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

Lodgement by email: agvetreview@agriculture.gov.au

Dear Review Panel

Draft Report of the Independent Review of the Agvet Chemicals Regulatory System

Animal Medicines Australia (AMA) is pleased to provide this submission on behalf of its members. AMA members represent more than 90% of Australian sales of registered veterinary medicine products. AMA members range from small to large companies, including local businesses, those with international heritage, and those who manufacture and export globally.

To assist the Review Panel, AMA's submission of 28 August 2020 to the Issues Paper consultation[1], included:

- detailed AMA's expectations for the Draft Report; including adherence to Best Practice Regulatory Principles, embodying Minimum Effective Regulation, and other criteria of science and risk-based approaches, robust methodologies, strategic focus and other coherent elements and principles;
- referencing the 2008 Productivity Commission Report on Chemicals and Plastics Regulation[2] which presented an institutional and regulatory approach for chemicals and plastics regulation:
  - *formulation of strategic policy and oversight of the institutional and regulatory arrangements;*
  - *assessment of the hazards and risks of chemicals;*
  - *risk-management standard setting; and*
  - *administration of agreed standards and monitoring of their impact.*
- providing information on Australian veterinary medicines, the Business Operating Environment, and markets, including livestock numbers or production numbers over more than 30 years. Information was also presented for companion animals.
- presenting detailed case studies on *Securing Animal Import MRLs in Australia's export markets* and the inappropriate proposed application of GHS labelling to certain veterinary medicines.

At consultation sessions the Panel Chair confirmed that this review represents a *once-in-a-decade* opportunity. AMA reaffirms its full agreement. There is need to capture the opportunity to bring forward much needed meaningful reforms that achieves progress towards long term goals and destinations.

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1 AMA's submission of 28 August 2020 to the Issues Paper consultation
2 Productivity Commission 2008, *Chemicals and Plastics Regulation*, Research Report, Melbourne

This submission provides further information that will assist the Review Panel in its deliberations.

It is critical that the Final Report contains a credible and implementable package of reforms that engenders the confidence of governments, regulators, regulated community, livestock producers, supply chain producers, export market participants, consumers, companion animal owners, and other stakeholders.

AMA notes the following issues were not pursued in the form identified in the Issues Paper:

- accreditation of holders;
- benefits test;
- pest groupings;
- complete removal of products of low regulatory concern; and
- synergistic effects;

Through the following sections of this submission, it is AMA's intention to:

- provide comment on the conduct of the Review from a primary stakeholder perspective;
- identify information that may have been missed from the Review Panel's considerations, including where such information may have led to different decisions or deliberative outcomes;
- suggest areas for improvement; and
- importantly, identify AMA's views and positions.

AMA is pleased to contribute the following:

1. Adherence to Best Practice Regulation Principles

AMA contends that the methodology supporting the 139 recommendations of the Draft Final Report could have been enhanced through adherence to Best Practice Regulatory Principles. AMA believes that the approach taken by the Panel reduces credibility, increases the extent of future work, and limits potential implementation.

AMA notes the following entries in the Draft Final Report:

> "The Panel considers that the conventional view of deregulation which centres on reduced or better regulation does not give effect to the full range of possibilities available. The Panel has taken a broader, and richer, approach to the concept of deregulation in developing its recommendations for the future pesticides and veterinary medicines regulatory system. The Panel's 30-year vision for the regulatory system eschews the traditional, process driven approach to regulation and instead drives towards a contemporary regulatory system that embodies the ideas of modern regulatory theory and practices, including principles-based, performance-based, responsive, and co-regulatory approaches. It embraces flexible, imaginative, and innovative forms of regulation, which is matched to the level of risks present to humans, animals, and ecosystems. In doing so it empowers governments, businesses and third parties to deliver regulatory outcomes where they are best suited to do so." (p.20)

> "The Panel notes that most governments across Australia have an agenda to deliver better regulation including reducing duplication and overlap. Meanwhile, the theoretical literature about deregulation has become more sophisticated and new models of good regulatory practice are becoming available (Gunningham, N, Sinclair, D 2017). Examples include regulatory arrangements that rely more formally on industry quality assurance and good stewardship practices, and arrangements that build-in continuous regulatory reform, rather than only responding to specific short-term issues." (p.11)

AMA believes this Review would have been better served through adoption of Government endorsed Best Practice Regulation approaches, in accordance with government guidelines for consultation. Most stakeholders will have had little or no experience or exposure to the 'theoretical literature about deregulation'. AMA believes that there needs to be consultation on the appropriateness of a theoretical approach and in particular a comparison with current Best Practice Regulation approaches.

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

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:-
    a. the benefits of the restrictions to the community as a whole outweigh the costs, and
    b. 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; and
8. government action should be effective and proportional to the issue being addressed.

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

> "A common misconception is that a RIS is only required for legislation. A RIS is required for all measures that seek to impose mandatory obligations on business and the community, including codes and advisory instruments for which there is a reasonable expectation of widespread compliance. The level of analysis required in a RIS depends on the significance of the proposed change."[6]

AMA has noted its expectations of adherence to government Best Practice Regulation approaches on multiple occasions. It is disappointing to note that there is little evidence of Best Practice Regulation principles in the methodology used, and recommendations of this report. This is apparent in the treatment of the following example:

> "Recommendation 117: Transition to PIC/s for export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period."

In this case:

- the problems and issues have not been accurately defined or articulated;
- the range of possible policy options have not been explored;
- complete information on overseas schemes appear not to have been fully understood and considered, leading to incorrect assumptions;

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

- key matters of competition policy appear not to have been considered;
- there are 165 entities on the APVMA maintained *list of Licensed Australian manufacturers of veterinary chemical products*[7]. Consequences for the large number of the small businesses have not been reported as being considered. It is not clear how many of these small businesses were part of the engagement process;
- anecdotal information indicates that implementation of PIC/s would affect business viability – for many, their Business Models are about the domestic market and not export;
- the proposals appear out of scope – the Draft Final Report states the purpose as:

  > "Aligning Australian manufacturing standards with international manufacturing standards to facilitate more efficient and effective export." (Draft Final Report p.x, underlining added)

- this is a high-cost regulatory intervention that could lead to loss of veterinary medicines to the Australian market, loss of employment, increased overseas sourcing, and increased imports.

More detailed information is provided at section 5.2 of this submission.

AMA suggests that the Review would have been better served through using current approaches to Best Practice Regulation, rather than bespoke methods based on theoretical literature about deregulation.

There is need for The Panel to demonstrate the benefits and applicability of the methodology it has chosen, following the Issue Paper, and adopted in the DRAFT Final Report.

2. Minimum Effective Regulation

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"*[8] 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[9] (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)

It is important to note that critical elements of food safety, animal welfare, environmental protection and export market access require a comparatively high level of regulation as the minimum standard required to maintain community confidence.

The above principles and approaches are essential 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.

The Final Draft Final Report does not explore the case for a Minimum Effective Regulation approach.

In its submission to the Issues Paper, the Queensland Department of Agriculture and Fisheries noted:

> "DAF believes that the current Agvet chemicals regulatory system works reasonably effectively, and the fundamental principles are sound."

[7] https://apvma.gov.au/node/12326
[8] https://www.wto.org/english/tratop_e/serv_e/workshop_apr11_e/porter_e.ppt
[9] Issues paper—review of the agvet chemicals regulatory system Future reform opportunities

The tone of the Queensland submission reflects the view that whilst tweaks and improvements can be made – the current system is not broken and careful analysis is required to support any changes.

Cooperation between the Commonwealth and States and Territories is fundamental to reform progress.

The Final Draft Report does not explore the case for a Minimum Effective Regulation approach either for current considerations or into the future where the policy options have not been explored.

3. Some challenges with focus

3.1 Focus and context

AMA sees the Draft Final Report as an inward-looking document that does not recognise that for production animal systems, veterinary medicines are key inputs.

The Draft Final Report could be improved through some analysis of what the future state will look like, and what the needs of the regulatory system will be over that time frame to support veterinary medicines and production livestock systems. This should include the international arena.

3.2 United Nations Organisations promoting food quality, food safety and trade

If Australia is to meet any future agricultural growth targets, then these targets will be driven by animal and commodity exports. The domestic market does not have the capacity to generate high levels of growth.

International developments will be key. Australia needs to actively influence this environment to support access to international markets.

"The Codex Alimentarius Commission (Codex)[10] is an intergovernmental body that:

- develops international food standards, guidelines and codes of practice;
- protects consumer health;
- ensures fair trade practices in food trade; and
- encourages international government and non-government organisations to coordinate their food standards.

Codex was formed by the World Health Organization and Food and Agriculture Organization in 1962.

The Department of Agriculture, Water and the Environment website[11] identifies:

We engage with Codex to:

- ensure international standards are based on sound scientific principles;
- contribute to consumer food safety;
- contribute to the success of Australian food manufacturing and exports; and
- create a level playing field for our exporters.

Australia participates in:

- Codex Alimentarius Commission;
- Codex Executive Committee;
- Coordinating Committee for North America and Southwest Pacific;
- all general subject matter committees; and
- relevant commodity committees.

[10] https://www.agriculture.gov.au/ag-farm-food/food/codex
[11] https://www.agriculture.gov.au/ag-farm-food/food/codex

The Department of Agriculture, Water and the Environment has highly qualified and respected staff, or nominees, dedicated to servicing key committees including:

- Codex Committee on Pesticide Residues (CCPR);
- Joint Meeting on Pesticide Residues (JMPR);
- Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF); and
- Joint Expert Committee on Food Additives (JECFA).

The Draft Final Report contains a few peripheral references to Codex and does not mention CCPR, JMPR, CCRVDF or JECFA at all. Yet this involvement is key to making long-term progress for Australian agriculture and the Australian economy.

There is also no mention of bi-lateral or multi-lateral arrangements such as the Asia Pacific Economic Cooperation (APEC) or the Association of Southeast Asian Nations (ASEAN) to facilitate trade.

This issue has been raised multiple times in presentations and written submissions, including at the invitation of the Review Panel, in AMA submissions to this review, and directly with the Department of Agriculture, Water and the Environment. Further background is provided at Appendix 3 of this submission in an AMA Briefing note titled "*Securing Animal Import MRLs in Australia's export markets".*

3.3 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;
- can 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 only be used in special circumstances and play a pivotal role where needed.

Further background is provided at Appendix 3 of this submission in an AMA Briefing note titled "*Securing Animal Import MRLs in Australia's export markets".* This issue has been raised multiple times in presentations and written submissions, with little response.

3.4 Companion animals and companion animal veterinary medicines

Companion animals and companion animal products have largely been orphaned and given scant recognition in the Draft Final Report. There are important considerations of public health, animal welfare and zoonoses for this sector that should not be overlooked.

AMA notes:

- there are almost 29 million pets in Australia today - more than the estimated Australian human population of 25 million;[12]
- in 2019, factory gate sales of veterinary medicines for the production sector was $509,701,994 and for companion animals, $550,622,532;[13] and
- 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.

Pets 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 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, behaviour, and performance.

3.5 Business environment and business decision-making

Understanding the Business Operating Environment is crucial to considerations of supportive policy settings for the future of veterinary medicines in Australia.

The fortunes of the veterinary medicines industry are intrinsically tied to Australia's animal populations. For most livestock species, except chickens, there is flat or long term decline.

For veterinary medicines, the Australian sales of companion animal products now exceeds those for production 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 Australian 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. An AMA 2020 submission extract dealing with livestock numbers is provided at Appendix 6.

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

The considerations of the Review Panel would have been enhanced through better understanding of the business environment and commercial decision making.

Interventions such as the proposed mandatory adoption of PIC/s for both domestic and export manufacture will be contrary to the business models of a range of businesses, including small-medium sized enterprises, identified in the *list of Licensed Australian manufacturers of veterinary chemical products* [14]. The Australian Government's Best Practice Regulation guidelines specifically flag the Competition Principles Agreement that legislation should not restrict competition unless certain conditions can be met.

The Review Panel may have benefited from directly meeting with the Boards of key stakeholder organisations. This may also have assisted with confidence building and established a meaningful dialogue. Engagement with other related government departments such as the Department of Industry, Science, Energy and Resources (DISER)[15] and Department of Foreign Affairs and Trade

[12] Animal Medicines Australia, Pets in Australia: A national survey of pets and people, 2019
[13] unpublished AMA survey data
[14] https://apvma.gov.au/node/12326
[15] https://www.industry.gov.au/

(DFAT)[16] would also have been desirable given involvement of the Department of Agriculture, Water, and the Environments (DAWE)[17] involvement in APEC and other fora.

4. Rational deployment of resources and comprehensibility

This section can be best described in the comment of a stakeholder as:

"The Report makes a complex area more complex".

The proposed addition of two new oversight levels (a Commissioner and a Board), in addition to the division of existing responsibilities between multiple agencies, is unjustified for a system that is not fundamentally broken. There is no analysis provided in the Draft Final Report that demonstrates how a new multi-level organisational structure would reduce regulatory burdens for stakeholders, whilst improving the efficiency, effectiveness or transparency of that regulation. Better resourcing of the existing system through public funding would be a more appropriate response to the issues noted by stakeholders and to address public interest concerns.

5. Basing evaluation and recommendations on incorrect information

Some examples, from the simple to the complex, include:

5.1 Imports of veterinary medicines

The Draft Final Report references the following:

> "Imports currently account for 52% of the Australian market for pesticides and for **11%** of veterinary medicines (IBISWorld Australia 2020 and 2020a)". (p.161 of Draft Final Report.)

AMA members represent more than 90% of Australian sales of registered veterinary medicines. Based on 2021 AMA unpublished member survey information the actual level of imports is **80%** of the Australia veterinary medicines market.

Such a key statistic should have been verified, and if approached, AMA would have been pleased to provide correct information.

As it stands, the Draft Final Report presents an inaccurate picture of imports that may adversely impact decision-making. This needs to be corrected.

5.2 Transition to PIC/s for export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.

During a meeting with the Review Secretariat on 20 September 2020, AMA identified that an APVMA process had already been established for updating the Australian GMP Code through the APVMA-MLS ILCF starting 2021. This was common and public knowledge.

APVMA sought stakeholder input into the management of the APVMA GMP Code on 9 September 2019 with close of submissions on 13 December 2019. [18]

The underpinning of the Australian GMP Code is:

- the **Agvet Code 1994** provides for controls on the Manufacture of chemical products;

[16] https://www.dfat.gov.au/
[17] https://www.agriculture.gov.au/
[18] https://apvma.gov.au/node/54126

- the Agvet Code Regulations 1995 provides interpretation for the ***Australian GMP Code.*** The Regs identify certain elements such as audits, steps etc but does not specify "GMP";

- the Manufacturing Principles 2014 (Legislative instrument) provide the building blocks for the GMP Code but does not specify details or what standards, references, or guidelines might apply; and

- the Australian GMP Code 2007. This is the "details" document.

This is an APVMA operational responsibility quite separate to the Independent Review of the framework.

AMA understands that a change to the Australian GMP Code does not require a change the Agvet Code 1994, or the Agvet Code Regulations 1995, but may require updating the legislative instrument to include the new name of the GMP document. This is because the changes to the Australian GMP Code are operational and not policy. This is similar to updating other APVMA guidelines, which is an ongoing process.

The Draft Final Report presents a number of misunderstandings. It is interesting in that it mixes incomplete information, incorrect interpretations, regulatory, and trade facilitation elements.

The Draft Final Report cites 53 members of the Pharmaceutical Inspection Co-operation Scheme (PIC/s). This is correct and it is a direct quote from the PIC/s website. However, when the membership is examined in detail, it is clear that in some countries (e.g.: UK, France), both the human veterinary agencies are members of PIC/S and apply those standards. However, in other countries, only the human pharmaceutical agency is a PIC/S member, and the veterinary agency is not. This includes New Zealand, where the Medicines and Medical Devices Safety Authority (Medsafe) is the PIC/S member, but not the Agricultural Compounds and Veterinary Medicines (ACVM). ACVM does not require PIC/s for local manufacture. Similarly, Australia is a member through the Therapeutic Goods Association (TGA) but the APVMA is not.

The statement in the Draft Final Report (p.167) for veterinary medicines tends to mislead:

> "This is a non-binding international co-operative arrangement between regulatory authorities on accepted standards for good manufacturing practice for medicinal products for human or veterinary use. PIC/S is the standard applied by 53 authorities globally, including in Europe, Africa, America, and Asia".

A country being a member does not mean that PIC/s is adopted for veterinary medicines in that country. Quoting 53 authorities is misleading in a veterinary context. There needs to be a clear understanding of which authorities adopt PIC/s for their veterinary medicines as opposed to just for their human medicines. The US Food and Drug Administration (US FDA) is a member, but it does not accept PIC/s TGA for its pharmaceutical or biological products. Having a PIC/s FDA certificate does not enable free access to the USA and a separate GMP audit to the FDA GMP Code is required.

