



28 August 2020

Agricultural and Veterinary Chemicals 1<sup>st</sup> Principles Review  
Department of Agriculture Water and Environment

Lodgement by email: [agvetreview@agriculture.gov.au](mailto:agvetreview@agriculture.gov.au)

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](http://animalmedicinesaustralia.org.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 1<sup>st</sup> 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, again and again, 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<sup>1</sup> 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<sup>2</sup>. 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."

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<sup>1</sup> Productivity Commission 2008, *Chemicals and Plastics Regulation, Research Report*, Melbourne

<sup>2</sup> 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 versus 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<sup>3</sup>; and the Ten Principles for Australian Government Policy Makers<sup>4</sup>:

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<sup>5</sup> 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:

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<sup>3</sup> <https://www.pmc.gov.au/ria-mooc/coag/principles-best-practice-regulation>

<sup>4</sup> <https://www.pmc.gov.au/ria-mooc/agrp/overview/australian-government-10-principles-policy-makers>

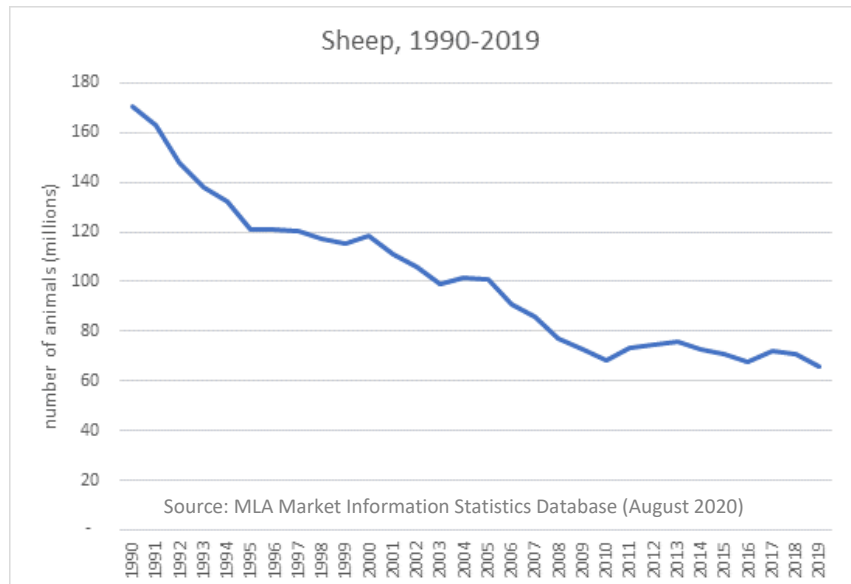
<sup>5</sup> <https://www.pmc.gov.au/ria-mooc/extra-detail>

