Animal Medicines Australia
ABN 76 116 848 344 | ACN 116 848 344
18 National Circuit
Barton ACT 2600, Australia
P: +61 2 6257 9022
animalmedicinesaustralia.org.au

28 August 2020

Agricultural and Veterinary Chemicals 1st Principles Review
Department of Agriculture Water and Environment

Lodgement by email: agvetreview@agriculture.gov.au

Dear Review Panel

Independent review of the agvet chemical regulatory framework

Animal Medicines Australia (AMA) is pleased to provide this submission on behalf of our members. AMA members represent more than 90% of Australian sales of registered veterinary medicine products. Our members include local companies, those with international heritage, and range from small to large participants.

During consultation sessions the Panel Chair commented that this 1st Principles Review represents a *once-in-a-decade* opportunity. We fully agree.

AMA recognises that views of the Review Panel have been informed by both the consultations it has conducted to date and the written submissions received in response to the Issues Paper. The panel's views will necessarily be refined in its Draft Final Report. It is therefore the Draft Final Report that will provide the basis for substantive comments on a package of proposals that meet the needs of stakeholders and fulfils the review's Terms of Reference. AMA encourages maximising the period of consultation on the Draft Final Report.

There are coherent elements and principles that AMA is anticipating in the Draft Final Report, including:

- adherence to Best Practice Regulatory Principles,
- embodying Minimum Effective Regulation,
- robust methodologies for institutional and regulatory approaches,
- embedding science and risk-based approaches
- strategic focus with clear reference to the Regulatory Framework as per the Terms of Reference,
- recognising the business operating environment for veterinary medicines,
- considering whether proposals are "implementable",
- preliminary evaluation of costs of implementation and maintenance of proposals,
- a clear roadmap with indicative timelines,
- progress and achievement of outcomes must be measured in years, not decades,
- selected scenario testing,
- considering strategies to reduce or remove barriers to progress, and
- clear and attributable accountabilities.

Elements of the National Registration Scheme (NRS) have been extensively reviewed over decades, commonly identifying the same issues or problems, <u>again and again</u>, without achieving needed reforms.

AMA's predecessor organisation, Avcare, made a submission to the 1998 *National Competition Policy Review of Agricultural and Veterinary Chemical Legislation*. The index of that 1988 submission included:

- The agvet chemical industry
- Industry stewardship and coregulation programs
- Australian regulatory requirements
- Industry research and development
- The legislated monopoly on agvet registration decisions
- Full cost-recovery and the balance of fees and levies
- Requirement of an agvet chemical to be effective
- State 'control-of-use' legislation, 'control-of-use' licensing, permits
- Manufacturer licensing schemes
- Data provision and protection
- Risk-based rationalisation of the NRA's product portfolio
- Acceptance of the agvet chemical label as a MSDS equivalent for the farm workplace

More than two decades on, we are still dealing with many of the same issues in this Review.

A foundation matter is the institutional arrangements for the NRS. The 2008 Productivity Commission Report on Chemicals and Plastics Regulation[1] proposed, after an extensive review across all chemicals sectors, an institutional and regulatory approach for chemicals and plastics regulation:

- *Formulation of strategic policy and oversight of the institutional and regulatory arrangements* — a national function, to be undertaken by ministerial councils underpinned by intergovernmental agreements.
- *Assessment of the hazards and risks of chemicals* — a national, science-based function to be undertaken under statutory independence.
- *Risk-management standard setting* — a national function to be undertaken by independent statutory agencies within the policy frameworks of the ministerial councils.
- *Administration of agreed standards and monitoring of their impact* — jurisdiction-specific functions to be undertaken by their own agencies or delegated to other bodies such as national regulators.

As intended by the Productivity Commission, the model provides a clear framework for establishing roles and responsibilities. It also assists with clarifying where feedback loops are best placed for informing policy and informing risk-management.

The Productivity Commission released a supplement to the research report that built on lessons for national approaches to regulation[2]. In its Forward, Chairman Gary Banks noted:

> "In this supplementary paper the Commission elaborates on the federalism issues arising in the research report and identifies a number of mechanisms that Australian governments have used to coordinate national approaches to regulation. The paper describes the governance arrangements, institutions, procedural mechanisms and incentive structures, assesses their strengths and weaknesses, and draws out some implications for the broader regulatory reform agenda, within the context of Australia's federal framework."

[1] Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne

[2] Productivity Commission 2009, Chemicals and Plastics Regulation: *Lessons for National Approaches to Regulation*, Supplement to Research Report, Melbourne

Institutional and regulatory approaches are further addressed in AMA's attached submission.

The Review Panel should consider the Productivity Commission's framework in its Draft Final Report. The Draft Final Report should also contain a list of all relevant reviews involving the NRS, including the APVMA. This is important for transparency and will help avoid reinventing the wheel.

National consistency of control-of-use makes an interesting case study. The first *control-of-use* legislation was implemented in New South Wales under the *Pesticides Act 1978*. Differences in jurisdictional approaches have been raised as a significant unresolved issue for nearly 40 years. The Productivity Commission also made *control-of-use* recommendations in 2008. The current Issues Paper notes:

> "In 2010, in response to a request from COAG, the Agriculture Ministers' Forum (AGMIN) agreed to develop a single national framework to harmonise the regulation of agvet chemicals …."
>
> "However, the current processes seeking harmonisation are based on negotiation and consensus. As a consequence, the panel notes that these efforts have had very limited success and, in most cases, have achieved, at best, in-principle support for a common goal or minimum consistency in implementation, thus diluting the benefits of harmonisation."
>
> "Looking at history, the panel is not confident that consensus on the incomplete harmonisation reforms will occur in the near future, despite the best intentions of all players. The resources available in jurisdictions appear to be insufficient to support both reform and ensure integrity of the system. Nor is the panel assured that the completed harmonisation efforts will not see the introduction of additional jurisdiction specific requirements in the future, leading to inconsistencies once again."
>
> "The lack of progress in, and effectiveness of harmonisation needs to be addressed. It appears to the panel that the competing demands of governments and parliamentary systems in each jurisdiction and the Commonwealth is unlikely to ever efficiently achieve national consistency in control of use. Given that each jurisdiction will act, understandably, in the interests of their own state or territory, the current process is fraught with difficulty and may only ever deliver small incremental reforms." (underlining added)
>
> "Therefore, the panel believes alternative approaches need to be considered. These approaches must recognise and build on the strengths within current arrangements and be focused on efficient and responsive regulation across the lifecycle of a chemical product."

This position is untenable, particularly regarding fundamental and underpinning elements of this reform.

There appear to be a range of common issues that arise in regulatory reform that are impediments to achieving successful outcomes that conform to *better regulation* principles. In many instances, the nature of the issues is not unique and understanding why they occur and how they may be rectified offers an important learning opportunity.

Some matters for reflection include:

- Ways to achieve consistency of implementation – legislative models, incentives, penalties
- What motivates jurisdictions to deviate from an agreed national model
- Completion of tasks verses achieving outcomes
- Non-delivery of benefits identified in Regulatory Impact Statements
- Are National Cabinet decisions and directions taken seriously by the relevant bureaucracies
- Who can, and should, provide the necessary leadership?
- Accountabilities

The Issues Paper outlines three governance options:

Option 1: Expanded applied law model

Option 2: Commonwealth exercising its full constitutional reach

Option 3: Re-invigorating the existing Intergovernmental Agreement on control of use

The legal and constitutional implications of these options may be beyond the expertise of many respondents to this Review. National consistency and *control of use* are fundamental issues and system design elements that must be resolved. AMA would welcome a careful, thorough consultation process that considers all governance options, and the relative benefits and costs of each, as a foundation stone for meaningful structural reform, possibly as part of a staged process.

Australian, State and Territory Governments have long established approaches to the development of regulation. AMA supports the Australian Government Principles of Best Practice Regulation[3]; and the Ten Principles for Australian Government Policy Makers[4]:

1. Regulation should not be the default option for policy makers: the policy option offering the greatest net benefit should always be the recommended option.
2. Regulation should be imposed only when it can be shown to offer an overall net benefit.
3. The cost burden of new regulation must be fully offset by reductions in existing regulatory burden.
4. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement.
5. Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals.
6. Policy makers must consult with each other to avoid creating cumulative or overlapping regulatory burdens.
7. The information upon which policy makers base their decisions must be published at the earliest
8. Regulators must implement regulation with common sense, empathy and respect.
9. All regulation must be periodically reviewed to test its continuing relevance.
10. Policy makers must work closely with their portfolio Regulatory Reform Units throughout the policy making process.

The Australian Government Regulation Impact Statement process[5] also identifies key questions that must be answered to satisfy the RIS requirements.

These principles and approaches are critical to ensure that regulatory responses are properly targeted, designed, and proportionate. They are supported by AMA as an essential evaluation tool which can be used to assess the merits of any legislative or regulatory proposal.

AMA anticipates that the necessary elements of the Government's requirements for Best Practice Regulation will be embodied in the Draft Final Report.

Understanding the Business Operating Environment is crucial to considerations of supportive policy settings for veterinary medicines. The fortunes of the veterinary medicines industry are intrinsically tied to Australia's animal populations. For most livestock species, except chickens, there is long term decline.

The following graphs present data from 1990 – 2018/19 (nearly 3 decades). Longer term data sets are presented for completeness in Appendix 2 of the attached submission. Seven pictures paint a story of Australian livestock agriculture and describe a key component of the Business Operating Environment:

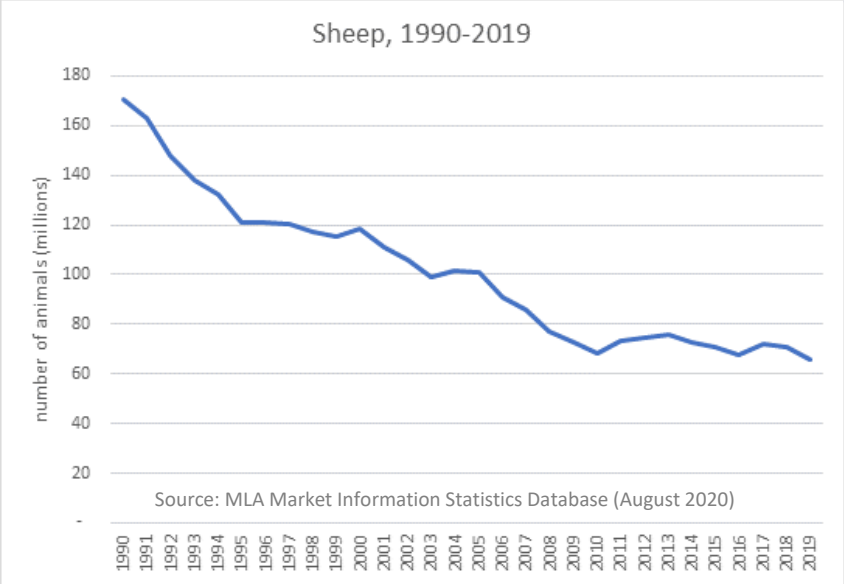
[3] https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation
[4] https://www.pmc.gov.au/ria-mooc/agrp/overview/australian-government-10-principles-policy-makers
[5] https://www.pmc.gov.au/ria-mooc/extra-detail

Sheep

Over the period 1990 to 2019 the Australian flock declined from 170.3 million to 65.8 million head.

MLA "estimates for June 2020 pin the national flock at 63.5 million head, its lowest level in more than a century."[6]

Since 2010 numbers have been relatively flat but within a still declining band of 63.5 million to 72 million head.

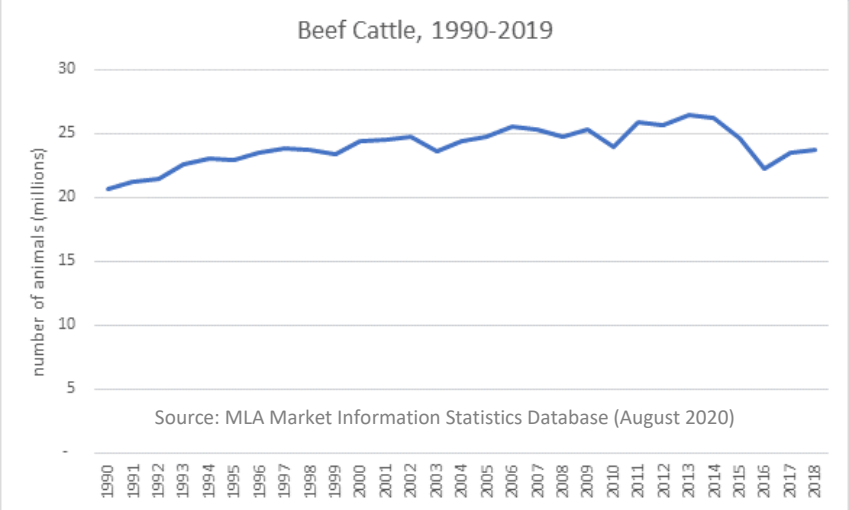


Beef cattle

Since 1990 the Australian beef herd has tracked in a band of 23 million to 28 million head.

The national herd peaked at 32.7 million head in 1975.

Australia exports red meat to over 100 countries, representing over 60% of the industry's total production.[7]

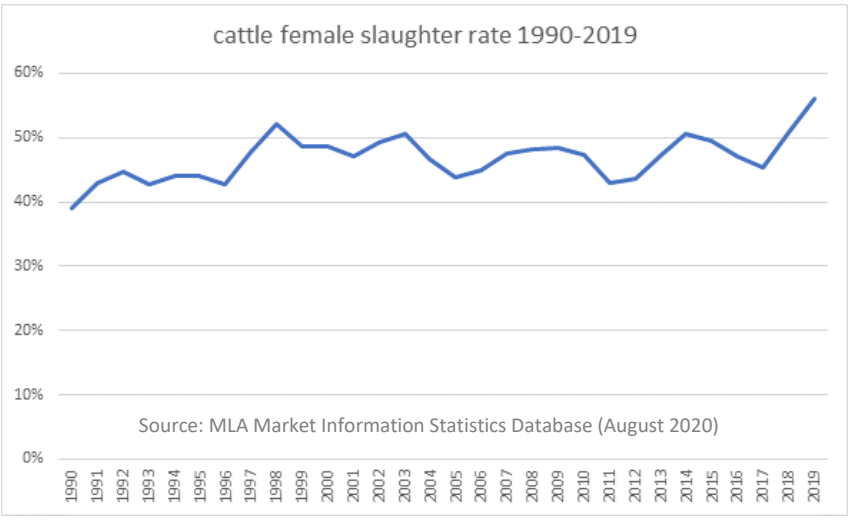


Cattle female slaughter rate

Current 44-year highs are due to drought-related destocking. High rates of female slaughter mean a smaller future breeding herd and production potential.

After averaging 56% in 2019, rates fell to an average of 52% in first quarter 2020.

Female slaughter rates lower than around 47% indicate herd rebuilding is taking place.

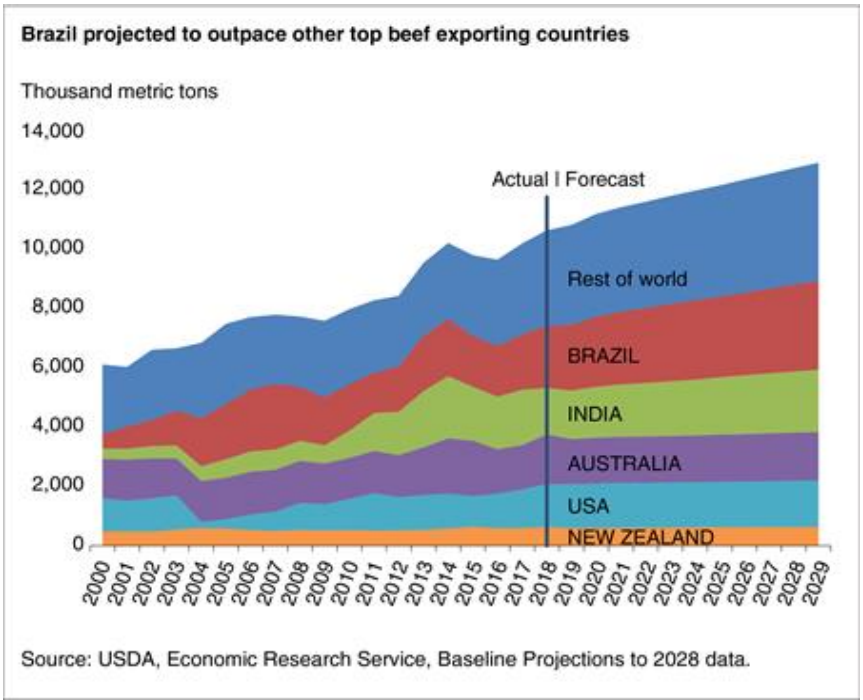


[6] https://www.mla.com.au/prices-markets/Trends-analysis/sheep-projections/
[7] https://www.mla.com.au/marketing-beef-and-lamb/international-markets/

Beef exports

Brazil has the world's second-largest cattle herd—232 million head—and its production is largely based on grass. Increased beef demand worldwide has stimulated increased production and productivity gains. In 2018, Brazil reached its highest level of beef production at 9.9 million metric tons.[8]

USDA's projections for Australia are flat till the end of the forecast period ending 2029. Brazil and India show continuing growth.

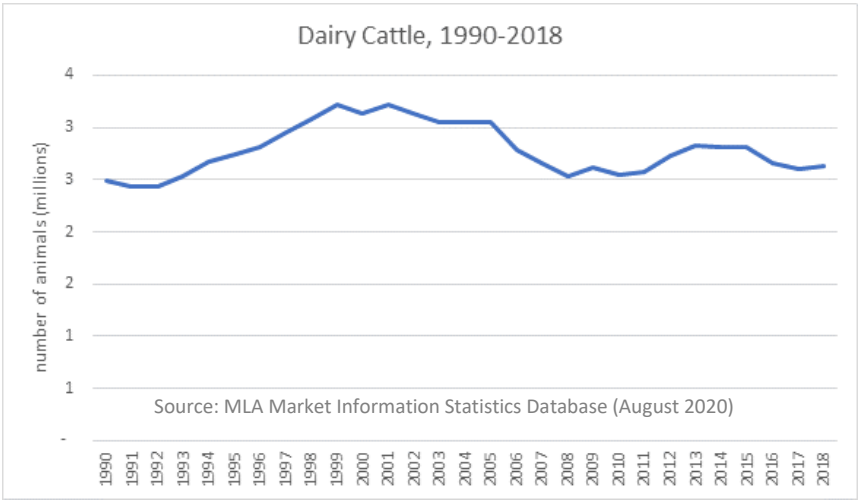


Dairy Cattle

Dairy cattle numbers peaked in the late 1950s and 1960s at about 5 million head.

Following a long-term decline, dairy cattle numbers appear to be stabilising a little north of 3 million head.

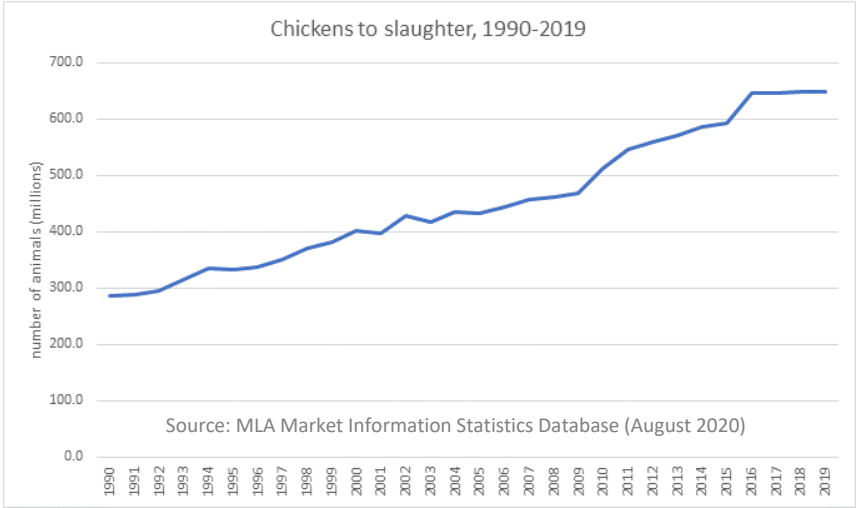
A noticeable characteristic in dairy has been strong growth in production per head due to a range of factors.



Chicken

'Chicken slaughtered' has grown consistently since the 1960s until the past 5 years when rates have flattened.

Australia is a small net exporter of chicken meat (about 3% of domestic production). There are no significant chicken meat imports except high-value specialised products.[9]

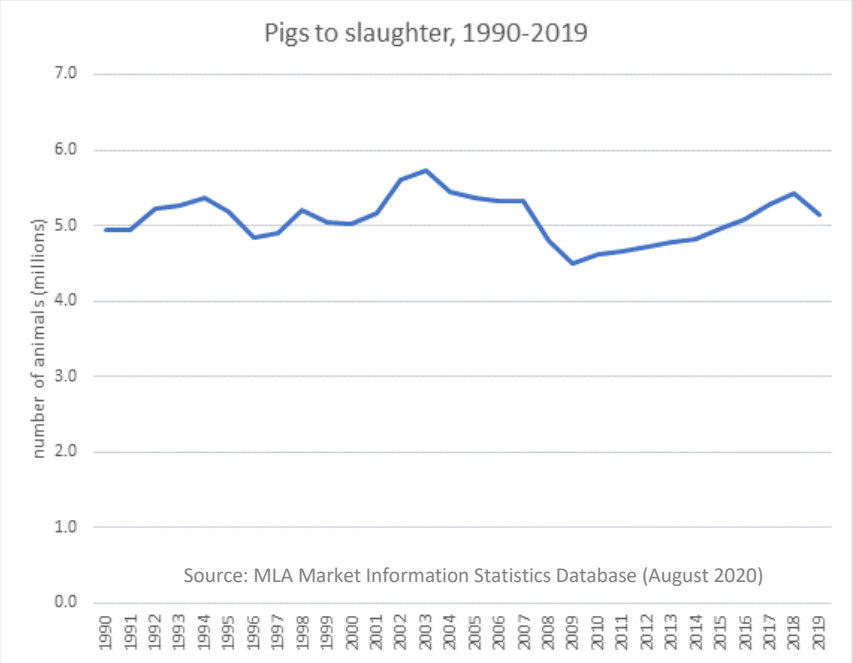


[8] Brazil is the world's largest beef exporter
[9] Australian chicken meat

Pigs

For the past 3 decades, 'pigs slaughtered' have fluctuated around the 5 million mark.

In Australia, pork accounts for about 12% of fresh meat consumption. Australia produces around 360,000 tonnes of pig meat a year, with about 8% of this exported to destinations like Singapore, New Zealand, and Hong Kong. While all fresh pork meat sold in Australia is also grown in Australia, around 70% of processed pork products, such as ham and bacon, are made from pork imported from overseas.[10]



The above graphs are only intended to provide a high-level picture, for the purposes of this submission, to give a context to part of the Business Operating Environment for veterinary medicines. AMA does note that during the above periods there have been significant increases in animal productivity through breeding, husbandry, management, and judicious use of veterinary medicines. This is due to the outstanding efforts of farmers, lot feeders, breeders, and a host of suppliers and actors ranging from veterinarians to researchers.

AMA included trend data in its 16 December 2019 presentation to the Review Panel. A copy of that presentation is provided at Appendix 5 of the attached submission.

The biggest impact to the veterinary medicines sector (as production inputs) would be a strong growth phase in sustainable livestock production and exports.

For each of the key species (beef, dairy, sheep-meat, sheep-wool, chickens-meat, chickens-eggs, and pigs) the 2018 ACIL Allen report *Economic contribution of animal medicines to Australia's livestock industries 2015-16*[11] identified:

- Diseases and estimated economic costs
- Method of attribution
- Contribution of animal health products to production

Note: other industries (for example horse racing), pets, minor livestock industries and other uses were not evaluated in this study.

Maintaining the health and welfare of livestock is critically important for productive, ethical, and sustainable livestock, dairy and poultry industries. There is a virtuous circle where careful management of animal health and welfare is not only good for animals, but also good for human health, the environment, and the economy. While this analysis focuses on the economic benefits, the animal welfare, human health, social and environmental benefits from maintaining animal health should not be ignored.

Throughout this Review, participants have described their experiences that lead to new products and new technologies not being introduced to the Australian market whilst the same products and technologies are widely available in advanced economies such as the European Union and North

[10] https://www.agrifutures.com.au/farm-diversity/pigs-meat-pork/

[11] ACIL Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries 2015-16, JUNE 2018

America. Commonly, the introduction of new chemicals does not pass even modest expectations for return on investment – this builds a barrier where Australia is just not considered for new introductions. Many companies no longer track foregone opportunities. It is very clear that options that do not deliver significant and meaningful reform will fail to address the range of endemic problems that have been described preceding and during this Review process.

From previous AMA presentations and engagement, the Panel is aware of AMA's concerns that Australia's approach to residue management in the trade of livestock and animal commodities continues to be a major limitation on the development of certain veterinary medicines in Australia. This aspect is further identified in the attached submission with a proposed focus on multilateral approaches as part of a strategic approach.

> *Whilst there will always be a market for livestock veterinary medicines in Australia (simple demand and supply), without significant reform, this market will be high cost, impede innovation and hamper access to world best technologies and products.*

There seems a clear need for injection of marketplace realities for veterinary medicines and the industries where they serve as a production input. AMA suggests that it may be an informative exercise to consider veterinary medicines as an input to agricultural livestock production and explore the business case for veterinary medicines, livestock production and trade.

The Panel has raised that it will consider COVID-19 as a factor in its deliberations. Farm Journals's Pork[12] reports comments that "It's no surprise that COVID has really sucked up a lot of the oxygen in the room when it comes to the outlook for animal protein." The same article quotes Rabobank's view that "ASF [African Swine Fever] will have more profound and longer-lasting impacts on global animal protein markets than COVID-19."

> "ASF has never occurred in Australia. Its changing distribution means it's a significant biosecurity threat to our country. An outbreak would be devastating for our pig production and health. It would also damage our trade and the economy."[13]

In August 2020 outbreaks of Avian Influenza occurred in Victoria, necessitating culling of chickens, turkeys and some 8000 emus. The Panel may wish to evaluate the ongoing threats to livestock production from a range of sources and the potential impacts for this Review. It is likely that climate change, continuing adaptation for agriculture, and mitigation measures will have significant impacts.