Currently the APVMA accepts GMP standards that are less than the APVMA GMP requirements (e.g. USDA GMP audits for vaccines) so a block on imports would occur where the supplier must have PIC/s GMP certificates.

AMA stresses that if local manufacturers have to meet a PIC/s standard (e.g. pass a PIC/s GMP audit) then ALL overseas suppliers have to also (including those supplying from FDA GMP facilities unless there is a mutual recognition between FDA and APVMA). The change would also require New Zealand suppliers to have PIC/s GMP certificates. The result would be a reduction in the products available to the Australian market.

Companies who decide to export to countries where the APVMA GMP is not recognised do so based on a commercial financial decision that includes an assessment of the additional costs for

access in those markets. The flip side also applies in that where a company does not want to export to countries where APVMA GMP is not recognised the company should not want to place additional cost onto the veterinary medicines sold in Australia – likely a cost to end-users.

The Panel should explore matters of competition and cross subsidisation. The Governments Best Practice Regulations state:

> "in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:
>
> – the benefits of the restrictions to the community as a whole outweigh the costs; and
> – the objectives of the regulation can only be achieved by restricting competition."

With the focus of the Terms of Reference on Regulatory Frameworks, AMA contends that it was not the intention of the Minister or the Review to venture into commercial decisions regarding exports and international trade of veterinary medicine products. AMA questions the rationale of the Review Panel making an intervention in this area:

> "Aligning Australian manufacturing standards with international manufacturing standards to facilitate more efficient and effective export." (Draft Final Report p.x)

AMA contends that this item is based on incomplete information and is out of scope for the Review.

AMA also has concerns that the consequences, and business viabilities, for the 165 business entities on the APVMA maintained *list of Licensed Australian manufacturers of veterinary chemical products* [19] have not been fully considered. Consequences for the large number of small businesses have not been reported, and it is not clear how many of these small businesses were part of the engagement process.

Table 1: APVMA Licensed Manufacturers

Licensees	Category
34	Category 1 – Immunobiologicals and sterile veterinary preparations.
58	Category 2 – Non-sterile veterinary preparations other than ectoparasiticides, premixes and supplements.
23	Category 3 – Ectoparasiticides.
38	Category 4 – Premixes and supplements.
17	Category 6 – Single step manufacturer.

Source: APVMA at https://apvma.gov.au/node/12326

AMA supports a properly constituted review of the Aust GMP Code as established by the APVMA.

6. Hazard vs risk

6.1 Definition of a veterinary medicine

Information for the following countries is provided at Appendix 5

- Australia
- Canada
- Europe
- New Zealand
- USA

[19] https://apvma.gov.au/node/12326

AMA considers that the inclusion of Globally Harmonised System of Classification and Labelling of Chemicals (GHS)[20] elements in the definition of a veterinary medicine to be inappropriate. AMA contends that the definition needs to describe the purpose of veterinary medicines e.g. preventing, diagnosing, alleviating a disease etc. This is consistent with the approaches taken in other countries. AMA is not aware of any country that has incorporated GHS elements into its veterinary medicine definition.

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)." (underlining added).

The GHS is not applied to therapeutic goods in their finished form.

Difference in definitions will likely be confusing to governments and stakeholders locally and overseas. The Draft Final Report does not present a compelling case for this change. AMA is unable to support this change.

6.2 Labelling of veterinary medicines

There are tomes that can be written on this topic but the time constraints of this consultation allow only brief comments. Simply, hazard-based labelling was not intended for veterinary medicines.

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 or for dealing with chemical diversion to illicit drugs.

The placement of both "hazard" and "risk" information on veterinary product labels represents duplication of regulation and poses significant potential for confusion for veterinary medicines users.

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).[21] 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."

[20] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 7th revises edition
[21] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 7th revised edition

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 to specify that veterinary medicines are not subject to hazard labelling (as previously identified in this submission).

Veterinary medicines are "defined-use-products". This is very different to industrial chemicals which have multiple use scenarios e.g. 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[22] describe:

"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

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

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. Further, 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 4. 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.

7. Commonwealth, State, Territory arrangements

"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) (Issues Paper p.25)

The legal and constitutional aspects of this proposal have not been adequately examined in the Draft Final Report.

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; and
- accountabilities.

8. Proposed statutory office holder: Commissioner for Pesticides and Veterinary Medicines Stewardship

> "The Panel identified that the current regulatory system as a whole lacks leadership, accountability, transparency, and a clear focal point. To address this, the Panel recommends establishing a Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner). The Commissioner will provide national policy leadership, accountability and guidance for Australia's pesticides and veterinary medicines regulatory system." (page xii)

> "The Commissioner will be required to report to parliament to demonstrate that the entire regulatory system is operating effectively, and problems are identified early. It is vital that there is oversight of the future regulatory system to strengthen accountability and transparency, increase public confidence, and maintain social licence." (page xiii)

The Commissioner is proposed to have broad responsibilities. Many of the Recommendations in the Draft Final Report are predicated on the establishment of this position. More than 30 recommendations have the Commissioner embedded in the proposal. This is unfortunate and hampers consideration of the underlying function or issue. Others will no doubt have raised these problems.

AMA is concerned that there has been insufficient exploration of alternatives that would support the proposed function within the existing authority. It is hard to see that the States and Territories would support a Commissioner imposing control over a future National Registration scheme. AMA suggests that specialist 'business-structures' advice may assist the Panel in exploring realistic alternatives.

9. Licensing of products registered overseas

AMA notes the rationale for treatment of products registered overseas but not registered in Australia expressed in the Draft Final Report:

> "By global standards, the Panel recognises that Australia is a relatively small market for pesticides and veterinary medicine products. A lack of access to products and their uses places Australian primary producers at a competitive disadvantage in comparison to their overseas competitors. It also restricts access to the most advanced alternatives to current pesticide and veterinary medicine products, many of which can be less harmful to the environment or pose lower hazards to users or which provide better animal health and welfare outcomes. (page xi)"

> "To improve access the Panel recommends an innovative licensing arrangement to provide an alternative regulatory pathway to products already registered by a comparable international regulator. This would allow a licensed entity to supply an internationally registered product in Australia without the need for registration in Australia. The entity must, however, address the risks associated with the use of the product and undertake measures to address any unique Australian circumstances. The Commissioner will be responsible for the licensing program and reviewing the measures proposed to manage risks (page xiv)

> "Looking ahead, the Panel considers that access to a broader and more extensive range of safe, effective, products and product uses, equivalent to those available to international counterparts, to be a vital goal for regulatory reform. Safety, however, must not be compromised. Unique Australian circumstances must continue to be considered, and public confidence must be retained. However, the Panel is convinced that competitive pressures and opportunities to achieve safety, environmental and other benefits will drive change in the regulatory system towards much improved access to chemicals and uses for Australians. While the Panel supports greater access, it is not proposing that all products available overseas should be available in Australia." (page 9)

The assumption that there is an "extensive range of safe, effective, products and product uses" is a misnomer. This is an example of where understanding the Business Operating Environment and business decision-making is crucial to supportive policy settings for the future of veterinary medicines in Australia.

The Review Panel needs to engage with Boards and Chief Executives (decision-makers) of registrants making investment decisions more directly in Australia.

AMA notes:

- products are not all the same. For the same branded product there may be variations in formulations between countries. For instance, a product formulated for use in Canada (temperature extremes) may be different to the same-branded product for use in Brazil or Mexico;
- there may be a wide range of arrangements overseas including licensing arrangements, intellectual property etc. – disruption could have adverse consequences for research and development collaboration and other beneficial activities;
- Australian regulatory controls go beyond the considerations of availability identified in the Draft Final Report, including the interfaces with:
  - gene technology regulation;
  - biosecurity and import regulations;
  - poisons scheduling;
  - maximum residue limits (domestic and export destinations;
  - export slaughter intervals;
  - access to industry stewardship programs such as DrumMuster, ChemClear, Agsafe;
  - Dangerous Goods transport (air, land and sea) and Dangerous Goods storage;
  - chemical diversion – illicit drugs and chemicals of security concern;
  - retail storage;
  - Australia-specific labelling requirements and Safety Data Sheets;
  - environmental impacts;
  - Work Health & Safety;
  - Australian Packaging Covenant;
  - Trade Measurement;
  - Trade waste; and
  - Waste management.

AMA believes that this proposal undermines confidence in the Australian regulatory system for both domestic consumers and international trade partners. An alternative, less rigorous pathway to the Australian market could result in significant issues associated with counterfeit and inferior products, and adverse events associated with risk assessments conducted by non-experts with a vested interest in the product.

AMA is supportive of simplifying and streamlining regulatory systems but considers this proposal to represent an unacceptably high risk. AMA is unable to support this proposal at this stage.

10 New technologies

Australia's ability to deliver on sustainability, efficiency, trade (animals and animal commodities), and economic goals is dependent on the successful adoption of new technologies. There is no doubt to this reality.

AMA has expressed a view that processes need to be established to allow evaluation of new technological developments – each will bring its own challenges. In this way, policy should establish clear pathways to technology and innovation adoption. Rather than picking a few "winners", AMA sees a need to foster technological advancement across broad areas – this could include use of drones, genetics, remote sensing, management systems, information technology, data mining, and many others.

In progressing an innovation agenda, there will be areas where governments can reduce hurdles or break roadblocks. This will include how industry, stakeholders and governments interface. The development phase also needs to recognise areas of intellectual property or other incentives that will assist development and employment. This could also boost the potential value of Australian developed technologies in international economies. Some elements of an *Innovation Agenda* could include:

- eliminating barriers;
- seamless systems;
- incentivising development;
- facilitating collaboration;
- inviting regulatory innovation;
- championing science and risk-based approaches;
- ensuring unencumbered trade of animals and animal commodities;
- supporting public health and animal welfare; and
- meeting the Social License challenge.

The Draft Final Report makes recommendations on smart-labels in Recommendations 56 and 57. Progress would be enhanced through a robust Project Plan leading to commercialisation.

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.

11. Data Protection

AMA supports Recommendation 108, with regard to veterinary medicines, which specifies that the periods of limitation on the regulator's use of information should be:

- 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent; and
- 5 years for information:
  - relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption.
  - provided in support of a chemical review.
  - which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.

It is noted that the amendment is a modest one to correct a long-standing anomaly between pesticides and veterinary medicines. Nonetheless, when enacted, it becomes one of the factors that is considered by companies in their evaluation of marketing proposals. It is one of the rare carrots in the Draft Final Report.

Regarding Recommendations 87 and 88, AMA wishes to defer detailing its view until the future position of an internationally registered product is determined. i.e. they should be considered together as a package.

12 Accredited assessor scheme

In principle, AMA supports the provision of a power to create a framework, sanctions and accreditation scheme in the future and if needed, to facilitate the use of external assessors. If the use of external assessors becomes an option for application, then some form of accreditation is required. It would be appropriate for the APVMA to set the standards for any such accreditation scheme, but the administration of that scheme (i.e. assessing the assessors) should be external as this is not core APVMA business.

However, 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 current use of pre-application assessments (PAAs) will be particularly informative.

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 assessor is suitably qualified to perform that assessment and that the advice of the external assessor would subsequently be followed by the regulator, thus providing 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 is also concerned that this could become another administration strain on APVMA when there are better 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.

13. APVMA or OGTR as the decision-maker

AMA notes the proposal contained in Recommendation 80; namely:

> "In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary."

AMA welcomes this proposal and pending final details is pleased to lend its support.

14. Some funding considerations:

With the APVMA to remain fully cost recovered – and include 100% recovery on application fees plus levy. AMA supports cost recovery for risk assessment and registration services in principle.

AMA has concerns that there may be ongoing appetite to access the levy where new areas of expenditures arise.

A range of 'Public Good' contributions have been identified; including:

- minor-use, in addition to monies from the levy (Recommendation 133);
- costs of data mining and analysis for system surveillance and monitoring (Recommendation 136);
- costs of environmental monitoring be publicly funded (Recommendation 137);
- cost of domestic produce monitoring should be publicly funded (Recommendation 138); and
- certain activities of the Commissioner (Recommendation 139).

It would seem unlikely that a Government would agree to new levels of funding under current or foreseeable economic conditions. Therefore, the function would need to be paid by identified beneficiaries/stakeholders or discarded unless alternate funding can be achieved. Alternate funding options need to be considered and project risk assess if these functions are not financed.

AMA supports cost recovery for risk assessment and registration services in principle.

15. Why the approach in the Draft Final Report doesn't lead towards a desired 30 year horizon

The Draft Final Report liberally sprinkles references to the Review Panel's 30 year vision yet it's content and methodology has not been explained.

In December 2019, Animal Health Australia published a Megatrends Report: [23]

> *"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."*[24]

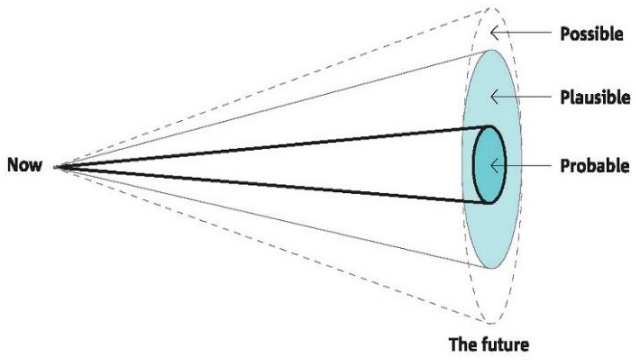
In 2013 Chemistry Australia undertook a *Strategic Industry Roadmap* exercise together with CSIRO Futures Group and supported by the Department of Industry:

> *"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."*[25]

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).

AMA was surprised that the Review Panel's vision was not more outward looking to:

- Global registrations; toxicology evaluations through an expert group such as JECFA or JMPR
- Optimised roles and responsibilities for Codex, JECFA, CCRVDF, JMPR, CCPR
- Recognising that Australia's need is for sustainable growth to drive exports – the domestic market alone will not grow the economy.
- Influencing trading blocks – APEC, ASEAN and others

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

16. Attempting to evaluate the Panel's recommendations

To assist in the identification and communication of 'ratings' and 'priorities' for the 139 Recommendations presented in the Draft Report, AMA has allocated the following symbols and priority numbers to each Recommendation. The results of this rating and prioritisation exercise are:

					
Supported	Needs work: Priority 1 (high)	Needs work: Priority 2 (medium)	Needs work: Priority 3 (low)	Not supported	Not applicable/ or not evaluated
11	22	18	10	68	10

These results indicate to AMA that the Draft Final Report and its considerations are incomplete. As AMA has considered the detail of the Review Recommendations it has become evident that some of the deficiencies are in major areas that have been identified in AMA submissions and meeting contributions.

The Panel asserts in the Draft Final Report that it has:

> "provided recommendations for reform of the regulatory framework to increase the value of Australian agriculture and allow Australia to remain competitive in global markets, while ensuring the safety of humans, animals, and ecosystems."

Overall, AMA is concerned that the Draft Final Report **does not present an implementable package** of reforms that will progress the interests of all stakeholders and meet the Review's Terms of Reference.

17. Timing

The 279 page Draft Final Report, with 139 recommendations, was released the week before Christmas 2020 (16 December 2020). With stakeholder responses due 26 February 2021, consideration of this complex document has suffered from a lack of genuine opportunity for stakeholder evaluation and contribution. This is relevant as the Draft Final Report is far more than refinement of the Issues Paper – many new concepts, that need detailed stakeholder consideration. Rushing this consultation has led to less informed consideration and input to this important Review.

In response to the 2020 Issues Paper, AMA provided a detailed submission. A range of matters and information in that submission remain relevant in current considerations. For that reason, a copy of AMA's 28 August 2020 submission to the Issues Paper consultation is included at Appendix 7.

Given that the Draft Final Report does not contain an implementable package there may be opportunity to 'take-stock' learnings to assist with identifying further actions.

AMA will be pleased to discuss any aspects.

Yours Sincerely

Unsigned for electronic lodgement

Ben Stapley
Executive Director

Diagrams:

Tables:

Appendices

Appendix 1

AMA responses to the Draft Final Report recommendations

List of Draft Final Report recommendations with AMA responses

AMA notes the following issues were not pursued in the form identified in the Issues Paper:

- Accreditation of holders
- Benefits test
- Pest groupings
- Complete removal of products of low regulatory concern
- Synergistic effects

Introductory comments on this section

To assist in the identification and communication of 'ratings' and 'priorities' for the 139 Recommendations presented in the Draft Report, AMA has designated the following symbols and priority numbers:


Supported

Needs work: Priority 1 (high)

Needs work: Priority 2 (medium)

Needs works: Priority 3 (low)


Not supported


Not applicable or not evaluated (commonly due to time constraints)

Draft Report, Chapter 1

1. Recommendation

The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system.