## 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.”<sup>6</sup>

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

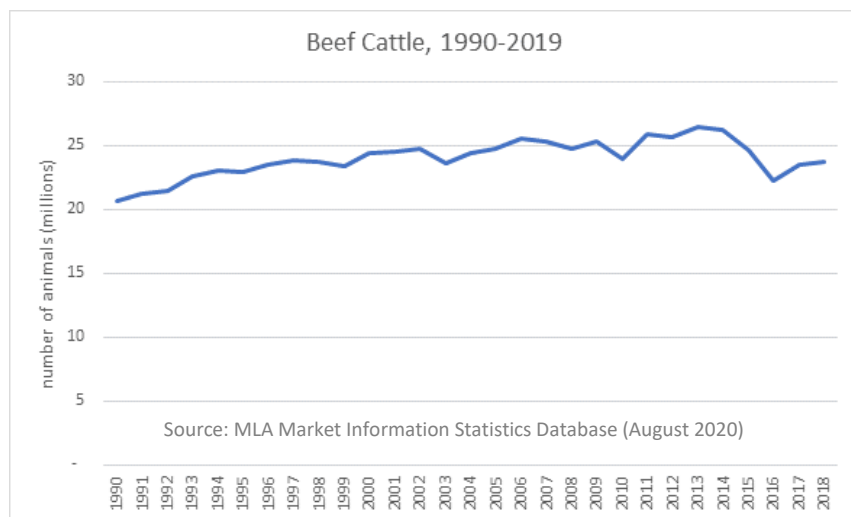


## Beef cattle

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.<sup>7</sup>

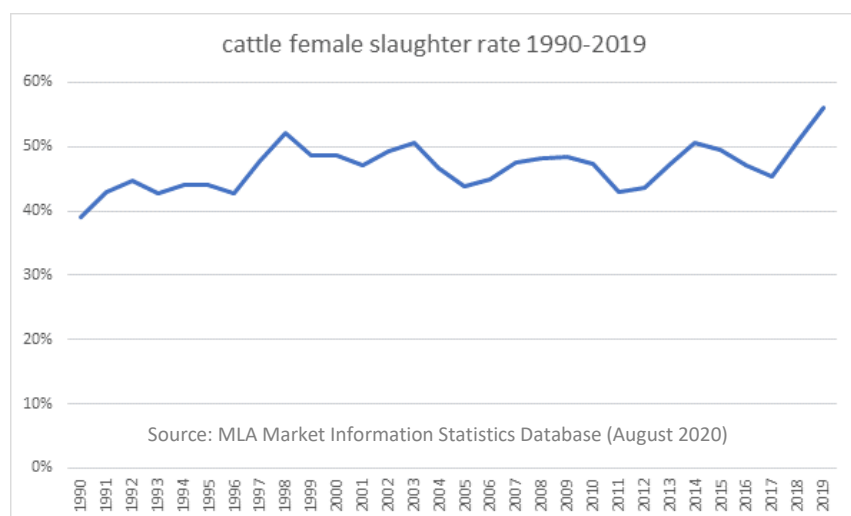


## Cattle female slaughter rate

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.



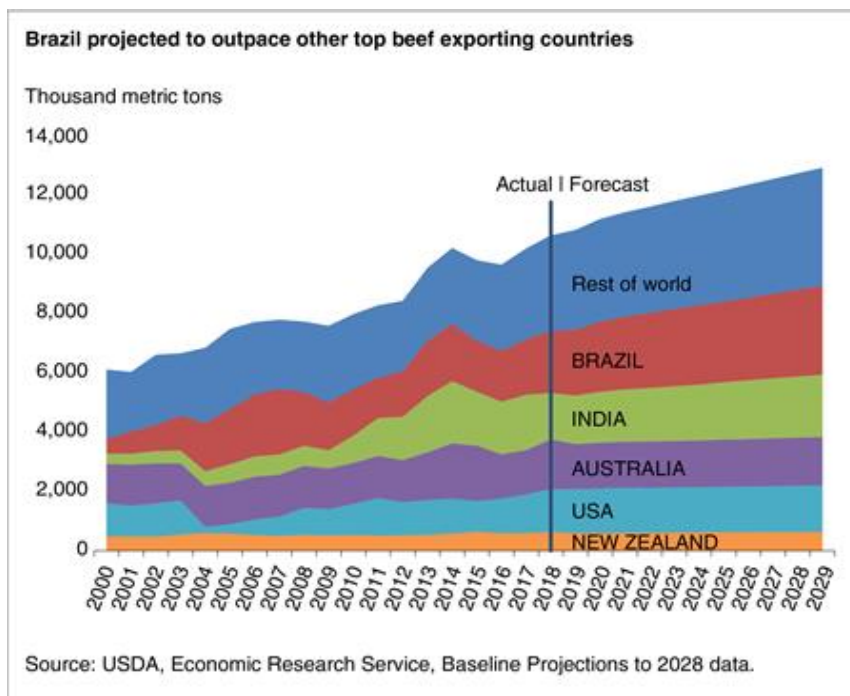
<sup>6</sup> <https://www.mla.com.au/prices-markets/Trends-analysis/sheep-projections/>

<sup>7</sup> <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.<sup>8</sup>

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

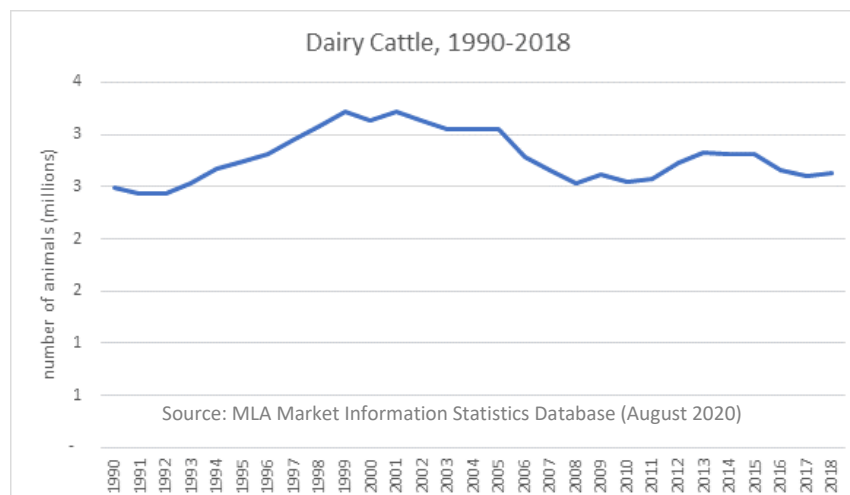


## Dairy Cattle

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.