[12] https://www.porkbusiness.com/article/african-swine-fevers-influence-prevails-over-global-pork-markets
[13] https://www.agriculture.gov.au/pests-diseases-weeds/animal/asf

Australian sales of companion animal products now exceed production animals

Companion animals now represent the majority of Australia veterinary medicines sales and must be considered through this review. In 2019, factory gate sales of veterinary medicines for the production sector was **$509,701,994** and for companion animals, **$550,622,532**.[14]

The Issues Paper does not actively consider companion animals. The Panel may have initially assumed that the Flagship Proposal to remove over-the-counter (OTC) veterinary medicines for companion animals from APVMA oversight would be implemented.

The rationale for removing companion animal OTC medicines from the regulatory system is not strong and there are compelling reasons for continued regulation of these products, based on animal safety, animal welfare, user safety, zoonotic disease risks and adverse consequences for pets and pet owners that arise from inefficacious flea or tick products. Internationally, these products are also captured within veterinary medicine regulatory regimes.

In consultations, AMA has been pleased to note that the Panel had been receptive to further information it has received on OTC companion animal products and their essential role in the community.

The Review Panel may find the following information of assistance and interest in understanding the Australian companion animal market and its relationship with veterinary medicines.

In November 2019 AMA released a report titled *Pets in Australia: A National Survey of Pets and People*[15]

- There are almost 29 million pets in Australia today - more than the estimated Australian human population of 25 million.
- Three in five Australian households - or 5.9 million in total - have a pet. 61% of Australian households have a pet today.
- 90% of all Australian households have experienced pet ownership at some point. This includes 75% of households currently without a pet.
- Pet ownership rates are higher in Australia than many other countries. The latest available statistics from the United States, for example, indicate that only 57% of American households have pets, while only 40% of households in the United Kingdom are estimated to have pets.[16]
- Around 40% of Australian households include at least one dog, making them the most popular type of pet. This is followed by cats (27%), fish (11%), birds (9%), small mammals (3%) and reptiles (2%) - with another 2% of households reporting that they have pets such as horses, goats, cows, alpacas and hermit crabs.
- The average number of dogs and cats owned per household has remained relatively steady in recent years - while the average number of fish, birds and small mammals has increased, and the average number of reptiles has fallen. If the 2019 survey results were extrapolated across all Australian households, this would represent an estimated total of 5.1 million dogs, 3.8 million cats, 11.3 million fish, 5.6 million birds, 614,000 small mammals, 364,000 reptiles and 1.8 million 'other' pets.

Pets play multiple, varied and important roles. They provide comfort, companionship, entertainment, and a sense of purpose, and are increasingly regarded as 'members of the family' rather than possessions. They are companions for relaxation, for physical activity or for teaching children care and responsibility. As assistance animals, they help those with chronic illness and disability (for

[14] unpublished AMA survey data

[15] Animal Medicines Australia, Pets in Australia: A national survey of pets and people, 2019

[16] Pet Food Manufacturers Association, Pet Population 2019

example, impaired vision, hearing or mobility, diabetes, seizure disorders and behavioural conditions) maintain independent, fulfilling lives, and help to build trust and connections with family and the wider community.

Service dogs and horses are a critical component of many key 'sectors', including law enforcement, emergency response, biosecurity, armed services and peacekeeping activities. The presence of animals in a range of educational settings has also been shown to have positive impacts on literacy, language and communication, social development and behaviour.

Progressing an *INNOVATION AGENDA*

In reviewing the Issues Paper, AMA members identified the benefits of a policy statement that included an *INNOVATION AGENDA as a centre piece*.

Such an agenda for veterinary medicines could capture the progressive elements of the Panel's forward plan and encompass what is needed to assist in directing policy settings to meet system goals.

INNOVATION AGENDA

- **Eliminating barriers**
- **Seamless systems**
- **Incentivising development**
- **Facilitating collaboration**
- **Inviting regulatory innovation**
- **Championing science and risk-based approaches**
- **Ensuring unencumbered trade of animals and animal products**
- **Supporting public health and animal welfare for Australia's companion animals**
- **Meeting the Social License challenge**

This approach can be linked back to the Panel's Terms of Reference with respect to the regulatory framework. AMA invites further dialogue on this initiative.

In the attached submission AMA focuses on the *Goals* and *Regulatory Framework* for the National Registration Scheme (NRS) as the basis for considering a future platform to address the needs of the Australian community, economy, environment, production and companion animals, and animal welfare.

The submission provides further information on the Business Operating Environment and responds to the detailed questions raised in the Issues Paper. Based on evaluation of the matters raised in its submission, AMA is pleased to make recommendations that will assist the Review Panel.

AMA will be pleased to discuss any aspects.

Yours Sincerely

Unsigned for electronic lodgement

Ben Stapley
Executive Director

Independent review of the agvet chemicals regulatory framework

28 August 2020

Animal Medicines Australia

(Note: This submission is intended to be read together with the Animal Medicines Australia letter to the Review dated 28 August 2020.)

Independent review of the agvet chemical regulatory framework

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Foreward

Review of Australia's National Registration Scheme (NRS) is welcomed. Animal medicines support the health and safety of humans, animals, and the environment. It is time to ensure policy and operational settings are right, including making adjustments to deliver effective and efficient outcomes for stakeholders and underpin much needed contribution to our domestic and export economies.

Animal medicine products are integral to the viability of livestock production and a report[1] undertaken by ACIL Allen Consulting confirms these essential roles in supporting Australia's livestock industries.

The report quantifies the additional economic value of animal medicines in key livestock industries. It considers the value added through the use of animal health products in seven key production industries including beef, dairy, wool, sheep meat, pigs, and chicken meat and eggs. Importantly, the report puts a dollar figure on the benefit that is supplied by animal medicine products.

The analysis and report, undertaken by ACIL Allen Consulting, showed that animal medicine products:

- contribute $2,668 million to the Australian economy,
- create 9,898 full time jobs,
- generate more than $578 million in wages, and
- resulted in costs savings on an average grocery bill of almost $270 per annum.

Consumers are beneficiaries of increased production. The responsible use of animal medicines results in healthier animals, higher production for farmers and a reduced grocery bill. The estimated productivity attributable to animal health products ranged from 14% for poultry meat to 28.5% in dairy farming. This is a considerable productivity gain for farmers, which in turn benefits consumers.

Similarly, animal health products protect and promote the health of Australia's 28.5 million pets, resulting in longer, more beneficial, and responsible relationships between pet owners and their animals.[2] Our pets play multiple, varied, and important roles in our lives, such that most Australians now consider their pets to be 'part of the family'. They provide companionship, love, entertainment and a sense of purpose. Many animals also play important societal roles as assistance and therapy animals, or in service roles within the law enforcement, biosecurity and defence sectors (for example).

Ben Stapley
Executive Director
Animal Medicines Australia

About Animal Medicines Australia

AMA is the peak industry body representing the leaders of the animal medicines industry in Australia. Its member companies are the innovators, manufacturers, formulators, and registrants of a broad range of veterinary medicine products to protect and treat animals with illnesses, diseases and injuries and promote animal welfare across the companion animal, livestock, and equine sectors.

AMA works closely with its members, a variety of organisations, and governments to **promote an evidence-based approach to public policy.** Additionally, AMA **advocates for the responsible and judicious use of all veterinary medicines** to improve and protect animal health and welfare.

For more information visit AMA's website at: https://animalmedicinesaustralia.org.au

[1] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018
[2] Animal Medicines Australia (2019), Pets in Australia: A national survey of pets and people, October 2019

Executive summary

Veterinary medicines:

- are inputs to Australian livestock production systems. They are intrinsically linked to livestock production, markets, weather/climate, technology, farming systems and other variables, and
- serve to protect the health and welfare of companion animals and their owners.

Australia has favourable rankings for stable financial and political systems, a skilled and capable workforce, good health and safety systems, environmental performance, and other positive metrics.

For veterinary medicines, the Australian sales of companion animal products now exceeds those for livestock. The Australian market is about 2.2% of global sales and compared to market size, the regulatory costs are significant. A characteristic of the business operating environment has been long-term decline or flat livestock numbers. For instance, the Australian national sheep flock dropped from 170.3 million head in 1990 to 63.5 million head in 2020.

This review provides a good opportunity to make course corrections to the regulatory framework, recognising that "*reducing the level of unnecessary or poorly designed regulation will contribute to improved productivity and future living standards for all Australians"*[3] . The principle of *minimum effective regulation* gives descriptive context to the way "regulation" should be approached.

Notwithstanding the above, AMA notes that that loading the veterinary medicines industry with costs may not achieve desired long-term objectives and outcomes. Indeed, sustainable funding of the NRA presents challenges where the contribution of all stakeholders will be important in the discussion.

In the following sections of this submission, AMA seeks to provide:

- snapshots of animal medicines – nationally and internationally;
- a brief consideration of the Australian regulatory landscape;
- recognition of the role of regulatory best practice;
- promotion of the concept of an *INNOVATION AGENDA;*
- identification of industry support through AgStewardship, Agsafe, DrumMuster, ChemClear;
- an approach for reviewing the NRS – methodologies and setting the framework;
- identification of an institutional and governance approach for the NRS;
- comment on a new legal definition of veterinary medicines;
- identification of the priority issues for veterinary medicines;
- analyses the merits of the Panel's 7 Flagship items;
- the need to align agvet data protection provisions;
- responses to a range of Issues Paper questions, ranging through operational to policy;
- resolution of approaches to chemical residues and trade – with multi-lateral preferred;
- consideration of funding options for the NRS;
- progress to 'Meeting the social licence challenge';
- case studies to underpin key arguments and proposals
- AMA's expectations of the Draft Final Report; and
- reinforcement that 2 decades of reviews have identified many of the same issues without them being addressed – there is important need to change course.

This is an expansive review. Progress will be made with continuing dialogue in working through the practicalities and workability of options and ultimately, development of a credible model for reform of the NRS.

[3] https://www.wto.org/english/tratop_e/serv_e/workshop_apr11_e/porter_e.ppt

Primary Recommendations

Animal Medicines Australia is please to make the following recommendations to the Review. General comments on questions contained in the Issues Paper are in *Appendix 1*:

Recommendation 1

The Panel provides recognition that veterinary medicines are essential to protect animal health and welfare, for food safety, for public health and to limit the spread of zoonotic disease.

Recommendation 2

The Panel notes elements of the business operating environment, including:

- Australia represents 2.2% of global sales of veterinary medicines
- Long term declining or flat livestock numbers for sheep, cattle, dairy and pigs
- In 2018-2019, sales of veterinary medicines for companion animals exceeded those for livestock

Recommendation 3

The Panel notes the analysis and report on key livestock species, undertaken by ACIL Allen Consulting[4], which showed that animal medicines:

- contribute $2,668 million to the Australian economy,
- create 9,898 full time jobs,
- generate more than $578 million in wages, and
- result in costs savings on an average grocery bill of almost $270 per annum.

Recommendation 4

The Panel notes the important role that pets play in modern Australian society, both in terms of the value people place on their pets and the value they deliver.

Recommendation 5

Considering the breadth of this review and potential funding allocations, the Panel recognises that adding significant costs to registrants may have unintended consequences for innovation.

Note: Innovation is meant in the broadest sense to include not only new chemical entities but also delivery mechanisms, formulations, packaging, compliance aids and other platforms that assist in the delivery of healthcare for animals.

Recommendation 6

The Panel promotes "*reducing the level of unnecessary or poorly designed regulation will contribute to improved productivity and future living standards for all Australians"*[5] *and* the principle of *minimum effective regulation* to give descriptive context to the way "regulation" should be approached. The Panel also promotes the Australian Government's Best Practice Regulatory Principles.

Recommendation 7

The Panel supports the Australian Pesticides and Veterinary Medicines Authority (APVMA) as prime and central to the regulation of veterinary medicines. This includes pre-market approvals, post-market product development, on-going post-market activities such as Good Manufacturing Practice (GMP), adverse experience reporting, and pharmacovigilance.

Recommendation 8

The notes that the APVMA may inform policy but its function is to operationalise and implement policy. The authority's principal responsibilities are described in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

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[4]https://animalmedicinesaustralia.org.au/wp-content/uploads/2018/08/AMA-Economic-Contribution-Final-Report-9-August-2018-FINAL.pdf

[5] https://www.wto.org/english/tratop_e/serv_e/workshop_apr11_e/porter_e.ppt

Recommendation 9

The Panel make recommendations, supporting science and risk-based classification and labelling of veterinary medicines. The Panel notes the case study at Appendix 3 and considers how this can be remedied.

Recommendation 10

The Panel promotes the Australian Government's principles of Best Practice Regulation[6]as providing an objective, practical and disciplined approach, and embeds these principles in its approaches to this Review.

Recommendation 11

The Panel recommends that the APVMA continues to deal with both agricultural chemicals and veterinary medicines.

Recommendation 12

The Panel embraces the AMA proposal for an *INNOVATION AGENDA* and engages in further development.

Recommendation 13

The Panel recognises the significant industry commitments through industry stewardship initiatives such as AgStewardship, Agsafe, DumMuster, and ChemClear, as well as wide range of industry initiatives that promote the responsible, judicious use, and management of veterinary medicines.

Recommendation 14

The Panel considers alternate methodologies in its future visions exercise.

Recommendation 15

The Panel establish a further dialogue to refine its approach to a vision and future trends.

Recommendation 16

The Panel consider using the 2008 Productivity Commission model in the formulation of an approach to institutional and regulatory approaches.

Recommendation 17

The Panel adopt the proposed change of definition of veterinary chemical product to veterinary medicine but the Panel note AMA's concerns with the definition, namely that AMA:

- does not support the use of a GHS hazard classification in defining a veterinary medicine.
- would like to explore the Panel's rationale for including "instructions" (bullet points 13-15)
- would like to explore the Panel's rationale for exclusion due to entry in Appendix B of the Poisons Standard (bullet point 17). The nexus of scheduling and efficacy of a veterinary medicine is not clear and requires more elaboration.
- does not support removal of over-the-counter veterinary medicines for companion animals.

AMA appreciates that the Panel will have engaged in lengthy discussion on the definitions of both agricultural chemicals and veterinary medicines during the consultation and submission phase of the review. It would be helpful for the Panel to further engage stakeholders prior to finalisation of definitions to be included in the Draft Final Report.

Recommendation 18

The Panel promotes science-based, evidence-based, risk-based approaches.

[6] https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation

Recommendation 19

The Panel recognise the importance of data protection as an incentive for innovation and recommend that the current 3 year period is extended to 5 years.

Recommendation 20

The Panel recognises and prioritises means to deal with securing animal import MRLs in Australia's export markets and in particular, establishing processes to enable multi-lateral approaches.

Recommendations: 21

In consideration of the Panels Flagship Items:

Flagship 1: Increasing national consistency of control of use

The need for nationally consistent outcomes must consider the overall policy objectives and provide for a seamless approach from the registration and approval processes, to sale and supply of products and their ultimate use. Such would encompass all elements of consistency with respect to control of use, control of use licensing, and the role of permits.

Flagship 2: Removing consumer and non-primary production products from the system

The Panel accept AMA's position that the rationale for removing some companion animal medicines from the system is not strong and there are compelling reasons for animal medicines to remain under APVMA oversight, based on animal safety, animal welfare, user safety, human health and consequences for pet owners that can arise with lack of efficacy from flea or tick products. AMA recommends that this proposal with respect to veterinary medicines does not proceed.

Flagship 3: Introducing a benefits test

AMA is not convinced that the institution of a benefits test would necessarily lead to better outcomes. AMA has submitted alternate options that the Panel is requested to consider.

Flagship 4: Changing the way chemical product efficacy is managed

The Panel accepts AMA's position that Options 1 and 2 not proceed. AMA, however, notes that there may be opportunity to refine Option 3 by maintaining the criterion and amending requirements and streamlining assessments.

Flagship 5: Introducing a registration by reference approach

The Panel recognises that the concept has merit but there are many potential complexities and workability issues. Also, given the machinery that needs to be established to give effect to this item, care needs to be taken with respect to costs, benefits and priority compared to other options.

Flagship 6: Introducing smart labelling

AMA suggests that the Panel avoid the temptation to try to 'pick winners'. To have a positive and enduring effect, new technologies in Australian agriculture and livestock production need to be enabled in a transparent way to ensure that clear benefits can be obtained. Part of the process will be to utilise the tomes available on technology development and to integrate these into an approach that deals with the technical, social and adoption challenges.

Flagship 7: Introducing an accredited assessor scheme.

AMA is generally supportive, but any final scheme must deliver efficiencies, timeliness and cost effectiveness. The efforts to manage an accredited assessor program must not outweigh the benefits.

The Panel should note that AMA has concerns that this could become another administrative strain on APVMA when there may be higher priorities to focus on, especially if this scheme is not likely to be widely used. This scheme could potentially impose additional costs on registrants and create an additional layer of project management and oversight that would not necessarily provide any concomitant improvements in performance or standards.

1. Introduction

Veterinary medicines are essential to protect animal health and welfare, for food safety and to limit the spread of zoonotic disease.

Animal Medicines Australia (AMA) supports the 1st Principles Review of the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), noting that the review will examine the agricultural and veterinary chemicals regulatory framework's aims, structure and operation, and make recommendations to ensure that it is contemporary, fit for purpose and reduces unnecessary red tape.

AMA notes the scope of the review and the mode of operation of the Review Panel:

> Terms of Reference[7]
>
> In undertaking the review, the panel will:
>
> 1. assess the appropriateness, effectiveness and efficiency of the regulatory framework underpinning the operations of the National Registration Scheme,
> 2. consider what the goals of Australian agvet chemical regulation should be,
> 3. consider the current and future requirements of Australia's regulatory framework for agvet chemicals, and
> 4. provide recommendations for reform of the regulatory framework to increase the value of Australian agriculture.
>
> The panel will have regard to regulatory roles and responsibilities at the national, state and territory level; interactions with other regulatory schemes and arrangements; any relevant domestic or international issues; any recent changes to the current framework, including reforms agreed by the Council of Australian Governments; and the government's agenda to reduce red tape wherever possible.
>
> The process will also review the Intergovernmental Agreement (2013) underpinning the National Registration Scheme, which was due for review in 2018.

AMA had the opportunity to meet with the Panel on a number of occasions directly, with AMA members, and as part of the Stakeholder Group. The Panel's efforts to consult extensively are well recognised.

This submission seeks to put forward AMA's views and experiences that may further assist the Panel in its deliberations.

Consistent with the Terms of Reference, AMA focuses on the *Goals* and *Regulatory Framework* for the National Registration Scheme (NRS) as the basis for considering a future platform to address the needs of the Australian community, economy, environment, production and companion animals, and animal welfare.

This submission provides further information on the Veterinary Medicines Industry, the Business Operating Environment and responds to detailed questions raised in the Issues Paper.

Based on evaluation of the matters raised in its submission, AMA is pleased to make recommendations that will assist the Review Panel.

AMA would be pleased to clarify or provide further information that may assist the Panel in its determinations leading to the publication of the Draft Final Report.

[7] https://www.agriculture.gov.au/ag-farm-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/independent-review-agvet-chemical-regulatory-framework

2. Animal Medicines - snapshots

2.1 International

Veterinary spending is on the rise around the world. According to *Fortune Business Insight*[8], the global animal healthcare industry was worth US$41.50 billion in 2018 (vs US$24 billion in 2015). However, the industry remains highly fragmented with many small players. The industry growth is mainly driven by:

- A growing awareness about animal diseases (especially zoonotic and food-borne diseases)
- The rise in pet ownership
- An increase demand for nutritious animal-based protein
- An increasing number of urbanized middle-income households in growing economies
- Market consolidation (mainly through mergers and acquisitions)

HealthforAnimals (2020) unpublished survey information

Table 1: Estimated share of HealthforAnimals companies' global revenues in 2018

Market ranked by size	%
USA	34.2%
EUROPE	19.0%
JAPAN	3.2%
CHINA	3.2%
BRAZIL	3.1%
AUSTRALIA	2.2%
CANADA	2.1%
MEXICO	1.5%
INDIA	0.9%
RUSSIA	0.8%
SOUTH AFRICA	0.7%

HealthforAnimals (2020) unpublished survey data

Research and development (R&D) for the animal health industry shares a lot of similarities with its human counterpart. Both industries depend on productive innovation to create value for their customers and sustainable growth. R&D is an economic and scientific process: *Science defines the opportunities and constraints, but economics determines which opportunities and scientific challenges will be addressed through industrial research*.[9] The development phase of veterinary medicines consist of 3 major stages and can take almost a decade:

- Drug discovery (identification of new chemical compounds)
- Product development (additional studies to better characterise the product and uses)
- Registration phase (drug submission, review and approval)

In order to advance a product through the development pipeline, companies must decide if the product caters to the market's needs and if they can get an acceptable return on the capital invested. Overall, top international companies directed their R&D spending mostly towards pharmaceutical (65%) and biological (26%) products. Globally, food-producing animal investments fell to 49% compared to 61% in 2014[10], while companion animal investments have increased to 51% in 2018 compared to 39% in 2014.

Post-registration, pharmacovigilance plays a key role as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. This ensures that products remain safe and efficacious for the long-term. New indications, formulation changes, enhancements, and other developments may take place in this part of the life-cycle.

Mandatory defensive R&D (MD-R&D) occurs when R&D budget is diverted into the defence of existing products to comply with new safety, quality, and efficacy requirements. The costs of new data requested by authorities, particularly at product reviews and renewals, and the cost of subsequent dossier variations, generally result in a decreased emphasis on innovation.

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8 https://www.fortunebusinessinsights.com/

9 U.S. Congress, Office of Technology Assessment, PhurrnaceuficaZ R&D: Costs, Ris/u and Rewards, OTA-H-522 (Washington, DC: U.S. Government Printing Office, February 1993).

10 financial year of reference for the GBS report

2.2 Australia

Total veterinary medicines product sales in the 2018–19 financial year were **$1 097 206 071**[11] This is segmented into sales of veterinary medicines for the production sector as **$509,701,994** and companion animals **$550,622,532**.[12] This represents approximately 2.2% of global market revenue.

In Australia, the companion animal sector has eclipsed the production animal sector (agricultural livestock – meat, fibre, dairy, eggs etc.) as the dominant sector.

A truncated list of veterinary product types is presented in Table 2 as indicative of product diversity.

Table 2: Veterinary Medicines Types

Alimentary system
Anaesthetics/analgesics
Antibiotic & related
Antidotes
Cardiovascular system
Central nervous system
Dermatological preps.
Ear, nose, throat preps.
Endocrine system
Genitourinary system
Immunotherapy
Musculoskeletal system
Nutrition & metabolism
Nutrition & metabolism
Ophthalmic preparations
Parasiticides
Respiratory system
Adapted from: APVMA Gazette No. 5, 10 March 2020

The Australian agricultural and veterinary chemicals regulator, the APVMA, publishes a wide range of information, including:

- monthly gazettes[13] which detail notices of registrations, new active constituents, cancellations, proposals to amend Schedule 20 of the Australia New Zealand Food Standards Code, amendments to standards, licensing of veterinary chemical manufacturers, approved active constituents and other detailed materials;
- reporting of annual veterinary product types, uses, number of products, and total sales,[14];
- product registrations and approvals[15], manufacturing[16];
- registered chemical products[17], permits[18];
- application summaries;
- notices of consultations[19]; chemical reviews[20];
- adverse experience reporting and pharmacovigilance[21];
- APVMA-initiated and manufacturer-initiated recalls[22], information for using chemicals[23];
- invitations for information and feedback and opportunities to subscribe to information feeds[24];
- the Chief Regulatory Scientist's Blog outlining the APVMA scientific approach[25].

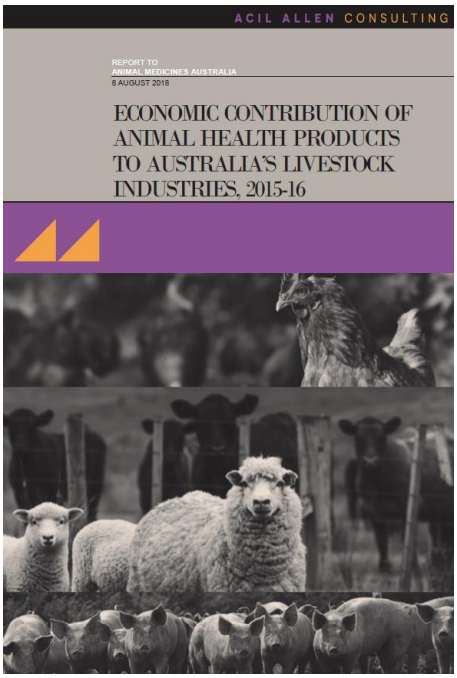
The above is not intended to be exhaustive but gives an indication of the nature and transparency of the public information that the agricultural and veterinary chemicals regulator, the APVMA, publishes on the services it provides.

[11] https://apvma.gov.au/sites/default/files/gazette_10032020_0.pdf
[12] unpublished AMA survey data
[13] https://apvma.gov.au/news-and-publications/publications/gazette
[14] https://apvma.gov.au/node/10756
[15] https://apvma.gov.au/node/6
[16] https://apvma.gov.au/node/1086
[17] https://portal.apvma.gov.au/pubcris
[18] https://portal.apvma.gov.au/permits
[19] https://apvma.gov.au/news-and-publications/public-consultations
[20] https://apvma.gov.au/node/10916
[21] https://apvma.gov.au/node/311
[22] https://apvma.gov.au/node/1081
[23] https://apvma.gov.au/node/10811
[24] https://apvma.us2.list-manage.com/subscribe?u=f09f7f9ed2a2867a19b99e2e4&id=a025640240
[25] https://apvma.gov.au/our-science

Information to support responsible use and management of veterinary chemical use is supported by a wide range of sources such as manufacturers, distributors and retail, veterinarians, industry associations, professional bodies, producer groups, processor groups, Commonwealth, State and Territory governments and agencies, consultants, and others.

Further information on the regulation of veterinary medicines is provided in Sections 3 and 4 of this submission.

AMA works closely with its members, a variety of organisations, and governments to promote an evidence-based approach to public policy. Additionally, AMA advocates for the responsible and judicious use of all veterinary medicines to improve and protect animal health and welfare.



