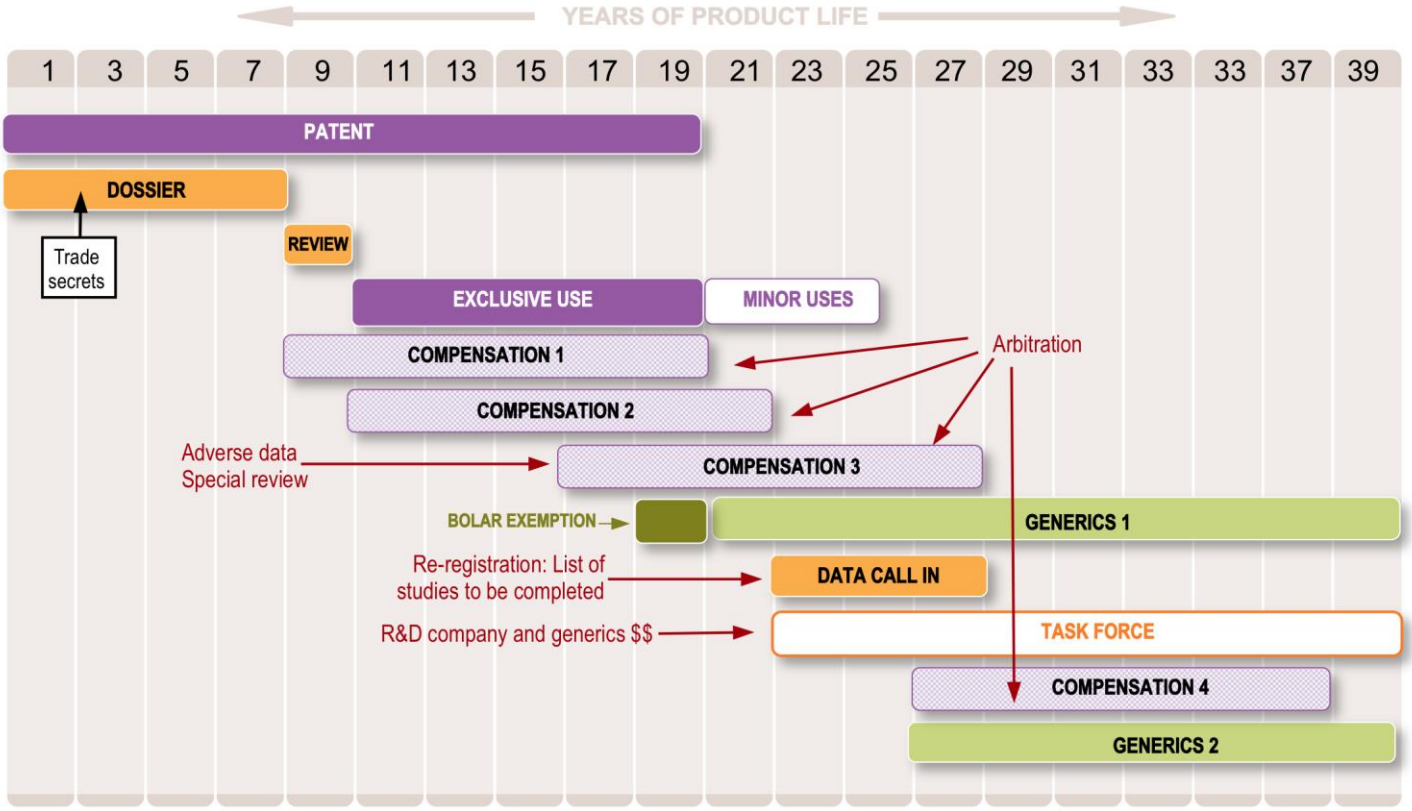
[85] See https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm123821.htm accessed on 20 August 2017.

[86] See https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052180.pdf accessed on 20 August 2017.

4.5 Canadian registration processes

The Canadian system is very similar to the US system as shown in **Figure 4.6** and regulatory review is based on data call-in. The key differences are that there is a Bolar exemption and the compensation periods are only of 12 years duration. At the heart of the Canadian system is the provision that, after the first 10 year period of regulatory data protection exclusive use, all further access to data is determined by ability to pay compensation. This avoids the complications of the EU process which uses multiple sequential periods of regulatory data protection / exclusive use. In Canada, however, it is not possible simply to offer to pay. Some form of compensation must actually be paid before a registration is granted. This means that generics are out of the market for 12 years, two years longer than in Australia.

FIGURE 4.6 CANADIAN REGISTRATION PROCESS FOR PLANT PROTECTION PRODUCTS



SOURCE: CARROLL MJ 2016, THE IMPORTANCE OF REGULATORY DATA PROTECTION OR EXCLUSIVE USE AND OTHER FORMS OF IP RIGHTS IN THE CROP PROTECTION INDUSTRY, PAGE 1634

4.6 New Zealand registration processes

All agricultural compounds (includes agricultural chemicals and veterinary medicines), manufactured, sold or used in New Zealand must be authorised under the ACVM Act and Regulations.[87] Unlike other reviewed countries, pre-application assessment is required prior to the New Zealand regulator's agvet chemical assessment, which correspondingly limits the work and time required for the latter. When the timeframes required for both pre-application and regulatory assessment are taken into account, they are similar to other countries.

There are five types of authorisation for agricultural chemicals:

[87] New Zealand Ministry of Primary Industries, not dated, accessed on 17 July 2017 at http://www.foodsafety.govt.nz/industry/acvm/agricultural-chemicals/authorisation/

1. Registration (to authorise a specific trade name product — this applies to most agricultural chemical products)
2. Provisional registration (to do trial work to obtain information on a trade name product other than that required for New Zealand registration and to determine whether it should be registered in New Zealand)
3. Exemption from registration under Regulations (to authorise product "types" or groups that are exempted from registration subject to conditions in the ACVM Regulations)
4. Approval in special circumstances (to allow agricultural chemicals to be used under strict conditions without registration or provisional registration).
5. Approval of an agricultural compound as Generally Recognized as Safe (GRAS).

When an agricultural chemical has been authorised, its supplier must comply with any conditions of that authorisation. These conditions may limit aspects of importing, manufacturing, selling and using.

Where the crop protection or veterinary medicine product is also a hazardous substance it also requires an approval (either Part 5 approval or compliance with a Group Standard) under the HSNO Act. An ACVM registration cannot be finalised until it has a HSNO approval (where required).

Protection of confidential information submitted with an application for registration, certain variations to a registered product, or reassessment of a registered product is outlined in Part 6 of the ACVM Act. The period of protection for confidential information is 5 years for non-innovative products, variations (e.g., additional pests, crops/animals, application methods) and reassessments and 10 years for innovative products (meaning contains an active ingredient not used in an already registered product).

This means during this protected period, another company wishing to register or vary an existing registration either has to supply the equivalent confidential information, or obtain a letter of support from the registrant owning the protected confidential information.

Key steps to register agricultural compounds are outlined below.[88]

Administrative pre-screen — at the start of the process applicants are advised that the application has been received and will be processed by the Operations Team of the Approvals and ACVM Group. The applications are checked for completeness in terms of the supporting documents that must be included. Whether complete or not, a number is assigned to the application, a product file is created to hold the documents and relevant information is entered into an internal database.

Technical pre-screen — at this pre-screen, the Technical Appraisers (TAs) make a preliminary appraisal to confirm whether or not the data supplied with an application are sufficient to be appraised to support registration.

Pre-screen Decision — if information provided is considered to be inadequate either at the administrative or technical pre-screen, the application is not accepted under the ACVM Act. The applicant is advised of the deficiencies and they can decide whether to re-submit the application.

Public notification — once accepted into the regulatory system, section 14 of the ACVM Act requires all applications for registration (and variations to existing registrations) to publish a notice in the NZ Gazette. However, section 15 of the Act grants MPI the ability to waive the notification if there is a registered TNP with the same active ingredients and an equivalent formulation as the TNP being submitted for registration and the variation to an existing registration does not affect the evaluation of risks relevant to the TNP. Typically, applications for registration of products containing new active ingredients and for registered trade name products with a new risk profiles require public notification. The decision whether or not to waive the requirement to publicly notify is made at technical pre-screen. The notification period is 30 working days and precedes the technical appraisal and risk assessment.

Technical appraisal and risk assessment — TAs carry out the technical appraisal and risk assessment of the applications, determining whether or not the product meets the criteria for registration and what conditions should be placed on the registration to manage any risks identified. This phase can take twenty-five working days. The TAs' recommendations on applications are made

[88] New Zealand Ministry of Primary Industries, not dated, accessed on 17 July 2017 at http://www.foodsafety.govt.nz/elibrary/industry/acvm_registration-ensures_that.htm

within the context of existing policies, which are set via a process that is separate from the registration process.

Waiver of time — during the technical appraisal and risk assessment, the applicant may be contacted for additional information or clarification. If the applicant is unable to provide the information within a reasonable period of time (normally 5 working days), the applicant has to ask MPI for a Waiver of Time (WOT) for a given period (normally not exceeding twenty working days). If the WOT request is accepted, the regulatory clock for the appraisal of the application is stopped until the additional information is received. If the WOT request is not made, or if the request is made but MPI declines to accept it (the reason will be communicated to the applicant), the TA will complete the appraisal based on the available information and is likely to recommend that the application be refused.

Extension of time — with certain applications MPI may require processing time that is likely to exceed the regulatory timeframe for completing the technical appraisal and risk assessment part of the registration process. In addition to staff resourcing issues, the reasons for this could be one or more of the following:

— TNPs that contain prescription medicines as defined under the *Medicines Act* require consent from the Director-General of the Ministry of Health before they can be registered under the ACVM Act. The time period for obtaining such consent is outside the control of MPI. Likewise, the regulators may have to consult with another directorate within MPI or with other governmental agencies before a decision on registration can be made. Such consultations add time to the appraisal of a registration application.

— Some applications may require new MPI policy to be drafted, or an existing policy amended, or in-house legal opinion obtained for the registration to occur.

If for the reasons stated above MPI requires more time to complete the technical appraisal and risk assessment, the regulators will ask the applicant for an Extension of Time. If the extension request is accepted, the regulatory clock for the appraisal of the application will be stopped for this period.

Decision — after the technical appraisal and risk assessment, the TA makes a recommendation either to grant the registration of the product or refuse the application (a split recommendation may also occur for multi-variation applications) to the delegate (under delegation from the Director-General of MPI), who decides whether the application should be granted or refused. As required by the ACVM Act, the decision must be made within 15 working days. If the recommendation is for granting and the TA also advises changes to the original product data sheet (PDS) and / or label content, the applicant is contacted for submission of an amended PDS and / or label content. The delegate's decision will be made after the registrant supplies the updated PDS and / or label, and all outstanding issues have been addressed.

Post decision — when an application is granted, the appropriate registration documentation is issued to the applicant. This includes the certificate of registration, which contains a unique registration number and any conditions applied, and the approved PDS, which details all the relevant information about the product, such as, manufacturer, formulation, use, and the approved label content.

Registrations are always conditional. If a registrant fails to comply with the relevant conditions, MPI may place a prohibition on the importation, manufacture and sale of the product. Therefore, it is important for registrants to read the list of conditions of registration on the certificate of registration so they are fully aware of their legal obligations under the ACVM Act.

4.7 Conclusions

There are significant differences in the agvet regulatory processes across the selected countries and the agencies involved are also quite varied in their roles, responsibilities and structures. In this sense, there is not a predominant agvet chemical regulation and registration model. Each country has specific registration arrangements for accommodating innovative and generic agvet chemical products. The overview of registration arrangements continues in the next chapter.

5 TIME AND COSTS FOR AGVET CHEMICAL PRODUCT REGISTRATION

This chapter documents and compares timelines and registration costs associated with registering agvet chemicals in Australia and overseas. The focus is on Australian arrangements. The analysis does not extend to assessing other regulators' performance against timeframes.

5.1 Australia

5.1.1 Assessment period

The assessment period in which the APVMA is required to determine an application varies depending on the complexity of the application. The legislation prescribes the assessment period for the various application types. The assessment periods may be extended in certain circumstances. The assessment period of an application commences on the day the notice advising the registrant that its application has passed preliminary assessment is issued.

The APVMA is required to finalise all agvet product evaluations within statutory timeframes.[89] More specifically, the APVMA is required to meet statutory timeframe for:

— Conducting preliminary assessments – once the application has been lodged, the APVMA must, within one month, make a preliminary assessment as to whether the application compiles with requirements.

— Finalising evaluations – if an application passes preliminary assessment then the application progresses to an evaluation. The APVMA is then required to make a decision on whether to register the product within one to twenty-four months (with extensions), depending on the type of application.[90]

Applications processed by the APVMA in 2015-16 are provided in **Table 5.1**. On average, the APVMA met only 68 per cent of the statutory timeframes for registration of agvet chemicals in 2015-16. This compares to a 2011 analysis (the *Better regulation of agricultural and veterinary chemicals regulation impact statement*),[91] that noted for 2006-07 to 2009-10, the APVMA met its statutory timeframe for 82–90 per cent and 88–96 per cent of pesticide and veterinary medicine applications respectively. However, these timelines are not strictly comparable because of a change in methodology in July 2014.