> 'A trusted and nationally consistent regulatory system for pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to safe products and uses."

AMA Response:

Recommendation supported.

2. Recommendation

The Panel recommends that the future pesticides and veterinary medicines regulatory system is underpinned by the following 4 equally weighted objectives:

- safeguard animal health and welfare
- support primary industries
- protect Australia's trade
- contribute to biosecurity preparedness.

AMA Response:

1

AMA recommends the following change: protect and enhance Australia's trade

3. Recommendation

The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:

- The regulatory system should be based on risk, not on hazard alone.
- Processes and decisions should be objective, independent and science based.
- Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.
- Risk management measures should be reviewed as new information becomes available.
- The system should be efficient and outcomes-focused by making use of streamlined and fit for purpose regulation.
- The system should achieve a single nationally consistent model with shared responsibility for controlling the manufacture, import, export, supply, use, and disposal for regulated products.
- The system should be adaptive to new technologies, practices, and knowledge.
- The regulatory system should support a resilient supply chain.

AMA Response:

1

AMA recommends the following amendment to the text:

- The regulatory system should be based on risk, ~~not on hazard alone~~.

The basis for this change is that hazard is a component of risk, therefore the words "not on hazard alone" are redundant.

The Draft Final Report (p.vii) notes:

> "In addition, the review provides an opportunity to deliver on the Australian Government's commitment to reduce unnecessary regulation to improve the processes for demonstrating compliance with agreed safety standards while retaining system integrity. (underlining added)

It is essential for the Government's commitment to reducing unnecessary regulation to be included at the design stage. Equally, Best Practice Regulation and Minimum Effective Regulation must be embedded at the design stage.

4. Recommendation

The Panel recommends that the Australian Government work with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. This would be hosted by the Commonwealth and operate on the basis of full Commonwealth constitutional reach.

AMA Response: 1

"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." (Issues Paper p.25)

"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) (Issues Paper p.25)

The legal and constitutional aspects of this proposal have not been adequately examined in the Draft Final Report. Possibly a separate consultation is required.

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

At this stage, AMA allocates a Needs work Priority 1 rating pending developments between the Commonwealth and States and Territories.

5. Recommendation

The Panel recommends that the need for, and the scope, role and form of a new IGA are considered as part of this review's implementation. The Panel recommends that the existing IGA be extended until this time, recognising that there are some matters, such as those relating to funding, that are unlikely to be resolved in the interim period.

AMA Response:

Refer to AMA's Response under Recommendation 4

1

6. Recommendation

The Panel recommends that should there be a need for an IGA in future, it should reflect the lessons learnt from the shortcomings of the current IGA including that it:

- provides that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail
- requires any jurisdiction that departs from the IGA approach to provide a public reason for such departure
- mandates minimum resource levels for regulating control-of-use, to effectively meet assurance and compliance obligations (perhaps as a proportion of each jurisdiction's domestic production value)
- requires regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals
- requires regular publication (or input to the Commissioner's reporting) of performance against these indicators and targets or goals.

AMA Response:

Refer to AMA's Response under Recommendation 4

1

7. Recommendation

The Panel recommends the establishment of a statutory office holder in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

AMA Response:

> "The Panel identified that the current regulatory system as a whole lacks leadership, accountability, transparency, and a clear focal point. To address this, the Panel recommends establishing a Commissioner for Pesticides and Veterinary Medicines Stewardship (the Commissioner). The Commissioner will provide national policy leadership, accountability and guidance for Australia's pesticides and veterinary medicines regulatory system." (page xii)

> "The Commissioner will be required to report to parliament to demonstrate that the entire regulatory system is operating effectively, and problems are identified early. It is vital that there is oversight of the future regulatory system to strengthen accountability and transparency, increase public confidence, and maintain social licence." (page xiii)

The Commissioner is proposed to have broad responsibilities. Many of the Recommendations in the Draft Final Report are predicated on the establishment of this position. More than 30 recommendations have the Commissioner embedded in the proposal. This is unfortunate and hampers consideration of the underlying requests. Others will no doubt have raised these problems.

AMA is concerned that there has been insufficient exploration of alternatives. It is hard to see that a pesticides/veterinary medicines Commissioner will be able to command control over a future National Registration scheme.

8. Recommendation

The Panel recommends that the Commissioner will have responsibility for control-of-use functions including associated licensing activities.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

9. Recommendation

The Panel recommends that the Commissioner advise Government on the performance of the regulatory system as a whole, based on public reporting of whole-of-system performance measures.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

10. Recommendation

The Panel recommends that the Commissioner have responsibility for convening and hosting a number of forums including a Stakeholder Forum, Operational Forum and Expert Advisory Panels.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 6.

The question of forums needs to be considered once there is greater clarity over new structures.

11. Recommendation

The Panel recommends that the Commissioner administer relevant grant programs and refer matters to operational areas for further accountable action as necessary.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

12. Recommendation

The Panel recommends the Commissioner report publicly on the progress of the reforms in its first year, and as part of regular biennial reporting on the state of the regulation system as a whole.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

13. Recommendation

The Panel recommends the establishment of a 5-member, skills-based board (including the CEO of the APVMA as an ex officio member) for the APVMA to strengthen the Authority's governance arrangements, provide the necessary oversight to support the regulator in managing operational, financial and performance matters, and drive the reform agenda.

AMA Response:

AMA **does not** support the establishment of a Board for the APVMA for the following reasons:

- A clear case for establishing a Board has not been established, despite repeated requests from industry.
- AMA encourages the government to consider the problems and challenges facing the APVMA and conduct an independent and transparent process to consider which solutions are likely to achieve the greatest benefits at lowest cost.
- This may or may not include establishing a Board, but it should also include meaningful consultation with industry and analysis of other options.
- It remains unclear whether any benefits that accrue from establishing a Board will exceed the costs imposed.
- As a cost-recovered agency, the APVMA is funded by a mix of fees and levies imposed on the regulated industry. A Board should be fully funded by government, not industry.

14. Recommendation

The Panel proposes the establishment of 2 formal and one ad hoc consultation mechanisms by the Commissioner to consider, and offer advice to Ministers and the Commissioner as appropriate on, the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are:

- a Stakeholder Forum
- an Operational Forum
- an Expert Advisory Panel (as needed).

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

The question of forums needs to be considered once there is greater clarity over new structures.

15. Recommendation

The Panel recommends the Stakeholder and Operational forums have terms of reference consistent with those set out in Annex 10 and Annex 11.

AMA Response:

The question of forums needs to be considered once there is greater clarity over new structures.

This level of detail is misplaced in a review of the governing framework.

16. Recommendation

The Panel recommends that the Commissioner establish a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The biennial reports would review progress in implementing the reforms decided by the Government in light of the Panel's current report. Reporting should commence 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Performance measures, as a minimum, should address:

- health impact
  - establishing formal human, animal, and environmental health risk indicators
  - number and nature of adverse experience reports and pharmacovigilance findings, and time taken to respond to adverse experience reports and any consequential actions.
- industry impact
  - supply, use and disposal of pesticides and veterinary medicines.
- community impact
  - social attitudes
  - community outreach and engagement.
- regulator performance
  - number and type of regulatory decisions by the APVMA and Commissioner

- number and type of audits and compliance activities, including information and education campaigns.

- responsiveness to community concerns raised.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

This information is already available to interested stakeholders (just not in one place, but that doesn't justify a whole new structure)

17. Recommendation

The Panel recommends that the Commissioner establish health risk indicators for Australia, similar to those used in the European Union, and publish outcomes in its reporting of performance measures.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

The EU Harmonised Risk Indicators scheme monitors trends in pesticide use on planted food crops and is focussed on food safety concerns. It is not relevant to veterinary chemicals. Residues of veterinary chemicals in Australia are already carefully monitored by the NRS – this is not a 'gap' in our regulatory system as implied in the Report.

18. Recommendation

The Panel recommends the retention of statutory timeframes for the APVMA to complete its pre-market assessments as a vital input measure to the regulatory system and recommends that statutory timeframes should be expanded to a range of other decisions, such as licensing and responsiveness to the Stakeholder Forum, in the future regulatory system to improve transparency and accountability.

AMA Response:

2

AMA would accept retention of statutory timeframes. In essence, timeframes are a balance between available resources and time, and support accountability of the Regulator alongside predictability (in terms of time and cost) for applicants. There are ways that these outcomes can be optimised.

The recommendation does not contain sufficient information to allow impacts to be evaluated.

Transparency – timeframe performance is already transparent! Anyone can access performance statistics by area, application type etc.

19. Recommendation

The Panel recommends that the Commissioner be assigned responsibility to build a surveillance system fit for the needs of a 30-year future. The system should:

- Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users records, literature searches, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions.
- Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.

AMA Response:

Refer to AMA's Response under Recommendation 7.

Industry quality assurance programs should not come under the umbrella of a government regulator – they are commercial activities. Market changes are the remit of DFAT, DAWE and industry groups, not the Regulator.

Not the role of Australian government to report on decisions of overseas regulators, or 'intelligence' from professional bodies and academics – what would that add for stakeholders? How would that make the use of chemicals here 'safer'/'better'?

Residues already reported on by NRS – why not just provide better resources to them to expand/improve the existing systems? They are best placed to know what is needed for future surveillance.

20. Recommendation

The Panel recommends that the Commissioner develop arrangements to curate all such sources of information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and system response purposes.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

21. Recommendation

The Panel recommends the Commissioner consider how to best utilise and capitalise on current record keeping requirements for use of pesticides and veterinary medicines in Australia.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

How would Commissioner have any visibility on USE?

22. Recommendation

The Panel recommends a Government-led national domestic produce monitoring program be established.

AMA Response:

1

A detailed proposal needs to be developed.

23. Recommendation

The Panel recommends that the domestic scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.

AMA Response:

1

A detailed proposal needs to be developed.

24. Recommendation

The Panel recommends the Commissioner finalise the design of the domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residues Survey, primary producers, manufacturers, state and territory governments, and the community.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

This should build on Recommendation 23 to expand the existing NRS, not assign it to an entirely separate entity

25. Recommendation

The Panel recommends that water, waterway sediment and soil samples be monitored to detect the levels of pesticides in the environment. The testing program should be scalable and targeted, based on risk. Implementation should be graduated to reflect available resources and ensure cost effectiveness.

AMA Response:

The recommendation is limited to pesticides. AMA defers to CropLife Australia.

26. Recommendation

The Panel recommends that an Environmental Monitoring Plan be developed through consultation to identify areas of priority for monitoring.

AMA Response:

The recommendation is limited to pesticides as identified in Recommendation 25 AMA defers to CropLife Australia

27. Recommendation

The Panel recommends the Commissioner use a risk-based methodology to determine the collection locations for environmental monitoring based on regulatory need and recommendations through consultation with the Stakeholder Forum and taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

The proposal is limited to pesticides as identified in Recommendation 25. AMA defers to CropLife Australia.

28. Recommendation

The Panel recommends the current guidance for levels of pesticides in potable and non-potable water ultimately be given the same status as MRLs and enforced by relevant water and environmental agencies.

AMA Response:

AMA has not evaluated this recommendation – specified for pesticides. AMA defers to CropLife Australia.

29. Recommendation

The Panel recommends that environmental monitoring of waterways, sediment and soil be funded by the government. Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy.

AMA Response:

AMA has not evaluated this recommendation – specified for pesticides

30. Recommendation

The Panel recommends that the machinery for streamlining processes for adverse experience reporting be provided in legislation for holders of approvals, registrations, exemptions, and licences. These holders will be obligated to notify the Commissioner when they become aware of an unintended effect, safety related issue, lack of efficacy, quality or contamination concern (either product related or through unintended exposure to humans, animals or the environment), or other adverse events associated with a pesticide or veterinary medicine product.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

31. Recommendation

The Panel recommends the Commissioner collates adverse experience reports to establish a system wide 'pharmacovigilance' approach, expanding on the approach adopted internationally for veterinary medicines.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

32. Recommendation

The Panel recommends that data presented through adverse experience reports is analysed to identify issues and trends arising from these reports and, in concert with the information available to the Commissioner through expanded monitoring and other intelligence sources, inform the broader surveillance system and priority setting.

AMA Response:

2

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

33. Recommendation

The Panel recommends sound information sharing practices be established between the APVMA and the Commissioner to allow APVMA access and the opportunity to respond to those matters relating to the registration and exemption of products, or the supply of those products.

AMA Response:

2

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

34. Recommendation

The Panel recommends the Commissioner establish an interface that provides users and the public with contemporary details of validated adverse experience reports. The Panel also recommends the interface support the streamlining of submission of adverse experience reports.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7

35. Recommendation

The Panel recommends that trends identified through system surveillance data be reported publicly in the Commissioner's biennial report.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

36. Recommendation

The Panel recommends that the residue monitoring results of domestic produce and environmental water and adverse experience reports should be publicly available, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken.

AMA Response:

2

AMA suggests that there is more work to be done, including whether this is a regulatory function, and the roles and responsibilities of a new regulatory framework. There is need to consider the package of reforms.

37. Recommendation

The Panel recommends that the results of these programs should be collated and published in an informative and educational manner. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

AMA Response: 2

AMA suggests that there is more work to be done, including whether this is a regulatory function, and the roles and responsibilities of a new regulatory framework. There is need to consider the package of reforms.

38. Recommendation

The Panel recommends improving the transparency and responsiveness of the chemical review process. This will be achieved by establishing a formal trigger (such as a relevant international decision in specific circumstances) for a chemical review to the APVMA.

AMA Response: 2

This item needs more work, including in direct consultation with the APVMA as the expert regulator.

39. Recommendation

The Panel recommends that the trigger should not result in repeated near identical reviews within a 3-year period.

AMA Response: 2

This item needs more work, including in direct consultation with the APVMA as the expert regulator.

40. Recommendation

The Panel recommends that, if in its judgement the APVMA does not consider that the trigger is relevant to Australian circumstances, it may determine not to undertake a review. The APVMA would be required to publish a statement of reasons for its decision, disclosing any information relied on to inform its decision.

AMA Response: 2

This item needs more work, including in direct consultation with the APVMA as the expert regulator.

41. Recommendation

The Panel recommends the APVMA continue to be able to initiate a review if it is concerned that the risks of a product are not being suitably managed.

AMA Response:

3

This item needs more work, including in direct consultation with the APVMA as the expert regulator.

This item seems less of a recommendation and more of a statement!

42. Recommendation

The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

43. Recommendation

The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.

AMA Response:

3

This item is operational and if the Panel wishes to pursue it then it should be taken up with the APVMA.

44. Recommendation

The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.

AMA Response:

AMA defers to the comments of organisations with direct experience in this area.

45. Recommendation

The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal.

AMA Response: 3

This concept was raised following the Issues Paper. There are a range of questions that need to be explored, including the legal status and enforceability. Further consultation is needed.

46. Recommendation

The Panel recommends the general product obligations build on existing processes already operating in industry, including codes of practice, WHS risk management plans, spray diaries, animal treatment records, and industry QA and stewardship schemes and be consistent with existing management practices to minimise regulatory burden with meeting these obligations.

AMA Response: 3

This concept was raised following the Issues Paper. There are a range of questions that need to be explored, including the legal status and enforceability. Further consultation is needed.

47. Recommendation

The Panel recommends the general product obligations be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicines products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harms to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).

AMA Response: 3

This concept was raised following the Issues Paper. There are a range of questions that need to be explored, including the legal status and enforceability. Further consultation is needed.

48. Recommendation

The Panel recommends a national licensing framework be developed by the Commissioner to operate under a single national law to regulate activities with pesticides and veterinary medicines. All licences for individual schemes created under the national licensing framework would, for the most part, be issued by the Commissioner, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. The exception would be good manufacturing practice licensing, which would continue to be administered by the APVMA.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

49. Recommendation

The Panel recommends that such licences, where relevant, incorporate mandatory licence conditions that allow for the recognition of industry quality assurance schemes.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

50. Recommendation

The Panel recommends that existing licensing schemes (Commonwealth, state, and territory) are transitioned to the new national licensing scheme, except where it is inefficient, or a licensing approach is no longer considered the most appropriate basis for regulation under the revised regulatory system.

The following are the Panel's proposals for initial licensing schemes under the new national licensing framework:

- supply of internationally registered products
- good manufacturing practice
- supply or use of substances for research purposes
- supply of hormonal growth promotants
- dealings with Stockholm Convention substances
- supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)
- aerial application of pesticides (pilots and contractors that employ pilots, drone operators)
- ground applicators
- commercial pest controllers (pest management technicians)
- special use licence to use a product contrary to the withholding period, re-entry interval, export slaughter interval or spray buffer zone.