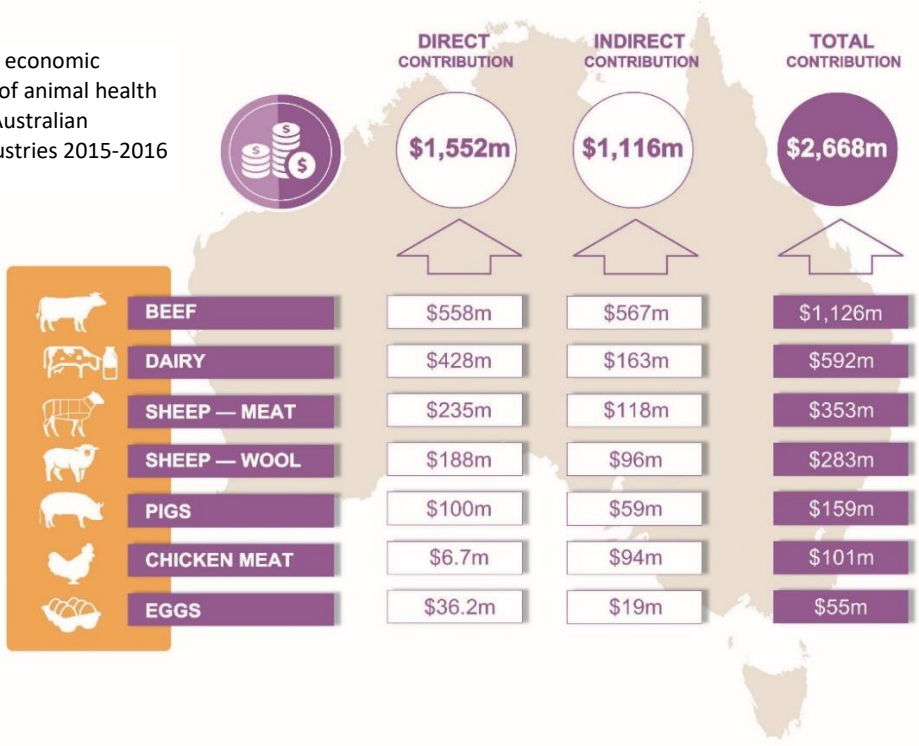
AMA engaged ACIL Allen Consulting to quantify the economic contribution made by animal health products (AHPs) in seven key commodity groups — Cattle, Dairy, Pigs, Sheep (meat), Sheep (wool), Chicken (meat) and Eggs.

The analysis[26] also estimates the consumer price impacts of animal health products on each commodity group. The analysis includes three components:

- An estimation of the production attributable to the responsible use of animal health products (in percentage terms) across the seven commodity groups,
- An estimation of the contribution made by the animal health industry to economic activity across the seven commodity groups, and
- An estimation of consumer price impacts that accrue from best practice management of animal health.

The results are summarised in Figure 1.

Figure 1: The economic contribution of animal health products to Australian livestock industries 2015-2016



[26] Acil Allen Consulting (2018), Economic contribution of animal medicines to Australia's livestock industries, 2015-16, June 2018

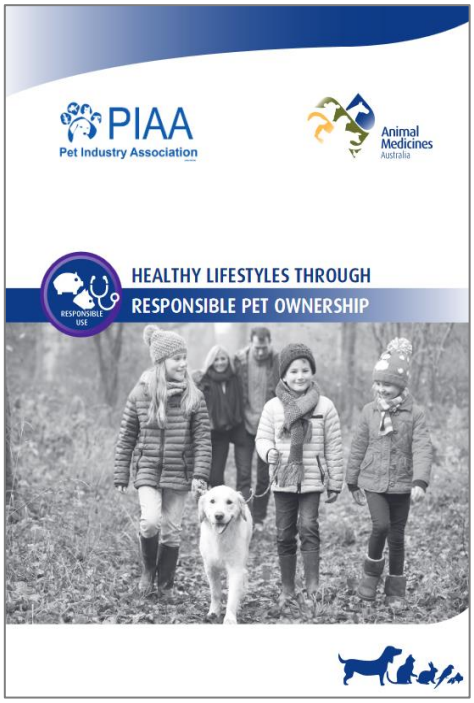
AMA also produces the triennial Pets in Australia report, which provides some of the most comprehensive information available on pet ownership in Australia. Understanding all the ways that pets contribute to Australian society is complex. The 2019 Pets in Australia Report[27] outlines key findings from the latest Newgate Research quantitative study of Australian households and the state of pet ownership. It also draws on information from experts in the pet-care industry to provide a comprehensive view of pet ownership in Australia today and over the past three years.

Through this report, there is better understanding of the role pets play in modern Australian society, both in terms of the value people place on their pets and the value they deliver to us. The report provides a comprehensive dataset to demonstrate that pets provide benefits to their owners on an individual level. When considering public policy for companion animals, we must also consider the positive contribution of pets to the broader community.

Identifying who owns pets and what type of pet they own or aspire to own, gives unique insights into:

- the breadth and diversity of the pet population, by animal type and role played in households;
- the drivers and barriers to pet ownership;
- reasons for purchase and attitudes, with insights into the human-companion animal bond;
- pet health and management, including incidences of de-sexing, adoption, microchipping, and pet insurance, as well as veterinary services and information sources; and
- estimated expenditure on pet-related purchases, by product, service type and purchase channels.

Understanding more about pet populations provides better advice to governments, industry and others about the beneficial role pets play in our community and how that can be enhanced.



AMA also provides stewardship information and guidance on a range of topics for the livestock, equine and companion animal sectors, including:

- Healthy Lifestyles through Responsible Pet Ownership[28];
- Animal Sector Commitments and Actions on Antibiotic Use[29];
- Livestock and Horses – 10 Recommendations for the Responsible Use & Judicious Use of Antibiotics[30];
- Companion Animals – 10 Recommendations for the Responsible & Judicious Use of Antibiotics[31].

AMA and its members are continuing to work to maintain the uninterrupted supply of veterinary medicines and animal health products during the COVID-19 pandemic.

[27] Animal Medicines Australia (2019), Pets in Australia: A national survey of pets and people
[28] https://animalmedicinesaustralia.org.au/wp-content/uploads/2019/10/Pet-Ownership-June-2018.pdf
[29] https://animalmedicinesaustralia.org.au/wp-content/uploads/2019/10/AB-Commitment-Designed.pdf
[30] https://animalmedicinesaustralia.org.au/wp-content/uploads/2019/10/RAUAVA-Livestock-horses-MAY-2018-23.pdf
[31] https://animalmedicinesaustralia.org.au/wp-content/uploads/2019/10/RAUAVA-Companion-Animals-MAY-2018-23-.pdf

3. The Australian regulatory landscape

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is prime and central to the regulation of veterinary medicines. This includes pre-market approvals, post-market product development, on-going post-market activities such as Good Manufacturing Practice (GMP), adverse experience reporting, and pharmacovigilance.

The APVMA may inform policy but its function is to operationalise and implement policy. The authority's principal responsibilities are described in the *Agricultural and Veterinary Chemicals (Administration) Act 1992* and the *Agricultural and Veterinary Chemicals Code Act 1994*.

The scientific quality of the APVMA is well regarded nationally and internationally.

The APVMA has had its challenges in recent years. The Authority relocated to Armidale in the Northern Tablelands of New South Wales in 2019, in the midst of severe drought and harsh water restrictions. There was a large staff turnover and significant loss of corporate knowledge. COVID-19 restrictions came into play from the first quarter of 2020.

APVMA has employed well, attracting well qualified and capable staff. APVMA has had to adapt its work strategies to enable business continuity from a remote location, including efficient use of video-conferencing. The success of videoconferencing has softened the tyranny of distance and, more recently, COVID-19 restrictions, such that important dialogue and consultations have been able to continue. Indeed, alternatives to physical meetings will no doubt become embedded as normal practice because of the efficiency benefits.

It is not intended to dwell on the opportunities for improvements in APVMA processes in this section. This is because APVMA implements policy and does not establish policy. AMA has commented on matters such as efficacy, registration by reference and other questions raised in the Issues Paper, and provided recommendations in these matters, at *Appendix 1* of this submission. Most importantly, in order to deal with questions such as these, the "system" needs to be able to progressively and continuously respond – not wait for a major review event. Efficient practices need to become embedded in the policy, approach, and operational systems to allow continuous improvements.

As the operational arm of policy, the APVMA needs to be able to evolve to deal effectively and efficiently with new technologies, methods, approaches and best practices. To do this requires an adept policy capability at the Department level.

The Issues Paper presents a complex picture of roles and responsibilities for agvet chemicals[32]. The diagram describes some of the "participants" and their outputs. An alternate high-level means of considering the system is discussed in Section 8 of this submission.

The regulatory management of veterinary medicines is part of a broader regulatory landscape for "chemicals" management, including:

- Dangerous Goods Transport (air, land, sea)
- Dangerous Goods Storage
- Chemicals of security concern
- Diversion to illicit drugs
- Retail storage
- Chemical Scheduling
- Biosecurity
- GHS labelling and Safety Data Sheets
- Environmental impacts
- Work Health & Safety
- Australian Packaging Covenant
- Trade Measurement
- Waste management
- Trade waste

[32] Matthews, K, Corbett, M, Suann, C & Astin, A 2020, *Issues paper—review of the agvet chemicals regulatory system: future reform opportunities*, Department of Agriculture, Water and the Environment, Canberra, March. CC BY 4.0. page 18

- National Pollutant Inventory
- Contaminated land management
- International treaties and conventions

For the most part, other regulation is complementary or additive rather than duplicative. For example, Dangerous Goods Storage has requirements for site manifests and site plans at eligible locations. Chemicals of security concern processes are in place to minimise the risk of commonly available chemicals being used for terrorist purposes; similarly dealing with chemical diversion to illicit drugs.

An ongoing issue where not only is there duplication, but there is potential for confusion for veterinary medicines users, is due to the placement of both "hazard" and "risk" information on product labels.

The issue arises from the classification and labelling reference used by work health and safety regulators – The Globally Harmonised System of Classification and Labelling of Chemicals (GHS).[33] The GHS is a hazard-based system. Its objectives are identified as:

> "It is anticipated that, when implemented, the GHS will:
>
> (a) enhance the protection of human health by providing an internationally comprehensible system for hazard communication;
>
> (b) provide a recognised framework for those countries without an existing system;
>
> (c) reduce the need for testing and evaluation; and
>
> (d) facilitate international trade in chemicals whose hazard have been properly assessed and identified on an international basis." (underlining added)

AMA notes that veterinary pharmaceuticals are specifically identified as out of scope of the GHS. In the GHS document's 534 pages the only reference to "veterinary" is the following:

> "At other stages of the life cycle for these same chemicals, the GHS may not be applied at all. For example, at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS (it should be noted that the risks to subjects associated with the medical use of human or veterinary pharmaceuticals are generally addressed in package inserts and are not part of the harmonisation process)."[34] (underlining added).

Veterinary medicines are "defined-use-products". This is very different to industrial chemicals which have multiple uses e.g. bulk sodium hydroxide may be used for purposes spanning chemical pulping in paper production, dissolving amphoteric metals and compounds, in the manufacture of biodiesel, as a catalyst for the transesterification of methanol and triglycerides, buffering in food products, paint stripping, and many others.

For industrial chemicals, it is necessary and appropriate to conduct a risk-assessment for each specific use, under specific circumstances of use.

For veterinary medicines, the APVMA undertakes an expert risk assessment for the defined use of a veterinary medicine.

Part 6 of the APVMA assessment modules is Occupational Health and Safety. Part 6 of the Veterinary Data Guidelines[35] describe:

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[33] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), seventh revised edition

[34] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), seventh revised edition, page 6

[35] https://apvma.gov.au/node/1021

"This document sets out recommendations and guidelines for submitting data in addition to the toxicological data recommended in Part 3 to enable the characterisation of the human health risks associated with the use of veterinary chemical products, as part of applications for registration or extensions of use and for permit applications.

The human exposure, hazard and risk data provide essential information on:

- the human health hazards of the product
- potential exposure during handling/use of the product by professional and/or domestic users
- potential post-application exposure, such as during re-handling of treated animals after spot-on or other dermally applied treatments.

Risks to people's health and safety are assessed by taking into account the hazard and the potential for exposure, using the following approach:

- Hazard evaluation—The identification of the type and nature of adverse effects that a substance has an inherent capacity to cause in an organism, animal species or human. The data relating to hazard identification are discussed in detail in Part 3 (Toxicology)

- Hazard characterisation (often referred to as the dose response characterisation)—The qualitative and, wherever possible, quantitative description of the inherent property of a substance having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

- Exposure assessment—Evaluation of human exposure to a substance based on measured, extrapolated and/or modelled exposure data for the situation.

- Risk characterisation—The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability that the adverse effect will occur in a given organism, animal species or humans under defined exposure conditions.

- Based on the risk assessment, risk management measures can be undertaken to reduce human health risks to an acceptable level where necessary. Those measures include engineering controls, safety directions (including for personal protective equipment), use restraints, re-handling intervals, and scheduling recommendations."

Overlaying the APVMA expert risk assessment with GHS hazard elements does not improve user safety and contributes to label clutter on already crowded labels. In any case, Safety Data Sheets are available to users to satisfy the additional requirements of WHS legislation.

In addition to the above, a current example is outlined at Appendix 3. In this case study, all Australian Work Health and Safety regulators, except ComCare (ACT), agreed to exempt certain veterinary medicines, in Schedules 4 or 8, from GHS hazard label requirements.

In February 2019, Safe Work Australia advised that "Subregulation 335(8) was not included in the model WHS Regulations, and the model WHS Regulations do not include any time limits on the labelling requirements for Schedules 4 and 8 veterinary medicines. This is an instance where the Commonwealth has chosen to vary the model laws and they are the only jurisdiction that has made this change." (underlining added)

AMA will be seeking to redress this situation but for the Panel, this example demonstrates the difficulties with achieving national consistency, but also that the smallest jurisdiction alone can control outcomes with national ramifications.

4. Best Practice Regulation

The Australian Government's principles of Best Practice Regulation[36] provides an objective, practical and disciplined approach to regulation and is outlined below:

> "COAG has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:
>
> 1. establishing a case for action before addressing a problem;
> 2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
> 3. adopting the option that generates the greatest net benefit for the community;
> 4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:-
>   1. the benefits of the restrictions to the community as a whole outweigh the costs, and
>   2. the objectives of the regulation can only be achieved by restricting competition;
> 5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
> 6. ensuring that regulation remains relevant and effective over time;
> 7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle;
> 8. government action should be effective and proportional to the issue being addressed."

Australian, State and Territory Governments have long established approaches to the development of regulation. AMA supports the Australian Government Principles of Best Practice Regulation[37]; and the Ten Principles for Australian Government Policy Makers[38]:

1. Regulation should not be the default option for policy makers: the policy option offering the greatest net benefit should always be the recommended option,
2. Regulation should be imposed only when it can be shown to offer an overall net benefit,
3. The cost burden of new regulation must be fully offset by reductions in existing regulatory burden,
4. Every substantive regulatory policy change must be the subject of a Regulation Impact Statement
5. Policy makers should consult in a genuine and timely way with affected businesses, community organisations and individuals.
6. Policy makers must consult with each other to avoid creating cumulative or overlapping regulatory burdens,
7. The information upon which policy makers base their decisions must be published at the earliest opportunity,
8. Regulators must implement regulation with common sense, empathy and respect,
9. All regulation must be periodically reviewed to test its continuing relevance, and
10. Policy makers must work closely with their portfolio Regulatory Reform Units throughout the policy making process

[36] https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation
[37] https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation
[38] https://www.pmc.gov.au/ria-mooc/agrp/overview/australian-government-10-principles-policy-makers

The Australian Government Regulation Impact Statement (RIS) process[39] also identifies key questions that must be answered to satisfy the RIS requirements.

From the early 2000s onwards, then Productivity Commission Chair, Gary Banks, and staff, made important speeches and presentations that discussed the concept of *minimum effective regulation*.

Together with identifying that "*reducing the level of unnecessary or poorly designed regulation will contribute to improved productivity and future living standards for all Australians"*[40] the principle of *minimum effective regulation* gives descriptive context to the way "regulation" should be approached.

AMA recognises the following statement from the Issues Paper (p.3):

> "The Australian Government aims to ensure that regulation is not unnecessarily restrictive and therefore only the minimum effective regulation needed to meet regulatory requirements should be implemented. This is an important consideration to be taken into account in the panel's deliberations on reforms to the agvet chemicals regulatory system." (underlining added)

The above principles and approaches are critical to ensure that regulatory responses are properly targeted, designed, and are proportionate. They are supported by AMA as an essential evaluation tool which can be used to assess the merits of any legislative or regulatory proposal.

5. Progressing an *INNOVATION AGENDA*

Building from *Principles of Best Practice Regulation* and the concept of *Minimum Effective Regulation* a policy statement and position could be developed that has an *INNOVATION AGENDA* as a centrepiece.

Such an agenda for veterinary medicines could capture the progressive elements of the Panel's forward plan and encompass what is needed to assist in directing policy settings to meet system goals.

INNOVATION AGENDA

- **Eliminating barriers**
- **Seamless systems**
- **Incentivising development**
- **Facilitating collaboration**
- **Inviting regulatory innovation**
- **Championing science and risk-based approaches**
- **Ensuring unencumbered trade of animals and animal products**
- **Supporting public health and animal welfare for Australia's companion animals**
- **Meeting the Social License challenge**

This approach could be linked back to the Panel's Terms of Reference with respect to the regulatory framework and deliver an easily understood platform.

[39] https://www.pmc.gov.au/ria-mooc/extra-detail
[40] https://www.wto.org/english/tratop_e/serv_e/workshop_apr11_e/porter_e.ppt

6. Industry stewardship and co-regulatory initiatives

"AgStewardship Australia is an industry-led, non-profit organisation which fosters on-farm chemical safety and waste reduction."[41]

Established in 2010, AgStewardship Australia:

- focuses on a life-cycle approach to managing agricultural and veterinary chemical products
- is responsible for the collection and management of levy contributions to fund two voluntary stewardship programs owned and operated by Agsafe Limited[42] – DrumMuster[43] and ChemClear[44], which collect empty agvet chemical containers and safely dispose of unwanted agvet chemicals respectively[45]
- has 4 member organisations: National Farmers' Federation, CropLife Australia, Animal Medicines Australia, and the Veterinary Manufacturers and Distributors Association

AgStewardship Australia identifies the scope of the undertaking (at 5 August 2020)[46] for unwanted agvet containers diverted from landfill to make useful recycled products and protect the environment:

- 35,804,368 total containers collected since 1998
- 70,434 containers saved from landfill in 2020-21
- 1,577,650 containers collected in 2019-20
- 2,821,476 containers collected in 2018-19
- 2,010,414 containers collected in 2017-18

***drum**MUSTER* collects and recycles crop production and on-farm animal health chemical containers. Empty, clean containers displaying the ***drum**MUSTER* logo are delivered to one of the 825 collection sites across Australia. Plastics make up the majority of agvet containers so by redirecting non-biodegradable plastic waste into recycling projects, ***drum**MUSTER* makes a significant commitment to environmental safety.

ChemClear collects and disposes of unwanted crop production and veterinary chemicals. It provides a safe and convenient method of disposal for chemicals that may have accumulated on properties over many years, helping to protect the environment and public safety. The focus is obsolete chemicals which may be out of date, superseded or are unused due to changes in cropping and animal management practices or regulations. Some property owners inherit unwanted chemicals when a property changes hands. ChemClear has collected more than 745,000 litres/kg of hazardous agricultural chemicals since it began in 2003.

Agsafe accredits stores supplying agvet chemical products. The accreditation process checks that stores are compliant with Commonwealth, state and territory regulations for the transport, storage and handling of agvet chemical products. AgSafe also provides training.

In addition to the above, there are a wide range of industry initiatives that promote the responsible, judicious use and management of veterinary medicines. These are at company and industry levels, and include manufacturers, distributors, retail, veterinarians, industry associations, professional bodies, producer groups, processor groups, Commonwealth, State and Territory governments and agencies, consultants, and others, as well as information such as the Animal Medicines Australia Factsheets[47].

[41] https://www.agstewardshipaustralia.org.au/
[42] https://www.agsafe.org.au/
[43] http://www.drummuster.org.au/
[44] http://www.chemclear.org.au/
[45] https://www.agstewardshipaustralia.org.au/
[46] https://www.agstewardshipaustralia.org.au/
[47] https://animalmedicinesaustralia.org.au/factsheet/

7. Reviewing the National Registration Scheme

Methodologies

Veterinary medicines, simply:

- are inputs to Australian livestock production systems. They are intrinsically linked to livestock production, markets, weather/climate, technology, farming systems and other variables; and
- serve to provide for the health and welfare of companion animals and their owners.

For the purposes of this section, the focus will be on livestock production due to the inherent complexities.

Having a view of a destination is a fundamental place to begin. It is why there are numerous plans that have titles like *2030 Road Map* or *Growing Australian agriculture to $100 billion by 2030* (setting a financial target). There is need to know what the destination looks like.

Veterinary medicines for livestock production are "inputs" to production systems. These inputs have little value in their own right - what use is a drench without a sheep to use it on? The Issues Paper does not establish a strong nexus between veterinary medicines, treated species and their ultimate commodity or purpose destination.

This is particularly important as the fate and opportunities for veterinary medicines is tied to the successes, or otherwise, of Australia livestock enterprises. In other words, the output of livestock production should be the *'centre of the universe'*, rather than the production inputs (fuels, chemicals, feeds, services etc). As suggested elsewhere in this submission "the biggest impact to the veterinary medicines sector (as production inputs) would be a strong growth phase in sustainable livestock production and exports."

AMA notes the following from a quick word search of the Issues Paper:

Table 3: References of animal species or descriptor in the Issues Paper

Animal species or descriptor	Word occurrence	Notes
Cattle	1*	* All instances are in one sentence on page 78 of the Issues Paper regarding autogenous vaccines ** 4 of the 8 mentions were in relation to an ACIL Allen study
Dairy	0	
Sheep	1*	
Pigs	1*	
Chickens	0	
Poultry	1*	
Livestock	8**	
Animal(s)	numerous	

The preceding discussion is, in no way, intended to diminish the critical role and importance of veterinary medicines. Indeed, there is value quantification in the ACIL Allen report identified in Section 2.

AMA recommends that the Panel reconsiders "the focus" in the Draft Final Report.

In December 2019, Animal Health Australia published a Megatrends Report: [48]

> *"Rapid and transformative changes in the way livestock farmers do business and the way consumers select products – driven by increasing demand, advances in technology, ecological considerations and climate variability – calls for a long-term, holistic approach to animal health and biosecurity policy in order to safeguard our investment in our herds and flocks and our adoption of new technologies.*
>
> *Central to the industry's success in this changing landscape will be addressing issues of protection against the risk of emerging diseases, and assurance of food safety, product integrity, provenance and traceability."*[49]

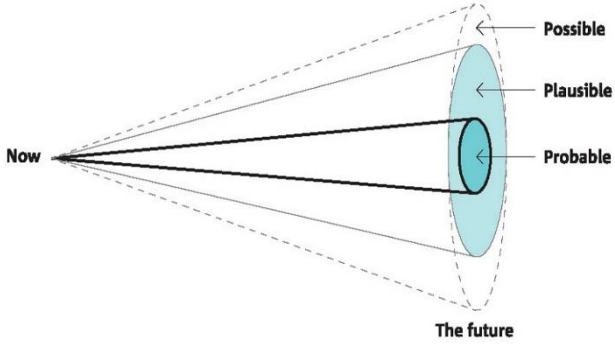
In 2013 Chemistry Australia undertook a *Strategic Industry Roadmap* exercise together with CSIRO Futures Group and supported by the Department of Industry:

> *"The Strategic Industry Roadmap is a proactive initiative of the Australian chemistry industry. It maps the requirements to drive sustainable growth and investment in the industry, and secure long-term benefits for the Australian economy, society and environment."*[50]

Given the uncertainties of the future, the study used a "futures cone" technique to identify the probable, the plausible, and the possible.

The project delivered a strategic directions report that examined the technological advances, changing environmental regulations, shifting consumer preferences and societal trends with the potential to open up new market growth areas for the chemicals and plastics industry. Importantly, the project also delivered a road-map with identified actions against timelines.

Diagram 1: The Futures Cone



Source: Adapted from Voros (2003) and Hancock et al. (1994).

The Issues Paper for this Review has provided a wide range of ideas, and no doubt consultation on these has provided the Panel with helpful and informative feedback.

It is therefore AMA's expectation that the consultation on the Draft Final Report will be more fruitful for stakeholder comment as it is hoped to provide a distilled view of a future system that will support market growth in the veterinary medicines area. It is also anticipated the Draft Final Report will also include metrics and a view of what success will look like.

7. Vision and future trends

AMA has made comments about the importance to maintain companion animals within the scope of a definition of a veterinary medicine. It is anticipated that this will be reflected in the Draft Final Report.

There is general agreement on the Vision statement, however the content of the Draft Final Report may lead to some refinements or sharpening of focus.

The future trends seem to lack a holistic focus that links the veterinary medicines sector to producers. This area may benefit from a more focussed megatrends analysis.

[48] Animal Health Australia (2009) Megatrends, opportunities and challenges facing Australian livestock industries
[49] https://www.animalhealthaustralia.com.au/our-publications/industry-publications/megatrends-report/
[50] https://chemistryaustralia.org.au/the-industry/strategic_industry_roadmap

8. Setting the framework

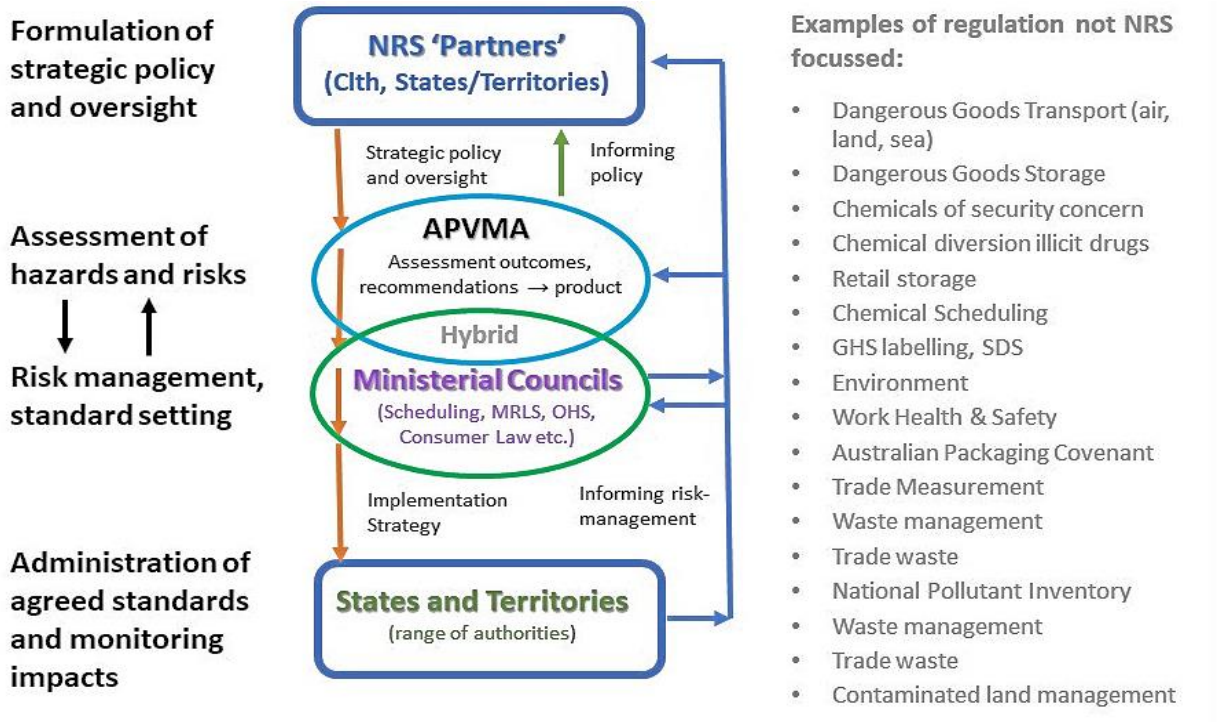
The 2008 Productivity Commission Report on Chemicals and Plastics Regulation, Research Report[51] proposed an institutional and regulatory approach for chemicals and plastics regulation:

- *Formulation of strategic policy and oversight of the institutional and regulatory arrangements* — a national function, to be undertaken by ministerial councils underpinned by intergovernmental agreements.
- *Assessment of the hazards and risks of chemicals* — a national, science-based function to be undertaken under statutory independence.
- *Risk-management standard setting* — a national function to be undertaken by independent statutory agencies within the policy frameworks of the ministerial councils.
- *Administration of agreed standards and monitoring of their impact* — jurisdiction-specific functions to be undertaken by their own agencies or delegated to other bodies such as national regulators.