The APVMA engaged the professional services firm Oakton to compare the application duration statistics between the period 1 July 2011 to 30 June 2014 and 1 July 2014 to 31 March 2016. The data from this comparison indicates that the weighted average timeframe duration to complete an application (where clock does not stop) has improved by 3.2 months or 97 days.[92] However, it should

[89] Productivity Commission (2008), Chemicals and Plastics Regulation, Productivity Commission Research Paper.
[90] See https://apvma.gov.au/node/1088 accessed on 20 August 2017.
[91] See http://ris.pmc.gov.au/sites/default/files/posts/2011/11/04-Better-Regulation-of-AGVET.pdf accessed on 20 August 2017.
[92] See https://apvma.gov.au/node/20231 (accessed 23 May 2017) accessed on 20 August 2017.

be noted that there is an inherent bias in the sampling used by Oakton, as shown by the small number of applications received for classes with a timeframe greater than six months post 1 July 2014.

TABLE 5.1 APPLICATIONS PROCESSED BY THE APVMA, 2015-16

Application type	Number commenced	Number finalised	Finalised within timeframe (%)	2014-15 in timeframe (%)
Product registration—pesticides	905	1029	57	81
Product registration—veterinary medicines	701	704	80	80
Actives	342	213	70	63
Permits	562	599	70	70
Total	2510	2545	68	

Note: On 1 July 2014, the APVMA adopted new legislation which changed the way they calculate and interpret regulatory timeframe performance within the Authority. These changes mean it is inappropriate to compare timeframe performance for 2015–16 with results published in their annual reports prior to 1 July 2014. Caution is also needed when comparing 2015–16 results to 2014–15 data, as 2014–15 data included applications from both sets of legislation. In contrast, from 1 July 2015, all applications are now subject to the new requirements (regardless of when they were received by the APVMA) and timeframe performance is to be calculated and interpreted in the manner required by the current legislation.

SOURCE: HTTPS://APVMA.GOV.AU/NODE/19751 ACCESSED ON 28 MAY 2017

These statistics provide an overall indication of the APVMA's performance, but they are strongly influenced by the high proportion of applications that are simply administrative in nature and have a short time frame (two to three months). The data provided in Table 5.1 suggest that APVMA generally has a high success rate meeting short statutory time frames, although it does not routinely meet them.

It is the APVMA's performance in the categories with time frames of five months or longer that has the most significant impact on the agvet chemical industry. Importantly, applications with time frames longer than 5 months represent a much higher investment by applicants than administrative applications require. The agvet chemical industry seeks to recover this investment though the sale of its product; hence predictability in the regulatory system and in the time-to-market is critical. Failure of the APVMA to complete applications within the statutory time frames contributes to uncertainty within the industry, impacting on decisions to develop agvet chemicals and their availability.

This point was discussed in the *Better regulation of agricultural and veterinary chemicals regulation impact statement*[93], which noted that:

> *The unpredictability of the current regulatory system (so far as it relates to the statutory time frames for assessment) is likely to be further exacerbated by the lack of substantive alignment between statutory time frames and the total elapsed time frame taken to complete assessment. This unpredictability is compounded by the APVMA not specifying the 'off the clock' period in which applicants are required to correct applications, often resulting in protracted delays at the request of the applicant. For example, for 2009–10 applications in 13–15-month categories, the average total elapsed time for pesticide and veterinary medicine applications was 46.2 and 33.1 months respectively—at least three times and two times the statutory time frame respectively. This in turn introduces disincentives into the regulatory system and can also contribute to inefficient use of APVMA resources through it having to manage low quality applications. The difference between elapsed and statutory time frames varies considerably across the range of applications and from year to year. This high degree of variation, coupled with the absolute increase in 'real' time taken to assess an application, leads to greater uncertainty and less predictability for business.*

Although several initiatives—including consolidation of application categories, consideration of a greater use of modular assessment categories and reduction or elimination of application requirements for some minor applications—have been undertaken by APVMA since an audit by ANAO (2006), consultations with the industry representatives for this project indicate the failure of the APVMA to meet statutory timeframes for assessments is still a major issue. Industry stakeholders have suggested that delays in the assessment process inhibit the ability of patent holders to realise a return on their R&D, which in turn threatens future flows of new agvet products into the Australian market.

[93] Department of Prime Minister and Cabinet 2011, Better regulation of agricultural and veterinary chemicals - regulation impact statement, November 2011, accessed on 27 October 2017 at http://ris.pmc.gov.au/sites/default/files/posts/2011/11/04-Better-Regulation-of-AGVET.pdf

Stakeholders believe that time frames established by the USEPA provide more efficient and transparent arrangements. For example, the *United States Pesticide Registration Improvement Act 2003* (PRIA), *the Pesticide Registration Improvement Renewal Act 2007* and the *Pesticide Registration Improvement Extension Act 2012* include specific provisions for maximum time limits throughout regulatory processes. These provisions specify the maximum timeframes for the submission of data and information, assessment reports and the regulator's final decision. Further, the US system requires that the applicant and the assessing agency must come to a mutual agreement to change the assessment timeframes. This study has not determined whether such timeframes are met.

Similar provisions can be found in the European Union Regulations 1107/2009.

5.1.2 Application fees

More details of timeframes and fees are provided in Appendix B. As this shows, the APVMA's application fees range between $350 and $84,115 in 2015-16 (see Appendix B.2 for calculation).[94] The APVMA is funded through fees, charges and levies imposed on the industry it regulates. Chemical companies pay fees so the APVMA can evaluate registration proposals and renew product registrations, as well as a levy based on the wholesale sales of chemical products in Australia.

The current APVMA cost recovery arrangements were implemented in 2013. There was a discussion paper released by the DAWR in 2014 on the future principles of APVMA cost recovery arrangements.[95]

The APVMA charges a fee (around 40 per cent of the cost of assessing applications) for approvals and registration, with the remainder of costs recovered across the life of the product via the levy collected by the companies at the point of wholesale sale. This approach was implemented in recognition that a higher level of cost recovery through the application fee would disincentivise new products and other innovations from coming to market, particularly in the case of low volume chemical products.

The Productivity Commission's (2008)[96] report indicated that the APVMA's fees are low by international standards. However it appears that the Productivity Commission's comparison included only the registration fee but not the levy. The APVMA recovers the costs through both fees and levies, whereas other countries recover assessment costs through registration fees alone. This makes comparisons of registration costs with other countries difficult. If the levy component is included, the estimated total cost of registering new active ingredients in current dollars was around $275,000 in 2015-16. This estimate does not include regulatory delay costs, product development costs and costs arising from uncertainties related to the timing of market launches.

5.1.3 Sources of APVMA income and expenditure

APVMA's 2015-16 Annual Report outlined the income and expenditure of the Authority for that year, as shown in **Figure 5.1**.

The APVMA received income of $30.6 million and incurred expenditure of $33.9 million in 2015-16, resulting in a net operating deficit of $3.2 million.

5.1.4 Calculation and allocation of costs by the APVMA

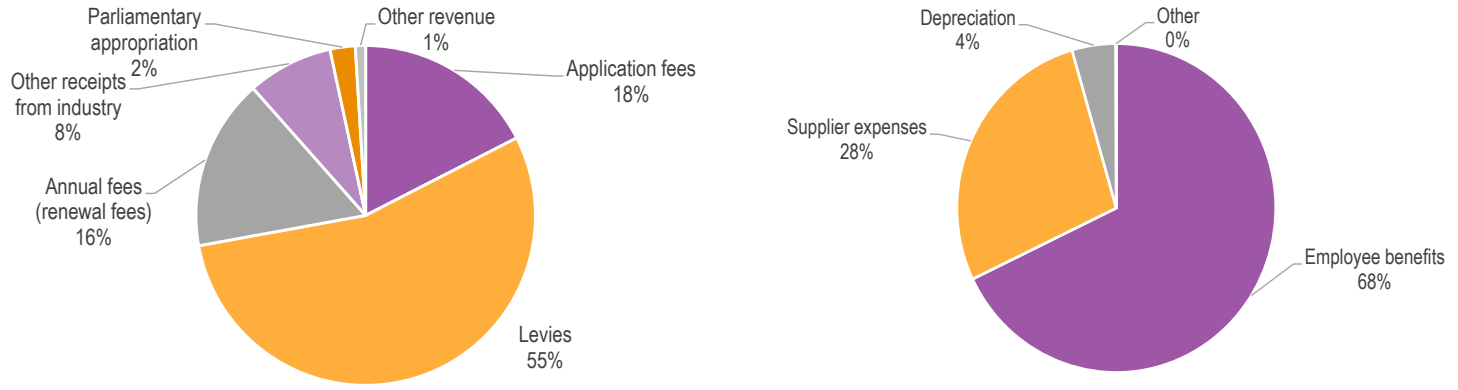
As noted above, the APVMA's regulatory operations are funded on a cost recovery basis. Apart from charges on registration applications, annual fee and a levy-based on product sales, the APVMA also charges a number of minor fees.

Annual fee

An annual fee of $430 per product serves to maintain each product's registration for a financial year. The fee is paid in advance and applies to all registered products regardless of sales.

[94] See https://apvma.gov.au/node/1088 accessed 28 May 2017
[95] See https://apvma.gov.au/node/4161 accessed 1 June 2017
[96] Productivity Commission 2008, Chemicals and Plastics Regulation, Research Report, Melbourne, accessed on 20 August 2017 at http://www.pc.gov.au/inquiries/completed/chemicals-plastics/report/chemicals-plastics-regulation.pdf

FIGURE 5.1 SOURCES OF APVMA INCOME AND EXPENDITURE, 2015-16



SOURCE: APVMA, 2015-16 ANNUAL REPORT

Levy

The APVMA is predominately funded by a levy on the sales of agvet products (see **Figure 5.1**).

By 31 October each year registrants are required to declare the value of sales for the previous financial year. Levies are calculated on a tier scale and apply to both importers and manufacturers of relevant chemicals. Payments have to be made on a yearly basis. Current levy tiers are provided in **Table 5.2**.

TABLE 5.2 AUSTRALIAN LEVY RATES BY TIER

Levy paid in	2013-14	2014-15
	Per cent	Per cent
Tier 1: sales up to $1 million	0.70	0.63
Tier 2: sales between $1 million and $5 million	0.40	0.35
Tier 3: sales over $5 million	0.28	0.25

NOTE: LEVIES ARE PAID ON THE BASIS OF SALES IN THE PREVIOUS YEAR.
SOURCE: APVMA, HTTP://ARCHIVE.APVMA.GOV.AU/ABOUT/WORK/BETTER_REGULATION/DOCS/FEES-CHARGES-SLIDES.PDF ACCESSED ON 24 MAY 2017

For products with sales greater than $5 million, the levy rate is 0.63 per cent on the first $1 million in sales, 0.35 per cent on the next $4 million in sales, and 0.25 per cent on sales above $5 million. In 2008 ACIL Tasman[97] argued that the tier levy system creates inefficiencies through cross subsidisation, and ultimately these inefficiencies are borne by users of agvet chemicals.

Permit fees

A fee of $350 must be paid for most permit applications except emergency use permits and some permits where a government agency is the permit holder. Fees for approvals of permits or extensions of the duration of permits made under section 110A or 115(3A) of the Agvet Code are provided in Appendix B.

[97] ACIL Tasman 2008, APVMA CRIS review, an independent review of the APVMA and its cost recovery policies, November 2008.

5.2 United Kingdom

5.2.1 Assessment period for crop protection period

The assessment period for authorisation of plant protection products depends upon the nature of the application and changes. For example, a simple change in product name will take less time than a change in field of use from a professional product to a minor use. The length of time needed to complete an evaluation is very much a case-by-case basis. Some timelines are defined by legislation and are similar to those in Australia. Timelines defined in Regulation (EC) No 1107/2009 are provided in **Table 5.3** and are generally around 12 months.

TABLE 5.3 TIMELINES FOR PESTICIDE REGISTRATION IN THE UK

Evaluation type	Article number of Regulation 1107/2009	Timeline	Comment
Authorisation or amendment of an authorisation	33, 34, 51[a] and 54	12 months	Timeline defined by legislation
Additional information request	33, 47 and 51[a]	-	A total of 6 months given for the provision of further information
Following zonal, mutual recognition and Low risk products	33, 40 and 47	120 days	Timeline defined by legislation
Art 43 Renewals	43 and 51[a]	26 weeks	Timeline defined by legislation / guidance
Parallel permit	52	45 days	Timeline defined by legislation
Import Tolerance	Regulation (EC) No 396/2005	12 months	No timeline in Regulation – align with timeline for other applications
Emergency situations in plant protection	53	As agreed with HSE	Agreed timelines with the registrants

NOTE: a ARTICLE 51 COVERS EXTENSION OF AUTHORISATIONS FOR MINOR USES.
SOURCE: HTTP://WWW.HSE.GOV.UK/PESTICIDES/TOPICS/PESTICIDE-APPROVALS/PESTICIDES-REGISTRATION/APPLICANT-GUIDE/THE-APPLICANT-GUIDE-APPLICA-2.HTM ACCESSED ON 20 AUGUST 2017

5.2.2 Market authorisation costs for crop protection products

Fees charged for individual application types range between £100 and £114,400[98] (at current exchange rate, A$191,000) for evaluation of a core dossier.