AMA Response:

AMA does not support the proposals for:

- supply of internationally registered products; or
- good manufacturing practice

for reasons that have been dealt with in detail elsewhere in this submission.

The "supply or use of restricted chemical products as defined under the Agvet Code (possibly including Schedule 7 Poisons Standard products)" sends mixed messages to stakeholders on the treatment of hazard and risk throughout the Draft Final Report.

AMA has concerns that the efficacy of the proposed arrangements may not be realised. There are a range of matters that need to be considered in the design.

Significant consideration and drafting is yet required.

51. Recommendation

The Panel recommends that all operators who apply chemicals in a commercial setting (be it agricultural or domestic) complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end of life cycle disposal and recycling, regardless of whether the activity is subject to licensing.

AMA Response: 1

There seems to be an interface question that arises from this recommendation. Some of what is being described is activities in workplaces and therefore opens the question of jurisdiction seems to need resolving.

52. Recommendation

The Panel recommends that the Commissioner completes the work of HACCUT to establish training standards for restricted chemical products and Schedule 7 poisons, and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides and veterinary medicines.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

Notwithstanding, AMA notes the good work done through AgStewardship, Agsafe, DrumMuster, ChemClear, and other schemes.

53. Recommendation

The Panel recommends that competency standards be established for roles introduced through other recommendations in this review. These include:

- accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6)
- government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.

AMA Response:

3

In principle, AMA supports the provision of a power to create a framework, sanctions and accreditation scheme in the future and if needed, to facilitate the use of external assessors. If the use of external assessors becomes an option for application, then some form of accreditation is required. It would be appropriate for the APVMA to set the standards for any such accreditation scheme, but the administration of that scheme (i.e. assessing the assessors) should be external as this is not core APVMA business.

However, 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 recent trial of pre-application assessments (PAAs) will be particularly informative.

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 is also concerned that this could become another administration strain on APVMA when there are better 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.

54. Recommendation

The Panel recommends that where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Commissioner.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

55. Recommendation

The Panel recommends that the Commissioner work with the ASQA and industry associations responsible for industry-based accreditations to ensure quality of training outcomes, and that training is adapted to meet the needs of pesticides and veterinary medicines users into the future. The Panel suggests that the Commissioner examine the benefits of micro-credentials when developing the standards.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

56. Recommendation

The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart-label content.

AMA Response:

3

This is an operational issue when the Review Terms of Reference is focussing on Regulatory Frameworks.

Notwithstanding, AMA members support the retention of critical information elements on labels that are attached to the product for both human and animal safety - certain information must always be on hand at the point of use (and not reliant on a technology to be useable).

Changes to label content need significant detailed consultation and should not be tied to a particular technology.

AMA members support the retention of critical information elements on labels that are attached to the product for both human and animal safety - certain information must always be on hand at the point of use (and not reliant on a technology to be useable).

Changes to label content need significant detailed consultation and should not be tied to a particular technology being used.

57. Recommendation

The Panel recommends that the opportunities to enhance labelling through additional smart-label content be actively pursued and implemented with a stronger sense of urgency than has been the case to date. The result should be safer use, a more informed user as well as an improved user experience.

AMA Response:

1

The Panel has not suggested who might champion this exercise? Without a champion then the proposal is left dangling. There is also need for some legal authority needed to take this forward.

58. Recommendation

The Panel recommends that the Commissioner continues to scan the technology horizon to identify additional emerging technologies that may assist with labelling reform.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

59. Recommendation

The Panel recommends that the regulatory assessed elements of the label approved by the APVMA be limited to that information which is not assessed by other regulatory systems.

AMA Response: 2

AMA sees this to be an operational matter and needs to be dealt with through a consultative process that includes APVMA.

This is not a new topic. In the past the concept had been described as 'dealing with the APVMA regulatory box'.

60. Recommendation

The Panel recommends the product label must comply with general conditions of registration to ensure the risks of the product can be managed. To implement this, the Panel recommends the establishment of general statutory conditions of registration to which the product label must comply, along with urgent completion of a labelling standard. Where relevant, compliance with the labelling standard would be made a condition of registration (or form part of the licence to supply overseas registered products). More details of these proposed conditions are provided in Annex 6.

AMA Response: 1

AMA sees this to be an operational matter and needs to be dealt with through a consultative process that includes APVMA

61. Recommendation

The Panel recommends manufacturers should be permitted to (and indeed, should be encouraged to include) include additional personal protective information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

AMA Response: 2

The label must contain instructions and specify necessary and correct PPE to allow veterinary medicines products to be used safely.

Does this scenario arise through application of the Globally Harmonised System of Classification and Labelling of Chemicals (never intended to be used for veterinary medicines)?

> 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)."[26] (underlining added).

The system failures that bring this recommendation forward need to be clearly described.

It would be extremely confusing for supply chains and end-users to be confronted with identical products (active constituent(s), formulation type, usepatterns etc.) but differing PPE.

62. Recommendation

The Panel recommends that every 5 years, at a minimum, the registration holder must conduct a review of label content to ensure the information on the label is current and remains correct – noting that emerging scientific evidence or consumer concerns could also trigger a review, including a labelling review, at any time (see chemical review discussion in Chapter 3).

AMA Response:

2

AMA sees this to be an operational matter and needs to be dealt with through a consultative process that includes APVMA.

63. Recommendation

The Panel recommends regulatory action to ensure responsible stewardship and control-of-use be considered against the regulatory assessed elements of label requirements and not against the 'approved label'.

AMA Response:

2

AMA sees this to be an operational matter and needs to be dealt with through a consultative process that includes APVMA, industry, and the States and Territories.

64. Recommendation

The Panel recommends that the Commissioner be empowered to publicly report a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs, addressing container management, recycling, and disposal or their equivalent.

- The list would be published on the Commissioner's website or as part of the Commissioner's biennial statutory public assessment reports on the state of the system.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

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

65. Recommendation

The Panel recommends encouraging industry QA schemes to include requirements and guidance on good disposal practice as part of being deemed to meet General Product Obligations (see Section 4.1).

AMA Response:

AMA has not had sufficient time to evaluate this recommendation.

66. Recommendation

The Panel recommends good disposal practice be considered as conditions for relevant licences.

AMA Response:

This recommendation may result in duplication with State and Territory legislation.

67. Recommendation

The Panel recommends that the Commissioner consult with industry and manufacturers to enhance safe recovery, recycling, and disposal arrangements for Intermediate Bulk Containers.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

68. Recommendation

The Panel recommends that veterinary medicine products compounded by a veterinarian or a pharmacist, for any animal treatment are brought within the scope of the future regulatory system for veterinary medicines but are exempt from requirements of registration where they comply with prescription by cascade.

AMA Response:

1

This issue has been problematic for many years. There have been suggestions that it is a compliance failure. The original intention was that a veterinary medicine is compounded to address animal welfare concerns that cannot be addressed via the previous levels of the cascade and where such products are manufactured on a case-by-case basis for a defined use in a single animal and are not produced in quantities for commercial sale.

AMA recommends that further work on this recommendation is required. This could best progressed through a targeted consultation of veterinary medicine stakeholders.

69. Recommendation

The Panel recommends that the prescription cascade provides that registered products must be considered first and compounded products are prescribed as a last resort in order to address an issue that is unable to be addressed through suitable and reasonably available registered or exempted products.

AMA Response:

1

Refer to the AMA response under Recommendation 68

70. Recommendation

The Panel recommends that the prescription cascade is finalised and implemented by the Commissioner under the single national law for control-of-use.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

Appropriate entity for administration of the cascade needs further consultation.

71. Recommendation

The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

AMA Response:

1

AMA suggests that further work on this recommendation is required. This could be best progressed through a targeted consultation of veterinary medicine stakeholders.

72. Recommendation

The Panel recommends that the APVMA works with the Australian Veterinary Association and Pharmacy Board of Australia to ensure one or more suitable standards are funded speedily to enable the exemption described in recommendation 68.

AMA Response:

1

Refer to response for Recommendation 68.

73. Recommendation

The Panel recommends establishing a national rule for pesticides under the single national law for control-of-use that sets out the requirements for a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use.

AMA Response:

This recommendation is pesticide specific.

74. Recommendation

The Panel recommends establishing a national rule for veterinary medicines under the single national law for control-of-use that sets out the requirements for a veterinary medicine's responsible use, including a prescription cascade that applies to all animal use, and the records that must be kept establishing responsible use.

AMA Response:

1

AMA gives in-principle support pending further consultation on the details.

Chapter 5

75. Recommendation

The Panel recommends refocusing the scope of the future regulatory system to better target assessment effort towards risk, and to provide a stronger identity to the regulatory system, and provide safe access to pesticides and veterinary medicines for Australian primary producers, veterinarians, and home and garden users.

AMA Response:

2

AMA notes that assessment may be required to establish the risk. This recommendation needs to be spelled out in terms of the package of reforms. It also applies to a wider range of users.

76. Recommendation

The Panel recommends new definitions for pesticides and veterinary medicines as outlined in Annex 5 and excluding product classes or uses that are expected to have low hazard or low exposure or are effectively regulated by other regulators.

AMA Response:

AMA has detailed its response to the Definition of a Veterinary Medicines in section 6.1 of its submission.

AMA considers that the inclusion of Globally Harmonised System of Classification and Labelling of Chemicals (GHS)[27] elements in the definition of a veterinary medicine to be inappropriate. AMA contends that the definition needs to describe the purpose e.g. preventing, diagnosing, alleviating a disease etc. This is consistent with the approaches taken in other countries. AMA is not aware of any country that has incorporated GHS elements into its veterinary medicine definition.

AMA also 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)." (underlining added).

The GHS is not applied to therapeutic goods in their finished form.

Difference in definitions will likely be confusing to governments and stakeholders locally and overseas. The Draft Final Report does not present a compelling case for this change. AMA is unable to support this change.

77. Recommendation

The Panel recommends the provision of exemption pathways which remove premarket regulation for certain low regulatory concern products. This would occur by either exemption from assessment or from registration where established standards are met.

AMA Response:

There appear to be elements of previous attempts for managing 'products of low regulatory concern'. By and large, the scheme was not a success. The Panel should better understand the failings so that mistakes are not repeated.

Some assessment is required to determine what are the low regulatory concern products/uses.

For what seems a simplistic recommendation, it will take significant work to establish a workable process.

78. Recommendation

The Panel recommends that relevant standards would be developed by the Commissioner in consultation with industry.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

[27] United Nations (2017) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 7th revises edition

Refer to AMA's Response under Recommendation 7.

79. Recommendation

The Panel recommends that in conjunction with this reform, a potentially hazardous or injurious substance (PHIS) list be established.

AMA Response:

"The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) does not register chemicals! The NRA registers products based on the USE of chemicals. That is why the formulation, conditions of use, the label, the restrictions, health and safety requirements and efficacy are paramount issues."

Professor, and inaugural APVMA chair Ben Sellinger, Search, Vol 26, No.6, July 1995

Throughout the Draft Final Report there are mixed messages on hazard and risk … with the predominance on favouring hazard (e.g. veterinary medicine definition, labelling etc.).

AMA can see little value in hazard-based lists?

This also seems a level of detail that is not proportionate to a review of Regulatory Frameworks.

80. Recommendation

In the case of pesticides or veterinary medicines that contain GMOs, the Panel recommends a system where one regulator (the APVMA or OGTR) becomes the decision maker for an application. Depending on the category of 'substance' and the risks it presents, the APVMA may play no role; that is, the substance may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it if and when the application is approved. For example, whole GM plants would be excluded from the pesticides regulatory system with the APVMA playing no role in their regulation. Conversely, vaccines containing GMOs could be regulated and assessed primarily as veterinary medicines with the OGTR being notified and providing advice as necessary.

AMA Response:

AMA supports the proposal subject to final details being acceptable.

81. Recommendation

The Panel recommends creating a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.

Under the licensing scheme, the Commissioner would be responsible for issuing and overseeing licences that allow for products registered by one or more equivalent international regulatory authorities to be supplied and used in Australia. Licence conditions would include the provision of a detailed Risk Management Plan. Licences would be granted under the single national licensing scheme (see Chapter 2) established under the single national law for control-of-use.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

AMA also notes the rationale for treatment of products registered overseas but not registered in Australia expressed in the Draft Final Report:

> "By global standards, the Panel recognises that Australia is a relatively small market for pesticides and veterinary medicine products. A lack of access to products and their uses places Australian primary producers at a competitive disadvantage in comparison to their overseas competitors. It also restricts access to the most advanced alternatives to current pesticide and veterinary medicine products, many of which can be less harmful to the environment or pose lower hazards to users or which provide better animal health and welfare outcomes. (page xi)"
>
> "To improve access the Panel recommends an innovative licensing arrangement to provide an alternative regulatory pathway to products already registered by a comparable international regulator. This would allow a licensed entity to supply an internationally registered product in Australia without the need for registration in Australia. The entity must, however, address the risks associated with the use of the product and undertake measures to address any unique Australian circumstances. The Commissioner will be responsible for the licensing program and reviewing the measures proposed to manage risks (page xiv)
>
> "Looking ahead, the Panel considers that access to a broader and more extensive range of safe, effective, products and product uses, equivalent to those available to international counterparts, to be a vital goal for regulatory reform. Safety, however, must not be compromised. Unique Australian circumstances must continue to be considered, and public confidence must be retained. However, the Panel is convinced that competitive pressures and opportunities to achieve safety, environmental and other benefits will drive change in the regulatory system towards much improved access to chemicals and uses for Australians. While the Panel supports greater access, it is not proposing that all products available overseas should be available in Australia." (page 9)

The assumption that there are an "extensive range of safe, effective, products and product uses" is a misnomer.

This is an example of where understanding the Business Operating Environment and business decision-making is crucial to progressing supportive policy settings for the future of veterinary medicines in Australia. The Review Panel needs to engage with Boards and Chief Executives (decision-makers) of registrants making investment decisions more directly in Australia.

AMA notes:

- products are not all the same. For the same branded product there may be variations in formulations between countries. For instance, a product formulated for use in Canada (temperature extremes) may be different to the same-branded product for use in Brazil or Mexico.
- there may be a wide range of arrangements overseas including licensing arrangements, intellectual property etc. – disruption could have adverse consequences for research and development collaboration and other beneficial activities.

- Australian regulatory controls go beyond the considerations identified in the Draft Final Report, including the interfaces with:
  - gene technology regulation
  - biosecurity,
  - poisons scheduling
  - maximum residue limits (domestic and export destinations
  - export slaughter intervals.
  - access to industry stewardship programs such as DrumMuster, ChemClear, Agsafe
  - Dangerous Goods transport (air, land and sea) and Dangerous Goods storage
  - chemical diversion – illicit drugs and chemicals of security concern
  - retail storage
  - GHS labelling and Safety Data Sheets
  - environmental impacts
  - Work Health & Safety
  - Australian Packaging Covenant
  - Trade Measurement
  - Trade waste
- AMA believes that this proposal potentially undermines confidence in the Australian regulatory system.

AMA is supportive of simplifying and streamlining regulatory systems but considers this proposal to be high risk. AMA is unable to support this proposal at this stage.

82. Recommendation

The Panel recommends that the Commissioner establish a list of prohibited chemistries and classes of products and uses that would not be allowed under licence. This list would be developed in consultation with the Stakeholder Forum.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

This also seems a level of detail that is not proportionate to a review of Regulatory Frameworks.

83. Recommendation

The Panel recommends licence holders be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia.

AMA Response:

Refer comments provided for Recommendation 81

84. Recommendation

The Panel recommends the Commissioner maintain an instrument setting out international regulators determined to be comparable, and that this be reviewed for currency in line with the Commissioner's reporting arrangements (see Chapter 2).

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

85. Recommendation

The Panel recommends the Commissioner's determination of comparable international regulators:

- be based on criteria developed by the Commissioner in consultation with the APVMA and stakeholders
- be conducted by the Commissioner.
- give priority to identifying equivalent regulatory systems among major launch markets for pesticides and veterinary medicines.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

86. Recommendation

The Panel recommends that licence holders:

- must develop and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances
- be subject to regular audits to ensure they are complying with the risk management plan and other licence conditions
- be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed.

AMA Response:

Refer to AMA's Response at Recommendation 81.

87. Recommendation

The Panel recommends an internationally registered product cannot be supplied under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active.

AMA Response:

Refer to AMA's Response at Recommendation 81.

88. Recommendation

The Panel recommends that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

AMA Response:

Refer to AMA's Response at Recommendation 81.

89. Recommendation

The Panel recommends the Commissioner should have powers to request information for the purpose of confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions. Information on products supplied under licence will be protected as confidential commercial information (commercial-in-confidence).

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

90. Recommendation

The Panel recommends a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.

AMA Response:

1

Fast-tracking is a function of dollars and time. There needs to be a detailed proposal on how the proposal would achieve its outcomes.