As intended by the Productivity Commission, the model provides a clear framework for establishing roles and responsibilities. It also assists with clarifying where feedback loops are best placed for informing policy and informing risk-management.

The model remains relevant and a representation. Diagram X presents the model adapted for the National Registration Scheme.

Diagram 2: Draft model for the National Registration Scheme



It is important to identify the non-NRS focused legislation as agvet chemicals are part of the larger chemicals' management framework. As identified in the Case Study at Appendix 1, other legislation has consequences. During the consultations, the Panel promoted science, risk-based approaches. If that is a core value, then it needs to be defended.

[51] Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne

9. The definition of a veterinary chemical product

A side by side comparison of the two definitions does not reveal significant simplification in the new veterinary medicine definition.

Table 4: Current and proposed definitions of a veterinary chemical product/veterinary medicine

The meaning given by section 5 of the Agvet Code	Issues Paper (proposal at page 112)
Definition of veterinary chemical product (1) This section defines what is meant by a veterinary chemical product for the purposes of this Code. (2) Subject to subsections (3) and (4), a veterinary chemical product is a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly: (a) preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest; or (b) curing or alleviating an injury suffered by the animal; or (c) modifying the physiology of the animal: (i) so as to alter its natural development, productivity, quality or reproductive capacity; or (ii) so as to make it more manageable; or (d) modifying the effect of another veterinary chemical product. (3) A veterinary chemical product includes: (a) a vitamin, a mineral substance, or an additive, if, and only if, the vitamin, substance or additive is used for a purpose mentioned in paragraph (2)(a), (b), (c) or (d); and (b) a substance or mixture of substances declared by the regulations to be a veterinary chemical product. (4) A veterinary chemical product does not include: (a) a substance or mixture of substances that is: (i) prepared by a pharmacist in accordance with the instructions of a veterinary surgeon; or (ii) prepared by a veterinary surgeon; in the course of the practice, by the person preparing the substance or mixture of substances, of his or her profession as permitted by or under a law of this jurisdiction; or (b) a substance or mixture of substances declared by the regulations not to be a veterinary chemical product.	2) A veterinary medicine (VM) is defined as a substance or mixture of substances that is represented as being suitable for, or is manufactured, supplied or used for, administration or application to an animal by any means, or consumption by an animal, as a way of directly or indirectly: • preventing, diagnosing, curing or alleviating a disease or condition in the animal or an infestation of the animal by a pest • curing or alleviating an injury suffered by the animal • modifying the physiology of the animal • to alter its natural development, productivity, quality or reproductive capacity • to make it more manageable • euthanizing an animal (other than through the application of physical force), and • the use will expose persons or the environment, other than at point of application, to the product or its residues, and • the product is hazardous under the GHS • hazardous means the product is classified as in any of the top 3 categories in hazard class. A VM does not include, regardless of representation or use: • a product that is a PPP • a vitamin, a mineral substance, or a feed additive of same, orally administered to or voluntarily consumed by an animal • a substance or mixture of substances prepared by, or on the instruction, of a veterinary surgeon • instructions of veterinary surgeons must be in writing and precede the creation of the substance or mixture of substances, except where there is no suitable VM registered • instructions must comply with the relevant order for included information • instructions must be carried out by a pharmacist suitably licensed by a jurisdiction • products incorporating solely ingredients on a GRAS list • a product that is listed in Appendix B of the Poisons Standard and represented, or intended for use on a single companion animal (including an equine) • products that are consistent with the definition of a consumer good as detailed in the ACL, but not products including any constituent prohibited by the regulations • products declared not to be a VM by regulation. A VM does include, regardless of hazard classification or exposure, those products: • with uses declared to be a VM by regulation • products intended or represented as vertebrate pest control • administered to an animal by injection, other than a product for administration by injection prepared by, or on the instruction, of a veterinary surgeon (subject to conditions outlined previously). 3) Provide that entities may seek inclusion, for a fee, of chemicals on the GRAS list(s). Criteria for inclusion on the list would include that the ingredients do not present an obvious threat to human or environmental health. The GRAS list to accept by reference, inclusions of equivalent international lists (e.g. US EPA).

AMA supports the change in terminology from Veterinary Chemical Product (the meaning given by Section 5 of the Agvet Code) to that proposed as Veterinary Medicine.

However, AMA:

- does not support the use of a GHS hazard classification in the definition of a veterinary medicine (bullet points 8 and 9)
- would like to explore the Panel's rationale for including "instructions" (bullet points 13-15)
- would like to explore the Panel's rationale for exclusion due to entry in Appendix B of the Poisons Standard (bullet point 17). The nexus of scheduling and efficacy of a veterinary medicine is not clear and requires more elaboration
- does not support removal of over-the-counter veterinary medicines for companion animals (bullet point 18)

AMA appreciates that the Panel will have engaged in lengthy discussion on the definitions of both agricultural chemicals and veterinary medicines during the consultation and submission phase of the review. It would be helpful for the Panel to further engage stakeholders prior to finalisation of definitions to be included in the Draft Final Report.

11. Priority issues for animal medicines

11.1 System expectations, including science risk-based

Throughout the Issues Paper, the Panel is seen to support scientific evidence and risk-based approaches. AMA strongly supports that science and risk-based approaches will be core and undying principles for operation of the NRS and the APVMA.

In its covering letter to this submission, AMA has outlined the coherent elements and principles that AMA is anticipating in the Draft Final Report, including:

- adherence to Best Practice Regulatory Principles,
- embodying Minimum Effective Regulation,
- embedding science and risk-based approaches
- robust methodologies for institutional and regulatory approaches,
- strategic focus with clear reference to the Regulatory Framework of the Terms of Reference,
- recognising the business operating environment for veterinary medicines,
- considering whether proposals are "implementable",
- preliminary evaluation of costs of implementation and maintenance of proposals,
- a clear roadmap with indicative timelines,
- progress and achievement of outcomes must be measured in years, not decades,
- selected scenario testing,
- considering strategies to reduce or remove barriers to progress, and
- clear and attributable accountabilities.

11.2 System characteristics

A fit for purpose **regulatory framework** that:

- recognises the business operating environment for veterinary medicines
- defines characteristics and attributes of a new framework to provide the vehicle for delivering new advances and developments e.g. rather than trying to pick winners such as smart labels, drone technology and others
- provides the conditions and environment for advances to be encouraged, developed and adopted. Given the advances in the last decade there is no way to foreshadow the types of advances that may occur over the next 3 decades
- is nationally consistent through a seamless national arrangement (incl. control of use)
- creates meaningful advances in efficiencies and effectiveness
- is implementable, and is implementable in a reasonable timeframe with minimum disruption
- is modelled on best practice regulation principles and regulatory impact analysis
- recognises that further costs of a new model for the NRS not be directed to registrants and approval holders
- "ideas" must have consideration of funding and ramifications
- resolves issues of MRLs and trading partners
- maintains, promotes and defends risk-based approaches, including resolution of existing anomalies in areas such as labelling
- ensures that OTC veterinary medicines are maintained within the definition of a veterinary medicine
- recognition that industry stewardship programs contribute to shared responsibility between industry and government
- there are synergies in having agvet chemicals housed together and this be maintained
- sustainable Funding of new regulatory scheme based on principles, Public Goods
- recognises that data protection periods for veterinary medicines need to be increased to provide incentives for developments and other activities

11.3 System must provide framework to resolve issues and facilitate new technologies – over the medium term it must be self-correcting

The flagship items in the Issues Paper lack some strategic context. Some:

- would seem to impact the regulatory risk-appetite - reduced levels of regulatory intervention; exclusion of certain products, changed efficacy requirements, registration by reference, registering 'me-too' products by declaration etc.
- are administrative options – accredited accessor scheme
- are symptoms of the current framework – lack of national consistency/uniformity of control-of-use

A new regulatory framework must provide the flexibility to enable change and new developments, but not prescribe them.

11.4 Maintained coverage of companion animal medicine products

The rationale for removing companion animal medicines from the system is not strong and there are compelling reasons for continued regulation of these products, based on animal safety, animal welfare, user safety, zoonotic disease risks and adverse consequences for pets and pet owners that arise from inefficacious flea or tick products. OTC products for companion animals should remain within the NRS definition of veterinary medicines.

11.5 Limitations on protected data – anomalies need to be resolved

An anomaly arose in the late 1990s/early 2000s in differences between the periods of data protection afforded to agricultural chemicals and veterinary medicines.

Whilst well established in North America and Europe, at the time of Australian introduction, attributing protection to certain types of data was new. In the negotiations, veterinary medicines ended up with a more conservative or lesser period of protection in some data categories, particularly those that related to innovation and product support.

The key difference is that agricultural chemicals data received 5 years of limited use, whereas veterinary medicines received 3 years. There was, and is, no logical or policy reason for this difference. This lesser period contributes to disincentives for veterinary medicine investment in innovation for Australia and needs to be rectified.

The table below[52] sets out the relevant limitation periods for information given in connection with an application made under section 10 or 27 of the Agvet Code (reproduced here from the APVMA website for convenience):

Item	Information types	Limitation periods
1	Information 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 and the information was relied on for approval of the active constituent	10 years after the active constituent is approved
2	Information given in connection with an application under section 10 for: a) 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 b) 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 the information was relied on to register the product or approve the label	10 years after the product is registered and the label approved
3	Information given in connection with an application (except one covered by item 2) made under section 10 for registration of an agricultural chemical product or approval of a label for a container for an agricultural chemical product, and the information was relied on to register the product or approve the label	5 years after the product is registered and the label approved

[52] https://apvma.gov.au/node/331

4	Information given in connection with an application (except one covered by item 2) made under section 10 for registration of a veterinary chemical product or approval of a label for a container for an agricultural chemical product and the information was relied on to register the product or approve the label	3 years after the product is registered and the label approved
5	Information given in connection with an application made under section 27 for variation of the relevant particulars or conditions of the registration of an agricultural chemical product or approval of a label for a container for an agricultural chemical product and the information was relied on to vary the relevant particulars or conditions	5 years after the relevant particulars or conditions are varied
6	Information given in connection with an application made under section 27 for variation of the relevant particulars or conditions of the registration of a veterinary chemical product or approval of a label for a container for an veterinary chemical product, and the information was relied on to vary the relevant particulars or conditions	3 years after the relevant particulars or conditions are varied

The table below sets out the limitation periods for information given to the APVMA under section 161 of the Agvet Code:

Item	Circumstance in which information is given	Limitation period
1	Given under section 161 in connection with an agricultural chemical product	5 years after the information is given
2	Given under section 161 in connection with a veterinary chemical product	3 years after the information is given

AMA notes that lack of consistency of national approaches to control of use, compliance, and enforcement undermines the intent of data protection and reminds us of the interlinking elements of the system that need to work together to achieve intended outcomes.

11.5 "Trade" must be resolved for the long-term

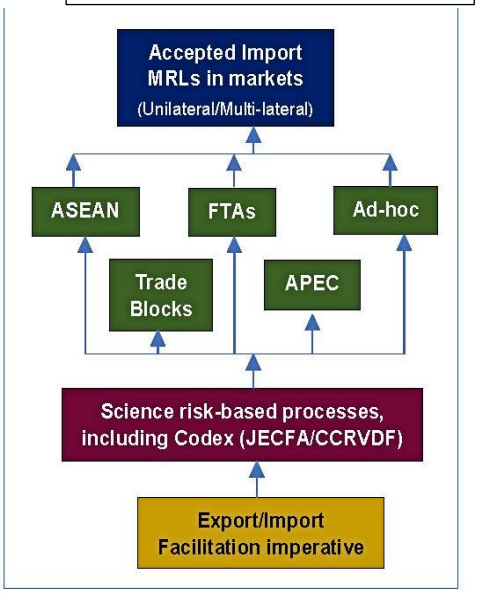
DAWE is aware of AMA's serious concerns in this area. The case for securing animal import MRLs in Australian export market was made at a meeting of AMA with the Panel, Departmental and APVMA personnel on 13 March 2020. A briefing note provided at that meeting is provided at Appendix 6 to this submission.

It is understood that the Department is keen to secure a FARAD-type database[53]. AMA is not supportive of such an approach as it is a band-aid to a symptom and does not address the larger problem.

AMA also notes that its outlined approach is consistent with the adopted approach for pesticides.

Trade considerations within the NRS remain an unresolved disincentive for product development of certain veterinary medicines in Australia. An informative case study has been provided by an AMA member direct to the review.

Diagram 3: Export Representation



[53] http://www.farad.org/

11.6 Regulator performance

The overall NRS and the APVMA need to be subject to continuous improvement. To do this, meaningful metrics need to be established to measure progress and the ongoing suitability of the Scheme.

12. Consideration of the Panel's Flagship items and other questions raised in the Issues Paper

The Panel has identified seven key flagship reform proposals that they consider could result in significant improvements to the system.

Some of the items under consideration would seem to modify the risk-appetite, including reduced levels of regulatory intervention (such as the exclusion of certain products, changed efficacy requirements, registration by reference and registering 'me-too' products by declaration), whilst other issues are **symptoms** arising from the lack of national consistency of control-of-use in the current framework.

A new framework needs to provide the flexibility to **enable new developments** e.g. smart labels, drones etc., without trying to pick "winners". Regulation can help to provide the environment and incentives to innovate, but government intervention directly into commercial areas must be avoided.

12.1 The Panel's Seven Flagship items

Flagship 1: Increasing national consistency of control of use

"There should be one coherent national system, with consistency in control of use and any differences amongst jurisdictions should be required to be justified publicly"

National consistency is a core issue. Rather than "increasing national consistency" the goal must be "a nationally consistent control of use regime".

The need for nationally consistent outcomes must consider the overall policy objectives and provide for a seamless approach from the registration and approval process, to sale and supply of products and their ultimate use. Such would encompass all elements of consistency with respect to control of use, control of use licensing, and the role of permits.

Flagship 2: Removing consumer and non-primary production products from the system

Removal of over the counter (OTC) companion animal products from the NRS scope.

The rationale for removing companion animal medicines from the system is not strong and there are compelling reasons for continued regulation of these products, based on animal safety, animal welfare, user safety, zoonotic disease risks and adverse consequences, for example, for pets and pet owners from inefficacious flea or tick products. AMA's position is that companion animal OTC products must remain within scope of the NRS.

Pet ownership in Australia is increasing. Pets play multiple, varied and important roles in the lives of the Australian population. Pets provide comfort, companionship, entertainment and sense of purpose, and are increasingly regarded as 'members of the family'. Companion animals also have important roles as assistance and service animals, supporting their owners to maintain independent lives and providing valuable community benefits. It would seem unlikely that removing OTC companion animal products from the system would be accepted by the public.

Regulation of OTC companion animal within the NRS is consistent with approaches in comparable regulatory jurisdictions (e.g. the EU, US, NZ).

Flagship 3: Introducing a benefits test

The panel proposes a benefits test to inform registration, reconsideration, and workflow prioritisation decisions that gives weight to new actives or uses; positive social or economic impacts; benefits to production, animal welfare and environmental outcomes; and other considerations.

AMA is not convinced that the institution of a benefits test would lead to better outcomes. The concept needs more development and viable alternatives examined through asking the simple Regulation Impact Statement (RIS) questions, including:

- What is the problem?
- Why is action needed?
- What policy or operational options are you considering?
- What are the likely pros/cons and likely net benefit each option?

Other options, for instance to promote innovation, might include reduced timeframes for certain "innovative" application types. More generally, the regulators resources could be balanced across all applications to deliver improved time-managed outcomes.

Importantly, the net benefits for options need to be established and fed into an impact statement process.

AMA suggests evaluation of fast-tracking initiatives already undertaken by the APVMA, including the following APVMA reporting:

> **New fast-track registration system**
>
> 29 July 2016
>
> The APVMA has developed a new fast track registration system to quickly process applications of low regulatory concern. The system aims to reduce regulatory burden by:
>
> - accelerating approvals
> - reducing the number of detailed assessments
> - increasing capacity for applications that require more detailed consideration.
>
> This system is being rolled out as a 'pilot' for repack (item 8) applications where the applicant is referencing their own product. Following the pilot study, it is expected that this fast track capability will be expanded over time.
>
> https://apvma.gov.au/node/20501

AMA suggests that the current Review confirms that APVMA has the authority to deal with urgent or emergency situations, such as dealing with a new exotic pest or disease. It would be helpful if this capability was communicated in the Draft Final Report.

AMA is unable to support a Benefits Test as a condition of registration, similar to the process in New Zealand, at this stage. AMA understands that this type of benefits test may pose potential barriers which can significantly delay the registration of products

Flagship 4: Changing the way chemical product efficacy is managed

The panel proposes three options: removing efficacy from the scope of regulation (except where its failure to perform as stated could create a human safety or animal welfare issue) (option 1); removing the requirement for efficacy assessment (option 2); maintaining the requirement but streamlining assessment (option 3). The panel states its inclination to:

- support option 1 for all crop protection products and non-scheduled veterinary medicines
- support option 2 for scheduled veterinary medicines

The Issues Paper (p.67) notes:

> "All comparable international regulators perform some level of efficacy assessment for veterinary medicines"

AMA understands that assessment of efficacy is generally not a time limiting factor compared other data assessments such as toxicology, residues and other data. It is suggested that reputable companies would continue to generate efficacy data in support of their products.

The Panel has indicated its interest in:

- support option 1 for all crop protection products and non-scheduled veterinary medicines
- support option 2 for scheduled veterinary medicines

The nexus of scheduling and efficacy is not clear and requires more elaboration.

The caveat provided by the Panel for Option 1 that "except where its failure to perform as stated could create a human safety or animal welfare issue" would also seem to apply to Option 2, thereby making the distinctions between the options somewhat nebulous for veterinary medicines.

AMA believes there is opportunity to refine Option 3 to maintain the efficacy criterion with amendments to the requirements and streamlining of assessments. Opportunities at the APVMA operational level should be maximised. The Issues Paper (p.70) identifies:

"There would be no changes to the current efficacy criterion but the circumstances where evidence of product efficacy must be provided could be further reduced, perhaps in line with the safety concepts explored in option 1.

There would also be scope to consider streamlining the assessment process through:

- accrediting efficacy assessors to allow the assessment to be completed prior to applications being submitted to the regulator
- mandating use of overseas regulatory decisions (and/or assessments) as sufficient to address efficacy requirements for an equivalent product use in Australia
- where available, establishing arrangements where the past behaviours and current stewardship practices of an applicant warrant reduced pre-market scrutiny of a product's efficacy."

Flagship 5: Introducing a registration by reference approach

The panel proposes adoption of registration by reference that has the following key features:

- products registered by one of more comparable international regulatory system would be accepted for registration in Australia with no assessment required, only aspects unique to Australia would require assessment;
- what is unique to Australia would be defined (e.g. streamflow, different strains and growing conditions on pest susceptibility and target plant/animal toxicity, Australian diet);
- defined parameters around when products could be considered under this approach;
- defining who and how comparability of another regulatory system is defined.

The concept has merit but throughout the Issues Paper discussion there is no mention of who may seek the Australian registration, particularly with regard to overseas entities and their relationships with a local applicant. It is essential to clarify authorities for accessing information and any property rights that might arise. This is required before further evaluation of the proposal.

Given the machinery that needs to be established to give effect to this item, care needs to be taken on costs and benefits, and in particular priority, compared to other options.

AMA would be pleased to engage in a process to further explore this topic.

Flagship 6: Introducing smart labelling

The panel proposes introducing smart labels (e-labels) that contain smart content and are machine readable. The panel is also proposing that containers above a certain volume would have to be machine readable.

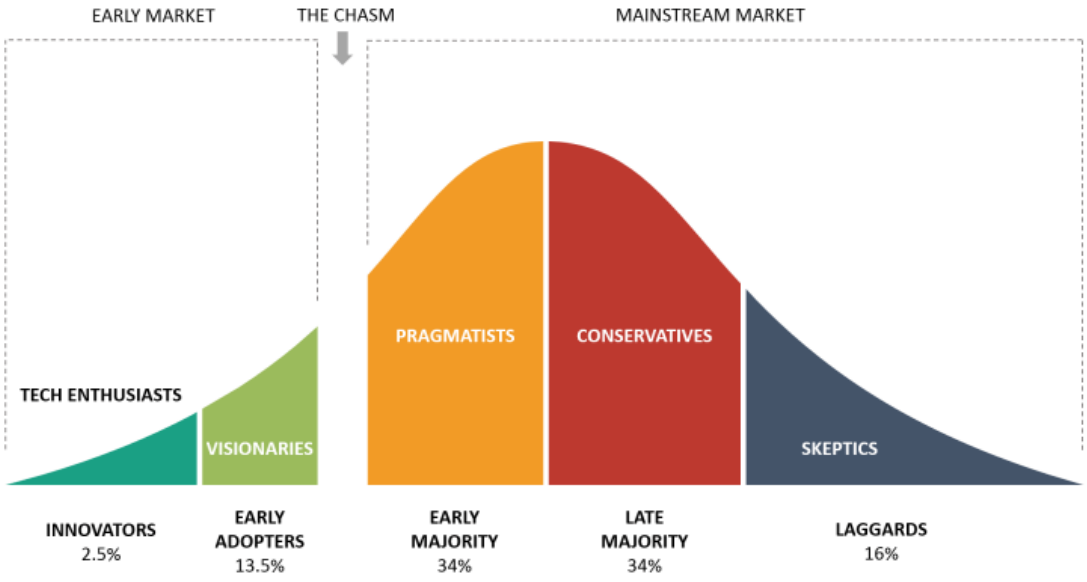
Australia has a reputation as an early adopter of new technologies.

Smart labels need to be considered as part of a range of new technologies - some not even yet imagined. It is understood that during the Panel's consultation process, a number of technology developments were raised, including the use of drones.

AMA suggests that the Panel avoid the temptation to try to 'pick winners'. To be enduring, facilitation of new technologies in Australian agriculture and livestock production needs to be effected in a transparent way to ensure that clear benefits can be harvested.

Part of the process will be to utilise the tomes available on technology development and to integrate these into an approach that deals with technical, social and adoption challenges.

Diagram 4: Innovation stages



https://www.business-to-you.com/crossing-the-chasm-technology-adoption-life-cycle/

AMA would be pleased to engage in a collaboration on this important topic with the view to establishing clear pathways to technology adoption. Smart labels may prove a useful first up case study and provide useful learnings as a basis for progressing a range of new technologies

Flagship 7: Introducing an accredited assessor scheme.

The panel is inclined to recommend the establishment of an accreditation scheme for third party assessors, like that which operates in New Zealand, based on the model proposed in the lapsed Streamlining Regulations Bill of 2019. The scheme would:

- be legislated; and specify minimum requirements for professional experience; insurance; conflict of interest protections; and data handling protocols;
- include oversight of audit and compliance by the regulator;

- Include provisions for the regulator to cost recover its accreditation functions;
- Include the accreditation of international assessors; and
- Include penalty provisions (administrative, civil, and criminal), and sanctions -compliance.

AMA responded to consultations leading to the lapsed Streamlining Regulations Bill of 2019.

AMA is generally supportive of the concept but any final scheme must deliver efficiencies, timeliness and be cost effective. The efforts to manage the assessor program must not outweigh the benefits.

From a workability perspective, there need to be timeshift options for the efficacy assessment to be provided during an overall APVMA assessment (not as part of the initial submission) to avoid lengthening timeframes. This was identified as a shortcoming of the 2019 scheme.

The administration of that scheme (i.e. assessing the assessors) should be external as this is not core APVMA business. APVMA must consider its impact on timeframes – if using external assessment pre-application does not reduce timeframes after application, then it will not be widely used.

The boundaries between, and responsibilities of, the external assessor and the APVMA, must be clearly defined when such an arrangement is used. Applicants would need assurance that the advice of the external assessor would subsequently be followed by the regulator, and thus provide an efficiency improvement. There should also be a reduction in the relevant fees to reflect the significantly lower burden placed on APVMA when an external assessor is used.

AMA has concerns that this could become another administration strain on APVMA when there may be higher priorities to focus on, especially if this scheme is not likely to be widely used. This scheme could potentially impose additional costs on registrants and create an additional layer of project management and oversight that would not necessarily provide any concomitant improvements in performance or standards.

12.2 Other questions raised in the Issues Paper

A range of questions contained in the Issues Paper have general responses detailed at Appendix 1.

13. Funding the NRS

AMA's position is that any new funding requirements from initiatives and programs that stem from this Review must not be directed to registrants and holders. Elements of the veterinary medicines business operating environment have been described elsewhere in this submission. Additional business costs will divert expenditures away innovation and other necessary investments.

AMA is mindful of the Australian Government Cost Recovery Guidelines and has welcomed the Panel teasing out a discussion on 'public good'. AMA looks forward to the Panels distillation of its thoughts in the Draft Final Report.

14. Meeting the social license challenge

AMA has included social licence as a framework element in its *INNOVATION PLATFORM* outline.

AMA believes that the consideration of a cross-sector approach encompassing value similarity, confidence, competence, and trust, leading to social license and freedom to operate, would best occur through a dedicated process. AMA would welcome further dialogue on this topic.