5.2.3 Market authorisation costs for veterinary medicines

Fees charged for individual application types range between £400 and £53,315[99] (at current exchange rate, A$89,036).

5.3 United States of America

Timelines and the registration service fee for new plant protection product active ingredient in USA are provided in **Table 5.4**.

To register an active ingredient for pesticide use in the USA takes between 14 and 24 months and costs between US$182,327 and US$627,568 (at current exchange rate, A$850,882), which at the top end is significantly more than Australian costs.

98 See http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/streams-and-fees.htm accessed on 20 August 2017.

99 See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/423370/719776_Fees_sheet_6.pdf accessed on 20 August 2017

TABLE 5.4 NEW ACTIVE INGREDIENT PESTICIDE REGISTRATION DECISION TIME AND FEE

EPA no.	New CR no.	Action	Decision review time (months)	2016-17 registration service fee (US$)
R010	1	New Active Ingredient, Food use	24	627,568
R020	2	New Active Ingredient, Food use; reduced risk	18	627,568
R040	3	New Active Ingredient, Food use; Experimental Use Permit application; establish temporary tolerance; submitted before application for registration; credit 45 per cent of fee toward new active ingredient application that follows	18	462,502
R060	4	New Active Ingredient, Non-food use; outdoor	21	436,004
R070	5	New Active Ingredient, Non-food use; outdoor; reduced risk	16	436,004
R090	6	New Active Ingredient, Non-food use; outdoor; Experimental Use Permit application; submitted before application for registration; credit 45 per cent of fee toward new active ingredient application that follows	16	323,690
R110	7	New Active Ingredient, Non-food use; indoor	20	242,495
R120	8	New Active Ingredient, Non-food use; indoor; reduced risk	14	242,495
R121	9	New Active Ingredient, Non-food use; indoor; Experimental Use Permit application; submitted before application for registration; credit 45 per cent of fee toward new active ingredient application that follows	18	182,327
R122	10	Enriched isomer(s) of registered mixed-isomer active ingredient	18	317,128
R123	11	New Active Ingredient, Seed treatment only; includes agricultural and non-agricultural seeds; residues not expected in raw agricultural commodities	18	471,861
R125	12	New Active Ingredient, Seed treatment; Experimental Use Permit application; submitted before application for registration; credit 45 per cent of fee toward new active ingredient application that follows	16	323,690

SOURCE: HTTPS://WWW.EPA.GOV/PRIA-FEES/PRIA-FEE-CATEGORY-TABLE-REGISTRATION-DIVISION-NEW-ACTIVE-INGREDIENTS ACCESSED ON 2 JUNE, 2017

TABLE 5.5 ANIMAL DRUGS USER FEE IN THE USA, FY2017

Type	Fees (US$)
ADUFA III (non-generics)	
Animal drug application	350,700
Supplemental Animal Drug Application requiring safety or effectiveness data and Animal Drug Application subject to criteria in 21 U.S.C. 360b(d)(4))	175,350
Product	8,195
Establishment	111,900
Sponsor	103,100
AGDUFA II (Generic)	
Abbreviated Generic New Animal Drug Application (except those subject to criteria in 21 U.S.C. 360b(d)(4))	232,400
Abbreviated Generic New Animal Drug Application subject to criteria (50% of application fee)	116,200
Product	10,200
Sponsor 100% (holds > 6 approved abbreviated applications)	96,350
Sponsor 75% (holds 2-6 approved abbreviated applications)	72,263
Sponsor 50% (holds 0-1 approved abbreviated applications)	48,175

SOURCE: HTTPS://WWW.FDA.GOV/ANIMALVETERINARY/NEWSEVENTS/CVMUPDATES/UCM513124.HTM ACCESSED ON 20 AUGUST 2017

ADUFA III and ADUFA II (generic) application fees for financial year 2017 are provided in Table 5.5. Animal drug user fees range between US$8,195 and US$350,700 (at current exchange rate, A$442,399) for new animal drug applications. For generics, the user fees range between US$10,200

and US$232,400 (at current exchange rate, A$293,166). The fee is 34 per cent lower for generic new animal drugs relative to new non-generic animal drugs.

5.4 Canada

The fee for an application for a new active ingredient for a pesticide is around C$330,000[100] (at current exchange rate, A$329,017). The annual fee charged by the Canadian regulator for the sale of approved veterinary drugs is $250. [101]

5.5 New Zealand

5.5.1 Assessment period

As noted earlier, pre-application requirements in New Zealand, including assessment by the NZEPA, reduce the work and time required for dedicated agvet assessment and registration. The ACVM Act specifies MPI has 40 working days to consider and make a decision on an application for registration. Where an application is publicly notified there is an additional 30 working days. The 40 working days can be extended if an approval for the product is required under the *Hazardous Substances and New Organisms Act*, administered by the NZEPA. In such situations, once it is approved, MPI has five working days to make a decision.

5.5.2 Registration costs

In line with pre-application requirements, NZEPA costs are generally incurred prior to the application to the agvet regulator.

The NZ fees are based on the time taken to register the product with ACVM. They are based on hourly rates. The fees are prescribed in the *ACVM Regulations 2015*. The rate is NZ$155 / hour excluding GST at July 2015. Estimated fees for ACVM regulatory assessment of agricultural chemicals for new applications are provided in **Table 5.6**.

Generally, the registration costs based on the fees in the regulations for registration of a product range between NZ$1000 and NZ$4,500 (at current exchange rate, A$4,175).

TABLE 5.6 ESTIMATED FEES FOR AGVET CHEMICAL REGISTRATION IN NEW ZEALAND

Type	Description of type	Pre-screen fee	Processing time	Estimate of time and fee
	New active ingredient	NZ$540 (excluding GST)	40 working days	12-25 hours @155 / hour = NZ$2,400 – NZ$4,415
A2	Existing Active Ingredient with different profile, such as new use	NZ$540 (excluding GST)	40 working days	12-18 hours @155 / hour = NZ$2,400 – NZ$2,790
B1	Identical to Registered Product (all the same except trade name)		40 working days	4-5 hours @155 / hour = NZ$775 – NZ$2,790
B2	Similar to Registered Product (same active ingredient, same formulation type, same dose regime, same use patterns)	NZ$540 (excluding GST)	40 working days	8-12 hours @155 / hour = NZ$1,780 – NZ$2,400

SOURCE: HTTP://WWW.FOODSAFETY.GOVT.NZ/ELIBRARY/INDUSTRY/ESTIMATED-FEES-FOR-REGULATORY-ASSESSMENT-OF-AGCHEMS.PDF ACCESSED ON 20 AUGUST 2017

[100] Health Canada, not dated, accessed on 17 July 2017 at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/fees-charges-regulations.html#a3.1

[101] Health Canada, not dated, accessed on 17 July 2017 at https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/vet/applic-demande/form/author_sell_vet_reg_vendre-eng.pdf

5.6 Summary of timeframes and costs

An indicative summary of timelines and costs of agvet chemical authorisation or registration is provided in **Table 5.7**. Timelines and registration fees vary across major economies to a register a new pesticide product.

The differences in costs appear to be related to the nature of cost-recovery arrangements. Australia and Canada recover part of their assessment costs through registration fees, while other countries recover the full costs of assessments through registration fees alone. It is therefore difficult to compare registration fees between countries. It is not appropriate to compare centralised registration costs in the EU with single country costs. For this reason, UK cost data have been used for comparison purposes. New Zealand costs are also not comparable because NZEPA costs are not included.

Timelines also vary between countries. They depend on regulatory procedures and the risk assessment approaches discussed in Chapter 4.

TABLE 5.7 TIMELINES AND REGISTRATION COSTS FOR NEW PESTICIDE PRODUCTS

Country	Timelines (months)	Registration fee (A$)[a]
Australia	3-24	275,000
UK	12-14	191,000
USA	14-24	240,000 – 840,000
Canada	10-14	330,000
New Zealand[b]	1-2	952– 4,286

Note: (a) Typical registration fees for a complete evaluation and registration of a new product with a new active ingredient. Exchange rate as at 8 June 2017 was used to convert UK, USA, Canadian and NZ registration fees into Australian currency.
(b) Because of New Zealand's pre-applications assessment being conducted prior to assessment, the NZ data is not comparable to the other countries listed in the table
SOURCE: ACIL ALLEN ESTIMATES BASED ON VARIOUS SOURCES

5.7 Conclusions

It is difficult to compare registration fees between countries because of the very different fee structures in use. Australian agvet chemical registration fees are broadly comparable with most North American and EU fees. However, the Australian market is about one tenth of the size of the US market, giving manufacturers less scope to recover registration costs.

A UK registration can be a stepping stone towards wider approval within the EU, again providing access to a market which is much larger than Australia's. What stands out in **Table 5.7** is the extended timeframe for Australian and some US approvals.

6 AGVET CHEMICAL MINOR USES

Access to agvet chemicals for minor uses and in particular getting minor uses registered or permitted, is a global challenge.[102] Minor uses are particularly relevant to specialist crops and are mainly associated with uses that do not attract commercial interest by product manufacturer / registrants where the potential economic return from those uses is insufficient to justify the cost of registration. Apart from a lack of economic returns from registration of a minor use, the key problems include the associated costs of generating the data required for obtaining and maintaining regulatory approval, the potential liability arising from those uses once approved, and delays in getting approval which limit economic returns.[103]

Minor uses often involve high value crops grown on a small scale (minor crops). In some instances, minor uses can involve controlling a minor pest within the major crop (e.g. wheat rust disease in Australia).

Australia is small country in terms of agriculture production, with diversified crops and livestock. Due to changing demographics and export market opportunities, minor use has become an issue for emerging crops grown for niche markets which have export potential. Minor use pesticides and agricultural chemicals are of major significance to many of the fruit, vegetables crops and livestock that could not be grown successfully without them.

This chapter discusses the importance of minor use registration in Australia for crops and livestock, differences in minor use definitions across countries and the use of economic and regulatory incentives to facilitate minor use approvals.

With low sales volumes, the costs involved in obtaining registration of a minor use in Australia can outweigh the benefits. Aligning Australia's approach with that of other countries could entice international companies to include more uses for Australia in global approaches to rolling out new products.

6.1 Minor use definitions

Most countries have developed definitions of minor use based on "risk assessment" or "economic return principles" or a combination of both.

The "risk assessment" approach is associated with the level of regulatory risk assessment required for a given use, by determining at what level a crop (or animal) may be considered minor or major based upon volume (area or tonnage) of production and / or dietary intake. These criteria are also used by regulatory authorities to determine data requirements commensurate with the level of risk assessment

[102] CropLife International 2015, Pesticide solutions for minor uses, Position Paper, September 2015.
[103] OECD 2011b, Guidance document on regulatory incentives for the registration of pesticide minor uses, Document ENV/JM/MONO(2011)16, accessed on 17 July 2017 at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2011)16&doclanguage=en

required. Thus minor crops may have reduced data requirements compared to major crops in areas such as residues and dietary risk assessment.

The "economic return" approach is associated with potential economic return to the manufacturer / registrant from a minor agvet product, where consideration of registration may be influenced by factors other than solely regulatory risk assessment principles.

These definitions serve as an important mechanism to ensure that minor uses are appropriately regulated and, where applicable, include mechanisms that reduce the regulatory burden. They are often complemented by regulatory incentives to encourage registration.

Agvet chemical users are constantly altering their agricultural production practices and diversifying into new crops and varieties. These dynamics and exogenous factors create an ever-changing agvet chemical market for agvet product suppliers. As previously noted, agvet product suppliers pursue registration only when there is likely to be a satisfactory return on investment (including the cost of registration). These decisions by suppliers not only affect which new products and registrations are pursued but also which uses may receive continued support should regulatory reviews be initiated.

An example of these two approaches—risk assessment approach and economic returns approach—to minor use is provided in **Box 6.1**. The example is taken from the OECD (2009).[104]

BOX 6.1 APPROACHES TO MINOR USE AND CONFLICTING OBJECTIVES

The following example explains how differences in minor use determinations can arise when considering the "economic return approach" compared to the "risk assessment approach". Consider two different crops with similar volumes of production and dietary consumption. From the risk assessment approach the registration of both crops would be subject to relatively similar data requirements and costs associated in registering that use. However from the economic return approach, factors such as dietary consumption often have little or no direct linkage to potential sales volume from that use when registered. While the volume of production may provide some insight into the potential market size, that alone may not determine which use would provide greater economic return to manufacturer / registrant and therefore which is more attractive to register. This may also be influenced by factors such as level of pest or disease pressure and / or value of the commodity.