91. Recommendation

The Panel recommends the criteria for prioritisation be determined by the Minister with advice from the Stakeholder Forum.

AMA Response:

AMA does not see this recommendation as practical.

92. Recommendation

The Panel recommends the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted by departmental risks.

AMA Response:

AMA does not see this recommendation as practical or a high priority.

93. Recommendation

The Panel recommends targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not correspond to climatic regions.

AMA Response:

AMA does not see this recommendation as practical or a high priority.

94. Recommendation

The Panel recommends making any pesticide or veterinary medicine use pattern registered in at least 2 jurisdictions lawful for use in all jurisdictions in line with the 2019 decision of the Agriculture Ministers Forum.

AMA Response:

1

Given the decision was taken by Agriculture Ministers Forum in 2019 there is need to articulate any issues under a single national law.

95. Recommendation

The Panel recommends the expanding the support by government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing the industries that benefit from access to the necessary tools for pest and disease management.

AMA Response:

AMA has not assessed this recommendation.

96. Recommendation

The Panel recommends, through the proposed single national law, implementing an exemptions model as a streamlined way of authorising specific activities that would otherwise not be permitted. Exemptions for minor, emergency and research use may be made as legislative instruments by the APVMA.

AMA Response:

AMA has not assessed this recommendation.

97. Recommendation

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use exemption as long as a use would not jeopardise safety, efficacy, and trade.

AMA Response:

2

AMA sees this as an operational issue for the APVMA.

98. Recommendation

The Panel recommends expanding the authorising of emergency use in advance of the emergency, establishing 2 categories within the public listing of exemptions for 'active emergency exemptions' and 'future-emergency exemptions'.

AMA Response:

3

AMA sees this as an operational issue for the APVMA. If there is a difference current APVMA practices and what they need then a gap-analysis should be undertaken and further actions developed.

99. Recommendation

The Panel recommends that, in granting an emergency exemption in advance of an emergency (a future emergency exemption), the exemption includes details of the trigger to transition from the 'future' to 'active' exemption category.

AMA Response:

1

AMA has not developed a position on this recommendation but suggests more dialogue.

100. Recommendation

The Panel recommends the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan is in place along with quality management systems and regular independent assurance checks including audits.

AMA Response:

The APVMA issues research permits (https://apvma.gov.au/node/10881)

If there is a problem with the APVMA processes and systems:

- 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?

101. Recommendation

The Panel recommends the continued investment in expertise and experience with non-synthetic pesticides and veterinary medicines for assessors within the APVMA.

AMA Response:

The level of training for APVMA officers is an operational issue that is and will be managed by the APVMA.

102. Recommendation

The Panel recommends that amendments be made to the Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016 to expand alternative conditions for imports of biological pesticides and veterinary medicines (and ingredients used to manufacture these commodities in Australia) to facilitate the import of safe material essential to Australian agriculture and manufacturing industries.

AMA Response:

AMA is supportive of streamlining measure that deliver efficiencies.

This is an important item and dialogue to finalise a position should be expediated.

103. Recommendation

The Panel recommends that the overall regulatory system performance measures include measuring the system's accessibility to biologically-based products by quantifying the number and growth over time of available biologically-based products.

AMA Response:

AMA is generally supportive but questions this level of operational detail (making lists) in a policy Framework Review.

104. Recommendation

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product if the APVMA is proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

AMA Response:

The Panel seems to be making a recast of the 'benefits test' proposal in the in the Issues Paper. APVMA's decisions should be based on sound-science and the management of risk.

105. Recommendation

The Panel recommends a simple, consistent approach to data protection for the new pesticides and veterinary medicines regulatory system. The ability to limit the regulator's use of certain information will remain a valuable component of the future system and will continue to be of great importance to industry. This is vital to protect the value of industry investments and ensure that Australians gain access to the latest innovations in pesticides and veterinary medicines.

AMA Response:

Refer to AMA's response under Recommendation 109.

It is noted that the amendment is a modest one to correct an anomaly between pesticides and veterinary medicines. Nonetheless, when enacted, it becomes one of the factors that is considered by companies in their evaluation of marketing proposals.

106. Recommendation

The Panel recommends that if a party provides confidential information to a regulator and that if information is used by the regulator for a relevant regulatory decision, then there should be limits on the regulator's use of that information to support a regulatory decision for a competitor's products.

- These should be consistent with Australia's established international agreements.
- Information in minor use and emergency exemption applications are a special case and while this may (as is the case for current permit applications) be considered confidential commercial information, it will not qualify for data protection.

AMA Response:

Refer AMA's response to Recommendation 108.

107. Recommendation

The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals but not needlessly impede flow-on innovation (e.g., new applications of established chemistry), competition, and access to alternative chemical products.

- Equivalent protection periods should be provided for pesticides and veterinary medicines.
- The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review).
- These periods should only be extended as an incentive to bringing priority uses to Australia, as per the measure in the Bill currently before parliament.

AMA Response:

AMA is supportive but disagrees with the wording of the final bullet point. There needs to be consistency of expression with Recommendation 108

108. Recommendation

The Panel recommends that the periods of limitation on the regulator's use of information should be:

- 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent.
- 5 years for information:
  - relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption
  - provided in support of a chemical review
  - which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.

AMA Response:

AMA supports Recommendation 108, with regard to veterinary medicines, which specifies that the periods of limitation on the regulator's use of information should be:

- 10 years for information relied on by the regulator to register new pesticides or veterinary medicines containing a new active constituent or to approve a new active constituent.
- 5 years for information:
  - relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent or to issue a research exemption.
  - provided in support of a chemical review.
  - which is new information provided to the regulator that contradicts the information in the Record or Register or shows the active constituent or product may not meet the statutory criteria.

Regarding Recommendations 87, 88. AMA wishes to defer detailing its view until the future position of a 'internationally registered product is determined. i.e. they should be considered together as a package.

109. Recommendation

The Panel recommends that if there is a public interest reason for the regulator to use information, then the regulator should be able to use that information irrespective of whether it would otherwise be subject to protection.

- For example, information about a product that is unfavourable (does not support continued registration of a product or use) should not be treated as protected.

AMA Response:

2

AMA would welcome further articulation of the problem.

110. Recommendation

The Panel recommends that the Commissioner be tasked with ensuring that any intellectual property protection measures for the new scheme to supply internationally registered products under licence align with the other recommendations (including consistency with international obligations), in consultation with industry.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

AMA also does not support the supply of internationally registered products.

Refer to AMA's response under Recommendation 81.

111. Recommendation

The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a private negotiation matter between companies.

AMA Response:

2

AMA recognises the complexities and legal nature of these considerations. The proposal needs a separate consultation.

112. Recommendation

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture.

AMA Response:

AMA supports Recommendation 112 to assess active pharmaceutical ingredients (API's) against internationally recognised veterinary pharmacopeial standards, independent of the site of manufacture.

113. Recommendation

The Panel recommends that the APVMA establish a standard for each active constituent prior to its inclusion in products. The Panel expects that in establishing standards for active constituents due regard is given to matters of commercial confidentiality and intellectual property protection.

AMA Response:

It is unclear how this proposal intersects with Proposal 112. his proposal could potentially result in significant duplication of effort by APVMA where appropriate standards exist in internationally recognised veterinary pharmacopoeia, which already set out minimum compositional standards including impurities. There is also need to consider the type and amount of variation permitted from an approved standard, and how those variations could alter the risk profile of that ingredient, which would then require the development of a new standard by APVMA.

114. Recommendation

The Panel recommends that the APVMA apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard.

AMA Response:

AMA supports APVMA retaining records of manufacturing sites for APIs. This information should remain as a registered particular.

115. Recommendation

The Panel recommends the APVMA becomes PIC/S accredited.

AMA Response:

In this case:

- the problems and issues have not been accurately defined or articulated.
- the range of policy options have not been explored.

- complete information on overseas schemes appears not to have been fully understood and considered, leading to incorrect assumptions.
- key matters of competition policy appear not to have been considered.
- there are 165 entities on the APVMA maintained *list of Licensed Australian manufacturers of veterinary chemical products*[28]. Consequences for the large number of the small businesses have not been reported as being considered. It is not clear how many of these small businesses were part of the engagement process.
- anecdotal information indicates that implementation of PIC/s would affect business viability – for many, their Business Models are about the domestic market and not export.
- the proposals appear out of scope – the Draft Final Report states the purpose as:

  "Aligning Australian manufacturing standards with international manufacturing standards to facilitate more efficient and effective export." (Draft Final Report p.x,)
- this is a high-cost regulatory intervention that could lead to loss of veterinary medicines to the Australian market, loss of employment, increased overseas sourcing, and increased imports.

More detailed information is provided at section 6.2 of this submission.

AMA supports a properly constituted review of the Aust GMP Code as established by the APVMA.

116. Recommendation

The Panel recommends the APVMA develop guidance material through engagement with industry to support a streamlined transition from cGMP to PIC/S.

AMA Response:

AMA supports a properly constituted review of the Aust GMP Code as established by the APVMA. Further information is provided in the AMA response to Recommendation 115.

117. Recommendation

The Panel recommends both export and domestically focused Australian veterinary medicine manufacturers transition to PIC/S level accreditation over a 5-year time period.

AMA Response:

AMA supports a properly constituted review of the Australian Code of GMP Code as established by the APVMA. Further information is provided in the AMA response to Recommendation 115.

[28] https://apvma.gov.au/node/12326

118. Recommendation

The Panel recommends the establishment of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA.

AMA Response:

Refer to comments provide to Recommendation 53.

119. Recommendation

The Panel recommends that the model for a third-party accredited assessor scheme be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

AMA Response:

3

Refer to comments for Recommendation 53

Chapter 7

120. Recommendation

The Panel recommends that in most circumstances the pesticides and veterinary medicines industry should bear the full and reasonable costs of the regulatory functions under the new regulatory scheme.

AMA Response:

AMA's position is that the veterinary medicines industry should bear the costs of assessment and registration services.

121. Recommendation

The Panel recommends that the existing levy on product sales be continued but at a reduced rate.

AMA Response:

There is no basis to make a decision on the recommendation. It is an isolated question without context.

122. Recommendation

The Panel recommends that the levy be divided into components relating to the costs incurred for undertaking different activities to minimise cross-subsidisation, with each component of the levy being charged only to those that receive the particular service.

AMA Response:

There is no basis to make a decision on the recommendation. It is an isolated question without context.

123. Recommendation

The Panel recommends that where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.

AMA Response:

There is no basis to make a decision on the recommendation. It is an isolated question without context.

124. Recommendation

The Panel recommends that hourly charging should be introduced for activities where regulatory costs are highly variable, while flat fees should be charged where there is little variation.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

125. Recommendation

The Panel recommends that the costs for applications for registration be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

126. Recommendation

The Panel recommends that where Government audits are routine and predictable the costs of this service should be incorporated into the fees for the parent program, for example via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

127. Recommendation

The Panel recommends that mechanisms be developed to allow more significant fees to be paid over time, such as through payment plans.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

128. Recommendation

The Panel recommends 100% recovery of the costs of issuing and maintaining licences (both for supply side and use activities), including scheduled audits with predictable costs, via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process.

129. Recommendation

The Panel recommends that the assessment of applications for accreditation, together with costs to maintain this accreditation, should be 100% recovered from the accredited parties.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

130. Recommendation

The Panel recommends that full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process.

131. Recommendation

The Panel recommends that a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines is maintained.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process

132. Recommendation

The Panel recommends that minor use exemption applications should attract a discounted application fee with the balance of the costs recovered as an identified component of the levy on product sales payable by the registrant (or licence holder).

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process.

133. Recommendation

The Panel recommends emergency use exemption applications should be fully recovered as a component of the levy. A small appropriation should be sought to offset some of the draw on the levy, in recognition that there is a public good element to this function.

AMA Response:

AMA suggests that this proposal be considered through the lens of the Cost Recovery Impact Statement process.

134. Recommendation

The Panel recommends that as chemical reviews and APVMA compliance and enforcement activities only exist to manage the risks associated with selling pesticide and veterinary medicine products in the Australian market, the costs of these regulatory activities should be recovered entirely from industry via a component of the levy on product sales.

AMA Response:

AMA recognises that APVMA currently has jurisdiction to the point of retail sale. AMA does not support further financial burdens being placed on registrants and holders through the levy on product sales.

135. Recommendation

The Panel recommends that the cost of control-of-use regulatory activities should generally be recovered entirely from industry, via a component of the levy on product sales. However, wherever possible, where the beneficiary is clearly identifiable, such as applicators licensing, a fee for services approach should be used.

AMA Response:

AMA does not support further financial burdens being placed on registrants and holders through the levy on product sales.

136. Recommendation

The Panel recommends that the costs of data mining and analysis for system surveillance and monitoring be publicly funding.

AMA Response:

AMA sees the benefits of public funding in this instance.

137. Recommendation

The Panel recommends that the costs of environmental monitoring be publicly funded.

AMA Response:

AMA sees the benefits of public funding in this instance.

138. Recommendation

The Panel recommends that the cost of domestic produce monitoring should be publicly funded.

AMA Response:

AMA sees the benefits of public funding in this instance.

139. Recommendation

The Panel recommends that activities of the Commissioner such as driving the reform agenda, policy development, and advisory responsibilities should remain Government funded and that all other Commissioner costs, being activities that only exist to manage the risks associated with selling products in the Australian market, should be 100% recovered from fees (e.g., licensing) or components of the levy as appropriate.

AMA Response:

At this stage, AMA **does not** support the establishment of a statutory office holder identified as the Commissioner for Pesticides and Veterinary Medicines Stewardship.

Refer to AMA's Response under Recommendation 7.

Appendix 2

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

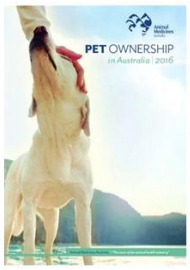
- Policy & Regulatory
- Political engagement
- Alliances, partnerships, research, and issues management

Animal Medicines Australia

16/12/2019

Promoting Animal Care Benefits

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



Animal Medicines Australia

16/12/2019

Supporting Innovation

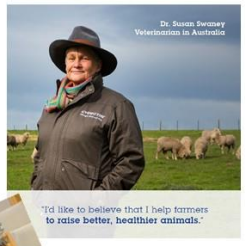
- Risk-based regulatory environment that adheres to COAG Principles
- Sustainability as a core strategy – product life-cycle, anti-microbial resistance, waste, responsible and judicious use of veterinary medicines