Appendix 1

Animal Medicines Australia responses to questions raised in the Issues Paper

The comments provided below are not intended to provide coverage of all questions or a full analysis or litigation of a topic but to provide a basis for the Panel to gauge sentiment. More detailed responses will be provided, where required, or for the Draft Final Report.

- **Improving engagement with all stakeholders on regulatory aspects of the NRS**

  It is important to clearly identify the intent of roles and responsibilities of consultative or engagement forums:

  - Informational – educating on the NRS
  - Informing policy
  - Informing APVMA operational matters

  In late 2019, the APVMA conducted a consultation on its stakeholder engagement framework[54] and identified a considerable range of committees or forums that already exist and which incorporate the categories above:

  - Industry consultative forum
  - Industry and community consultative forum
  - State and territory regulators (Harmonised Agvet Chemicals Control of Use Task Group—HACCUT)
  - International regulator forums
  - GRDC roadshow, northern regions
  - Manufacturers and distributors working group

  AMA supports a disciplined approach to committee/forum management:

  - clear terms of reference, including purpose
  - best practice regulatory principles as a foundation
  - developed forward agenda and workplans
  - articulated metrics and success measures with annual evaluation

  Operation of these groups, and any others that may be proposed, needs to have clear consideration of funding sources.

- **Establishing a formal consultative committee to facilitate communication with the regulator**

  A consultative committee is one way of communicating with interested parties. It seems that this proposal would benefit from further scoping. Noting:

  > "The panel sees value in establishing a formal consultative mechanism that brings together and facilitates communication between governments (regulators and policymakers), agvet chemicals suppliers, users and community groups."

  This appears to be a different audience to that described in the UK Pesticide Forum Model.

  As the Panel suggests, a Consultative Forum should have active functions (deliverables) to improve its "chances of survival." This is unfortunate wording, because it makes it sound as though the tenure of the Forum may be tenuous from the outset.

  One of the challenges for the previous APVMA Community Consultative Committee was that it was placed within an **"operational"** organisation rather than the **"policy"** Department. This should be considered in the further scoping of a proposal.

[54] https://apvma.gov.au/node/60086

- **Is there a need for more community information on regulatory actions?**

  The Australian agricultural and veterinary chemicals regulator, the APVMA, publishes a wide range of information for public consumption, including:

  - monthly gazettes[55] detailing notices of registrations, new active constituents, cancelations, proposals to amend Schedule 20 of the Australia New Zealand Food Standards Code, amendments to standards, licensing of veterinary chemical manufacturers, approved active constituents and other detailed materials;
  - reporting of annual veterinary product types, uses, number of products, and total sales[56];
  - product registrations and approvals[57], manufacturing[58];
  - registered chemical products[59], permits[60];
  - application summaries;
  - notices of consultations[61]; chemical reviews[62];
  - adverse experience reporting and pharmacovigilance[63];
  - APVMA-initiated and manufacturer-initiated recalls[64], information for using chemicals[65];
  - invitations for information and feedback and opportunity to subscribe to information[66]; and
  - the Chief Regulatory Scientist's Blog outlining the APVMA scientific approach[67].

  The above list is not intended to be exhaustive but gives an indication of the nature and transparency of the public information that the agricultural and veterinary chemicals regulator, the APVMA, already publishes on the services it provides.

  Given its policy role, it may be helpful for DAWE to coordinate a web-based resource that encompasses Commonwealth, State and Territory information – such a resources would be of value not only to direct stakeholders but also to the broader community.

- **Operational regulatory working group – must have industry representation**

  Prior to establishing an operational working group, the terms of reference and mode of operation need to be carefully evaluated, particularly how to best use streams for agricultural chemicals, veterinary medicines and informing policy.

  There is an important interface between operational considerations and policy. Solutions commonly involve the policy arm.

  AMA recognises the benefits of the past committee structures, and positive experiences of those committees.

- **Assessing chemical use by region, environmental conditions etc. instead of state boundaries.**

[55] https://apvma.gov.au/news-and-publications/publications/gazette
[56] https://apvma.gov.au/node/10756
[57] https://apvma.gov.au/node/6
[58] https://apvma.gov.au/node/1086
[59] https://portal.apvma.gov.au/pubcris
[60] https://portal.apvma.gov.au/permits
[61] https://apvma.gov.au/news-and-publications/public-consultations
[62] https://apvma.gov.au/node/10916
[63] https://apvma.gov.au/node/311
[64] https://apvma.gov.au/node/1081
[65] https://apvma.gov.au/node/10811
[66] https://apvma.us2.list-manage.com/subscribe?u=f09f7f9ed2a2867a19b99e2e4&id=a025640240
[67] https://apvma.gov.au/our-science

The concept is interesting and has been raised in the past. The complexities, State and Territory legislation, mapping regional boundaries and other factors, may prove insurmountable.

For veterinary medicines, this is not a priority item of endeavour.

- **Adopting a national approach to compliance and enforcement of agvet chemical use**

  The Panel has sought responses to a range of questions on risk-based approaches, national consistency and regulatory tools.

  All regulators have a suite of tools available to them. In moving to nationally consistent approaches, an optimal set of regulatory tools needs to be determined, based on current best regulatory practices. It would be a consultation on those tools where stakeholder comment will be most valuable.

  Compliance and enforcement needs to be part of the processes that work towards administrative simplification, transparency, and communication. Enforcement tools, with defined escalation, need to be directed to encouraging desired behaviours.

  The question relating to screening of registration-holders will be best considered in working through elements leading to a new nationally consistent control of use, compliance and enforcement plan. There needs to be a coherent plan where an element like screening of registration holders can be evaluated – it is not an outcome in its own right, and there may be other responses that achieve the same objective but have not yet been evaluated.

  AMA would be pleased to engage in a process to further explore this item.

- **International networks – linkages**

  The APVMA Annual Report 2018-19[68] identifies APVMA's program of international engagement, and includes:

  - American Chemistry Society;
  - FAO/WHO Joint Meeting on Pesticide Residues;
  - VICH Anthelmintic Working Group;
  - APEC food safety cooperation forum, maximum residue limits harmonisation workshop;
  - Codex Committee on Pesticide Residues; and
  - Other specialist working group meetings.

  As the "operational" arm of the NRS, it is important that APVMA maintains engagement with parties that it needs to fulfill its functions as the national agvet regulator. Its role should not be to go beyond its legislative mandate and this should be transparently demonstrated.

- **Considering of 'public goods' and future funding of the NRS**

  Earlier sections of this submission have described elements of the veterinary medicines business operating environment, including a relatively small market (2.2% of world sales) and long term declining or flat agricultural livestock numbers. For sheep, the numbers are stark, with a reduction of more than 100 million head in the national flock since 1990.

  The future funding of the National Registration Scheme needs to consider the consequences of scenarios and proposals. It is important to avoid a simplistic drive of loading costs to the veterinary medicines market participants. In terms of innovation, an increasing cost regime may have the opposite to intended effects.

  Earlier in this submission, AMA made the following observation:

[68] https://apvma.gov.au/sites/default/files/publication/57211-apvma_annual_report_2018-19.pdf

Whilst there will always be a market for livestock veterinary medicines in Australia (simple demand and supply), without significant reform, this market will be high cost, impede innovation and hamper access to world best technologies and products.

AMA will be pleased to provide ongoing contribution to the development of a reformed NRS.

- **Increasing accountability and shared responsibility of industry for the safety and use of products**

  The veterinary medicines industry makes significant contributions to support the judicious and responsible use of its products. This occurs at a range of levels, from the efforts of individual companies through to activities at the industry level. Part 4 of this submission identifies the long-standing industry steward initiatives through:

  - AgStewardship Australia
  - AgSafe
  - DrumMuster
  - ChemClear

  AgStewardship Australia identifies the following outcomes:

  - 35,804,368 total containers collected since 1998
  - 70,434 containers saved from landfill in 2020-21
  - 1,577,650 containers collected in 2019-20
  - 2,821,476 containers collected in 2018-19
  - 2,010,414 containers collected in 2017-18

  These are significant contributions from an industry committed to health, safety and the environment for the long term. In addition to the above, there are a wide range of industry initiatives that promote the responsible, judicious use and management of veterinary medicines. These are at company and industry levels, and include manufacturers, distributors and retail, veterinarians, industry associations, professional bodies, producer groups, processor groups, Commonwealth, State and Territory governments and agencies, consultants, and others.

- **Do you agree that certain product uses, such as those administered by injection, warrant the direct involvement of veterinarians, separate to the controls under the poisons scheduling?**

  The Issues Paper does not provide background or justification for this proposal.

  There are many registered non-prescription injectable veterinary medicine products. The risk of which has already been assessed as not requiring veterinary intervention.

  To restrict such injectable veterinary products to be administered by or under the instruction of a veterinarian would severely compromise the current use of many such critical products, in particular by primary producers (for example, livestock vaccines and injectable nutritional products).

  AMA invites further evidence of a problem from the Panel.

- **Improving chemical residue monitoring programs in food, waterways and the environment.**

  From its consultations and submissions received, the Panel may have increased its understanding of current schemes that are operating by the public and private sectors. In particular, those run through the retailers and grower industry groups.

Residue monitoring is essential to demonstrate system compliance to confirmed standards. This is important to domestic customers and to overseas markets for Australian products.

On the topic of harmonisation and national consistency, the Issues Paper identifies:

"The lack of progress in, and effectiveness of harmonisation needs to be addressed. It appears to the panel that the competing demands of governments and parliamentary systems in each jurisdiction and the Commonwealth is unlikely to ever efficiently achieve national consistency in control of use. Given that each jurisdiction will act, understandably, in the interests of their own state or territory, the current process is fraught with difficulty and may only ever deliver small incremental reforms." (underlining added)

When more thoroughly investigated, there may be as-yet undescribed, viable options.

For veterinary medicines, AMA would be pleased to engage on this matter.

- **GMP as a basis for not requiring separate site evaluation**

  There is insufficient information in the Issues Paper to be able to fully evaluate this proposal. It is suggested that the Panel refer this matter to the APVMA Manufacturer Licensing Committee Industry Liaison Group (MLC-ILC).

  The MLC-ILC is next scheduled to meet on 20 September 2020.

- **Accreditation schemes for permit and registration holders**

  Insufficient information is available from the Issues Paper for AMA to be able to form a view.

- **Duty of care proposal**

  This is a significantly large topic. AMA would be pleased to engage further on this topic.

- **Chemical combinations**

  For pesticides, the European Food Safety Association (EFSA) recently completed two pilot studies investigating the cumulative effects of pesticide residues. These studies concluded that the consumer risk for dietary cumulative exposure was below the threshold that triggers regulatory action in the EU.[69]

  The Panel will be aware that the APVMA's current pharmacovigilance and adverse experience reporting program provide the APVMA with the ability to investigate the potential impacts of chemical combinations and respond through the chemical reconsideration process.

  Notwithstanding, APVMA will be monitoring developments such as these on an ongoing basis.

- **Regulatory simplification – document and comment on each proposal: registration by declaration, removal of efficacy, use of standards, registration by reference**

  Registration by reference

  AMA' position is detailed at Section 12.1 of this submission dealing with the Flagship Items.

  Removal of efficacy

  AMA' position is detailed at Section 12.1 of this submission dealing with the Flagship Items.

[69] https://www.efsa.europa.eu/en/news/cumulative-risk-assessment-pesticides-faq

Registration by declaration

The panel provides three options (notification, linking repack products to the pioneer product and maintaining the status quo). The panel is disposed towards making repack applications a declaration/notification process that does not require any further assessment by the regulator.

AMA is supportive of simplifying and streamlining the repack application process. There appears merit in further exploring the Panel's recommendation that repack applications become a declaration/notification process. An opportunity for the regulator to confirm that a formulation is in fact the same as the reference product must be retained.

In the event that the registration of the pioneer product is cancelled, AMA conjectures that it may be appropriate to also cancel the registration of all repacks, except where the registration holder is in possession of appropriate data and product information. This may come about through certain authorisations granted by the pioneer prior to the reference product ceasing to be registered.

In the current marketplace, there could be a large numbers of products registered where the pioneer product ceased to exist as an entity long into the past.

Whilst AMA provides in-principle agreement to simplifying and streamlining the process for repacks, there is significant work and engagement yet to be undertaken on this issue in order to progress a proposal.

AMA would be pleased to engage in a process to further explore this item

- **Standards**

It should be noted that the use of EPA Group Standards in NZ only applies to assessment of hazards – it does not allow for a complete registration through compliance to a Group Standard, ACVM still assesses efficacy, safety, and chemistry and manufacture data.

Use of standards may nevertheless simplify the registration process for some chemicals and groups and is has in-principle support.

The Issues Paper rightly identifies

> "The APVMA's use of standards is currently significantly under-utilised. The APVMA has established only two listed product standards, home swimming pool and spa products and joint health products for dogs and horses; and one reserved product standard for some hard surface disinfectants. Both mechanisms require direct implementation through changes to the regulations, by contrast the NZ EPA Group Standards only need to be published in the Gazette."

AMA recalls that some of the impediments to progressing the APVMA provisions, included:

- the complexity of the provisions (as identified in the Issues Paper);
- who was motived to prepare specifications for listing or reservation (registrants, industry associations or the regulator)

In any case, the APVMA experience did not achieve its desired outcome. It would be worth interrogating this aspect further to avoid previous pitfalls.

- **Data mining**

AMA does not have a current view. The Issues Paper describes some of the challenges to be resolved, including in regards to intellectual property and privacy. The interface of data mining

with other systems, as well as validation methodologies, seems to be an area yet to be explored for Australian livestock, companion animals and veterinary medicines.

Notwithstanding, the Issues Paper suggests:

> "It could also play an important role in a post-market safety surveillance program for veterinary products. For instance, data mining algorithms have been developed to improve the detection of products of concern in Adverse Event Reporting (AER) databases. The panel sees this as a significant potential benefit for animal welfare".

It is helpful for the Panel to raise the opportunity, but this needs full and careful consideration through a dedicated process that may also involve other areas of the Commonwealth and State and Territory governments.

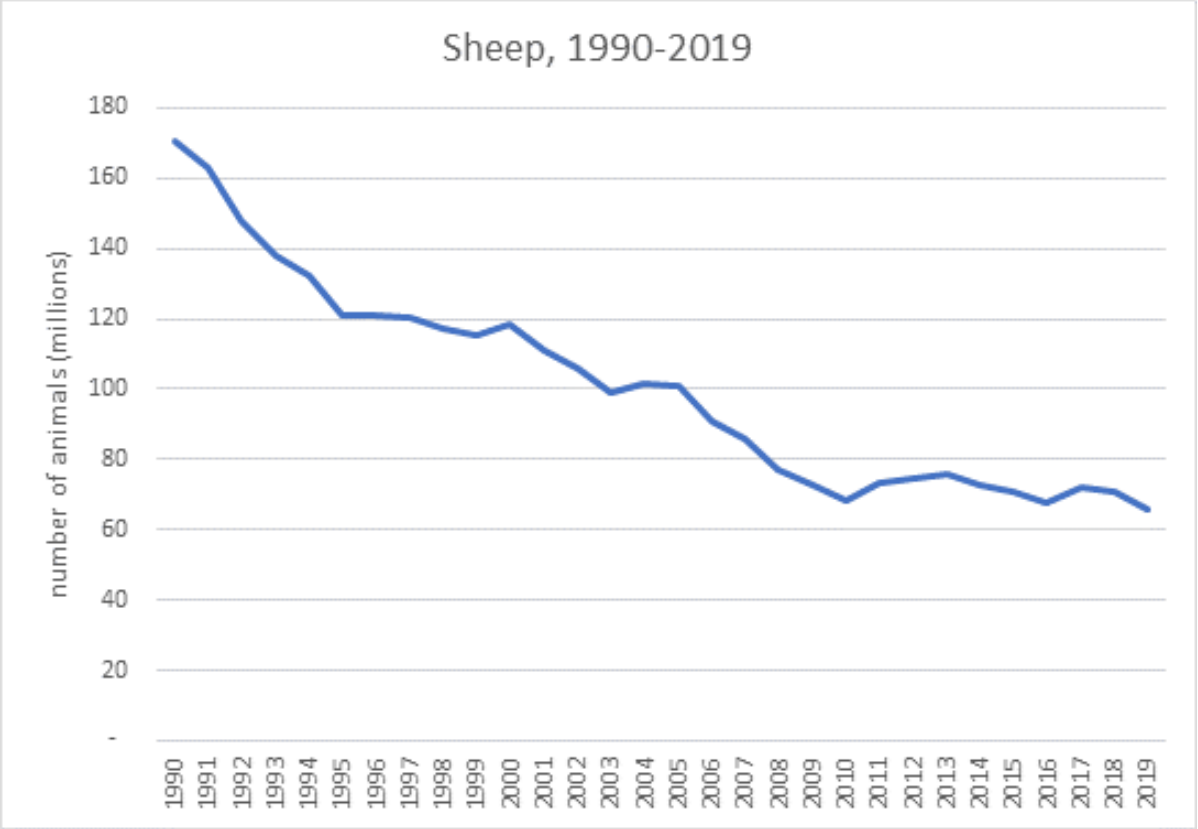
Appendix 2

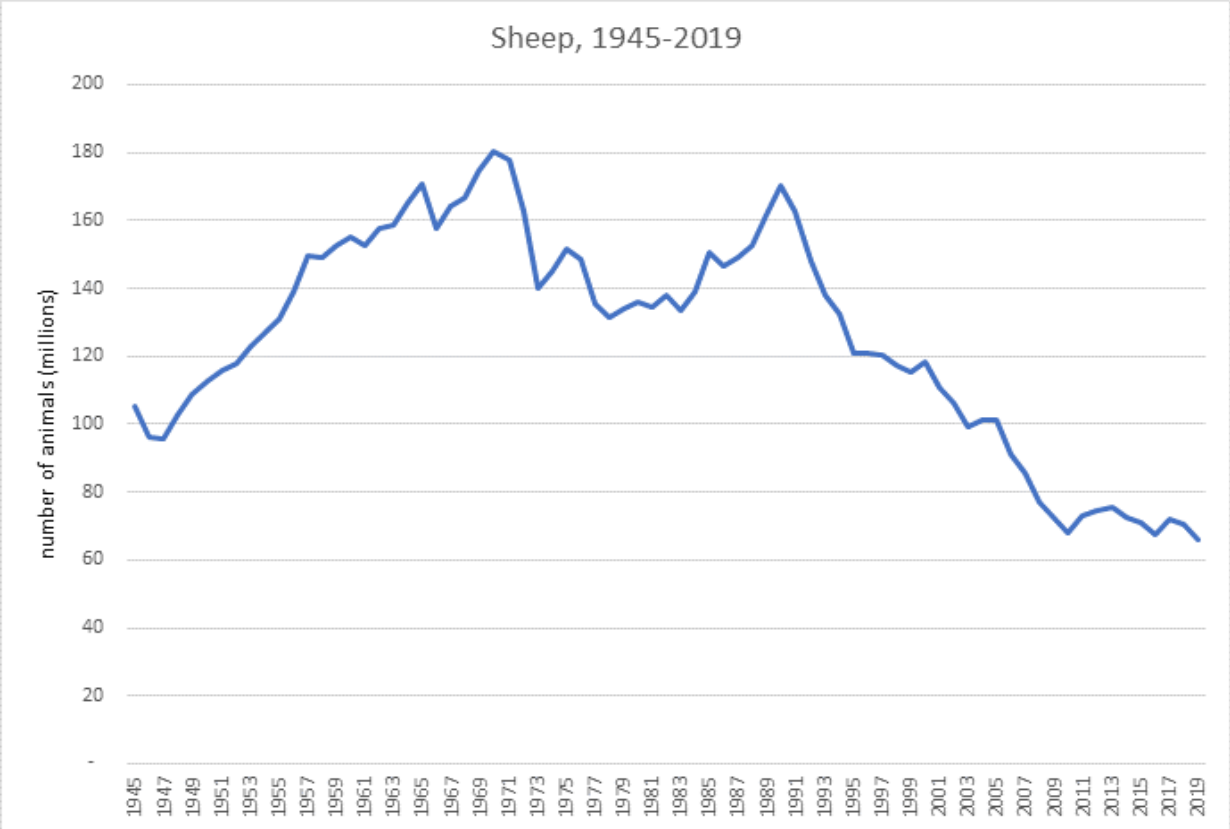
Compilation of historic agricultural livestock trends

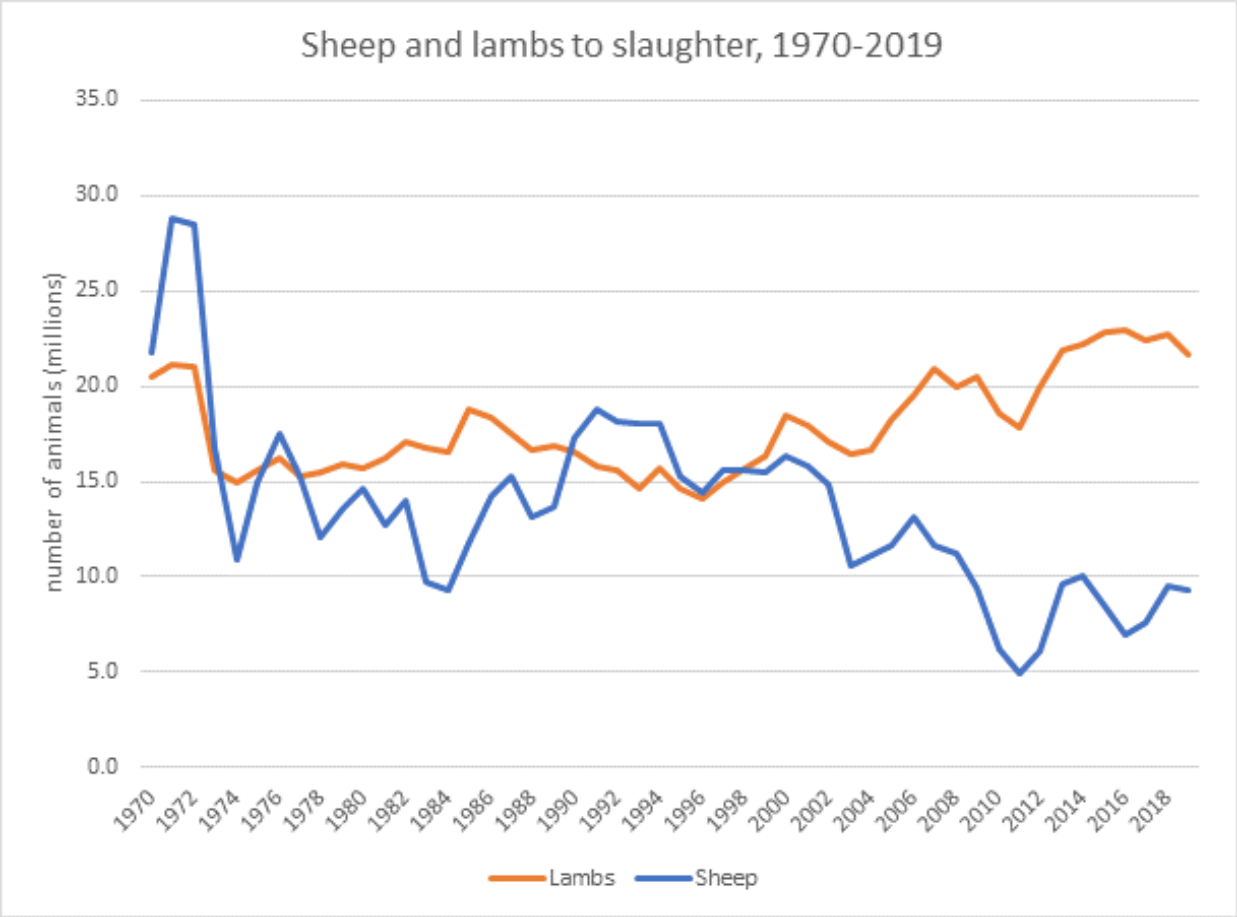
Historic agricultural livestock trends

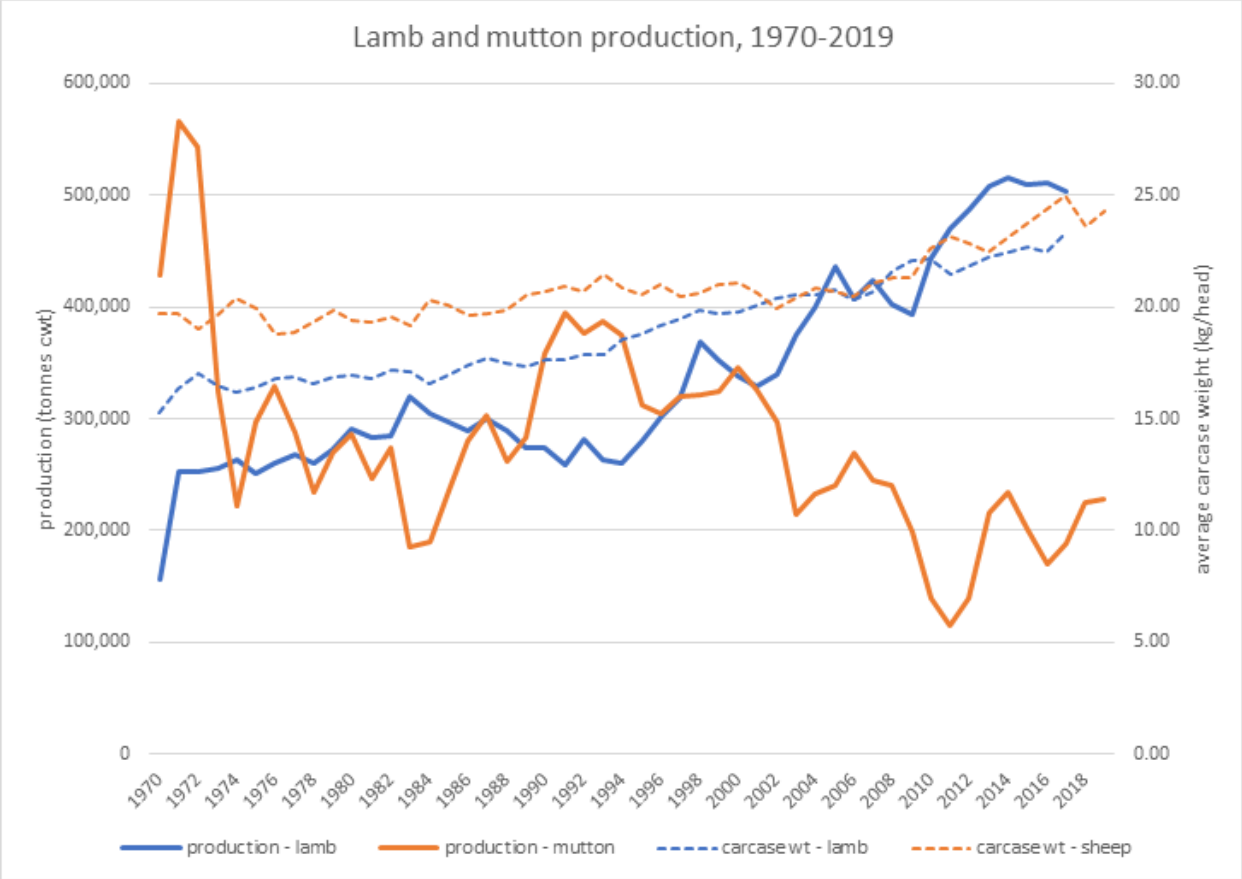
Note: the graphs are self-explanatory, so no specific commentary is provided.