- Firstly, a crop that is subject to greater pest or disease pressure will have a greater potential need for crop protection products and will therefore provide a market of greater interest to manufacturers / registrants.
- Secondly, if the value of the crop being produced is high, that in turn will determine agvet chemical users' decisions on input costs in producing and protecting the crop and, similarly, be a market of greater interest to manufacturers / registrants.

The opposite can also be true for high value commodities where potential liability to the manufacturer / registrant may outweigh or significantly offset potential economic returns. This potentially creates a 'see-sawing' effect to determining what may be a minor use in the economic return approach, and where that may be influenced by factors other than those utilised in the risk assessment approach where the emphasis is entirely on regulatory risk assessment principles. This often results in differences where a use from one perspective could be classified as major whilst the alternative approach could classify the use as minor and vice-versa. This creates a conundrum where the risk assessment approach and the economic return approach do not always equate and is perhaps the reason why differences of opinion can exist between regulators, manufacturers and agvet chemical users as to what uses are minor in the agvet chemical market.

SOURCE: OECD (2009), OECD GUIDANCE ON DEFINING MINOR USES OF PESTICIDES, ENV/JM/MONO(2009)39

[104] OECD 2009, Guidance on defining minor uses of pesticides, ENV/JM/MONO(2009)39 accessed on 17 July 2017 at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2009)39&doclanguage=en

6.1.1 Australia minor use definition

The Australian minor use definition is based on the economic return approach. The APVMA has provided a guide for determining minor use in Australia.[105] The Agvet Code regulations define a minor use:

> *In relation to a chemical product or an active constituent, means a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)*
>
> *Agricultural and Veterinary Chemicals Code Regulations 1995*

The Agvet Code recognises that a minor use can include:

- use on a minor crop, animal or non-crop situation, or
- limited use on a major crop, animal or non-crop situation.

The APVMA recognises that, while the current legislative definition is still relevant, it is nonetheless somewhat difficult to regulate because the criterion of "sufficient economic return" is a very subjective concept.

6.1.2 European Union minor use definition

There is no legislative definition in the European Union for major or minor crop species. However, major species were defined by the Committee for Medicinal Products for Veterinary Use (CVMP). All animal species which are not considered major are, as a consequence, classified as minor species. For the purposes of defining minor use policy, *major species* have been defined in two groups:

- Major food-producing animal species include cattle (dairy and meat animals), sheep (meat animals), pigs, chickens (including laying hens) and salmon, and
- Major companion animal species include cats and dogs.

All other animal species are classified as minor species. Minor use in a major species is generally considered as the use of veterinary medicinal products for the treatment of diseases that occur infrequently or occur in limited geographical areas. The European Medicines Agency (2014)[106] has considered that there is insufficient data in the veterinary domain with respect to the incidence and prevalence of diseases to enable objective cut-off values to be established below which a disease is considered minor. Therefore, a case-by-case approach continues to be used in classifying a product as Minor Use Minor Species (MUMS).

Minor use veterinary medicinal products are defined as those that are limited in size due to a product being indicated for a disease or condition that represents a minor use in a major species or that occurs in a minor species. This minor use terminology is retained, as is used in Article 79 of Regulation (EC) No 726/2004 (but is interchangeable with the term MUMS).

6.1.3 UK minor use definition

UK regulations define minor uses as either uses of pesticides on small area cropping, or against infrequent pests, or those uses which are too small to warrant sufficient return for manufacturers to develop plant protection products for them.

6.1.4 US minor use definition

The US minor use definition is based both on risk assessment and economic return principles. The USEPA[107] considers that the term 'minor use' means:

[105] APVMA not dated, accessed on 17 July 2017 at https://apvma.gov.au/node/10931
[106] EMA 2014, accessed on 17 July 2017 at http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/09/WC500172928.pdf
[107] USEPA, not dated accessed on 17 July 2017 at https://www.epa.gov/pesticide-registration/minor-uses-and-grower-resources

The use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where:

1. the total US acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture, or
2. the USEPA, in consultation with the USDA, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and:

— there are insufficient efficacious registered alternatives available for use

— the alternatives to the pesticide use pose greater risks to the environment or human health

— the minor use pesticide plays or will play a significant part in managing pest resistance, or

— the minor use pesticide plays or will play a significant part in an integrated pest management program.

Status as a minor use pesticide continues as long as the USEPA has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

Many fruits and vegetables qualify as minor crops in the USA. Minor uses also include pesticides applied for control of disease vectors such as mosquitoes, ticks, cockroaches, rodents and disease-causing organisms.

There are some similarities between the US and Australian definitions of minor use. For example, both include an area of land (acreage) provision.

6.1.5 Canada minor use definition

Agriculture and Agri-Food Canada[108] states that

"A 'minor use' pesticide refers to the crop-protection treatments – fungicides, insecticides, and herbicides – usually used on low acreage, high-value crops, or where pest control is only needed on a small portion of the overall crop acreage. These pesticides are usually used in such small quantities that manufacturers find the sales potential is not sufficient for them to seek registration in Canada. Crops grown in small areas include vegetables, fruits, specialty crops, herbs, and spices, as well as nursery and landscape plants and flowers. These are often high-value, and are sometimes called "minor crops" because they are grown on significantly smaller areas of land compared to the large acreages of crops like corn, soybeans and wheat"

The Canadian definition of minor use is similar to that in the USA. However, it is interpreted to include pesticide use in high-value, low-acreage crops.

6.2 Incentives to encourage minor use registration

Key economic and regulatory incentives to encourage minor use registration are summarised in **Table 6.1**.

TABLE 6.1 TYPES OF INCENTIVES FOR MINOR USE

Incentive type	Details
1. Economic incentives for registrants	
Data protection	Increased periods of data protection of three to five years are provided for the registration of minor uses. In some countries (but not Australia), by registering the minor use, data protection can then be applied (extended) to all registered uses, making the minor use registration more economically attractive by the additional returns provided through exclusivity attained in other major crops on the label.
Expedited reviews	In many countries, regulatory assessments of minor uses are subject to the same assessment timeframes and procedures as other major uses seeking registration. However when emergency uses are needed (for both minor uses and major uses), reviews are expedited. In these cases only a temporary use approval may be granted, with the ongoing use approval, if required, still subject to standard registration procedures.

[108] Agriculture and Agri-Food Canada, not dated, accessed on 17 July 2017 at http://www.agr.gc.ca/eng/?id=1286197216280

Incentive type	Details
Fee reductions or waivers	Most countries have implemented fee reductions or waivers to enhance the registration of minor uses, noting that the economic costs of registering minor uses can be a major factor hindering their approval. Whilst costs of data generation generally far outweigh regulatory assessment costs, these provisions are seen to lessen the overall costs to some extent and are considered to be government support for minor uses.
2. Technical arrangements based on sound science	
Extrapolation and mutually accepted data	For minor uses, most countries utilise the concept of data extrapolation, be that in residues, efficacy and / or crop safety and worker protection (occupational health & safety). In addition, many countries also accept within limitations, the use of data generated in other regions globally, and typically where it can be demonstrated that the data is relevant to the region where use is sought, either by consideration of geography, climate, soil, agronomic growing conditions and a comparable use pattern.
Number of trials	In addition to extrapolation and use of international data, there are also fewer trials required for minor uses (or minor crops). Generally there is a reduction of 50–75 per cent in the number of trials required compared with the registration of a major use. This is often a reflection of the fact that the product is evaluated with the normal authorisation, and for minor uses it must only be proved that they are similar to the uses of the basic authorisation. Combining data internationally would more than likely provide a more robust data set overall.
3. Authorisation process arrangements	
Third party registrations	Standard regulatory procedures require that an application for registration of a new product or new use be submitted by the product manufacturer / registrant. Some countries operate schemes where persons other than the registrant (third parties) may seek to have minor uses considered for approval. This may include submissions seeking registration (on-label) or off-label approvals. For registration, third parties may make regulatory submissions that are assessed by the regulatory agencies and, if supported, product registrants may then seek to have those uses labelled (or the third party may maintain the label for the given use). In some cases it is a requirement that the registrant must submit their proposed new label at the same time as the third party submission is lodged. For off-label approvals, third parties may also make regulatory submissions for assessment by the regulatory agencies. If supported, these approvals are authorised via the issuance of a document separate to the official (or approved) product label, which outlines the approved use pattern, typically for a defined period.
Temporary approvals (off-label & emergency schemes)	In addition to standard registration procedures, several countries also operate schemes that can allow approvals to be granted for off-label use. These mechanisms are utilised not only for minor uses but also to allow rapid responses to emergency needs. Off-label provisions are provided generally to third parties where the registrant is not interested in seeking minor use registration. Approvals granted by these mechanisms are typically time-limited and may in some cases also be temporarily approved, with requirements on the provision of additional data during the life of the approval. In some cases, temporary approvals may be granted based upon international data alone, and with a requirement for local data to be generated during the term of the initial approval.
4. Research	
Data generation assistance schemes	Several countries have developed dedicated minor use programs that are specifically designed to assist grower groups and registrants in undertaking the necessary data generation and making of regulatory submissions. These programs may rely on government funding or may contain a level of co-investment between government, growers and registrants. Often government funds are needed to leverage private funds. In some countries, grower groups have mechanisms to generate funds through grower levies on production levels which in turn can be utilised to invest in various activities relating to research and development including data generation for minor uses. These programs are considered critical and, in some cases, may be the only mechanism to drive solutions for many minor uses that are not economically attractive to registrants. The most successfully recognised of these programs is the US IR-4 Project that has operated since 1963 (see **Box 6.2**). In that time the program has achieved over 10,000 approvals for use on food crops and another 10,000 on non-food ornamental crops. The IR-4 Project is internationally recognised as a model program for other countries seeking to develop national programs, or in processes of identifying, prioritising and generating data for minor uses.
5. Promotion of safer alternatives	
Reduced risk incentives	Some countries provide incentives for the registration of reduced risk pesticides, including biopesticides.

Incentive type	Details
6. Liability	
Liability waivers / disclaimers	Liability arising from the registration of minor uses is an economic disincentive for many agvet companies, and in some cases is the leading reason for not seeking registration of a particular use. To alleviate this disincentive, some countries have determined that uses such as third party authorisations and off-label uses are at the risk of the end user. Commonly the registrant is still liable for other components of the product such as its quality (formulation / composition) and its risks to human health and the environment.

SOURCE: OECD 2011, GUIDANCE DOCUMENT ON REGULATORY INCENTIVES FOR THE REGISTRATION OF PESTICIDE MINOR USE, SERIES ON PESTICIDES NO. 63, ENV/JM/MONO(2011)16

ACIL Allen consultations with industry indicate that the US IR-4 program is considered to be a very attractive way of addressing the minor uses problem as it deals effectively with market failures, and overcomes genuine barriers to research including cost-effective ways for applicants to collect data for minor use. A brief discussion of IR-4 and its funding model is provided in **Box 6.2**.

BOX 6.2 US IR-4 PROGRAM

Interregional Research Project No. 4 (IR-4) is a federally funded program (through USDA and Land Grant Universities) established in 1963 to conduct the research necessary for obtaining registrations of pest control agents needed for minor crops. IR-4 works with farmers, agricultural scientists, and extension personnel to conduct research and submit proposals to USEPA regarding tolerances for specific pesticides. The program has grown to include biological pest control agents and biochemicals. The IR-4 Program is headquartered at Rutgers University.[109]

The economic Impacts of the IR-4 Program was assessed in 2011.[110]The authors found that the IR-4 Project had been a pivotal resource in providing US residents a plentiful and low-cost array of vegetables, fruits, berries and tree nuts. It found that IR-4 supported 104,650 US jobs and increased annual US gross domestic product by $7.3 billion. The findings supported public investment in the IR-4 Program in alleviating an economic market failure, were the pesticide industry for minor-uses to be left to its own devices.

SOURCE: IR-4, UNDATED, ACCESSED ON 2 AUGUST 2017 AT HTTP://IR4.RUTGERS.EDU/

Liability issues are cited by respondents to the OECD survey[111] as a barrier to both chemical companies and third parties seeking registration for minor uses. The survey shows that, of the sixteen OECD countries that responded, only Canada had sought to address this issue in any substantive way, although several other countries including the Netherlands, Germany, the UK and the Slovak Republic sought to pass responsibility for any problems arising from off-label of other minor uses to the end user.

Canada responded that it provides for limitations on liability. The registrant may include a statement on the label and a further statement in the directions for use. Specifically:

- "The directions for use for this product for the use(s) described on this label were developed by persons other than (company name) and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program.
- (company name) itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed on this label.
- Accordingly, the buyer and user assume all risks related to performance and crop tolerance arising, and agree to hold (company name) harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described on this label".