Animal Medicines Australia

16/12/2019

Maximising Value: Services and Opportunities

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



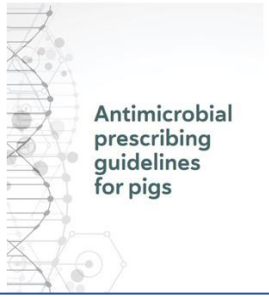
Animal Medicines Australia

16/12/2019

Issues Management Group

- Emerging issues
- Policy development
- Stewardship
- Industry engagement

RESPONSIBLE USE

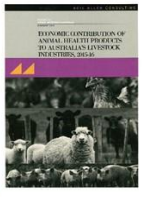


Animal Medicines Australia

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

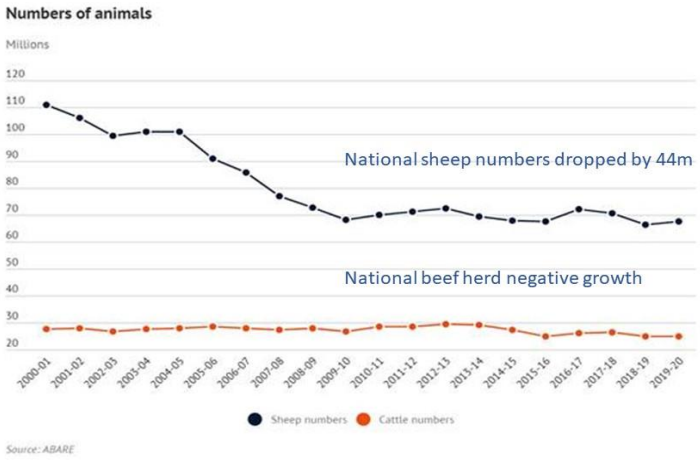
Business operating environment

- Current trends directly impacting animal medicines
- Case studies

Regulatory roles and responsibilities

16/12/2019

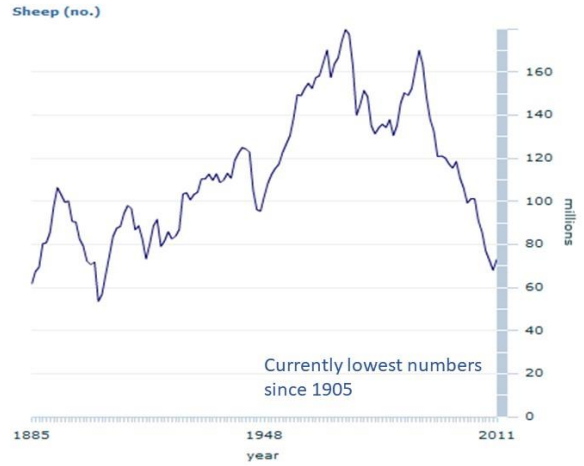
Business operating environment



Animal Medicines Australia

16/12/2019

Business operating environment

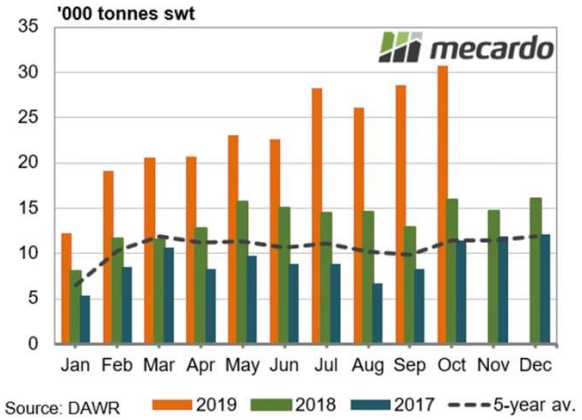


Animal Medicines Australia

16/12/2019

Business operating environment

Australian Beef Exports - China



Exports

Beef ↑ 122%

Lamb ↑ 69%

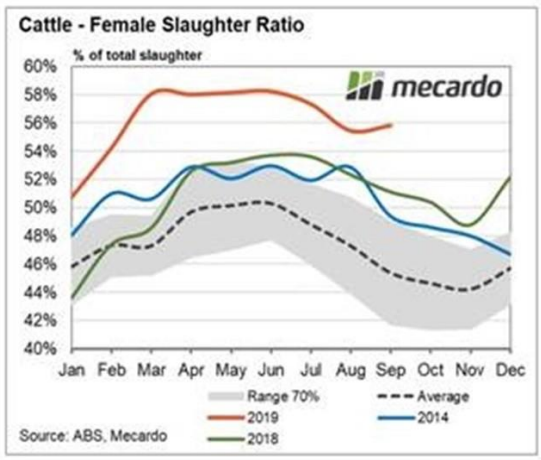
Mutton ↑ 118%

Reflective of ASF effects – alternate protein sources

Animal Medicines Australia

16/12/2019

Business operating environment

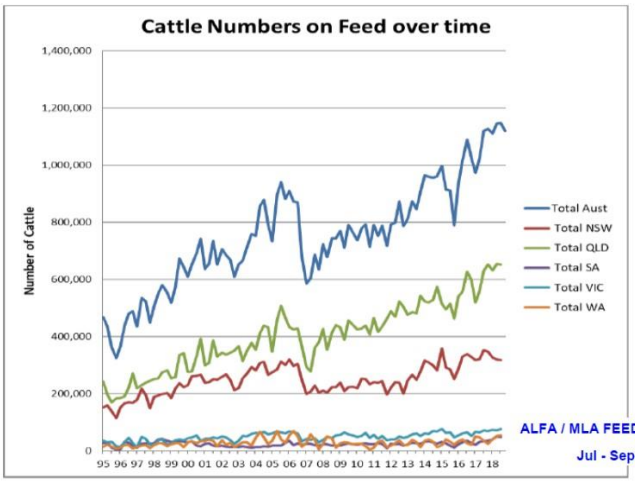


Female cattle slaughter ratios are high. 47% is neutral for zero growth – we are at high 50s which means we are slaughtering the breeding stock

Animal Medicines Australia

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!*

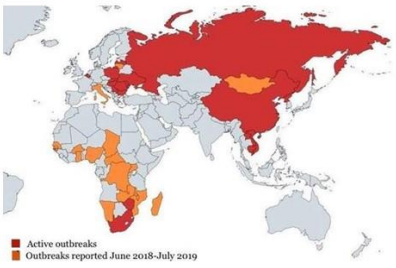
Animal Medicines Australia

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

Animal Medicines Australia

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

Animal Medicines Australia

16/12/2019

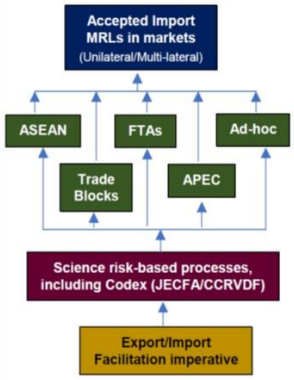
Case study: Importing Country MRLs (continued)

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

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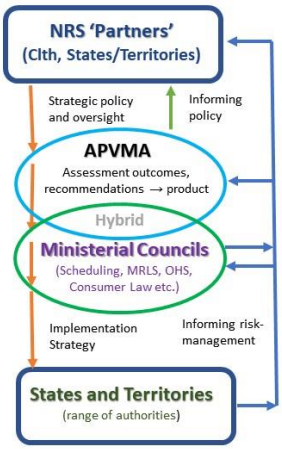
DRAFT Model for efficient and effective management of certain aspects of veterinary chemicals regulation

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 3

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[29], commissioned by Animal Medicines Australia (AMA), has estimated that animal health products were responsible for 10.6% of production in seven key commodity groups[30] 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."[31]

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

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

Outcomes sought

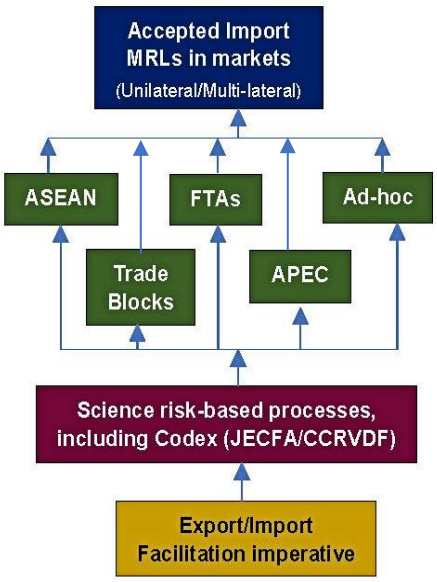
The goal is to achieve recognition of Australian and established internationally recognised standards, such as Codex, and accelerate harmonisation in regional trade fora. There is good opportunity for Australia to piggy-back the good work that has been undertaken in the pesticides field.

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 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.

Appendix 4

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)[1]

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 Appendix 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.

[1] 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.[2]

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[3]. "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."[4]

The Poisons Standard[5] 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[6]

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

[2] https://apvma.gov.au/node/15931
[3] https://www.tga.gov.au/stateterritory-scheduling-information
[4] https://www.tga.gov.au/scheduling-medicines-poisons
[5] https://www.tga.gov.au/publication/poisons-standard-susmp
[6] https://www.ava.com.au/siteassets/resources/prescribing-guidelines/guidelines-for-prescribing-authorising-and-dispensing-veterinary-medicines-october-2013.pdf

Appendix 5

Definitions of veterinary medicines:

- Australia
- New Zealand
- USA
- Canada
- Europe
- United Kingdom

Definitions of 'veterinary medicines' – key countries

AUSTRALIA

Agvet Code

https://www.legislation.gov.au/Details/C2016C00999/Html/Text

5 Definition of *veterinary chemical product*

…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.

NEW ZEALAND

Ministry for Primary Industries, Agricultural Compounds and Veterinary Medicines *(ACVM)*

https://www.mpi.govt.nz/agriculture/agricultural-compounds-vet-medicines/

Agricultural Compounds and Veterinary Medicines Act 1997
https://www.legislation.govt.nz/act/public/1997/0087/latest/DLM414583.html

agricultural compound means—

(a) any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purposes of—

(i) managing or eradicating pests, including vertebrate pests; or

(ii) maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or

(iii) fulfilling nutritional requirements; or

(iv) the manipulation, capture, or immobilisation of animals; or

(v) diagnosing the condition of animals; or

(vi) preventing or treating conditions of animals; or

(vii) enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or

(viii) marking animals; and

(b) includes—

(i) any veterinary medicine, substance, mixture of substances, or biological compound used for post-harvest treatment of raw primary produce; and

(ii) anything used or intended to be used as feed for animals; and

(iii) any substance, mixture of substances, or biological compound declared to be an agricultural compound for the purposes of this Act by Order in Council made under subsection (2)

…

veterinary medicine *means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal.*

USA

(3 Regulators)

FDA Centre for Veterinary Medicines

https://www.fda.gov/animal-veterinary/products

Regulates:

- animal drug products
    - 'product relies on a chemical reaction in or on the animal's body to work'
    - Includes SOME flea and tick products (most regulated by EPA)
- medical devices for veterinary use
    - regulatory oversight over devices intended for animal use
- animal food
    - 'must be produced under sanitary conditions, contain no harmful substances and be truthfully labelled' and be 'free of viable microorganisms'
    - Medicated feed mills must be licensed to manufacture feeds containing certain medicinal components (eg: that require a withdrawal period)

The Food, Drug, and Cosmetic Act (FD&C Act) gives FDA and its centers, including the Center for Veterinary Medicine (CVM), their legal authority:

https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=granuleid%3AUSC-prelim-title21-section321&num=0&saved=%7CZ3JhbnVsZWlkOlVTQy1wcmVsaW0tdGl0bGUyMS1jaGFwdGVyOS1zdWJjaGFwdGVyMi1mcm9udA%3D%3D%7C%7C%7C0%7Cfalse%7Cprelim

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C)

USDA Animal and Plant Health Inspection Service – Centre for Veterinary Biologics (CVB)

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics

Regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin)

CVB's work centres around enforcement of the Virus Serum Toxin Act - https://www.aphis.usda.gov/animal_health/vet_biologics/publications/vsta.pdf

- The VSTA is Chapter 5 of the Food, Drug and Cosmetic Act, and uses the same definitions.

Environmental Protection Agency (EPA)

https://www.epa.gov/pesticides

Regulates flea and tick products for cats and dogs, ectoparasiticides for large animals

Administers various sections of federal law under broad authority granted in two major statutes:
- the Federal Insecticide, Fungicide, and Rodenticide Act, and
- the Federal Food, Drug, and Cosmetic Act.

"pesticides…prevents, destroys, repels or mitigates a pest"

CANADA

Veterinary Drugs Directorate – part of Health Canada (Health Products and Food)

https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/veterinary-drugs-directorate.html

VDD administers the Food and Drugs Act - https://lois.justice.gc.ca/eng/acts/F-27/

drug includes any substance or mixture of substances manufactured, sold or represented for use in

- **(a)** the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- **(b)** restoring, correcting or modifying organic functions in human beings or animals, or
- **(c)** disinfection in premises in which food is manufactured, prepared or kept;

https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products.html#a3

Veterinary Health Products (VHP) -VHPs are low risk drugs in dosage form. They are used to maintain or promote the health and welfare of companion and food-producing animals. They are not for use to treat, prevent or cure disease.

VHPs contain ingredients such as:

- vitamins
- minerals
- traditional medicines

EUROPE

European Medicines Agency – Veterinary Medicines Division (VMD)

https://www.ema.europa.eu/en/about-us/who-we-are/veterinary-medicines

The legal framework for authorization, manufacture and distribution of medicines in the EU are set out in Directives 2001/82/EC and 2001/83/EC.

The Community code relating to veterinary medicinal products is part of the consolidated text of Directive 2001/82/EC

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2001L0082:20090807:EN:PDF

2. Veterinary medicinal product:

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

UNITED KINGDOM

Veterinary Medicines Directorate (VMD)

https://www.gov.uk/government/organisations/veterinary-medicines-directorate

https://www.gov.uk/guidance/legal-controls-on-veterinary-medicines#definition-of-veterinary-medicinal-product-vmp

A VMP is legally defined as:

- any substance or combination of substances presented as having properties for treating or preventing disease in animals
- any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

Appendix 6

Understanding the Business Environment

Extract from AMA submission to the Issues Paper, 28 August 2020

Understanding the Business Environment

Extract from AMA submission to the Issues Paper, 28 August 2020

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:

Sheep

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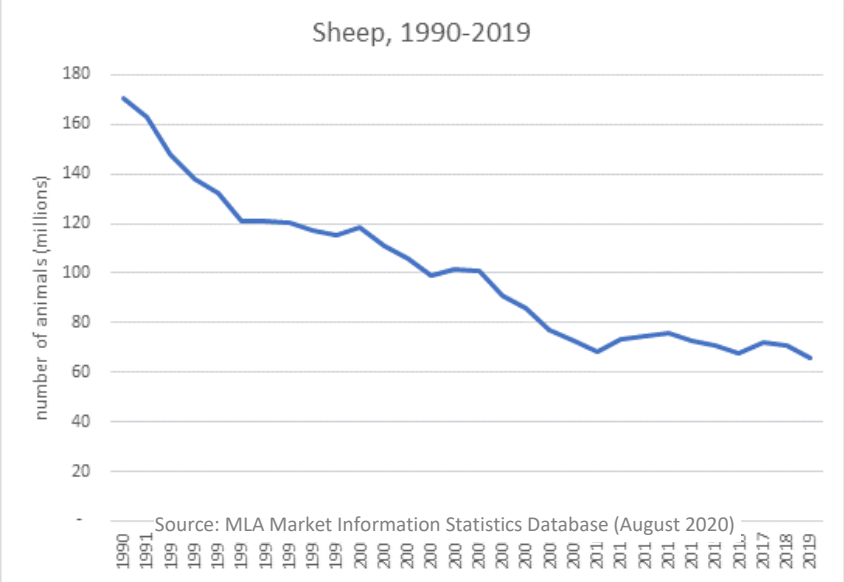

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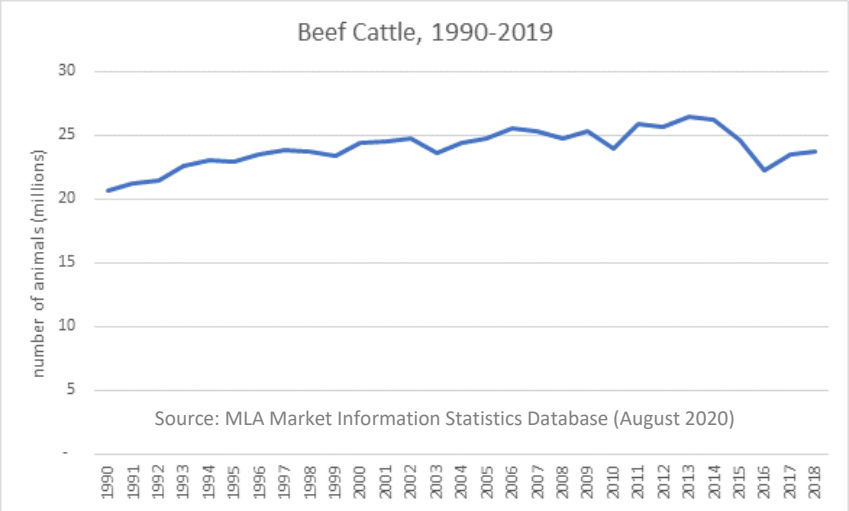

[1] https://www.mla.com.au/prices-markets/Trends-analysis/sheep-projections/

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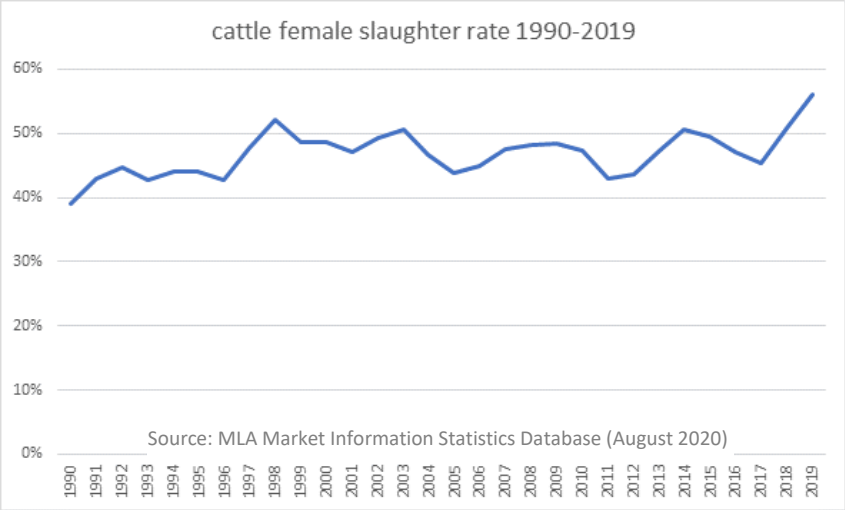

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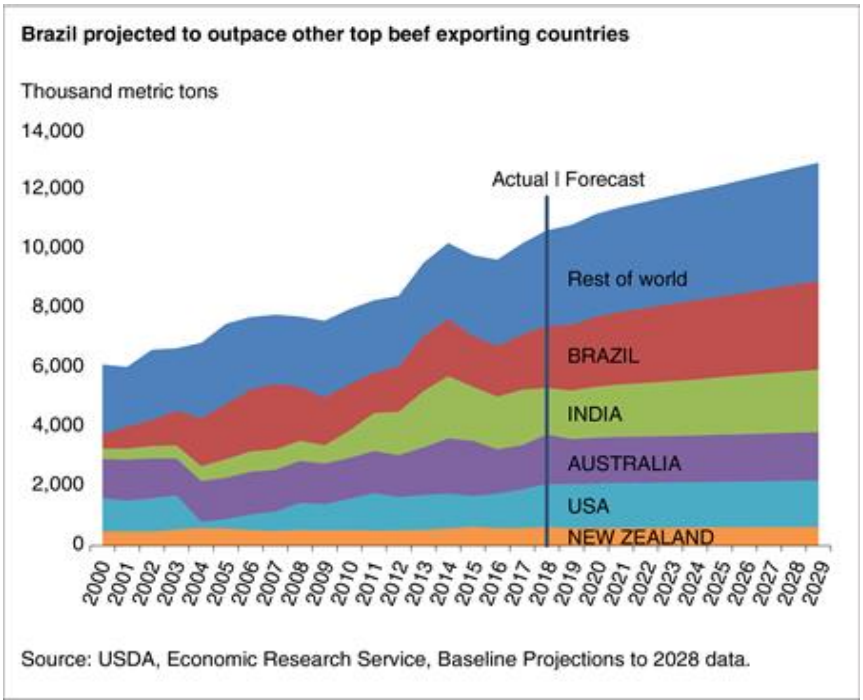

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Dairy cattle numbers peaked in the late 1950s and 1960s at about 5 million head.