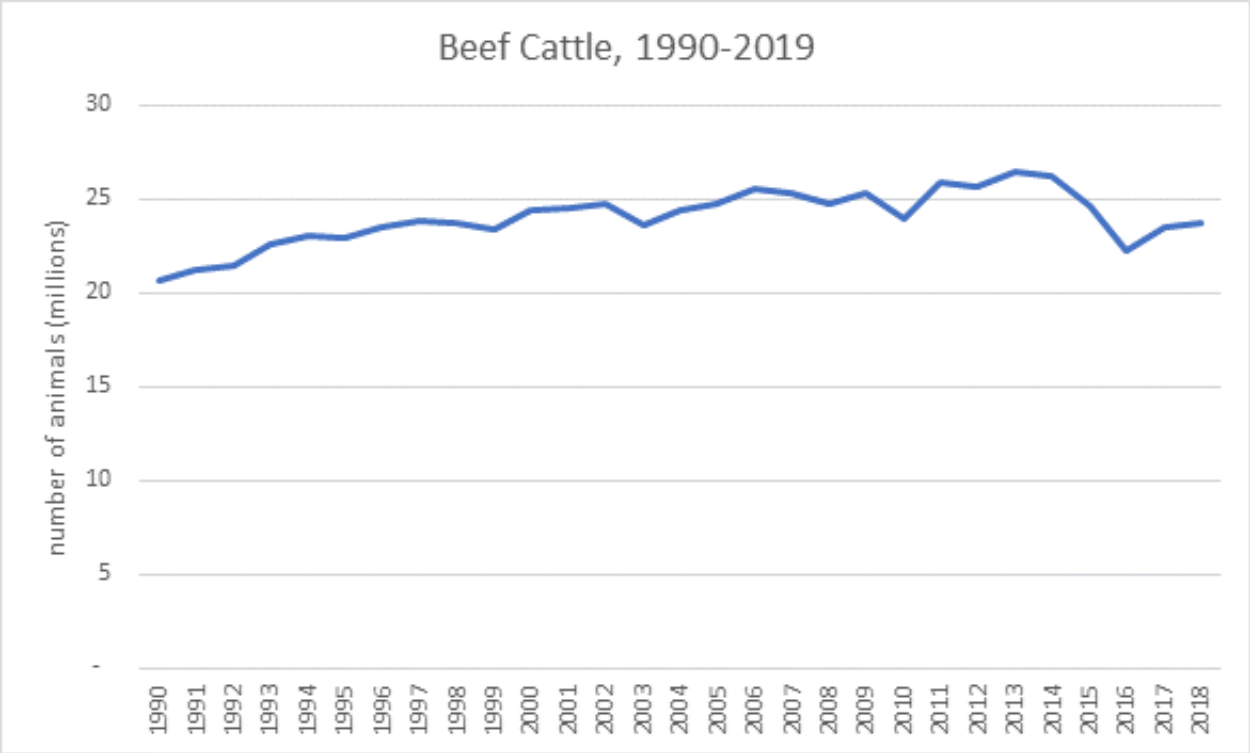
Source: MLA Market Information Statistics Database, August 2020

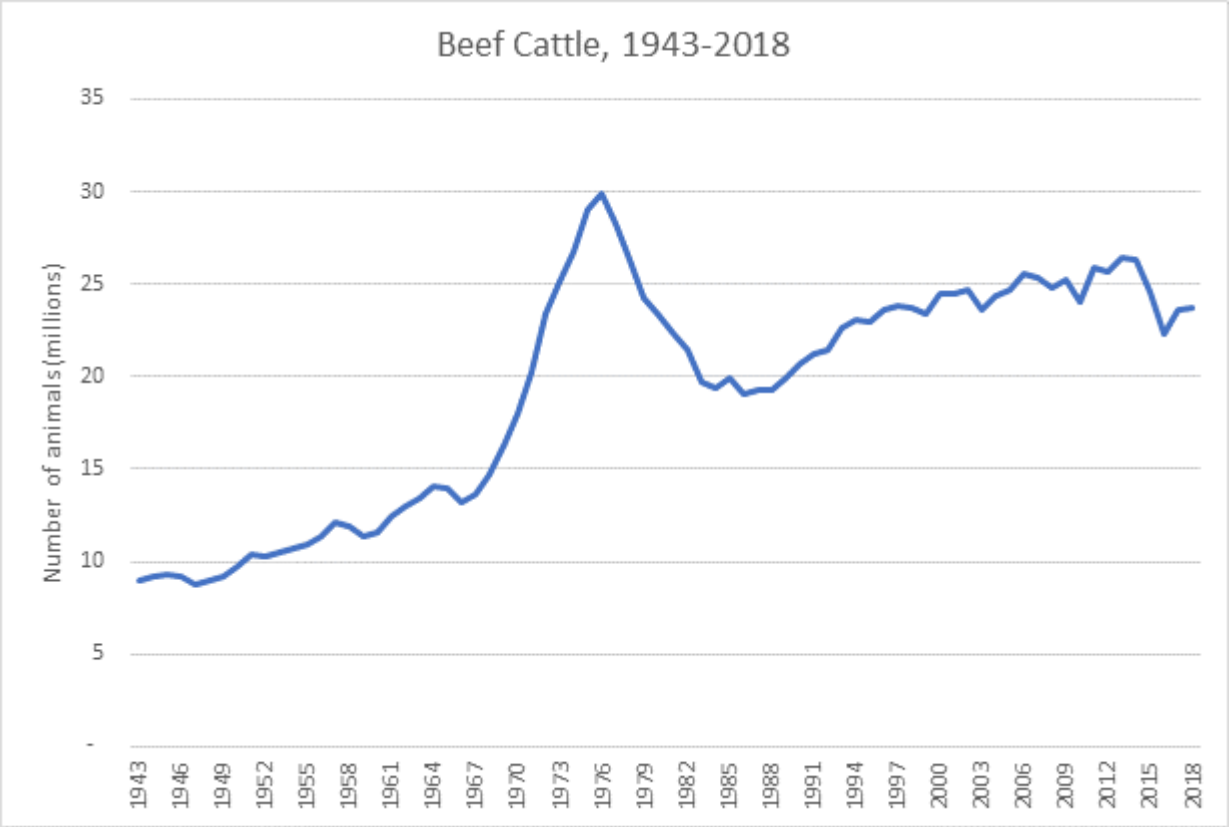


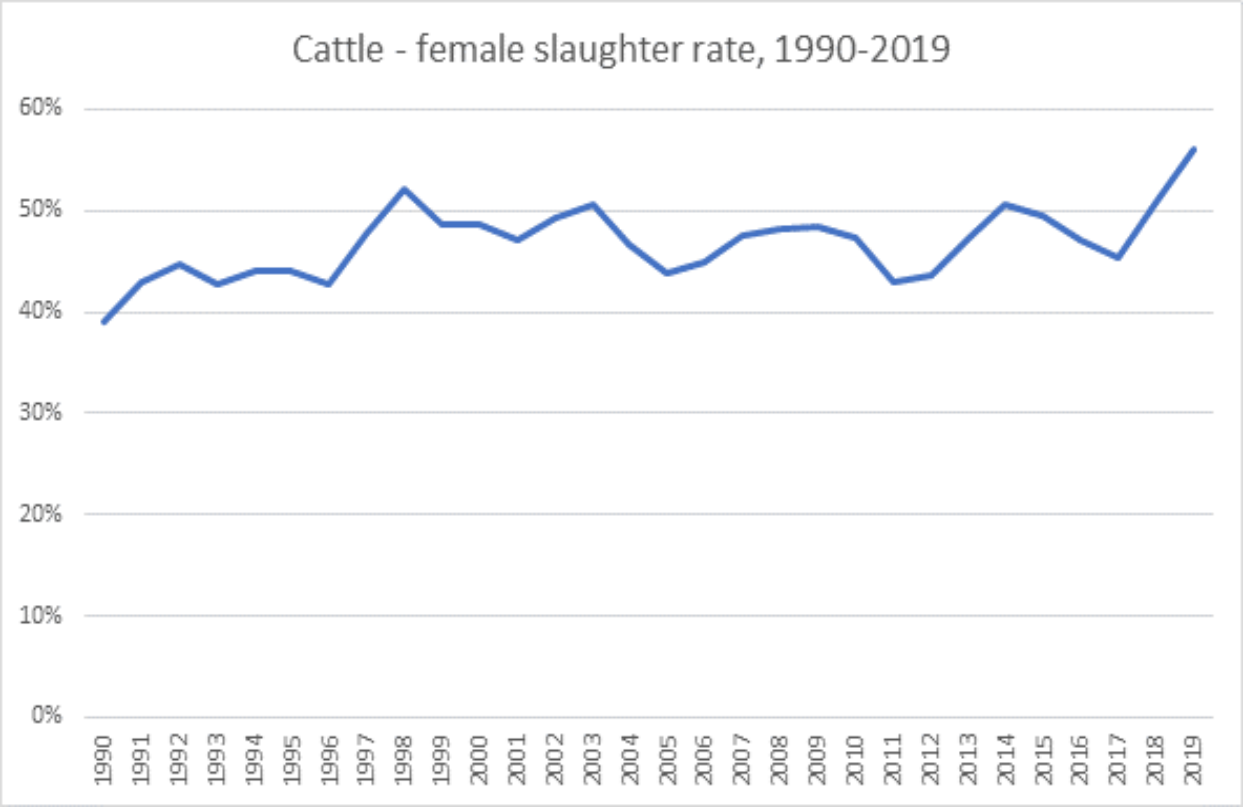


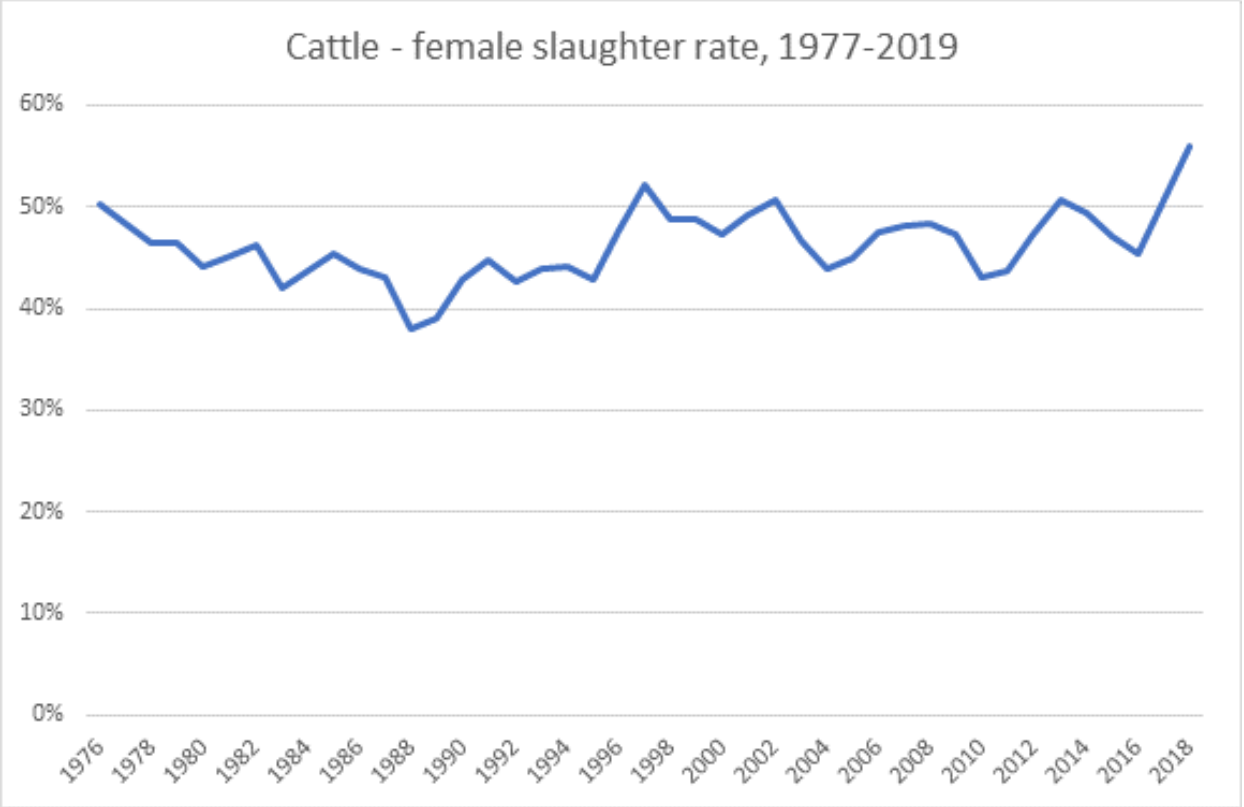

Sheep and lambs to slaughter, 1970-2019
number of animals (millions)
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018
Lambs
Sheep

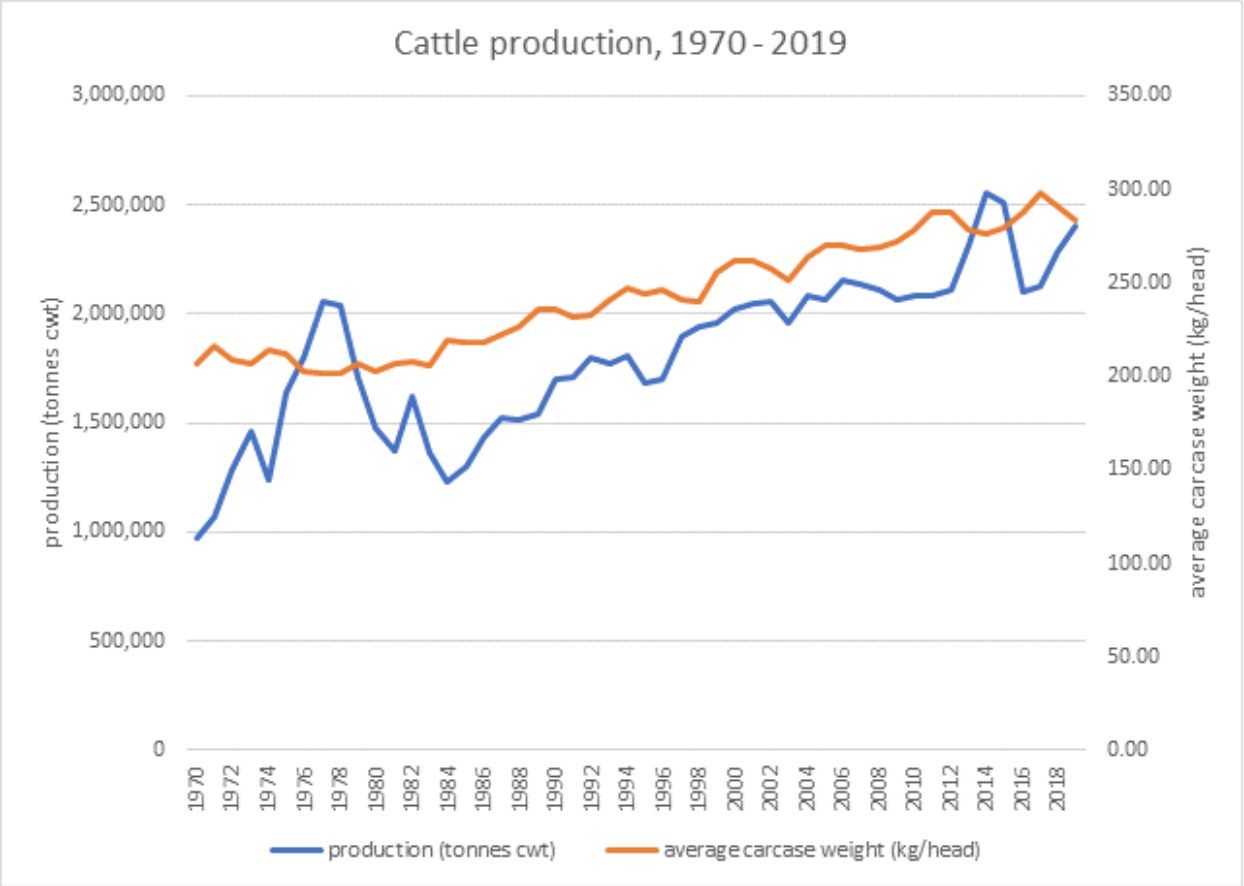

Lamb and mutton production, 1970-2019
production (tonnes cwt)
600,000
500,000
400,000
300,000
200,000
100,000
0
30.00
25.00
20.00
15.00
10.00
5.00
0.00
average carcase weight (kg/head)
1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018
production - lamb
production - mutton
carcase wt - lamb
carcase wt - sheep

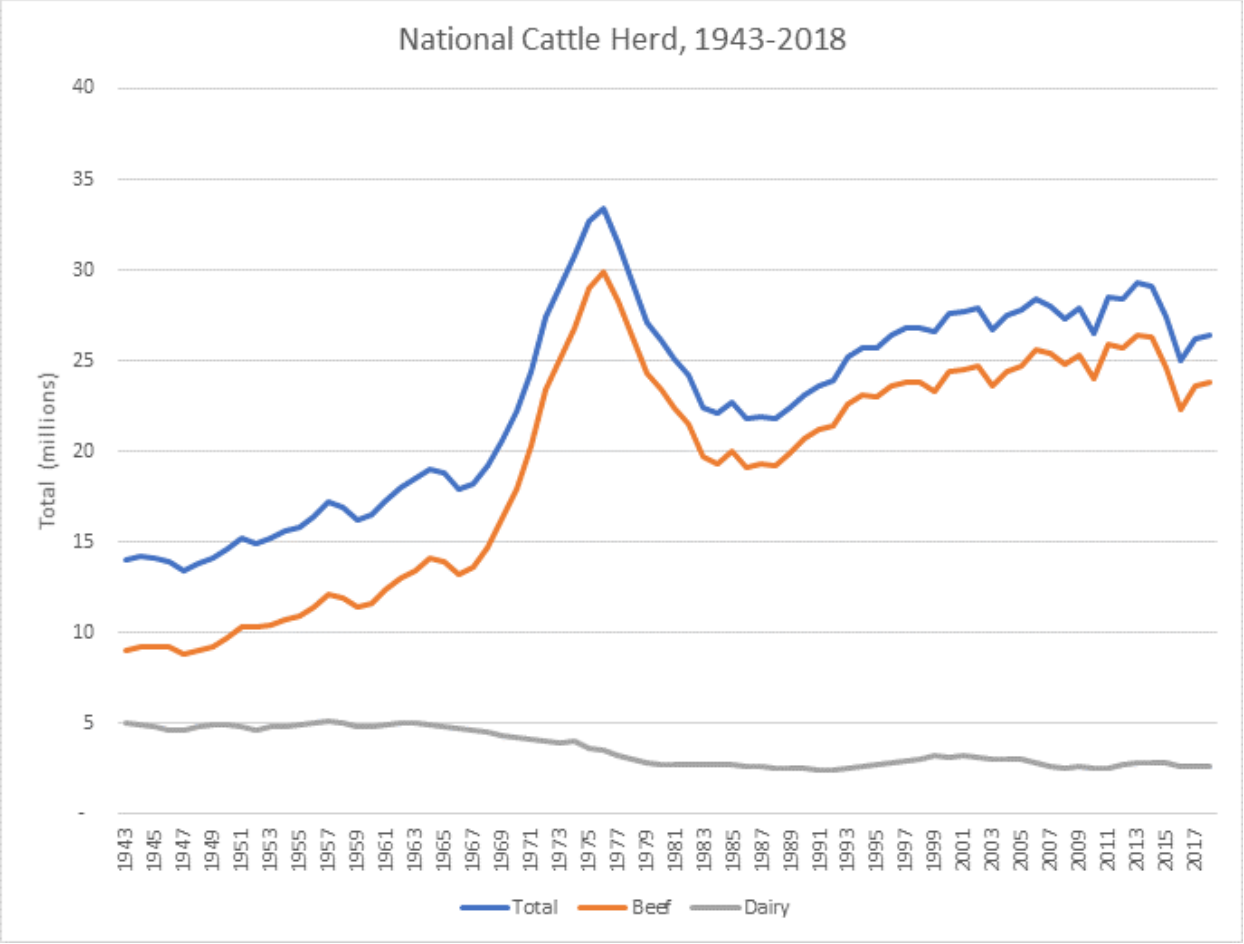

Beef Cattle, 1990-2019
number of animals (millions)
30
25
20
15
10
5
-
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018

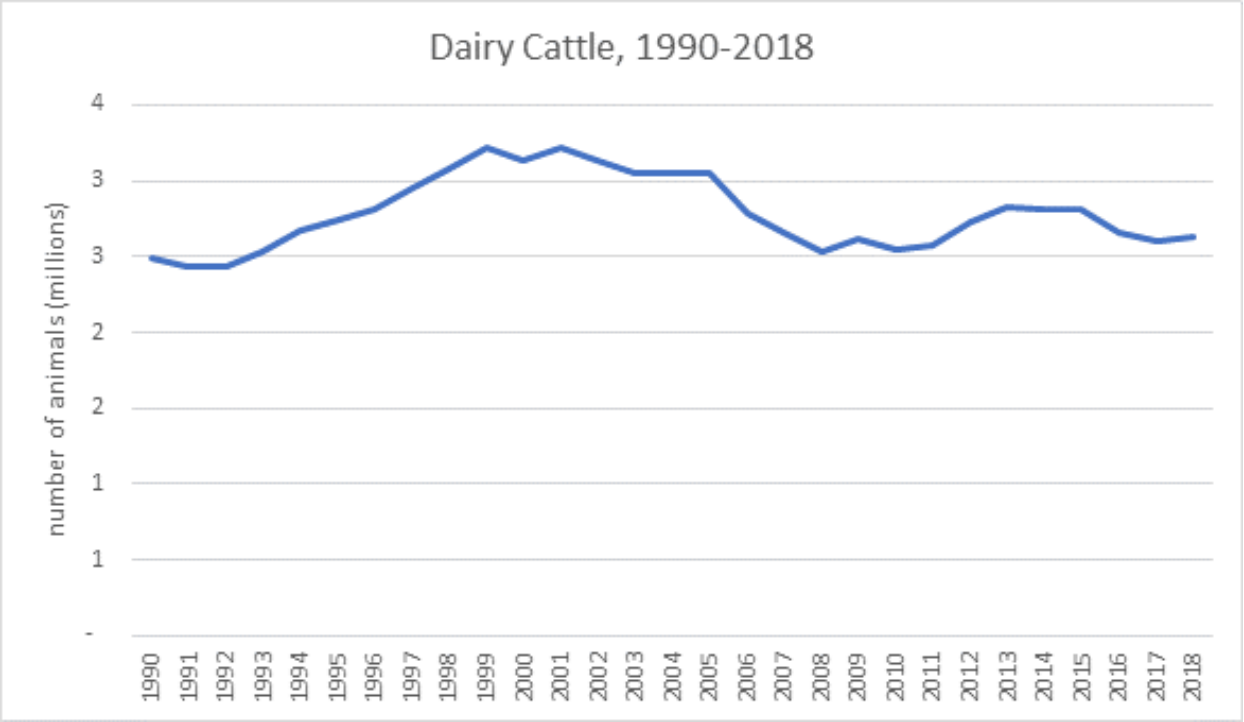

Beef Cattle, 1943-2018
Number of animals (millions)
35
30
25
20
15
10
5
-
1943
1946
1949
1952
1955
1958
1961
1964
1967
1970
1973
1976
1979
1982
1985
1988
1991
1994
1997
2000
2003
2006
2009
2012
2015
2018

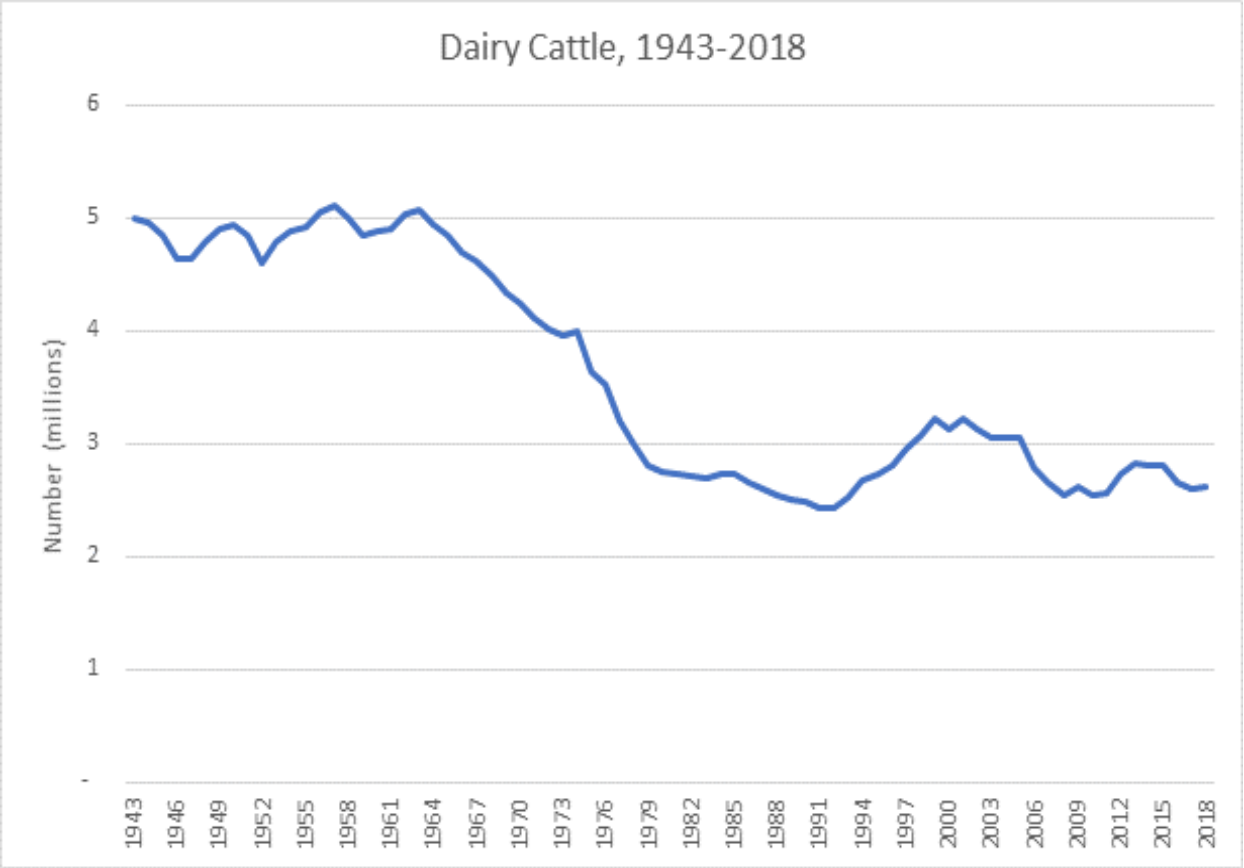

Cattle - female slaughter rate, 1990-2019
60%
50%
40%
30%
20%
10%
0%
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019