The Canadian survey response noted that the limit-of-liability waiver was frequently used but had not, until then, been legally tested. CropLife International also responded to the OECD survey. They

109 IR-4 Program, undated, accessed on 4 August 2017 at http://ir4.rutgers.edu/

110 Miller SR and Leschewski A 2011, Economic Impacts of the IR-4 Project and IR-4 Project Programs, Center for Economic Analysis, Michigan State University, accessed on 4 August 2017 at http://ir4.rutgers.edu/Other/IR4EconomicImpact.pdf

111 OECD Working Party on Chemicals, Pesticides and Biotechnology 2011a, OECD Survey of Regulatory Incentives for the Registration of Pesticide Minor Uses: Survey Results, Document ENV/JM/MONO(2011)14, Series on Pesticides No. 62, accessed on 17 July 2017 at http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2011)14&doclanguage=en

wanted to see liability on the manufacturer restricted and suggested that countries should legislate so that liabilities are shared between the applicant, the regulator and the end user. The Australian response supported liability limitations, waivers and disclaimer statements on labels in relation to efficacy and crop safety, where the minor use was a grower-requested registration.

It is not known what steps have been taken in other countries since the OECD survey to implement this approach.

6.3 Australian measures to address minor uses

In response to an industry request, Australia introduced a minor use permit system in 1995 for uses where no relevant registered products or use patterns existed because registering the use pattern would not produce a sufficient economic return.

Five sectors make up the majority of minor use permit applications: vegetables, fruit and tree, non-crop situations, broadacre crops and forestry. Horticultural crops represent the vast majority of minor use permit applications, comprising more than half of all APVMA permit applications. There are currently over 1,000 minor use permits issued by the APVMA.

To assist in determining whether a proposed use is a 'minor use', the APVMA has outlined three criteria in its guidance material that are considered to assess eligibility for a minor use permit.[112] One of the criteria must be satisfied, and they are generally considered in the following order:

- The crop, animal or situation should not be a major use. A list of major uses has been defined for crop, animal or non-crop situations on the basis of:
  - Volume of commodity production
  - Area under cultivation
  - Dietary consumption
  - Value of crop or animal
  - Export quantities, or
  - Limited use within a major crop, animal or situation
- The proposed use meets the criteria for a limited use within a major crop, animal or situation. The criteria include:
  - Less than ten per cent of total crop area, number of animals, or area of situation, or
  - 10,000 hectares.

  Per annum criteria may also be applicable.
- Registration would not produce 'sufficient economic return'[113] where the applicant must demonstrate that there is insufficient economic return to consider registration of the product and / or use. Applicants must supply full costs and projected incomes associated with a particular use covering a period of no less than three years. This includes investment costs and return on investment.

Several approaches have been developed to facilitate the registration of greater numbers of minor use products in Australia:

- When situations arise where chemicals are needed for a use not specified on the label (off-label uses), the APVMA considers applications for permits that allow for the legal use of chemicals in ways different from those set out on the product label. In certain circumstances, the limited use of an unregistered chemical may also be allowed by permit. Off-label provisions are generally provided to third parties when the original registrant is not interested in seeking registration.
- Enhanced international collaboration includes development of equivalent zones for acceptance of international efficacy and residues data.

Unlike some other countries, registering a minor use in Australia does not extend data protection to all registered uses of the product. Data submitted in seeking approval for a minor use is treated in the same way as data submitted for a normal registration. If the minor use is the only use of the active

[112] APVMA not dated, accessed on 17 July 2017 at https://apvma.gov.au/node/10931

[113] Sufficient economic return means in relation to the costs of obtaining registration for a specific use pattern compared with the returns to the registrant from making the use available.

ingredient, then data is protected for 10 years. If not (e.g. an existing product) the period is between 3 and 5 years.

The key costs of *not* addressing the minor uses include:[114]

— Increased illegal use of other pesticides registered for major uses, which can result in adverse environmental, health and trade effects, and

— Animosity towards regulators.

6.3.1 Minor use funding

Users and affected industries may form consortia to seek regulatory approvals for off-label uses in the form of minor use permits. The process is described on the APVMA website.[115] Industry bodies, through their R&D programs, can coordinate the necessary data generation and regulatory submission for a large proportion of minor use permit applications lodged with APVMA. For example:

— Horticulture Innovation Australia is a major organisation which engages with its member industries to identify needs, prioritise projects, and find data generation and make regulatory submissions. The Minor Use Permit Pesticide Program is part of the National Nursery Industry Biosecurity Program funded by Horticulture Innovation Australia Limited using the Australian Nursery Industry levy and with support from the Australian Government.[116]

— The broadacre grains industry, through the Grains R&D Corporation has also, for number of years, sought to address minor use issues facing Australia's grain, oilseed and pulse industries through the use of off-label approvals.

6.3.2 Minor use risk assessment

In establishing the maximum residue levels (MRLs), the APVMA states that it considers all available data, including overseas data if available and determined to be relevant. This last point is a significant caveat which may be inhibiting more efficient processing of minor use proposals.

In considering permits for minor uses, the APVMA can extrapolate residue data between like commodities provided that the data is sound and a similar use pattern is being proposed. This allows the APVMA to establish temporary MRLs to enable permits to be issued for interim periods while additional local supporting data is generated, usually over two to three years. The APVMA claims that the level of data requested reflects the minimum required for sound decision making, while keeping regulatory costs for minor uses to a minimum. The APVMA has developed and published guidelines outlining residue data requirements for new uses. Making more use of MRLs determined overseas could be a useful way of reducing costs and improving efficiency.

During the course of this project, stakeholders consulted expressed concerns that, when assessing minor use proposals, the APVMA's environmental assessment looks at the most sensitive Australian species, which stakeholders consider is not always appropriate (e.g. for products to treat some domestic animals). Bioassays carried out offshore on foreign sensitive species should be acceptable. For minor uses, stakeholders also consider that assessments undertaken by overseas regulators should be adequate and recognition of the outcomes of those assessments should also be accepted by the APVMA. Stakeholders also considered that there should be separate procedures for companion animals.

6.4 Summary comparison of minor use incentives in selected countries

Countries provide different incentives to register minor uses of agvet chemicals. They are compared in **Table 6.2**. In some countries such as Germany, incentives are being used for nearly every minor use approved, and are used extensively for off-label third party uses.[117]

[114] Productivity Commission 2008, Chemicals and Plastics Regulation, Research Report, 2008. p. 213.
[115] APVMA, not dated, accessed on 17 July 2017 at https://apvma.gov.au/node/1114
[116] Horticulture Innovation Australia, not dated, accessed on 16 June 2017 at http://horticulture.com.au/wp-content/uploads/2017/02/Nursery-Papers-December-2016.pdf
[117] OECD 2011b, Op cit.

In reporting on the results of its survey, the OECD reported that some countries had suggested that minor use solutions needed to be provided in a more timely manner.[118] Expedited reviews could also make minor uses more economically attractive to registrants, particularly if expedited approval for a major use could be provided when a minor use was included in the same submission.

The OECD noted that fee reductions or waivers provided only a modest incentive, given the other costs involved in providing data for a minor use approval.

At the time of the OECD survey (2011) the EU had just introduced new regulations[119] on a data protection extension for minor uses. Data protection periods can be extended by three months for each minor extension of use added by the authorisation holder (when submitted within five years of product authorisation). It is not yet clear how successful this measure has been in encouraging the registration of minor uses.

TABLE 6.2 MINOR USE INCENTIVES IN SELECTED COUNTRIES

Incentives	Australia	EU	UK	Germany	USA	Canada	New Zealand
Data protection		√		√	√	√	
Expedited reviews (fast track)			√			√	
Fee reductions or waivers					√	√	
Extrapolation and mutually accepted data	√	√	√	√			√
Reduced number of trials	√						√
Third party registrations							√
Temporary approvals (off-label / emergency schemes)	√		√				
Data generation assistance schemes	√				√	√	

SOURCE: ACIL ALLEN REVIEW OF VARIOUS DOCUMENTS

The US approach to facilitating access for minor uses through the IR-4 program is probably the most successful measure.

6.5 Conclusions

It is difficult to reach conclusions about the relative success of the various measures to encourage minor uses. Theoretically, there should be a correlation between the incentives offered and the number of minor uses registered. However, each of the national (and EU member country) markets has its own characteristics in terms of market size and barriers to minor use approvals.

It has been suggested[120] that Australia is currently missing out on up to 50 per cent of the potential new technologies to which competitors in Europe and the USA have access. Comparing the extent of minor use approvals in different countries is complicated by differences in definition between countries as to what constitutes a minor use. Even if this problem could be solved, simple comparisons of the numbers of minor uses approved in different countries would be meaningless because of differences in the crops being grown, pest problems being addressed, etc. A product-by-product comparison would again be very difficult, even if the data were available.

Australia could draw on the definitions of minor use in other countries to develop a more detailed definition than the one currently in use.

Australian policy measures to encourage and assist minor uses have changed over the years. A mix of measures is required and need to be in place for some time before their effects can be assessed.

118 OECD 2011b, Op Cit
119 Articles 59 – 62 (Chapter 5) and Article 80 of Regulation (EC) No 1107/2009
120 Rainbow R 2017, Delivery of Access to AgVet Chemicals Collaborative System —AgVet Collaborative Forum, a report to the Rural Industries R&D Corporation

7 VETERINARY AND HUMAN PHARMACEUTICAL ARRANGEMENTS COMPARED

For the most part, the application of patent law and IP arrangements to veterinary pharmaceuticals parallels the application of laws to human pharmaceuticals, with outcomes dependent on the particular aspects in each case. That said, there are several areas where they differ. These areas include patent term restoration or extensions, data exclusivity, springboarding and evergreening. However, *registration* arrangements for human and veterinary products differ significantly.

This chapter summarises the ways in which registration and IP arrangements for veterinary and human pharmaceuticals differ.

7.1 Legislative frameworks

In Europe and North America, veterinary chemical products (veterinary medicines) are regulated by agencies responsible for human medicines. In Australia, however veterinary chemical products are defined in the Agvet Code and are regulated by the APVMA.

7.1.1 European Union

In the European Union, veterinary products are regulated under a number of Directives, which include the following considerations.[121]

- The general data requirements and performance of tests are included in Directive 2009/9/EC (which amends the original Directive 2001/82/EC)[122]
- The Directive also provides information to sponsors or applicants on the presentation and content of the application dossier[123]
- Monographs or assessments prepared by the European Medicines Agency (EMA) address aspects as set out in the Directive, and
- Biocide products are regulated by the European Chemicals Agency (ECHA) and legislated under BPR Regulation (EU) 528/2012.

The use of centralised and decentralised procedures within and between European Union Member States is unique to the EU.

7.1.2 North America

In the USA, veterinary medicines are approved by the CVM at the USFDA, while veterinary immunobiological products are regulated by the Center for Veterinary Biologics (CVB) at the Animal

[121] Veterinary products are included in Directive 2001/82/EC and Directive 90/167/EEC outlines the conditions for preparation and marketing of medicated feedstuffs in the EU.
[122] Variations of authorisations are in Directive 2009/53/EC; Criteria for exemptions of certain products for food-producing animals from requiring a veterinary prescription are in Directive 2006/130/EC.
[123] Chapter II: Presentation of Particulars and Documents, page 34, Commission Directive 2009/9/EC.

and Plant Health Inspection Services (APHIS) at the USDA. In Canada, veterinary medicines and immunobiologics are regulated by the VDD at Health Canada. Both the CVM and the VDD operate under food and drug legislation that includes human and veterinary medicines, food, devices and cosmetics.

7.2 Patent term restoration or extensions

The jurisdictions covered in this report — the European Union, UK, USA, Canada, Australia, and New Zealand — provide for a standard patent term of twenty years, and all of them except New Zealand provide for extensions of protection for certain products that are subject to regulatory approval before they can be marketed.

For the European Union and the UK, SPCs are available that extend the protections of patents for medicinal and plant protection products to cover the period needed for regulatory approval of the product, typically to a maximum of five years.

Australia similarly provides for patent term extensions, but limited to human pharmaceutical substances, to account for the period needed for regulatory approval to provide an effective patent life of 15 years.

Under the Comprehensive Economic and Trade Agreement (CETA) with the EU, Canada will provide patent term extensions of two years for qualifying pharmaceutical products (c.f. five years in the EU). Patent term extensions are not available in New Zealand.

As noted earlier, the Productivity Commission reported on Intellectual Property Arrangements in 2016[124]. Medicines Australia[125] claimed in its submission to the Productivity Commission inquiry that there is a strong case for granting patent term extensions. The average effective patent life for pharmaceutical products with an extension of term in Australia is between 13 and 14 years, while the median patent receives 15 years of effective life.[126] A summary of patent extensions is provided in **Table 7.1**.