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

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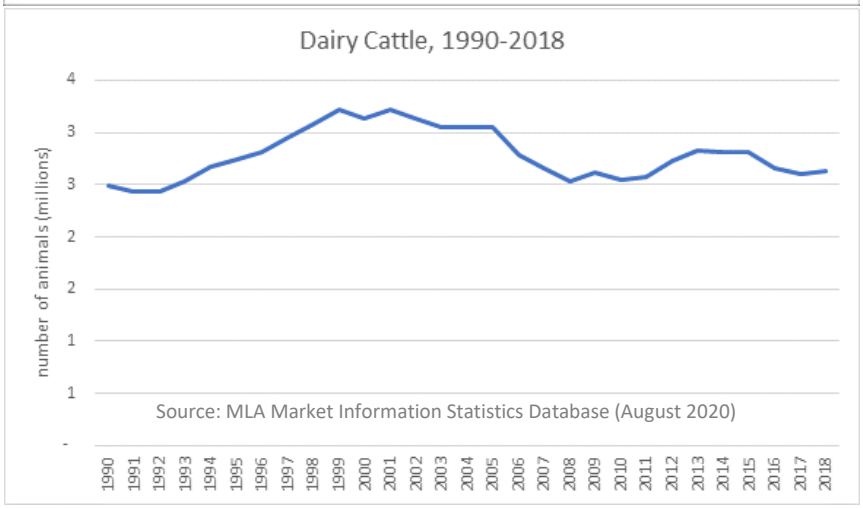

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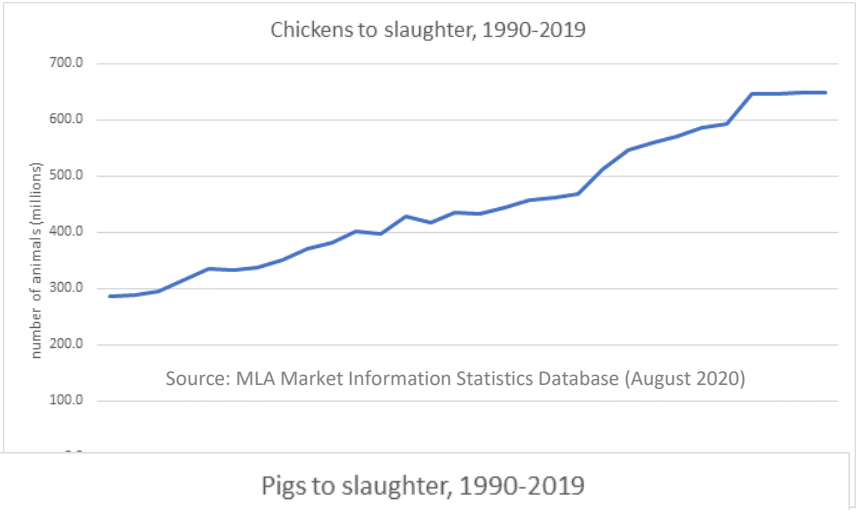

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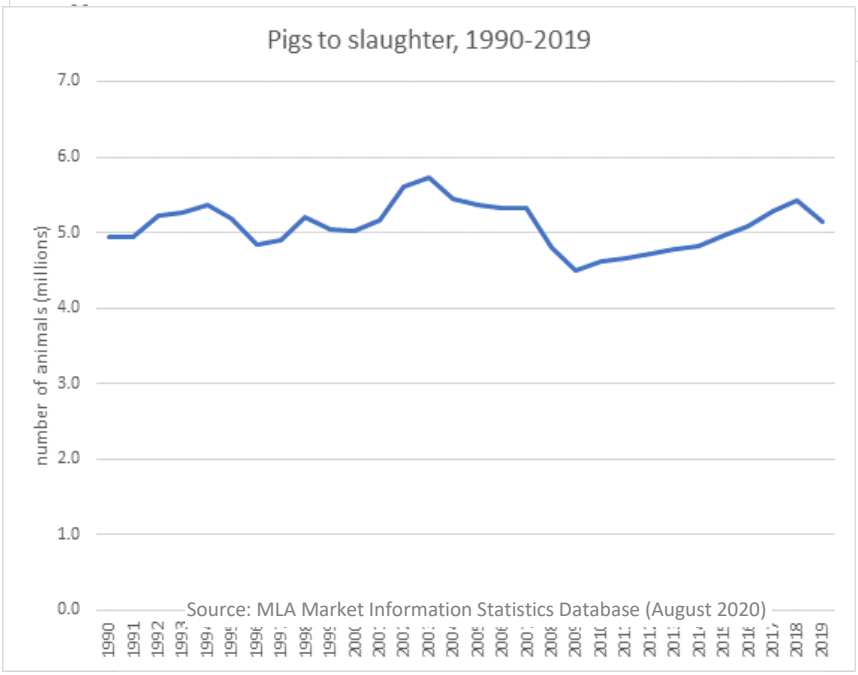
For the past 3 decades, 'pigs slaughtered' have fluctuated around the 5 million mark.

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.[5]



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*[6] identified:

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

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- Diseases and estimated economic costs
- Method of attribution
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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 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.

-oo0oo-

Appendix 7

AMA submission to the Issues Paper, 28 August 2020

Animal Medicines Australia
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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

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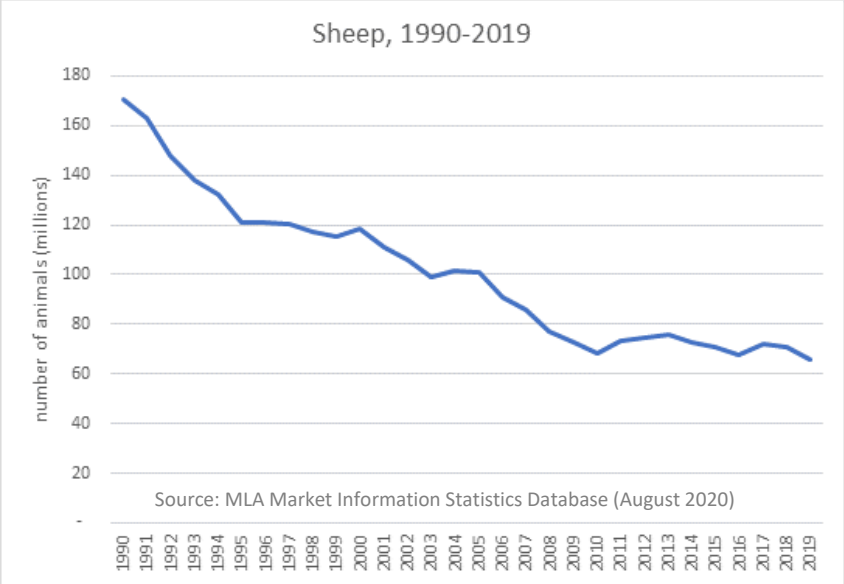

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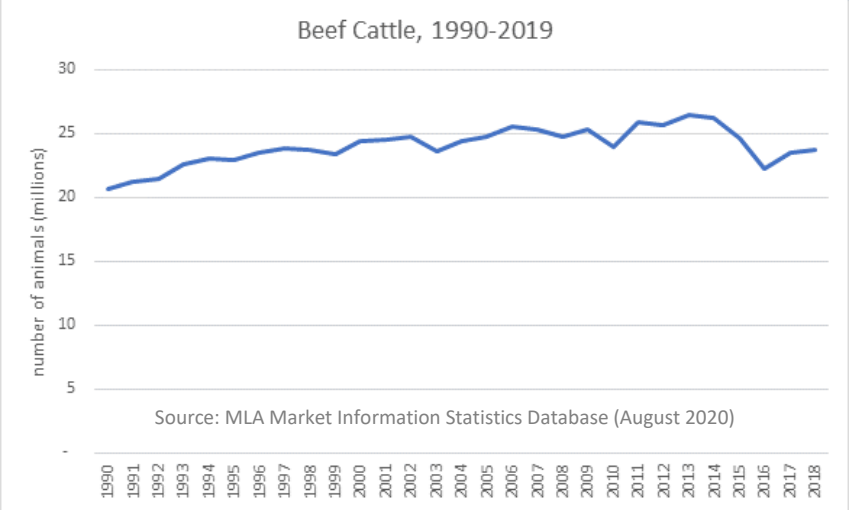

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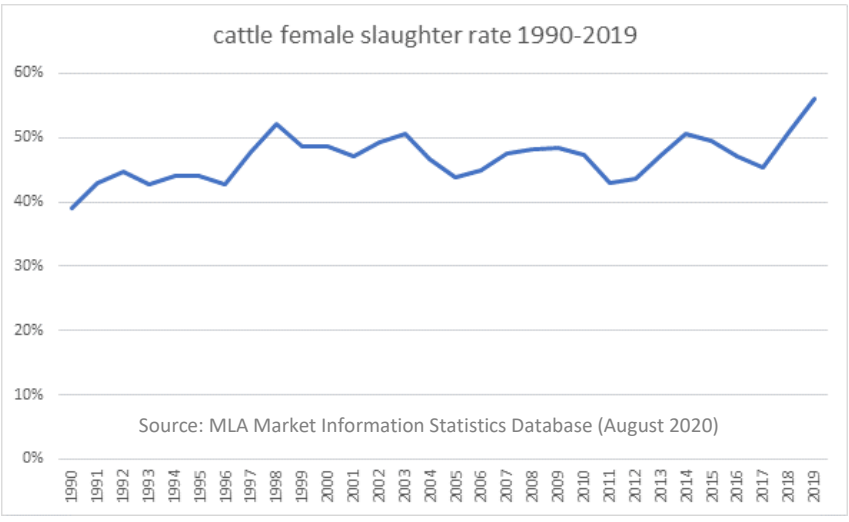

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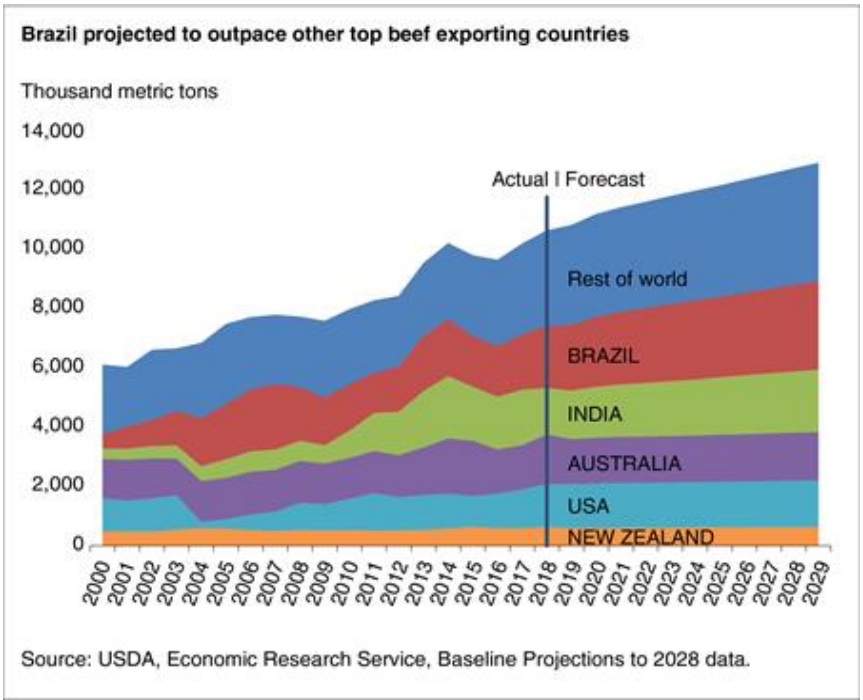

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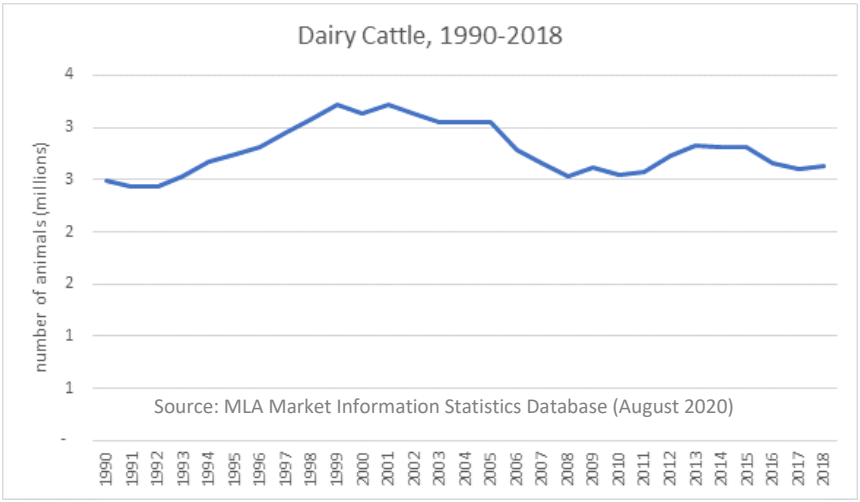

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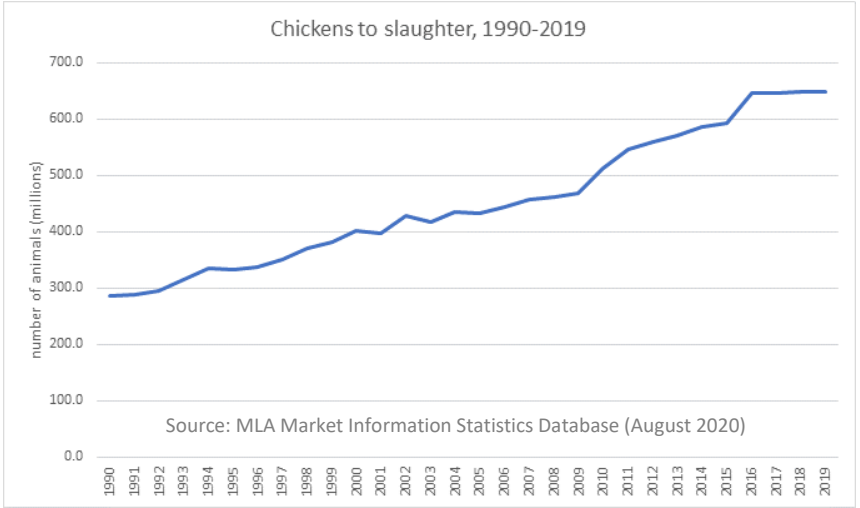