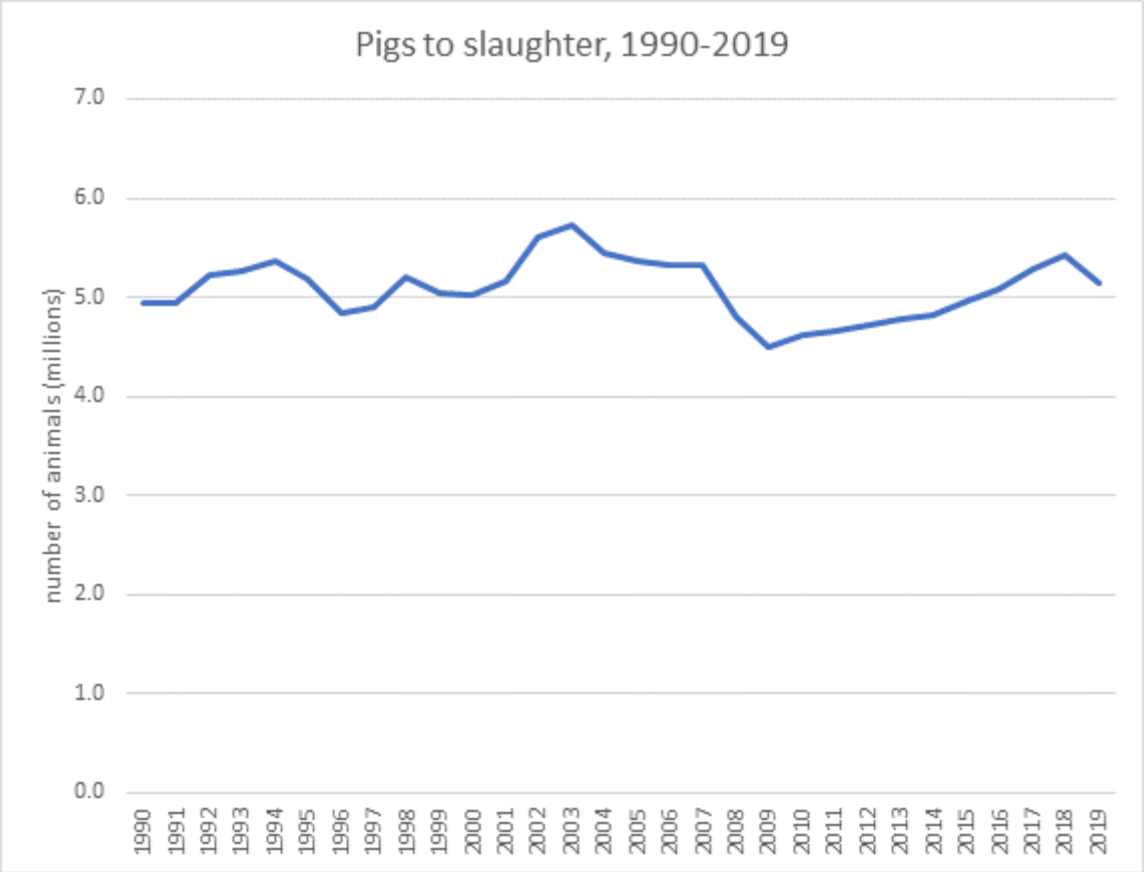

Cattle - female slaughter rate, 1977-2019
60%
50%
40%
30%
20%
10%
0%
1976
1978
1980
1982
1984
1986
1988
1990
1992
1994
1996
1998
2000
2002
2004
2006
2008
2010
2012
2014
2016
2018


Cattle production, 1970 - 2019
3,000,000
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
production (tonnes cwt)
350.00
300.00
250.00
200.00
150.00
100.00
50.00
0.00
average carcase weight (kg/head)
1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018
production (tonnes cwt)
average carcase weight (kg/head)


National Cattle Herd, 1943-2018
40
35
30
25
20
15
10
5
-
Total (millions)
1943 1945 1947 1949 1951 1953 1955 1957 1959 1961 1963 1965 1967 1969 1971 1973 1975 1977 1979 1981 1983 1985 1987 1989 1991 1993 1995 1997 1999 2001 2003 2005 2007 2009 2011 2013 2015 2017
Total
Beef
Dairy


Dairy Cattle, 1990-2018
number of animals (millions)
4
3
3
2
2
1
1
-
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018


Dairy Cattle, 1943-2018
Number (millions)
6
5
4
3
2
1
-
1943
1946
1949
1952
1955
1958
1961
1964
1967
1970
1973
1976
1979
1982
1985
1988
1991
1994
1997
2000
2003
2006
2009
2012
2015
2018


Pigs to slaughter, 1990-2019
number of animals (millions)
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
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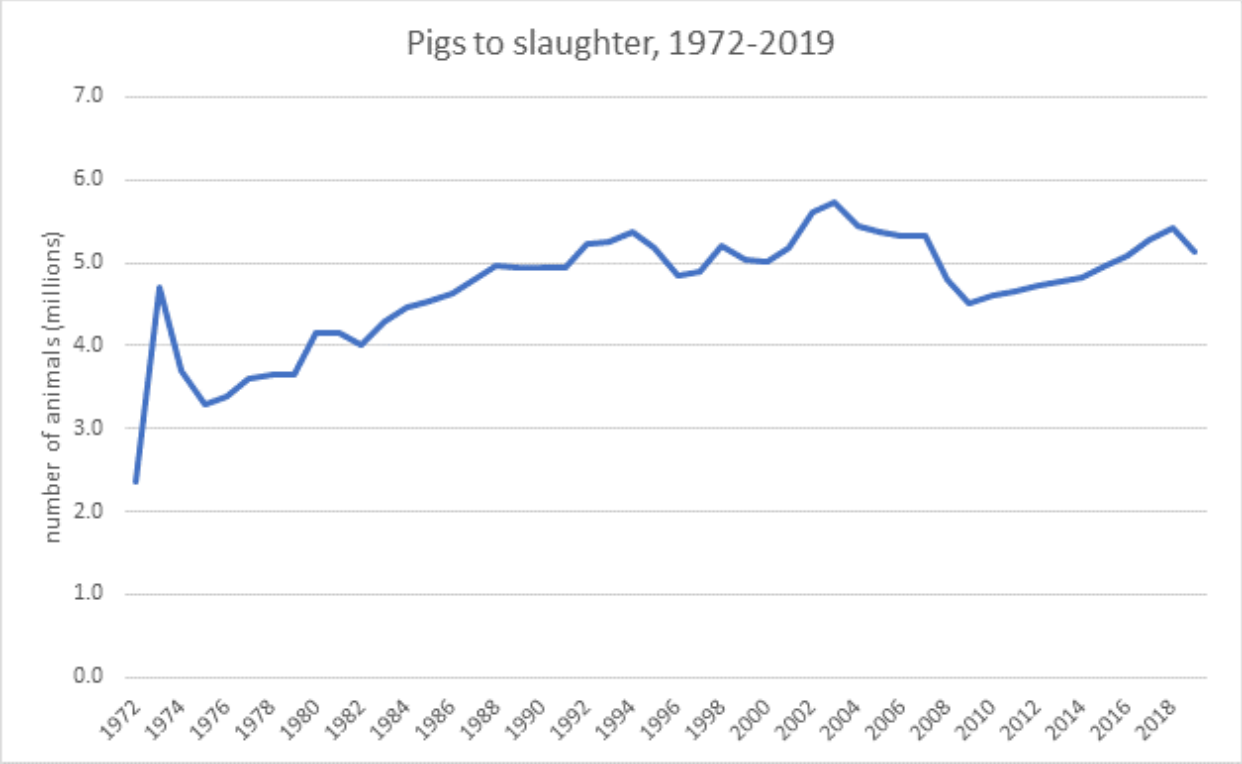
Pigs to slaughter, 1972-2019
number of animals (millions)
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
1972
1974
1976
1978
1980
1982
1984
1986
1988
1990
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1994
1996
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2002
2004
2006
2008
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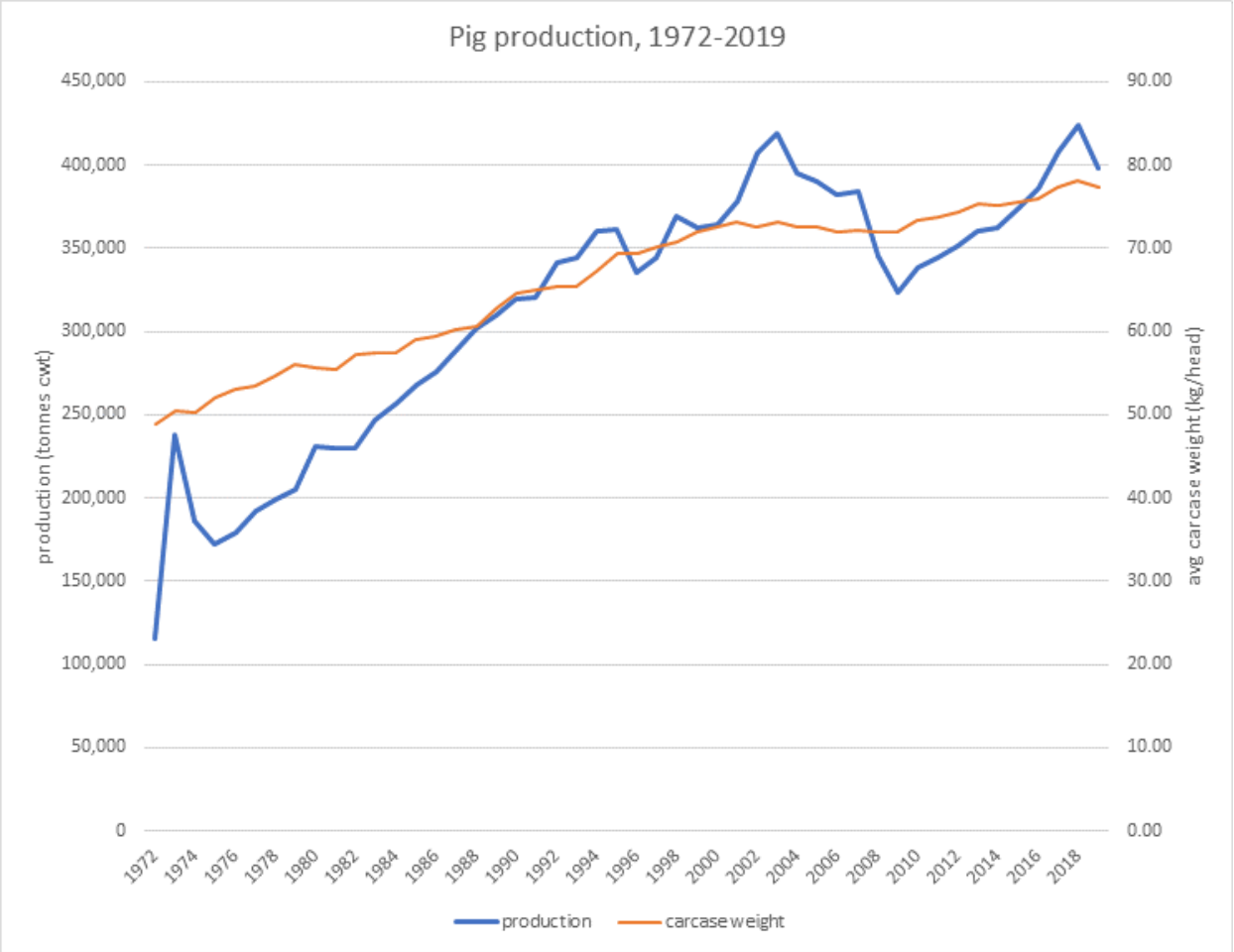
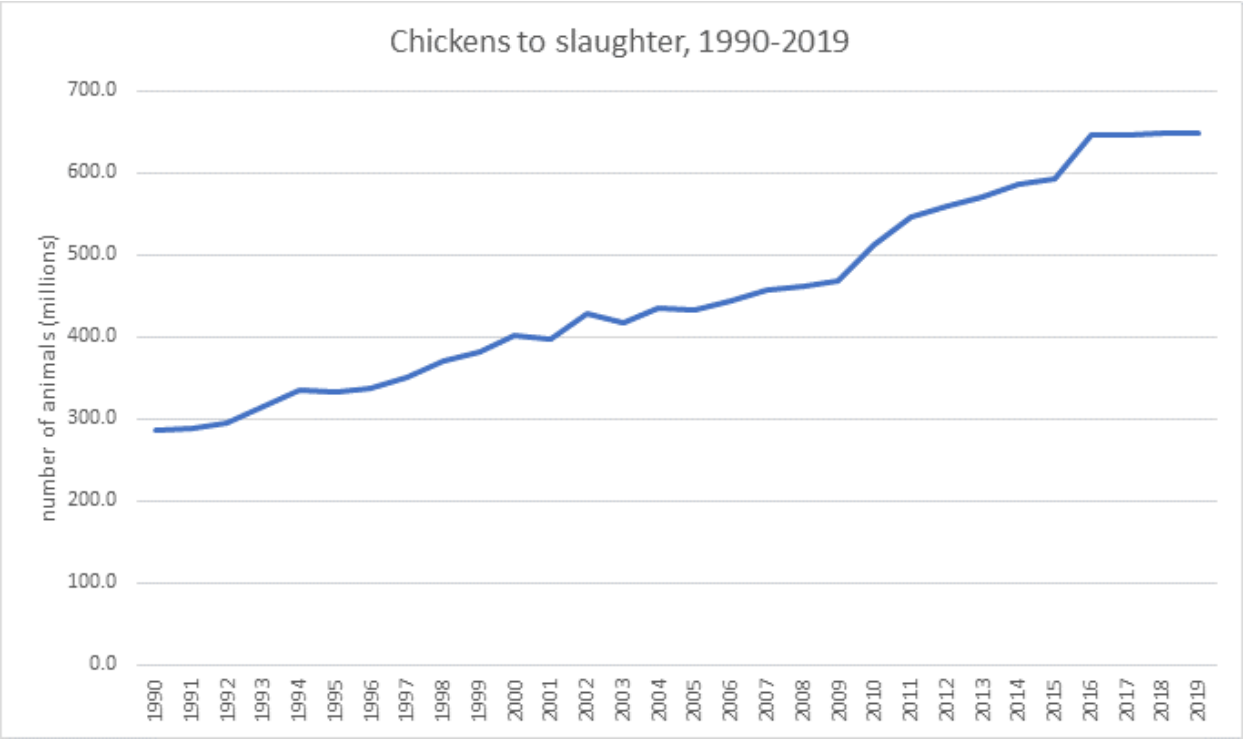
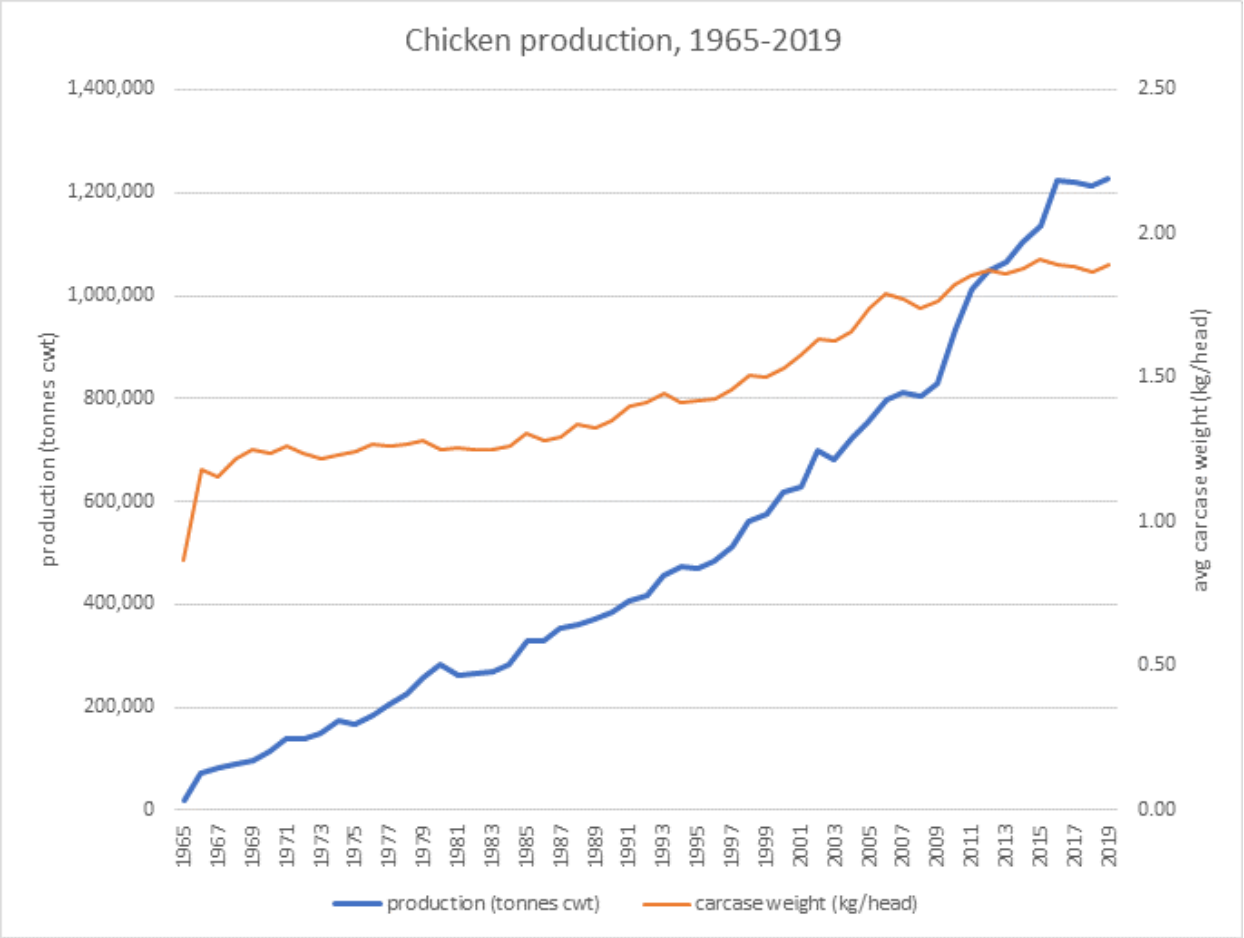
2012
2014
2016
2018


Pig production, 1972-2019
production (tonnes cwt)
avg carcase weight (kg/head)
450,000
400,000
350,000
300,000
250,000
200,000
150,000
100,000
50,000
0
90.00
80.00
70.00
60.00
50.00
40.00
30.00
20.00
10.00
0.00
1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018
production
carcase weight


Chickens to slaughter, 1990-2019
number of animals (millions)
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019


Chicken production, 1965-2019
1,400,000
1,200,000
1,000,000
800,000
600,000
400,000
200,000
0
2.50
2.00
1.50
1.00
0.50
0.00
production (tonnes cwt)
avg carcase weight (kg/head)
1965
1967
1969
1971
1973
1975
1977
1979
1981
1983
1985
1987
1989
1991
1993
1995
1997
1999
2001
2003
2005
2007
2009
2011
2013
2015
2017
2019
production (tonnes cwt)
carcase weight (kg/head)

Appendix 3

Case Study

GHS hazard labelling S4 and S8 veterinary medicines is unnecessary

GHS hazard labelling S4 and S8 veterinary medicines is unnecessary

The issue:

Every Work Health and Safety Regulator in Australia, except ComCare, agreed to exempt certain veterinary medicines from hazard labelling of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[70]

Insertion of a sunsetting sub-regulation under amendments to the Commonwealth *Work Health and Safety Regulations 2011* has the effect of bringing veterinary medicines listed in Schedule 4 and Schedule 8 of the Poisons Standard products within the scope of GHS hazard labelling requirements under Comcare. ComCare is the only jurisdiction to be moving in this direction. The sunsetting would bring the requirements into effect on 31 December 2023.

In February 2019 Safe Work Australia advised "Subregulation 335(8) was not included in the model WHS Regulations, and the model WHS Regulations do not include any time limits on the labelling requirements for Schedules 4 and 8 veterinary medicines. This is an instance where the Commonwealth has chosen to vary the model laws and they are the only jurisdiction that has made this change." (underlining added)

Reproduction of Safe Work Australia media release of 10 November 2016

Certain veterinary medicines exempted from labelling requirements

On 7 October 2016, Safe Work Australia agreed to amend the model Work Health and Safety (*WHS*) laws to exempt certain veterinary medicines from the labelling requirements for hazardous chemicals.

From 1 January 2017 the following veterinary medicines will be exempt from labelling requirements for hazardous chemicals under regulation 335 of the *model WHS Regulations* 2011:

1. All veterinary medicines listed in Schedule 8 of the All veterinary medicines listed in Schedule 8 of the Poisons Standard.
2. Veterinary medicines listed in Schedule 4 of the Poisons Standard that are in a form and packaging consistent with direct administration to animals, for example, small containers, tablets, syringes and chewables.

To have effect, the *model WHS laws* must be implemented in a jurisdiction. Each jurisdiction that is currently implementing the *model WHS laws* are now required to amend their *WHS* Regulations according to Safe Work Australia's decision.

All information relating to these amendments to the *model WHS laws* are in the process of being updated on our website. These updates will be complete before 1 January 2017, when the Globally Harmonised System of Classification and Labelling of Chemicals takes full effect.

For further information, contact the WHS regulator in your jurisdiction.

https://www.safeworkaustralia.gov.au/media-centre/news/certain-veterinary-medicines-exempted-labelling-requirements

Section 3 of this submission highlights that overlaying the APVMA expert risk assessment with GHS hazard elements does not add value and contributes to label clutter on already crowded labels. In any case, Safety Data Sheets are available to users to satisfy requirements of WHS legislation. Regulatory controls under the Poisons Standard for Schedule 4 and Schedule 8 substances are listed at Attachment 1.

For the Panel this example demonstrates the difficulties with achieving national consistency but also that the smallest jurisdiction alone can control outcomes with national ramifications.

Outcome sought: AMA will be seeking to discuss this issue with ComCare with desired outcome that the *Work Health and Safety Amendment (Labelling of Hazardous Chemicals) Regulations* are amended to delete paragraph 335(8) which sunsets certain exclusions for veterinary medicines. This would be consistent with all other Australian jurisdictions.

[70] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), seventh revised edition

GHS hazard labelling S4 and S8 veterinary medicines unnecessary

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemical products. For an agvet chemical product to legally be manufactured, imported, supplied, sold or used in Australia, it must be registered by the APVMA—unless exempt by the Agvet Code. The registration process involves scientifically evaluating the safety and efficacy (effectiveness) of a product in order to protect the health and safety of people, animals, plants and the environment.[71]

The Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals, or as it is more generally known, the FAISD Handbook. The FAISD Handbook is updated quarterly (March/June/September/December) and is published on the Australian Pesticides and Veterinary Medicines Authority (APVMA) website.

In addition to the rigorous requirements of APVMA evaluation for registration and approvals a veterinary medicine is subject to Poisons Scheduling and state/territory Poisons legislation[72]. "Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical, required to protect public health and safety."[73]

The Poisons Standard[74] includes controls for scheduled categories – S4 and S8. An indicative sample list includes entries in the below table, also noting professional standards such as the Australian Veterinary Association GUIDELINES FOR PRESCRIBING, AUTHORISING AND DISPENSING VETERINARY MEDICINES[75]

Schedule 4	Schedule 8
Prescription Only Medicine, or **Prescription Animal Remedy** – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription. Examples: Paracetamol when packed and labelled for the treatment of animals. Others are antibiotics, local and general anaesthetics, antihypertensive agents, benzodiazepines, corticosteroids, diuretics, some analgesics, muscle relaxants, neuroleptics and most, but not all, non-steroidal anti-inflammatory drugs (NSAIDs). Strict controls on storage and handling A person who sells or supplies Schedule 3 or Schedule 4 poisons must keep those poisons in a part of the premises to which the public does not have access. Substance specific controls Advertising is restricted	**Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. Examples: fentanyl, ketamine, oxycodone, morphine, pethidine, pentazocine, buprenorphine, and butorphanol Strict controls on storage and handling Dispensing or prescription of Schedule 8 drugs should be done only in conjunction with a fully documented clinical examination on each occasion. A person who supplies any Schedule 8 poison must ensure that the Schedule 8 poison is packaged in such a way that its primary pack is so sealed that, when the seal is broken, it is readily distinguishable from other sealed primary packs Substance specific controls Advertising is restricted

[71] https://apvma.gov.au/node/15931
[72] https://www.tga.gov.au/stateterritory-scheduling-information
[73] https://www.tga.gov.au/scheduling-medicines-poisons
[74] https://www.tga.gov.au/publication/poisons-standard-susmp
[75] https://www.ava.com.au/siteassets/resources/prescribing-guidelines/guidelines-for-prescribing-authorising-and-dispensing-veterinary-medicines-october-2013.pdf

Appendix 4

Case Study

Harmonised Agvet Chemicals Control of Use – missing impetus

Case study

Harmonised Agvet Chemicals Control of Use – missing impetus

Background:

The first *control-of-use* legislation was implemented in New South Wales under the *Pesticides Act 1978*. Differences in jurisdictional approaches have been raised as a significant unresolved issue for nearly 40 years.

- The 2008 Productivity Commission report on the regulation of chemicals and plastics identified variable regulatory requirements for users of agricultural and veterinary (agvet) chemicals between jurisdictions as an impediment to businesses operating across jurisdictional borders.
- It has been suggested that lack of national consistency may also challenge system integrity and create additional risks.