TABLE 7.1 SUMMARY OF PATENT EXTENSIONS

Country	Nature	Coverage	Maximum length of extension (years)	Maximum effective life (years)
Australia	Products claims only (unless R-DNA process used)	Only human pharmaceuticals, extended only once	5	15
European Union	Product, process and use claims	Extends to – human pharmaceuticals – veterinary pharmaceuticals – plant protection products	5	15
USA	Product, process and use claims	Extends to – human pharmaceuticals – veterinary pharmaceuticals	5	14
Canada	Product claims only	Extends to – human pharmaceuticals – veterinary pharmaceuticals	2	10

SOURCE: UPDATED VERSION BASED ON CHRISTIE AF ET AL, 2002, REVIEW OF PHARMACEUTICAL PATENT EXTENSION AND SPRINGBOARDING PROVISIONS IN VARIOUS JURISDICTIONS, ACCESSED ON 2 AUGUST 2017 AT HTTP://ACHRISTIE.COM/WP-CONTENT/UPLOADS/2011/08/IPRIA-PATENT-EXTENSION-REVIEW-2.PDF .

124 Productivity Commission 2016, Intellectual Property Arrangements, Report No 78, September 2016.
125 Medicines Australia 2013. Submission to the Pharmaceutical Patents Review accessed on 16 June 2017 at https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20121218-sub-Pharmaceutical-Patents-Review.pdf
126 Harris T, Nicol D, Gruen N 2014, Pharmaceutical Patents Review Report 2013, pp 204-5.

The Productivity Commission noted that extensions of term for human pharmaceuticals in Australia were intended to attract pharmaceutical research and development investment to Australia and to improve incentives for innovation by providing an effective market life for pharmaceuticals more in line with other technologies. The Productivity Commission considered that these arrangements have had little effect on innovation in Australia. It found that "poor targeting means that more than half of new chemical entities approved for sale in Australia enjoy an extension in patent term, and consumers and governments face higher prices for medicines".

For human pharmaceuticals, Australian legislation aims to provide an effective patent life of fifteen years from the first regulatory approval date to the expiry date of the extension of term, subject to a maximum twenty-five year patent term. This is similar to the situation in European Union.

In relation to product claims, the US extension provisions and the EU extension provisions apply to a broader class of patent claims than the corresponding Australian provisions. In particular, the US extension provisions apply to patents which claim methods of manufacturing or using a 'product', in addition to claims to the 'product' itself: Similarly, by virtue of the definition of 'basic patent' in the EU SPC Regulations, applications for extensions through SPCs may be made by reference to patents which protect the active ingredient of a medicinal product, a method of producing the active ingredient of a medicinal product and an 'application' (i.e. use) of a medicinal product.

In contrast, the Australian extension provisions apply only to 'product claims' (claims to the pharmaceutical substance *per se*) and do not extend to 'process' or 'use' claims (methods of manufacturing and use claims respectively), except to the extent that recombinant DNA processes may be subject to patent extensions. The significance of these differences relates to the relationship between the Australian extension provisions and the Australian springboarding provisions (discussed below). In relation to nature of substances covered, in contrast to Australia, the US extension provisions cover the active ingredient of new animal drugs and veterinary biological products. Similarly, in the EU, extensions through SPCs are available for substances used for treating and diagnosing disease in animals (and are also available in respect of patented plant protection products).

No further extensions beyond the five year term are possible in Australia and USA. This is different to the situation in most EU countries, which generally allows for an additional six month extension of the basic SPC term for paediatric medicines.[127]

However, the uniformity in *maximum* length of extension does not necessarily result in uniform lengths of extension (see **Table 7.1**). This is due to the use of different frames of reference and different methods used to calculate the length of extension.

7.3 Regulatory data protection

Australia

In Australia, the commercialisation of human pharmaceuticals and veterinary chemical products involves obtaining regulatory and marketing approval based on proof of safety, quality and efficacy. The Therapeutic Goods Administration (TGA) has responsibility for human pharmaceuticals and the APVMA for agvet chemicals.

For human pharmaceuticals, the data exclusivity regime is set out in section 25A of the *Therapeutic Goods Act* 1989, which provides that 'protected information' about other therapeutic goods may not be used when evaluating a new therapeutic good for registration.

Under section 25A, 'protected information' is referred to as information, not in the public domain, about an active component relating to an application to register therapeutic goods. Section 25A(3) of the TGA Act defines an 'active component' as a substance that is, or one of the substances that together are primarily responsible for the biological or other effect identifying the goods as therapeutic goods. The prohibition on the use of this data lasts five years from the date the therapeutic goods were first

[127] Pizzeys 2009, Pharmaceutical extensions in Australia, A reference guide, accessed on 20 August 2017 at http://www.pizzeys.com.au/Articles/Pharmaceutical%20Extensions%20in%20Australia.pdf

registered. However, the prohibition applies only where there are no other therapeutic goods 'consisting of or containing' the same active component already on the register.

For human pharmaceuticals, **five years** of data protection is provided for therapeutic goods containing a new active component where no other therapeutic goods consisting of, or containing that active component were included in the Australian Register of Therapeutic Goods. An "active component" is defined as a substance that is, or substances that together are, primarily responsible for the biological or other effect identifying the goods as therapeutic goods. Data exclusivity or protection is not provided for new dosage forms, routes of administration, indications or combinations with other active ingredients.

In contrast to the arrangements for human therapeutics, veterinary chemical products get up to **10 years** data protection in relation to an application to register a new active constituent (i.e. an active constituent that was not a previously endorsed active constituent at the time of registration), or a product containing a new active constituent, where that product has been accepted for evaluation before the active had been approved.

The exclusivity periods apply to confidential information provided under the Act or Agvet Code in support of the application for the registration of a product. The period of data protection commences from the date on which the new product is registered under the Act. The effect is that generic competitors are blocked for the period of exclusivity from using an innovator company's data in support of their own application for approval of an equivalent product.

EU

The EU's pharmaceutical legislation and data exclusivity system for original medicines provides a period of data protection of 8 years (protecting against filing of a generic application), and then an additional 2 year exclusivity provision (protecting against marketing of the generic) for marketing authorisation applications made since November 2005. This is the period of time during which a generic company may not market an equivalent generic version of the originator's pharmaceutical product (although their application for authorisation may be processed during this period, such that they are in a position to market their product on the expiry of this additional 2 year period).

An additional year may be obtained in a number of circumstances, such as where the innovator company is granted a marketing authorisation for a significant new indication for the relevant medicinal product. In such situations, the generic company can only market their product after eleven years from the grant of the innovator company's marketing authorisation.

This effective 10-year exclusivity period can be extended by an additional one year if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison to existing therapies. This is referred to as the '8+2+1 formula' and is applicable in all EU and EEA Member States for innovative products. Before 2005, data exclusivity lasted up to 10 years.

For marketing authorisation applications made before November 2005, the period of data exclusivity varied between EU member countries — it was either 6 years or 10 years.

As noted earlier, for new veterinary chemicals, EU provides a data protection of 10 years, with an additional year for applications to use already authorised products for other species, up to maximum of 18 years.

USA

In the USA, through the Hatch-Waxman Act, generic manufacturers were given the benefit of earlier entry possibilities in exchange for pioneer companies able to retrieve some of the years of valuable patent life lost due to the regulatory approval process. More specifically:

- Under US patent law there is an option for the patentee to take its patent term extension for a food producing animal indication even if a companion animal indication is approved first. This is only for the first approved use — no such extensions exists for human pharmaceutical patents
- Genetically engineered animal drugs are excluded from patent term restoration — there is no such exclusion in the case of human therapeutics

— Genetically engineered animal drugs are excluded from safe harbour provisions in the USA. There is no such exclusion in the case of human therapeutics
— In general, the second patent term restoration for same active ingredient is prohibited in the USA for animal drugs, but not for human drugs
— Unlike human drugs, there is no paediatric exclusivity for animal drugs in the USA, and
— Orphan drug status–for rare diseases–can be obtained under the US *Orphan Drug Act*, where the holder is entitled to several specified benefits. This does not extend to animal drugs. However, animal drugs meeting certain criteria have the possibility to obtain so called Minor Use / Minor Species (MUMS) designation, which provides seven years exclusivity for that indication.

The length of time that FDA grants new drug exclusivity depends on the type of exclusivity. Hatch Waxman exclusivity (5-year, 3-year, and 180-day) is described in 21 C.F.R. 314.108.[128] There are four types of exclusivity that fall under the NDA statutory requirements:

— Orphan Drug Exclusivity — 7 years
— New Chemical Exclusivity — 5 years
— Other Exclusivity — 3 years, and
— Paediatric Exclusivity — 6 months.

As noted earlier, veterinary chemicals follow similar data protection periods — orphan veterinary drug exclusivity for 7 years, new chemical entity exclusivity for 5 years, general antibiotic incentives now provided with exclusivity for 5 years, and new clinical investigation given exclusivity for 3 years.

Canada

Canada currently provides eight years of data protection for an innovator drug. This applies to both biologics and conventional small molecule pharmaceuticals. This same time period applies to veterinary pharmaceuticals.

New Zealand

New Zealand provides a data protection period of 5 years for new human pharmaceutical products. Data protection is not available for data relating to new uses or new formulations of known active ingredients for human pharmaceutical products.

Similar to Australia, New Zealand provides a data protection of 10 years for new veterinary chemical products as discussed earlier in this report.

A comparison of regulated data protection period for human and veterinary pharmaceuticals are provided in **Table 7.2**. As noted, the data protection period for human and veterinary pharmaceuticals differ and there are number of reasons for the differences. Some of them include:

— Ethics — it is considered unethical under the Declaration of Helsinki to undertake duplicative clinical trials on humans in different countries[129]
— Number of species
— Relative R&D costs and risks, and
— Others.

From an economic perspective, industries where the R&D process is costly and risky need longer data protection periods to realise the benefits of new products compared to those industries where innovation is easier and relatively less costly.

[128] See https://www.fda.gov/downloads/drugs/developmentapprovalprocess/smallbusinessassistance/ucm447307.pdf accessed on 20 August 2017.
[129] World Medical Association 2013, Ethical Principles for Medical Research involving human subjects, JAMA 2013(310(20: 2191-2194.

TABLE 7.2 DATA PROTECTION FOR NEW PHARMACEUTICAL PRODUCTS

Country	Human pharmaceuticals	Veterinary pharmaceuticals
Australia	5 years	10 years
EU	8+2+1 years	10+1 years
USA	Orphan drug exclusivity for 7 years, new chemical entity exclusivity for 5 years, new clinical investigation exclusivity for 3 years and paediatric exclusivity for 6 months.	Orphan drug exclusivity for 7 years, new chemical entity exclusivity for 5 years, general antibiotic incentives now exclusivity for 5 years, new clinical investigation exclusivity for 3 years.
Canada	8 years	8 years
New Zealand	5 years	10 years

SOURCE: VARIOUS SOURCES

7.4 Springboarding

Chapter 3 discussed springboarding in relation to agvet products. This section compares springboarding provisions in selected countries. The US, Canadian and Australian legislation permits the use of springboarding for human and veterinary pharmaceuticals. The EU allows springboarding, however, the scope and timing of the exemption varies between countries. A summary of springboarding provisions in selected countries is provided in **Table 7.3**.

TABLE 7.3 SPRINGBOARDING PROVISIONS

Country	Human	Veterinary	Timing	Type of patent	Purpose of use
Australia	Yes	Yes	At any time during the patent term and patent extension term	Since 2012, any technology	Solely for or in connection with obtaining an approval required by a Commonwealth, State or Territory law to exploit a product, method or process
USA	Yes	Yes, except certain new animal drugs	At any time during the patent term and not apply during the patent extension period	Any patent	Solely for uses reasonably related to the development and submission of information under a Federal law that regulates the manufacture, use of sale of human drugs or veterinary biological products
Canada	Yes	Yes	At any time during the patent term	Any patent	Solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product
New Zealand	Yes	Yes	At any time during the patent term, patent extensions are not available in New Zealand	Any patent	

SOURCE: UPDATED BASED ON CHRISTIE A F ET AL (2002), ALLENS (2006) AND PIZZEYS (2009)

In the USA, New Zealand and Canada, springboarding is allowed at any time during the patent term for any type of patent. In Australia, springboarding can occur at any time during the patent or patent extension term. In 2012, springboarding became possible in Australia for all technologies where regulatory approval is required.

Australia, Canada and New Zealand allow springboarding in relation to any patent for the purposes of obtaining domestic or foreign regulatory approval. In the USA, springboarding is permitted only in relation to obtaining domestic regulatory approval for both pharmaceuticals and veterinary medicinal products.

Overall, the springboard provisions in selected countries are consistent — springboarding is only allowed in connection with obtaining regulatory approval of a generic version of the patented product. Use of a patented product beyond this purpose may constitute patent infringement.