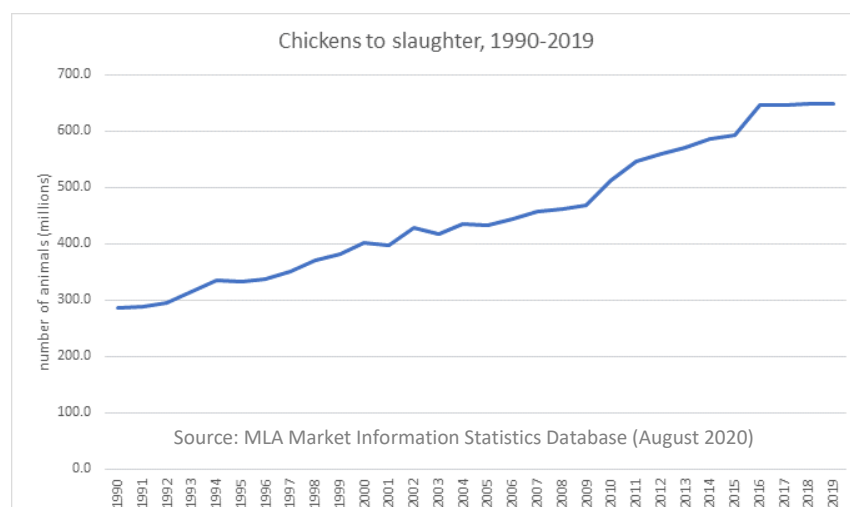
A noticeable characteristic in dairy has been strong growth in production per head due to a range of factors.



## Chicken

‘Chickens 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.<sup>9</sup>



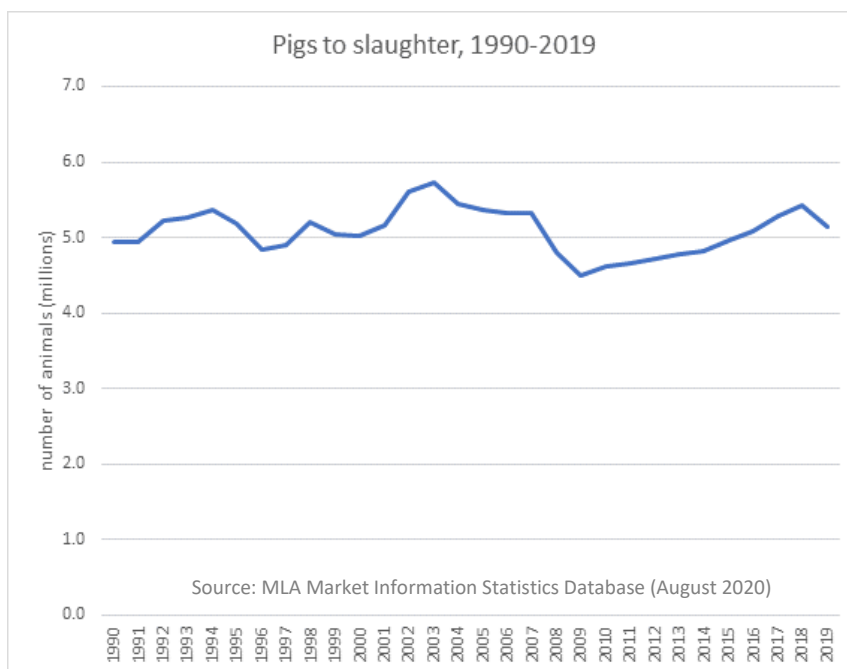
<sup>8</sup> Brazil is the world’s largest beef exporter

<sup>9</sup> 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.<sup>10</sup>



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*<sup>11</sup> 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

<sup>10</sup> <https://www.agrifutures.com.au/farm-diversity/pigs-meat-pork/>

<sup>11</sup> 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<sup>12</sup> 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.”<sup>13</sup>



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.

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<sup>12</sup> <https://www.porkbusiness.com/article/african-swine-fevers-influence-prevails-over-global-pork-markets>

<sup>13</sup> <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**.<sup>14</sup>

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*<sup>15</sup>

- 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.<sup>16</sup>
- 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

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<sup>14</sup> unpublished AMA survey data

<sup>15</sup> [Animal Medicines Australia, Pets in Australia: A national survey of pets and people, 2019](#)

<sup>16</sup> 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.)*