The Issues Paper comments:

- "In 2010, in response to a request from COAG, the Agriculture Ministers' Forum (AGMIN) agreed to develop a single national framework to harmonise the regulation of agvet chemicals …."
- "However, the current processes seeking harmonisation are based on negotiation and consensus. As a consequence, the panel notes that these efforts have had very limited success and, in most cases, have achieved, at best, in-principle support for a common goal or minimum consistency in implementation, thus diluting the benefits of harmonisation."
- "Looking at history, the panel is not confident that consensus on the incomplete harmonisation reforms will occur in the near future, despite the best intentions of all players. The resources available in jurisdictions appear to be insufficient to support both reform and ensure integrity of the system. Nor is the panel assured that the completed harmonisation efforts will not see the introduction of additional jurisdiction specific requirements in the future, leading to inconsistencies once again."
- "The lack of progress in, and effectiveness of harmonisation needs to be addressed. It appears to the panel that the competing demands of governments and parliamentary systems in each jurisdiction and the Commonwealth is **unlikely to ever efficiently achieve national consistency** in control of use. Given that each jurisdiction will act, understandably, in the interests of their own state or territory, the current process is fraught with difficulty and may only ever deliver small incremental reforms." (bolding added)
- "Therefore, the panel believes alternative approaches need to be considered. These approaches must recognise and build on the strengths within current arrangements and be focused on efficient and responsive regulation across the lifecycle of a chemical product."

This position is untenable, particularly regarding fundamental and underpinning elements of this reform.

This reform, originally proposed by the Productivity Commission in 2008, is now at the twelve-year mark. Even if progressed in 2020, the States and Territories would have another four years to implement. This would make a sixteen-year exercise. But it seems more likely that this reform will not be implemented.

Concerns have been expressed to the Department that there does not appear to be a valid Regulation Impact Statement (RIS) to support legislative changes. This may lead to further delays (as States/Territories undertake RIS development) and create further potential for differences.

For veterinary chemicals the last round of consultations were completed with stakeholder submissions in January 2019. The following was included as a recommendation by Animal Medicines Australia:

> *HACCUT should comply with the Commonwealth Government's commitment to best practice regulation and prepare a Regulatory Impact Statement for harmonisation of veterinary prescribing and compounding.* (AMA HACCUT Submission 22 January 2019)

Lessons:

The scenario has obvious difficulties and speaks for itself but it also makes a useful "learning" case study.

There appear to be a range of common issues that arise in regulatory reform that are impediments to achieving successful outcomes that conform to *better regulation* principles. In many instances, the nature of the issues is not unique and understanding why they occur and how they may be rectified offers an important learning opportunity.

Some matters for reflection include:

- Ways to achieve consistency of implementation – legislative models, incentives, penalties,
- What motivates jurisdictions to deviate from an agreed national model?
- Completion of tasks verses achieving outcomes,
- Why do "process" problems occur on major items such as ensuring Regulation Impact Statement requirements,
- Non-delivery of benefits identified in Regulatory Impact Statements,
- Are National Cabinet decisions and directions taken seriously by the relevant bureaucracies?
- Who can, and should, provide the necessary leadership?
- Accountabilities

Significant resources are expended by Industry Associations and their members in reviewing, consulting, evaluating feedback, preparing responses, and other activities. The opportunity costs are not insignificant.

It would also be helpful to governments, bureaucracies, industry, stakeholders, the community and others if reform was scheduled for implementation in years and mechanisms put in place so they do not run out to decades.

Appendix 5

Animal Medicines Australia slides
presented to the Review Panel,
16 December 2019

AMA Priorities
NRS Independent Review

16 December 2019

16/12/2019

Animal Medicines Australia

- **Peak industry body** for animal medicine leaders
- members are the **innovators, manufacturers, formulators and registrants** of animal medicines to protect and treat animal illnesses, diseases and injuries and promote animal welfare across the companion animal, livestock and equine sectors
- animal medicines support up to **15% of livestock production output** contributing an additional **$2.7 billion in added value** and **9,900 FTE jobs**
- animal medicines protect and promote the health of Australia's **28.5 million pets**, resulting in longer, more beneficial and responsible relationships between pet owners and their animals

16/12/2019

AMA Purpose:

Add value to our member businesses by supporting innovation in animal health and promoting the benefits of animal care.

AMA Priorities:

- Advocating persuasively for animal health
- Supporting innovation
- Promoting animal care benefits

16/12/2019

Advocacy For Animal Health

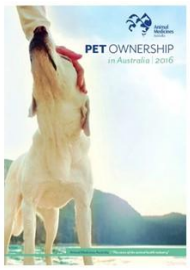
- Policy & Regulatory
- Political engagement
- Alliances, partnerships, research, and issues management

Animal Medicines Australia

16/12/2019

Promoting Animal Care Benefits

- Pet industry network
- Responsible pet ownership
- Encourage like-minded organisations
- PAWS



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16/12/2019

Supporting Innovation

- Risk-based regulatory environment that adheres to COAG Principles
- Sustainability as a core strategy – product life-cycle, anti-microbial resistance, waste, responsible and judicious use of veterinary medicines

Animal Medicines Australia

16/12/2019

Maximising Value: Services and Opportunities

- Communications services
- Whole of industry representation
- AMA events
- Industry Sales Audit

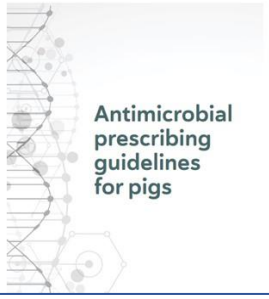
Animal Medicines Australia

16/12/2019

Issues Management Group

- Emerging issues
- Policy development
- Stewardship
- Industry engagement

RESPONSIBLE USE



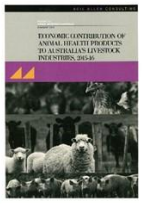
Animal Medicines Australia

16/12/2019

MRC/Strategic Communications Committee

- Input into industry strategic messaging
- Developing Industry research projects
  - PAWS
  - Pet Industry Survey
  - Industry Value Study
- Sales Audit Categorisation

PAWS The Physical and Affective Wellbeing Study of dog owners



Animal Medicines Australia

16/12/2019

Partnerships and Networks

- Health for Animals
- VICH
- Agsafe, drumMUSTER
- Australian Chamber of Commerce and Industry

16/12/2019

Outline

Animal Medicines Australia

Review of the NRS:

- COAG Principles of Best Practice Regulation; the Ten Principles for Australian Government Policy Makers; Development of a Best Practice Regulatory Culture

Business operating environment

- Current trends directly impacting animal medicines
- Case studies

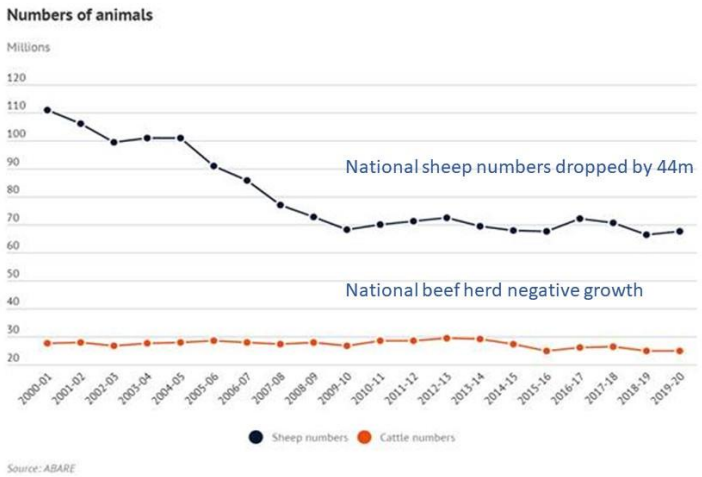
Regulatory roles and responsibilities

16/12/2019

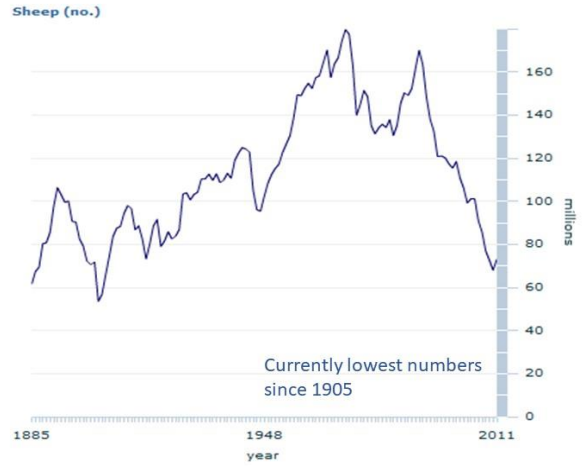
Animal Medicines Australia

16/12/2019

Business operating environment



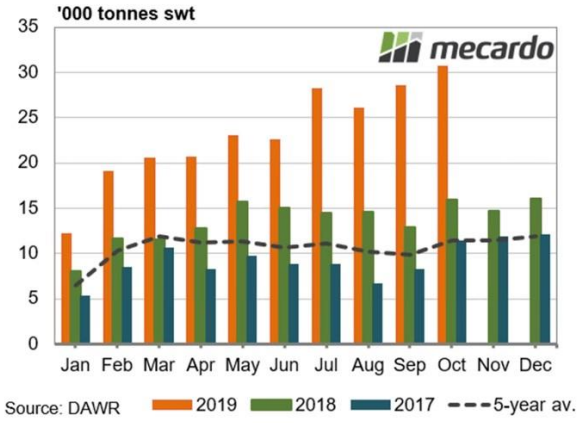
Business operating environment



16/12/2019

Business operating environment

Australian Beef Exports - China



Exports

Beef ↑ 122%

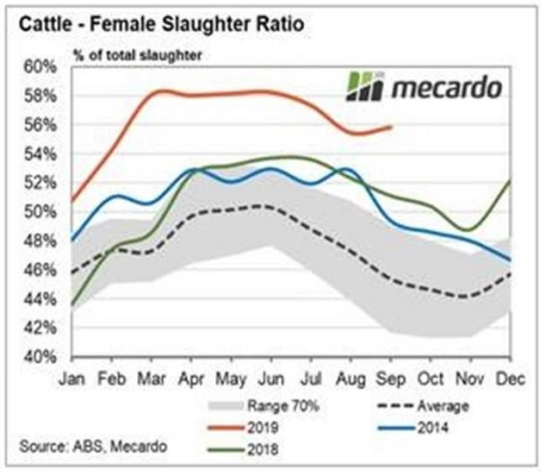
Lamb ↑ 69%

Mutton ↑ 118%

Reflective of ASF effects – alternate protein sources

16/12/2019

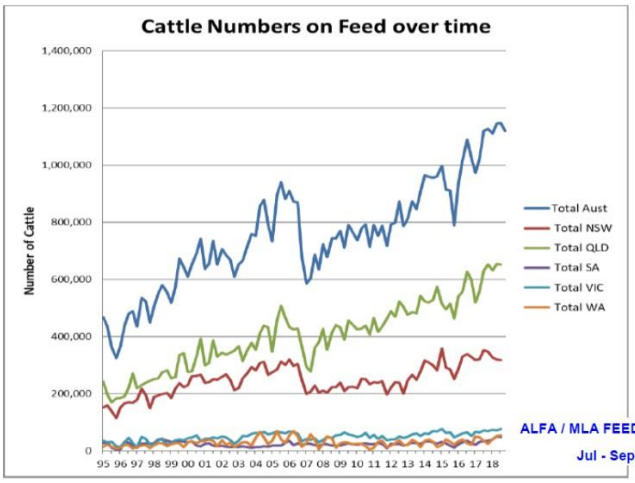
Business operating environment



Female cattle slaughter ratios are high. 47% is neutral for zero growth – we are at high 50s which means we are slaughtering the breeding stock

16/12/2019

Business operating environment



Animal Medicines Australia

16/12/2019

Case study: Harmonised Agvet Chemicals Control of Use Task Group (HACCUT)

- **2008 PC *control-of-use* recommendations**
- **COAG agreed** to develop a single national framework
- For animal medicines the **last round of consultations** were completed with stakeholder submissions in **January 2019**
- Possible consideration by **AgMin in 2020**?
- If adopted jurisdictions have 4 years to implement (i.e. **2024**)
- From PC recommendation to possible adoption **16 years**
- During 4 years implementation continuing fragmentation
- Recognised that there **does not appear to be a valid Regulation Impact Statement** (RIS) – *consequences!*

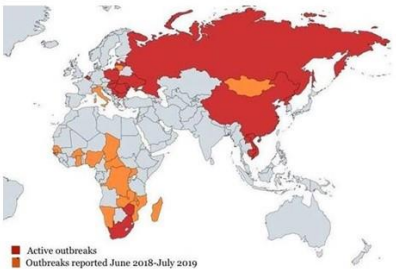
Animal Medicines Australia

16/12/2019

Case study: Market shocks

African Swine Fever

Paradigm shift in markets, species demand, protein sources



European Veterinary Medicines Legislation, Article 118

New rules apply from **28 January 2022** that may restrict (ban) the use of certain anti-microbial class(es) or actives in/on animal products that are destined for the EU. Lists of such chemicals have not yet been made available

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16/12/2019

Case study: Importing Country MRLs*

Australia's approach to meat export destinations is largely for animal medicine registrants to seek individual standards/ approvals in individual export destinations; or to apply an analytical default (limit of quantification or LOQ).

The LOQ approach:

- limits the ability of Australian producers to use certain veterinary medicines as intended;
- may restrict Australian producers from maximising therapeutic treatments and financial benefits;
- puts pressure on the ability to manage resistance; and may hinder animal welfare goals; and
- is unique to Australia

<u>In short, Australian standards for meat and meat products for domestic consumption are not accepted in a range of countries</u>

* MRL: Maximum Residue Limit

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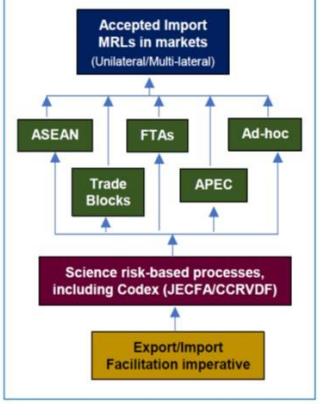
Case study: Importing Country MRLs (continued)

An alternate, yet complementary, response may be to deal with the import requirements of Australia's export destinations on a multi-lateral basis

The outcome sought is recognition of Australian and established internationally recognised standards, such as Codex, and accelerate harmonisation in regional trade fora

<u>The same work is well advanced with pesticides</u>

Figure 1: Process to safe food, trade outcomes



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16/12/2019

Regulatory roles and responsibilities

The **2008 Productivity Commission Report** proposed an institutional and regulatory approach for chemicals and plastics regulation:

Formulation of strategic policy and oversight *of the institutional and regulatory arrangements* — a national function, to be undertaken by ministerial councils underpinned by intergovernmental agreements

Assessment of the hazards and risks of chemicals — a national, science-based function to be undertaken under statutory independence

Risk-management standard setting — a national function to be undertaken by independent statutory agencies within the policy frameworks of the ministerial councils

Administration of agreed standards and monitoring of their impact — jurisdiction-specific functions to be undertaken by their own agencies or delegated to other bodies such as national regulators

Animal Medicines Australia

16/12/2019

Animal Medicines Australia

16/12/2019

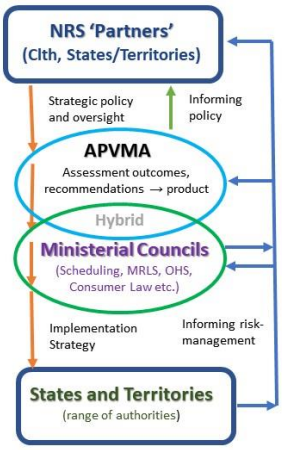
DRAFT Model for efficient and effective management of certain aspects of veterinary chemicals regulation

Formulation of strategic policy and oversight

Assessment of hazards and risks

Risk management, standard setting

Administration of agreed standards and monitoring impacts



Examples of regulation not NRS focussed:

- Dangerous Goods Transport (air, land, sea)
- Dangerous Goods Storage
- Chemicals of security concern
- Chemical diversion illicit drugs
- Retail storage
- Chemical Scheduling
- GHS labelling, SDS
- Environment
- Work Health & Safety
- Australian Packaging Covenant
- Trade Measurement
- Waste management
- Trade waste
- National Pollutant Inventory
- Waste management
- Trade waste
- Contaminated land management

Animal Medicines Australia

16/12/2019

Opportunities for early stage progress

Establish a meaningful, informed dialogue

- Common understanding of principles
- Common language and background

Strategic context

- Who are the key stakeholders
- The operating environment(s)

Goal setting

Using the PC as a useful starting reference

- Roles and responsibilities
- Mechanisms for national regulatory approaches

Appendix 6

Animal Medicines Australia
briefing note:

Securing Animal Import MRLs in Australia's export markets

provided to the Review Panel,
13 March 2020

Briefing Note

Agvet Review Panel Discussion
13 March 2020

Securing Animal Import MRLs in Australia's export destinations: multi-lateral opportunities

Animal medicines critical contribution to meat production

Animal medicines protect and treat animals with illnesses, diseases and injuries. They include vaccines, antimicrobial products, parasiticides, pain relief and other animal health products. They are critical to Australia's livestock industries that rely on them to produce high quality, safe and market ready food and fibre.

A recent study[76], commissioned by Animal Medicines Australia (AMA), has estimated that animal health products were responsible for 10.6% of production in seven key commodity groups[77] in 2015-16.

Meeting importing country standards

Australia's current approach to its meat export destinations has been for veterinary medicine registrant companies to seek individual standards/approvals in individual export destination countries; or to apply an analytical default called the limit of quantification (LOQ). An Export Slaughter Interval (ESI) is then applied to allow the residue to decline to the LOQ. This approach:

- limits the ability of Australian producers to use certain veterinary medicines as intended.
- may restrict Australian producers from maximising therapeutic treatments and financial benefits.
- puts pressure on the ability to manage resistance; and may hinder animal welfare goals; and is unique to Australia.

An alternate, yet complementary, response may be to deal with the import requirements of Australia's export destinations on a multi-lateral basis. Establishing MRLs or gaining acceptance of Codex MRLs in export destinations would support the ESI process – but in the majority of situations:

Export Slaughter Interval = Australian Withholding period

In this way ESIs would be used in special circumstances and play a pivotal role where and when needed.

Supporting Codex

Australia has a long-term commitment to Codex and is recognised for its professionalism and standing. Codex standards ensure that food is safe and can be traded.

The 188 Codex members have negotiated science-based recommendations in all areas related to food safety and quality.

> "Codex standards are recognised by the World Trade Organization (WTO). They are not imposed on member countries. As a WTO member, Australia is obliged, where possible, to harmonise its domestic regulations with Codex standards such as food additives, pesticide residues and veterinary drugs."[78]

Brief information on some relevant International Organisations is provided at Attachment 1.

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[76] Acil Allen Consulting (2018), Economic Contribution of Animal Medicines to Australia's Livestock Industries 2015-2016
[77] Beef, dairy, sheep-meat, sheep-wool, pigs, poultry-meat, poultry-eggs
[78] http://www.foodstandards.gov.au/science/international/codex/pages/default.aspx

Outcomes sought

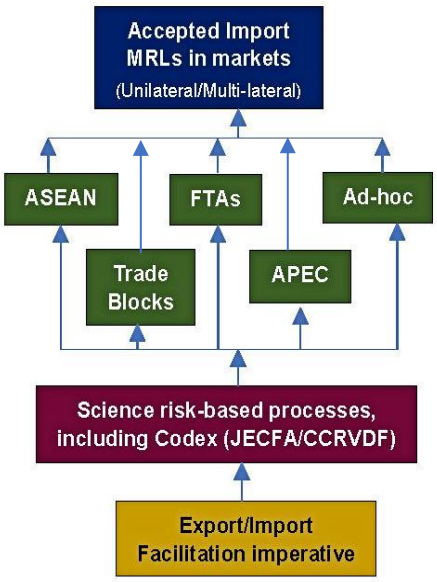
The goal is to achieve recognition of Australian and established internationally recognised standards, such as Codex, and accelerate harmonisation in regional trade fora. There is good opportunity for Australia to piggy-back the good work that has been undertaken in the pesticides field.

Multi-lateral approaches offer wider benefits

Recognising the traded food commodity issues within the region for agricultural chemicals, the Asia Pacific Economic Cooperation (APEC) has been progressing a project, under the Food Safety Cooperation Forum (FSCF), for harmonising import MRL for pesticides. The FSCF has identified:

> "APEC member economies agreed to work together to build robust food safety systems; to accelerate harmonisation with international standards to improve public health and facilitate trade; and strengthen capacity building activities and information sharing."

Figure 1: Process to safe food, trade outcomes



Further, an APEC Pesticide MRL Roadmap seeks to promote alignment of APEC members' MRLs to relevant international standards, using 4 broad principles:

- participation in the development of MRLs in Codex;
- work sharing, or exchanging data to support the establishment of pesticide MRLs by member economies, in cases where there is no domestic equivalent for a member economy;
- adoption of Codex MRLs in domestic legislation and trade; and
- develop unilateral "recognition" or "import tolerances" where practical and appropriate in domestic regulation of specific pesticide/commodity MRLs of trading partners on a case-by-case basis.

The Association of Southeast Asia Nations (ASEAN) *ASEAN Australia New Zealand Free Trade Agreement* (AANZFTA) is a comprehensive and single-undertaking free trade agreement that opens up and creates new opportunities for approximately 663 million peoples of ASEAN, Australia and New Zealand – a region with a combined Gross Domestic Product of approximately USD 4 trillion as of 2016. AMA understands that an Import MRLs Project, including veterinary medicines was submitted to the AANZFTA Committee in 2019. The project is believed to have been refined to focus on capacity building and aimed at policy makers to help them understand the reasons and purpose for having an Import MRL system.

Potential Long-Term Benefits

- Improved position for producers and processors – outcome is the same as having MRLs set in export destination country – see Figure 1;
- Improved position and related benefits for the correct therapeutic use of animal medicines;
- ESIs may become the exception – goal for greater regulatory convergence of MRLs across APEC and ASEAN economies; and potentially other trading partners;
- In APEC there is a process started for pesticide MRLs – therefore there is good opportunity to replicate the approach for veterinary medicines; and
- Dealing at the international level beneficial to multi-national companies.

For further information contact: Ben Stapley, Executive Director: +61 2 6257 9022

International Organisations

The Codex Alimentarius Commission (CAC)

The Commission is the central part of the Joint FAO/WHO Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade. It held its first meeting in 1963 [... more]

Codex standards ensure that food is safe and can be traded. The 188 Codex members have negotiated science-based recommendations in all areas related to food safety and quality. Codex food safety texts are a reference in WTO trade disputes [... more]

Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

Terms of reference:

- to determine priorities for the consideration of residues of veterinary drugs in foods;
- to recommend maximum levels of such substances;
- to develop codes of practice as may be required; and
- to consider methods of sampling and analysis for the determination of veterinary drug residues in foods

Meetings: The Committee meets every second year

- Last meeting: CCRVDF in Chicago. USA, 23-27 April 2018 → Agenda / Report
- Next meeting: May 2020, San Diego, USA

Joint Expert Committee on Food Additives (JECFA)

Areas of work are risk assessment/safety evaluation of food additives (intentionally added), processing aids (considered as food additives), flavouring agents (by functional groups), residues of veterinary drugs in animal products, contaminants, and natural toxins

JECFA also undertakes exposure assessment, development of specifications, analytical methods, residue definitions, MRL proposals (veterinary drugs); and work on general principles – see JECFA Fact Sheet.

Outputs from JECFA feed into the considerations of CCRVDF

Meetings are held annually but rotate on veterinary drugs, contaminants, food additives

- The last meeting was held in Geneva on 17 to 26 October 2017 → Report
- Next Meeting TBC

Publications, Guidelines, Summary reports, Full reports, Toxicological monographs, Dietary exposure

ASIA Pacific Economic Cooperation (APEC)

APEC is an inter-governmental forum for 21 Pacific Rim member economies that promotes free trade throughout the Asia-Pacific region. It was founded in 1989. Members of APEC and ASEAN are identified in Table 1

Food Safety Cooperation Forum (FSCF)

The FSCF was established under the APEC Sub-Committee for Standards and Conformance (SCSC) in April 2007

The FSCF seeks to facilitate trade in food while protecting public health and safety. This is done by strengthening food safety systems in the APEC region that are consistent with the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) of the World Trade Organization (WTO)

The Forum is co-chaired by Australia (FSANZ) and China's General Administration of Customs of China (GACC)

The work program of the FSCF includes initiatives on:

- Food safety modernisation
- Maximum residue limits harmonisation
- Import and export certification
- Antimicrobial resistance
- Antimicrobial resistance surveillance
- Equivalence
- E-Commerce
- Trade Facilitation through the recognition of Food Safety Systems Equivalence
- Trade Facilitation through a Framework on Food Safety Modernisation

Upcoming work is expected in areas of:

- Development of guidance on general best practices, and risk communication with regard to MRL compliance, and modernization of food safety systems
- Antimicrobial resistance
- continued streamlining use of export certificates in the region through bilateral work with Peru

Import MRL Guideline for Veterinary Medicines: DAWE has flagged that a Concept Paper from Chile may be anticipated and it may be possible for Australia to support this initiative. It is assumed that Chile will seek APEC funding, so could be delayed

Association of Southeast Asia Nations (ASEAN) was established in 1967. Its current 9 members are identified in Table 1 (note some members of ASEAN are also APEC Member Economies).

The ASEAN Australia New Zealand Free Trade Agreement (AANZFTA) *Import MRLs Project*, includes both pesticides and veterinary medicines.

Table 1: APEC and ASEAN Economies

Member economy	APEC	ASEAN
Australia	✓	-
Brunei Darussalam	-	✓
Cambodia	-	✓
Canada	✓	-
Chile	✓	-
Chinese Taipei	✓	-
Hong Kong	✓	-
China	✓	-
Indonesia	✓	✓
Japan	✓	-
Laos	-	✓
Malaysia	✓	✓
Mexico	✓	-
Myanmar (Burma)	-	✓
New Zealand	✓	-
Papua New Guinea	✓	-
People's Republic of China	✓	-
Peru	✓	-
Republic of Korea	✓	-
Republic of the Philippines	✓	✓
The Russian Federation	✓	-
Singapore	✓	✓
Thailand	✓	✓
United States of America	✓	-
Vietnam	✓	✓

Missing MRL Project

This project was initiated by the USA and Canada with participation from Australia. It is currently focussed on grains and horticulture. The objective is to have MRLs accepted in key importing countries. USA/Canada are funding training for residue chemists to build capacity in specific markets.