7.5 Conclusions

The major differences between the registration and supporting IP arrangements for human and veterinary products lie in:

- **Administrative responsibility**: The international agencies responsible for veterinary product regulation are generally also responsible for the regulation of human pharmaceuticals.
- **Patent extensions**: The EU, USA and Canada allow patent extensions for both veterinary and human pharmaceuticals (albeit in different ways) — Australia and New Zealand do not.
  - The EU allows patent extensions for plant protection products — Canada, Australia, the USA and New Zealand do not
  - Canada's patent extensions are less generous than those provided by the USA, EU and Australia
- **Regulatory data protection**: For agvet products, Australia provides 10 years of data exclusivity from the date of registration. For human pharmaceuticals the data protection period is 5 years.
  - In the EU, pharmaceutical products generally receive 8+2+1 year data protection while agvet products receive 10+1 year data protection.
  - In the USA pharmaceuticals can receive 5 or 7 years of data protection
  - In Canada pharmaceuticals can receive 8 years of data protection
  - In New Zealand, 10 years of data exclusivity is provided for agvet products from the date of registration. For human pharmaceuticals the data protection period is 5 years, equivalent to the Australian data protection period.
- **Springboarding**: Australia, New Zealand and Canada allow springboarding for both human pharmaceutical and veterinary products, as does the USA (with some exceptions). The EU allows springboarding, however the details vary between countries.

It is difficult to draw conclusions from the above comparisons. Given that the EU and the USA are both large markets with significant agvet and human pharmaceutical manufacturing activity, their regulatory practices are likely to be influenced by the factors listed immediately above. Canada may be the most relevant comparator, but regulatory practices in Canada appear to be influenced by its US neighbour. New Zealand and Australia are somewhat different.

Australia's springboarding provisions for agvet products have been in place for only a few years and it may take more time before their impact on encouraging generics can be seen.

8 POLICY CONSIDERATIONS

This report examines how Australian agvet product registration processes, IP, data protection and CCI arrangements compare with those in selected OECD countries. Registration processes and related arrangements have a significant impact on the competitiveness of Australia's agriculture sector. One major objective of this project is to propose policy options to improve Australian agricultural producers' access, through registration by the APVMA, to innovative agvet chemicals while also supporting access to generic products.

Agriculture is an important pillar of Australia's economy and, as such, it needs good access to both high quality innovative and generic agvet chemical products. The Australian Government is committed to reforming agvet regulation to ensure farmers get access to these agvet chemicals to support agricultural profitability and sustainability.

The study has taken account of the very small size of Australia's agvet chemical mark — 1.5 per cent of the global market. The small size of the Australian agvet chemical market means it provides relatively small returns to manufacturers, which are predominantly from Europe and the USA and focused on those much larger markets. Nearly half of Australia's pesticides are imported. Veterinary products are much less import dependent, but across both sectors the value of imports is rising. All agvet chemical products, whether domestically produced or imported, must be assessed and registered by the APVMA before they can be made available to Australian farmers.

In regulating agvet products, Australia needs to both:

— Ensure that original product manufacturers are encouraged to register their products in Australia and at an early stage in product life cycles, and

— Provide generic manufacturers with the opportunity to enter the Australian market soon after patent protection for the original product has lapsed.

It is clear from the preceding chapters and analysis, and previous reviews and stakeholder inputs that, while there are some areas of Australian agvet regulation that are internationally competitive, there are other areas that are in need of targeted reform.

KEY FINDING 1 AN INTERNATIONALLY COMPETITIVE AGVET REGULATORY SYSTEM

In order for Australia's agriculture sector to be internationally competitive, fast access to agvet chemicals is essential. To achieve this, the relevant regulation needs to be internationally competitive in relation to costs, administrative hurdles, application processing time, intellectual property and data protection, and incentives. Overall, the analysis has found that Australia's arrangements are internationally competitive in several of these areas.

8.1 IP, data protection, CCI and minor uses

IP, data protection, CCI and minor uses are some key matters that this project was asked to examine. Australia's IP and data protection arrangements have been reviewed by the Productivity Commission (2016). Other organisations have made numerous submissions on these matters to government reviews over the past decade. This study has found that Australia's agvet chemical regulation — as it relates to intellectual property and data protection — is comparable to, and competitive with that provided by the EU, the US, Canada and New Zealand. As highlighted in previous chapters, patent protection across these nations lasts for twenty years and regulatory data protection for new active ingredients stands at 10 years. While there are some differences in the extent of data protection available for minor uses, which in part reflects the variety of ways in which this issue is addressed, Australia's IP and data protection arrangements are generally appropriate for our market.

Increasing the patent term for agvet products is sometimes suggested as an indirect incentive to increase Australian registrations of innovative, new agvet chemicals. US Hatch-Waxman type legislation in relation to extensions of term to compensate agvet chemical manufacturers for regulatory and patent approval delays would increase the complexity of the system, have no impact on regulatory delays within the APVMA and would increase costs for agricultural producers. There is no reason to believe that such legislation would increase the numbers of new agvet products being registered in Australia. Furthermore, the Australian Patent Office performs well by comparison with its counterparts in major OECD countries, so delays in patent approvals are not an issue.

When it comes to patent term extensions, agvet products are different to human pharmaceuticals because, in Australia, the Government sets the price and meets most of the cost of human pharmaceuticals. Decisions on patent terms for human pharmaceuticals are determined by factors which do not apply to agvet products. Arguments for agvet patent term extensions sometimes refer to the need to encourage R&D. Australia provides incentives for business R&D and assistance to growers through the Rural R&D Corporations.

KEY FINDING 2 AUSTRALIA'S AGVET IP AND DATA PROTECTION ARRANGEMENTS

Australia's agvet IP and data protection arrangements are generally appropriate and comparable to, and competitive with, those in the EU, the USA, Canada and New Zealand. There is no compelling case for change.

Confidential commercial information

There is a need to clarify CCI in Australia. The practices in other countries suggest the following approach:

- Define a list of categories of information which will be treated as CCI. These would include manufacturing processes and trade secrets. See the analysis of CCI in other countries and the documents referenced for what should be included in this list.
- Define a second list of categories of information and data which will not be treated as CCI. This includes name and structure of active ingredients and test results. Again, other countries have already developed such lists.
- Allow a third category where an applicant may seek to have information or data not falling in the two areas defined above classified as CCI. The applicant would have to make a case for this categorisation. The APVMA would apply a set of published criteria in deciding whether to accept the proposed classification, appealable through the Administrative Appeals Tribunal.

KEY FINDING 3 CLARIFYING CCI

There is a case for adopting an approach to defining CCI based on the approach used in some other countries where some information and data is automatically categorised as CCI and some categorised as not CCI.

Minor uses

For minor uses, Australia provided extensions until 2014 to data protection for registration of minor uses. This provision was removed because there was no take-up of it and it was considered to have been ineffective. However, there are a number of factors which influence minor use registration including small market size, the costs of trials and testing and liability concerns.

As chapter 6 shows, securing agvet products for minor uses is a problem even for large countries such as the USA. What that chapter shows is that no country relies on just one measure to address the minor uses problem. Options for Australia include re-introducing data protection extensions but with greater targeting, such as limiting their availability to applications lodged within the first few years after the original approval. This might encourage more minor uses to be sought at the time of initial registration (as in the USA).

Based on the research undertaken for this report, the APVMA's assessment processes for minor uses seem to be as detailed and time consuming as for a major use, even though the risks and hazards are often significantly lower. More specifically, the APVMA appears to apply the same effort to permits as for registrations. Stakeholder organisations complain that the costs involved in obtaining APVMA permits for minor uses are too high and that the process is too slow. Data requirements for these uses could be reduced in many cases because they are also low risk.

The Commonwealth Government-funded program providing grants to support organisations preparing the case for minor use registrations draws on a very successful US model (IR-4) and is supported by stakeholders. This program should continue with additional funding (the need for this support appears to exceed the resources that are available).

The incentives to new agvet product manufacturers for early registration of minor uses could take the form of SPCs (as in Europe), or reduced fees / levies in relation to the minor uses. These incentives could be structured so as to be limited to minor uses included in the original approval application, or sought during a short period (five years) after the original application is lodged. Of course, if this were to delay approval of the original application, any incentive effect would be negated.

Another measure to encourage minor uses which could be considered is limiting the liability of the manufacturers in the way that Canada has done, through disclaimers on the label and in the instructions for use. However this approach would need to be examined in the context of Australian Consumer Law and other relevant Australian legislation, which is different to that in Canada.

The analysis presented in this report suggests that the best strategy for Australia is to provide a regulatory approach where there is certainty about the requirements of the regulator and which is at least as fast as competitors such as Canada and involves total costs that are less than Canada and the USA.

KEY FINDING 4 INCENTIVES FOR MINOR USES

A mix of measures are needed to facilitate access to agvet products for minor uses:

- The Government's program to assist the process of obtaining registration and permits for minor uses should continue
- Adopting the Canadian approach to limiting liability of manufacturers in relation to minor uses should be explored,
- Minor use registration and permits should be fast-tracked by the APVMA.

8.2 Registration processes

Agvet chemical registration arrangements were also overviewed across the selected countries to help contextualise associated IP and data protection provisions and, more broadly, to facilitate consideration of ways to improve Australian registration rates for innovative agvet chemicals while supporting access to generics. The outcome of this overview and analysis is a strong sense that elements of Australia's agvet regulatory framework, particularly the time taken and complexity of local assessment and registration processes, are not always internationally competitive.

This conclusion echoes the recent Productivity Commission inquiry, which observed that the regulation of agvet chemicals has been subject to numerous reviews, and subsequent reforms, but that concerns remain. The concerns are primarily about unnecessarily lengthy, complex and duplicative registration procedures.[130]

The Commission recommended that the APVMA increase its use of international assessments and decisions for products already registered by trusted comparable regulators overseas. While it is noted that the APVMA is seeking to make operational improvements, the evidence examined in the preparation of this report supports the findings published by the Productivity Commission in 2016. Delays in registration directly affect the ability of suppliers of agvet chemical products to obtain a commercial return in the Australian market within patent terms, with flow-on impacts including some overseas companies starting to bypass the Australian market. In ACIL Allen's opinion, these issues are strong disincentives to registering agvet chemicals in Australia and should be addressed.

Acceptance of hazard data from one or more internationally recognised regulators which draw on best practice standards (e.g. USA or the European Union) should be considered to meet aspects of the APVMA requirements. The Therapeutic Goods Administration appears to be well ahead of the APVMA in this regard.[131] If the APVMA considers that legislative action is needed to protect decisions based on the acceptance of such data, then the legislation should be amended.

KEY FINDING 5 USING DATA AND ASSESSMENTS FROM OVERSEAS REGULATORS

There is scope for the APVMA to make greater use of data, analyses and assessments undertaken for / by trusted overseas regulators. This information should be requested from applicants and should be used to expedite Australian approval processes.

Regulatory delays could be reduced by the APVMA focusing more of its limited resources on high-risk products, and simplifying procedures for low-risk products as has been done in Canada and the USA (see **Table 4.1**) and the UK (see **Table 5.3**). In relation to APVMA processes, minor actions such as updating applicant details in APVMA systems could be better managed through a self-service web-based approach, reducing time delays and administrative burden being placed on all parties involved.

The more efficient processing of low risk agvet product proposals would provide immediate gains and allow the APVMA to focus more of its efforts in areas where more detailed attention is justified, consistent with the Productivity Commission's 2016 comments on fit-for-purpose regulation. There is a strong case for bringing Australian handling of low risk proposals into line with some of the best practices in other countries, described in this report.

Procedural changes are needed to achieve faster throughput and to accelerate the processing of applications for companion animals, golf course chemicals, household and anti-fouling chemicals. This aligns with the concept of responsive regulation. Some work on simplifying low risk proposals has already been done by the regulator, but this needs to be provided with additional resources and accelerated.

130 Productivity Commission 2016, Regulation of Australian Agriculture, Inquiry Report No. 79, 15 November 2016.

131 See for example TGA, 2016, Consultation: Criteria for comparable overseas regulators, accessed on 2 August 2017 at https://www.tga.gov.au/consultation/consultation-criteria-comparable-overseas-regulators

The APVMA should accelerate the development of "standards"[132] (in particular, standard application forms for some categories such as for anti-fouling paints). These need to be simpler, shorter and more widely applicable than the example provided to ACIL Allen. If designed appropriately, these standards have the potential to reduce the time and cost involved in securing approvals for low risk products.

Self-assessment of some low risk product categories should be permitted. Relevant categories would include consumer products which are not going to be used on farm crops or food animals. When a product approved for crop use (or golf course use) is reformulated for home garden use, self-assessment could be appropriate.

In ACIL Allen's opinion, there is a culture within the APVMA to avoid rather than manage risks. The project team heard many examples during consultations about the unwillingness of staff to tolerate any risk associated with an application. This approach is sub-optimal and contrary to effective regulation. It can lead to significant demands for additional Australian data and to reviews of data that has been previously reviewed and accepted by North American and / or European regulators. Organisations consulted for this project all agree that this is unnecessary, inefficient and time consuming. There is a need to scale the level of regulatory effort to the level of risk as noted above.

It is ACIL Allen's view that APVMA staff need assurance that where no uniquely Australian issue is evident, they can and should rely on data and data assessments by US and European regulators. In particular, hazard assessments involving toxicity, effectiveness and chemical data should not be reassessed.

Commonwealth committees which have a role in the assessment process (e.g. the Advisory Committee on Chemicals Scheduling and the Advisory Committee on Medicines Scheduling, which meet only three times each per annum) need to meet more often. The current schedule appears to be a source of unnecessary delays, impacting on the time taken by the APVMA to assess agvet products, although early engagement with the scheduling process is possible. Agvet companies should be able to submit material directly (as do pharmaceutical companies) to these Committees.

ACIL Allen understands that crop grouping is another area in which the APVMA has been undertaking work that could result in savings of time and effort. Work on crop grouping needs to be completed and implemented so that the APVMA practices in this area align with those internationally.

APVMA import consents should not be required for an unapproved active or an unregistered product where this is for use under an APVMA permit, or for use under the direction of a veterinary surgeon. Importers undertaking these activities could, if necessary, be required to lodge details on the APVMA website.

8.3 Other considerations

Legislation and regulation

As noted in the introduction of this report, the Productivity Commission has pointed out that regulation should be fit-for purpose. It should be:

— **targeted** — the scope of the regulation (that is, who or what the regulation applies to) should be clear and appropriate for addressing the regulatory problem

— **evidence-based** — there should be an apparent and demonstrable connection between the content of the regulation and the regulatory objective, and

— **proportionate** — the burden imposed by the regulation on government agencies and the public should be proportionate to the regulatory outcome being sought.

The complexity and drafting of the agvet chemical legislation is, in itself, a significant barrier to providing Australian agricultural producers with timely access to innovative agvet chemicals and generic products. ACIL Allen notes that the Deputy Prime Minister announced a comprehensive legislative review in an interview on 27 April 2017. The team which prepared this report found the Act, Regulations and Code difficult to navigate and unnecessarily complex. There is a strong case for simplifying the complexity of the legislation. Unnecessary complexity in data protection could be

[132] This use of the term "standards" is not related to Australian Standards or to the work of Standards Australia.

removed and the wording simplified. For example, there are three different categories of protected data with different provisions for managing each scattered throughout the legislation. It is also difficult to see why the legislation needs to refer to patents or patented chemicals — patents are adequately covered in the *Patents Act*.

In the longer term, the legislation needs to be rewritten. In 2016, the Federal Court judge hearing *Abbey Laboratories Pty Ltd v Australian Pesticides and Veterinary Medicines Authority [2016] FCA 704* described it as a "legislative labyrinth that defies comprehension by mere mortals" and a "legislative morass".

KEY FINDING ES 4 LEGISLATIVE REVIEW

The legislative review announced by the Deputy Prime Minister is urgently needed. The legislation and regulations urgently need to be simplified and rewritten.

Administrative issues impacting on APVMA performance

ACIL Allen understands that the APVMA is undertaking a project to improve its registration processes and that this is due for completion in late 2017. The APVMA should continue to be funded by the Commonwealth to complete this work as soon as possible (in recent years some $15 million has been provided). The new procedures should provide a systematic approach to processing applications, with appropriate documentation.

Stakeholders consider that the current pre-application process adds between four and five months to the process for no detectable gain. Stakeholder organisations consulted for this report want these to occur in a shorter time frame and to be given greater certainty about the process and timetable which will be followed in the assessment phase.

ACIL Allen also understands that the APVMA's information technology systems are being upgraded. The project team has been advised that there are currently inefficiencies in data handling and the recording of assessment outcomes. The information technology systems upgrade needs to be accelerated requires investment by the Commonwealth Government. The result should be significant gains in administrative efficiency and regulatory productivity.

Stakeholders are critical of the demise of ongoing consultative arrangements. It is crucially important that regulators maintain formal contact with stakeholder organisations. To this end, the APVMA should re-establish industry and expert consultative arrangements.

A CONSULTATIONS WITH STAKEHOLDERS

ACIL Allen has consulted the organisations listed in **Table A.1** in preparing this report.

TABLE A.1 CONSULTATIONS

Number	Institution or organisation
1	ACCORD Australasia
2	Animal Medicines Australia
3	Australian Paint Manufacturers Federation
4	Australian Pesticides and Veterinary Medicines Authority
5	Chemistry Australia (formerly PACIA)
6	CropLife Australia
7	Department of Agriculture and Water Resources
8	Department of Industry, Innovation and Science
9	IP Australia
10	National Farmers Federation
11	New Zealand Ministry for Primary Industries
12	Productivity Commission
13	Veterinary Manufacturers and Distributors Association

B

APVMA TIMEFRAMES AND FEES

The material in this Appendix is drawn from the APVMA website: https://apvma.gov.au/node/1088

B.1 Introduction

The assessment period in which the APVMA is required to determine an application varies depending on the complexity of the application. The legislation prescribes the assessment period for most application types; however, depending on the type of application, the assessment period may be extended in certain circumstances.

The assessment period for an application for approval, registration or variation commences on the day:

- the notice advising that an application has passed preliminary assessment is issued, provided that there is no requirement to provide copies of the application or pay an outstanding amount of fees or
- the applicant complies with a notice requesting the balance of fees or additional copies of the application.

As soon as practical after the commencement of the assessment period, APVMA aims to determine:

- if an application should be re-categorised to ensure that the item and level of module assessment originally identified is appropriate
- if argument provided in the application in lieu of data is appropriate
- if there are any obvious and critical information gaps in the dossier

The assessment period may change if one of the circumstances listed below applies to the application

- If a notice requiring specified information under section 159 of the Agvet Code is issued, the extended assessment period prescribed by the Agvet Code Regulations will apply. This extension can be applied only once, regardless of how many notices are issued under section 159
- If a notice is issued changing the item or module level or type that is required to determine the application and this results in a change to the assessment period or fees, the assessment period may be lengthened or shortened. Where an applicant is required to pay an additional fee the assessment period will be extended to allow for the period until the fee is paid. Fees must be paid within 28 days from the date of notice
- If a Notice of Proposal to refuse or to approve or register an active constituent, chemical product or label with instructions or relevant particulars other than those set out in the application is issued, the assessment period is paused for a twenty-eight day period within which the applicant is invited to respond to the notice.

B.2 Assessment periods and fees

The application fee and the assessment period in which the APVMA is required to determine an application vary depending on the complexity of the application.

Table B.1 provides approvals and registrations made under section 10 of the Agvet Code. In addition to other fees, the category 1 in Table B.1 would cost $84,115.

Table B.2 provides variation of approval or registration relevant particulars or conditions made under section 26B or 27 of the Agvet Code.

Table B.3 provides module levels, types, periods for completion and fees.

TABLE B.1 APPROVALS AND REGISTRATIONS MADE UNDER SECTION 10 THE AGVET CODE

Item	Description of application	Assessment period	Fee July 2014	Max pre-application assistance rebate
1	Approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and product	18 months	$84,115	$1,400
2	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		$1,400
3	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	$56,545	$1,050
4	Registration of a chemical product containing an approved active constituent, and approval of the product label, if there is a registered chemical 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	$32,090	$1,050
5	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	$4,260	$700
6	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 required	8 months	$3,755	$700
7	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	$1,535	$350
8	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	$1,455	$350
9	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	$1,395	$350

Item	Description of application	Assessment period	Fee July 2014		Max pre-application assistance rebate
10	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			$350
10A	Application for approval of a label for containers for a registered chemical product	Modular assessment period and fee (relevant modules anticipated to be preliminary assessment and finalisation)			$350
15	Approval of an active constituent requiring a full assessment	14 months	$26,730	$30,550	$1,400
16	Approval of an active constituent requiring less than a full assessment but requiring a toxicological assessment	9 months	$16,455	$18,805	$700
17	Approval of an active constituent requiring less than a full assessment but not requiring a toxicological assessment	7 months	$2,760	$3,155	$700
24	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			$350
27	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			$1,400

SOURCE: HTTPS://APVMA.GOV.AU/NODE/1088 ACCESSED ON 28 MAY 2017

TABLE B.2 VARIATIONS MADE UNDER SECTION 26B OR 27 OF THE AGVET CODE

Item	Description of application	Assessment period	Fee July 2014	Fee July 2015	Max pre-application assistance rebate
11	Vary particulars or conditions of registration or label approval where a full assessment of the chemical product is required	10 months	$25,035	$28,610	$1,050
12	Vary particulars or conditions of registration or label approval if the variation is to allow a minor change and no data of a technical nature is required	3 months	$1,020	$1,170	$350
13	Vary particulars or conditions of registration or label approval if the variation is to allow a minor change and no data of a technical nature is required and the variation is a change required by the APVMA	3 months	Nil	Nil	Nil
13A	Vary particulars or conditions of registration or label approval if the variation is to allow a minor change and no data of a technical nature is required and the variation is a change required by the APVMA	3 months	Nil	Nil	Nil
14	Vary particulars or conditions of registration or label approval if the application is not of a kind described in any of items 11 to 13A	Modular assessment period and fee			$350
18	Vary particulars or conditions of an approved active constituent	7 months	$2,155	$2,465	$700

SOURCE: HTTPS://APVMA.GOV.AU/NODE/1088 ACCESSED ON 28 MAY 2017

TABLE B.3 MODULE LEVELS, TYPES, PERIODS FOR COMPLETION AND FEES

Module level	Module type	Period	Fee 7/2014	Fee 1/2015
1	Preliminary assessment	Not applicable	$620	$710
2.1	Chemistry	13 months	$8,065	$9,220
2.2	Chemistry	9 months	$2,690	$3,075
2.3	Chemistry	6 months	$1,380	$1,580
2.5	Chemistry—timeshift only	As per project plan	$8,065	$9,220
3.1	Toxicology	13 months	$24,430	$27,920
3.2	Toxicology	9 months	$14,620	$15,795
3.3	Toxicology	5 months	$3,540	$4,050
3.4	Toxicology—timeshift only	As per project plan	$24,430	$27,920
4.1	Toxicology requiring poison schedule classification	13 months	$2,435	$2,435
4.2	Toxicology requiring poison schedule classification—timeshift only	As per project plan	$2,435	$2,435
5.1	Residues	13 months	$15,900	$18,170
5.2	Residues	8 months	$9,210	$10,525
5.3	Residues (permit only)	8 months	$7,175	$8,200
5.4	Residues	4 months	$6,535	$7,465
5.5	Residues (permit only)	4 months	$1,750	$2,000
5.6	Residues—timeshift only	As per project plan	$15,900	$18,170
6.1	Occupational health and safety	13 months	$4,310	$4,410
6.2	Occupational health and safety	7 months	$2,900	$3,185
6.3	Occupational health and safety	4 months	$3,480	$2,910[1]
6.4	Occupational health and safety—timeshift only	As per project plan	$4,310	$4,410
7.1	Environment	13 months	$23,095	$26,390
7.2	Environment	7 months	$6,400	$7,315
7.3	Environment	4 months	$1,505	$1,720
7.4	Environment—timeshift only	As per project plan	$23,095	$26,390
8.1	Efficacy and safety	6 months	$2,075	$2,370
8.2	Efficacy and safety	4 months	$855	$975
8.3	Efficacy and safety	3 months	$505	$580
8.4	Efficacy and safety—timeshift only	As per project plan	$2,075	$2,370
9	Non-food trade	6 months	$1,175	$1,175
10.1	Special data	13 months	nil	nil
10.2	Special data	7 months	nil	nil
10.3	Special data	7 months	nil	nil
10.4	Special data—timeshift only	As per project plan	nil	nil
11.1	Finalisation	3 months	$3,545	$4,055
11.2	Finalisation	2 months	$1,350	$1,545
11.3	Finalisation	2 months	$755	$865
12	Data protection	Not applicable	$400	$460

SOURCE: HTTPS://APVMA.GOV.AU/NODE/1088 ACCESSED ON 28 MAY 2017

B.3 Permit fees

TABLE B.4 PERMIT APPROVALS MADE UNDER SECTION 110A OR 115(3A) OF THE AGVET CODE

Item	Description of application	Assessment period	Fee July 2014	Fee July 2015	Max pre-application assistance rebate
19	A permit, or extension of a permit, to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product, where no data of a technical nature is required	3 months	$350	$350	$350
20	A permit, or extension of a permit, where a previous assessment remains valid and no data of a technical nature is required	3 months	$350	$350	$350
21	A permit, or extension of a permit, where the proposed use is a minor use	Modular assessment period	$350	$350	$350
22	A permit, or extension of a permit, in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use	Nil			Nil
23	A permit, or extension of a permit, in respect of a chemical product or an active constituent if the application is not of a kind described in any of items 19 to 21	Modular assessment period and fee			$350

SOURCE: HTTPS://APVMA.GOV.AU/NODE/667 ACCESSED 28 MAY 2017

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