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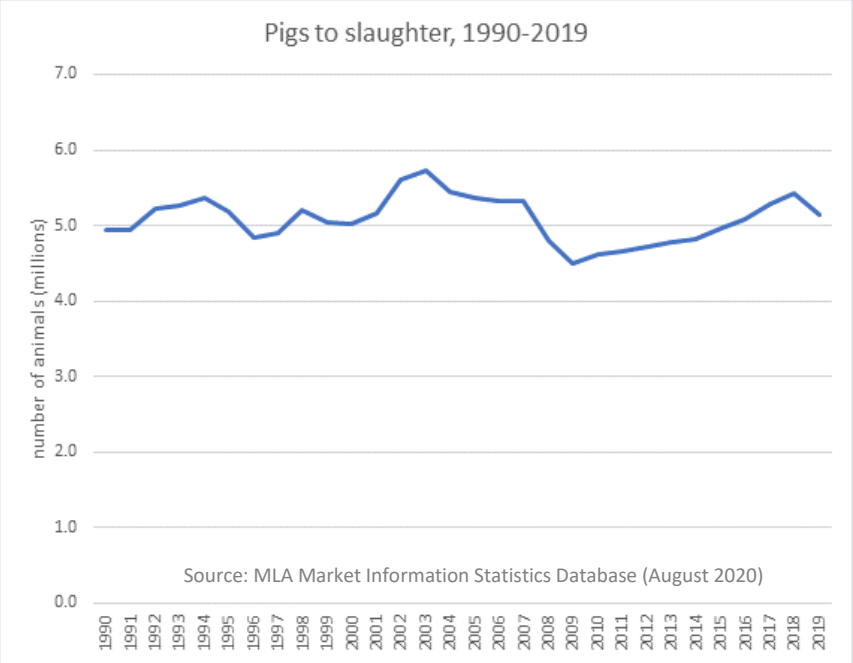

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There seems a clear need for injection of marketplace realities for veterinary medicines and the industries where they serve as a production input. AMA suggests that it may be an informative exercise to consider veterinary medicines as an input to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

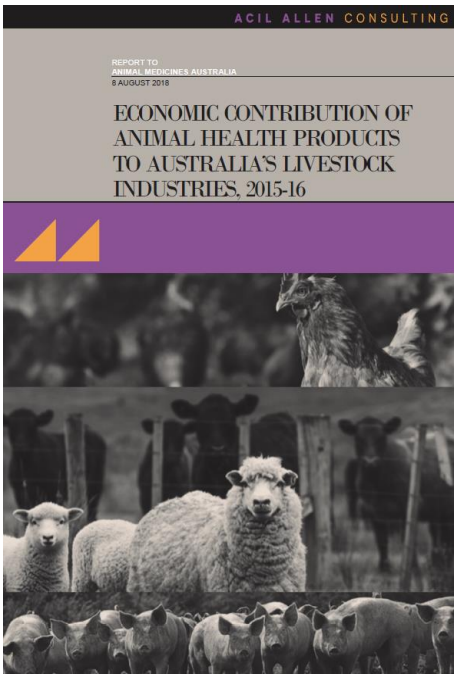
The above is not intended to be exhaustive but gives an indication of the nature and transparency of the public information that the agricultural and veterinary chemicals regulator, the APVMA, publishes on the services it provides.

[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.



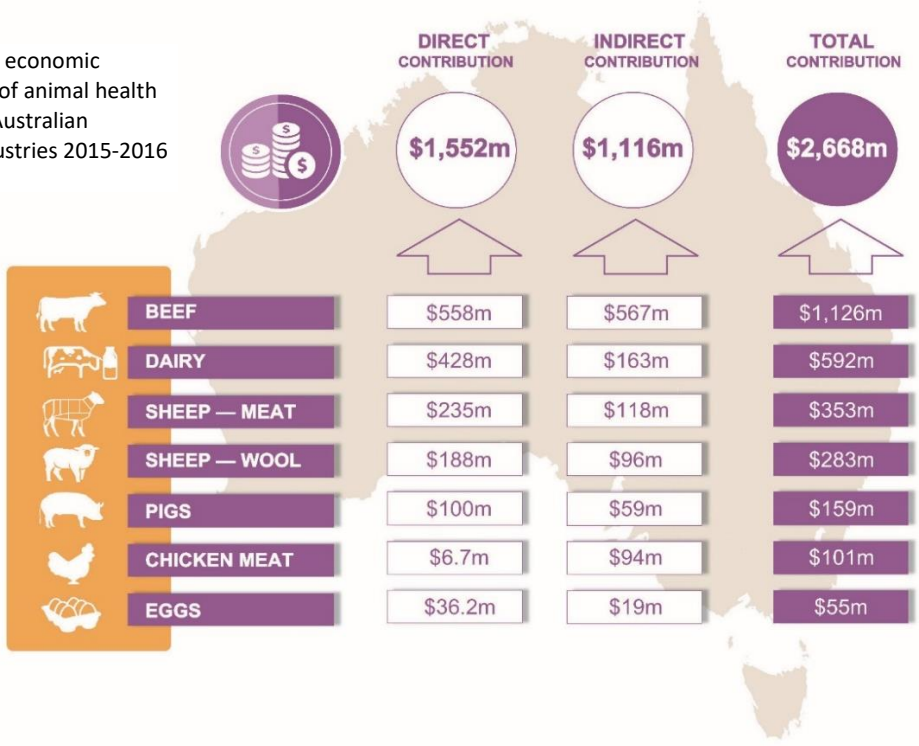
AMA engaged ACIL Allen Consulting to quantify the economic contribution made by animal health products (AHPs) in seven key commodity groups — Cattle, Dairy, Pigs, Sheep (meat), Sheep (wool), Chicken (meat) and Eggs.

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

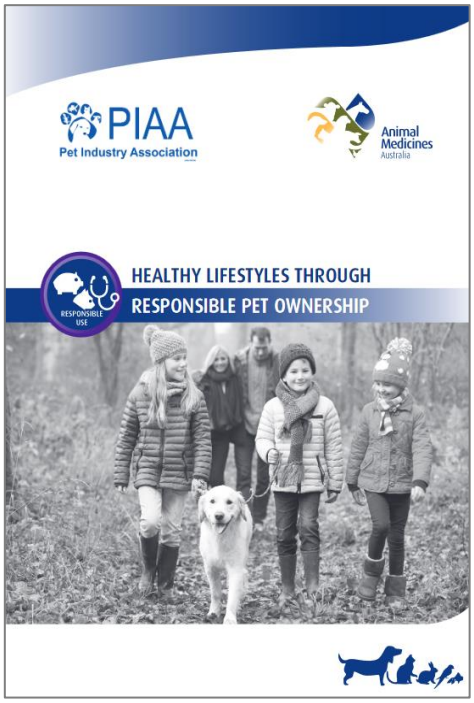
AMA also produces the triennial Pets in Australia report, which provides some of the most comprehensive information available on pet ownership in Australia. Understanding all the ways that pets contribute to Australian society is complex. The 2019 Pets in Australia Report[27] outlines key findings from 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]

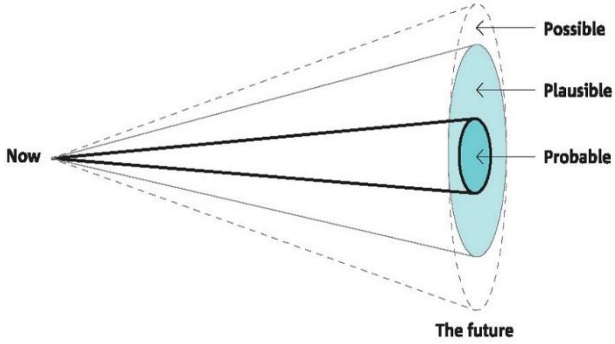
In 2013 Chemistry Australia undertook a *Strategic Industry Roadmap* exercise together with CSIRO Futures Group and supported by the Department of Industry:

> *"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

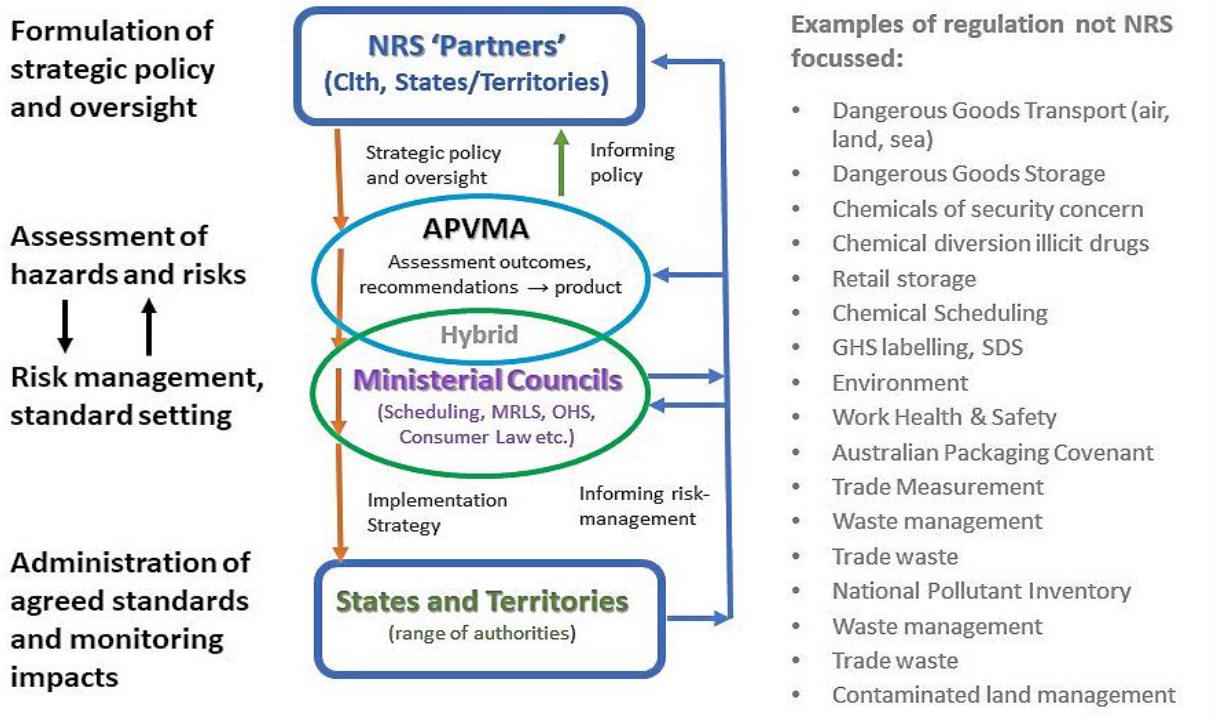
The 2008 Productivity Commission Report on Chemicals and Plastics Regulation, Research Report[51] proposed an institutional and regulatory approach for chemicals and plastics regulation:

- *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

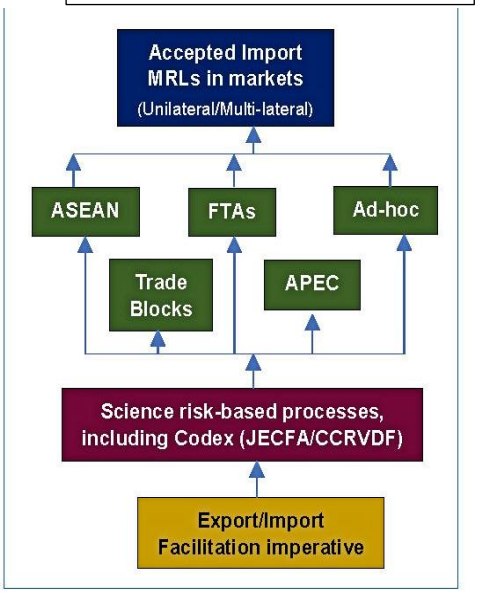
DAWE is aware of AMA's serious concerns in this area. The case for securing animal import MRLs in Australian export market was made at a meeting of AMA with the Panel, Departmental and APVMA personnel on 13 March 2020. A briefing note provided at that meeting is provided at Appendix 6 to this submission.

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.

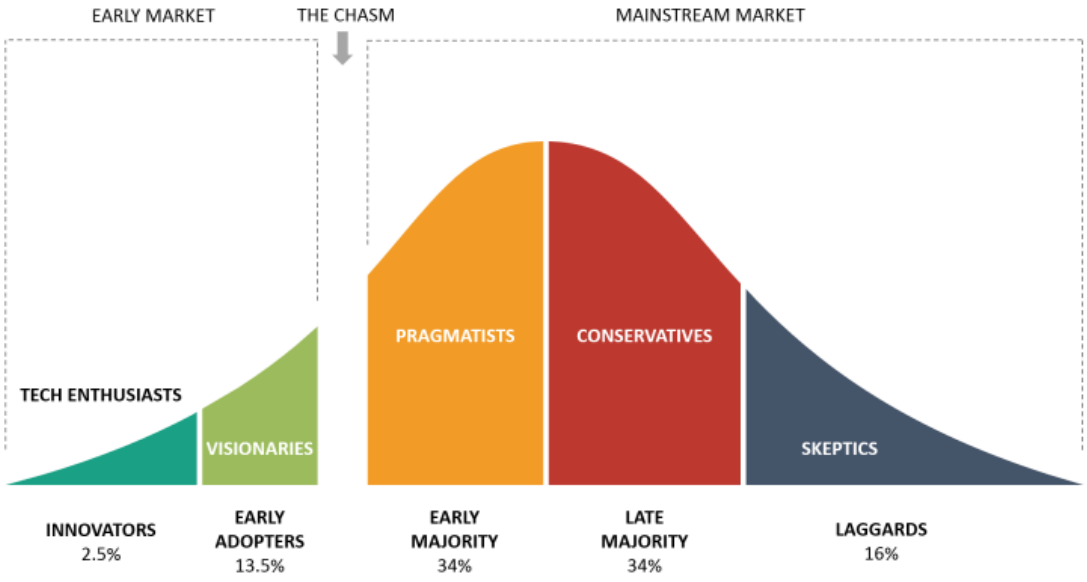
Australia has a reputation as an early adopter of new technologies.

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.

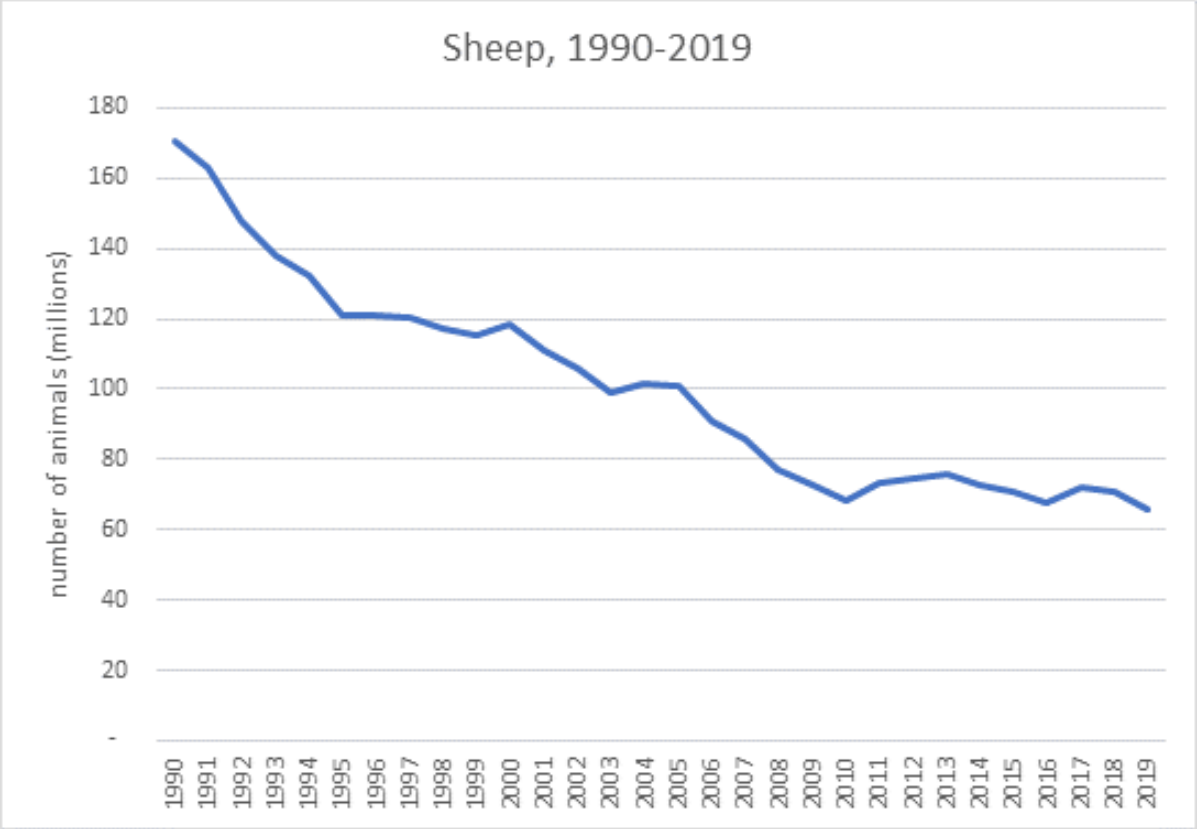
Appendix 2

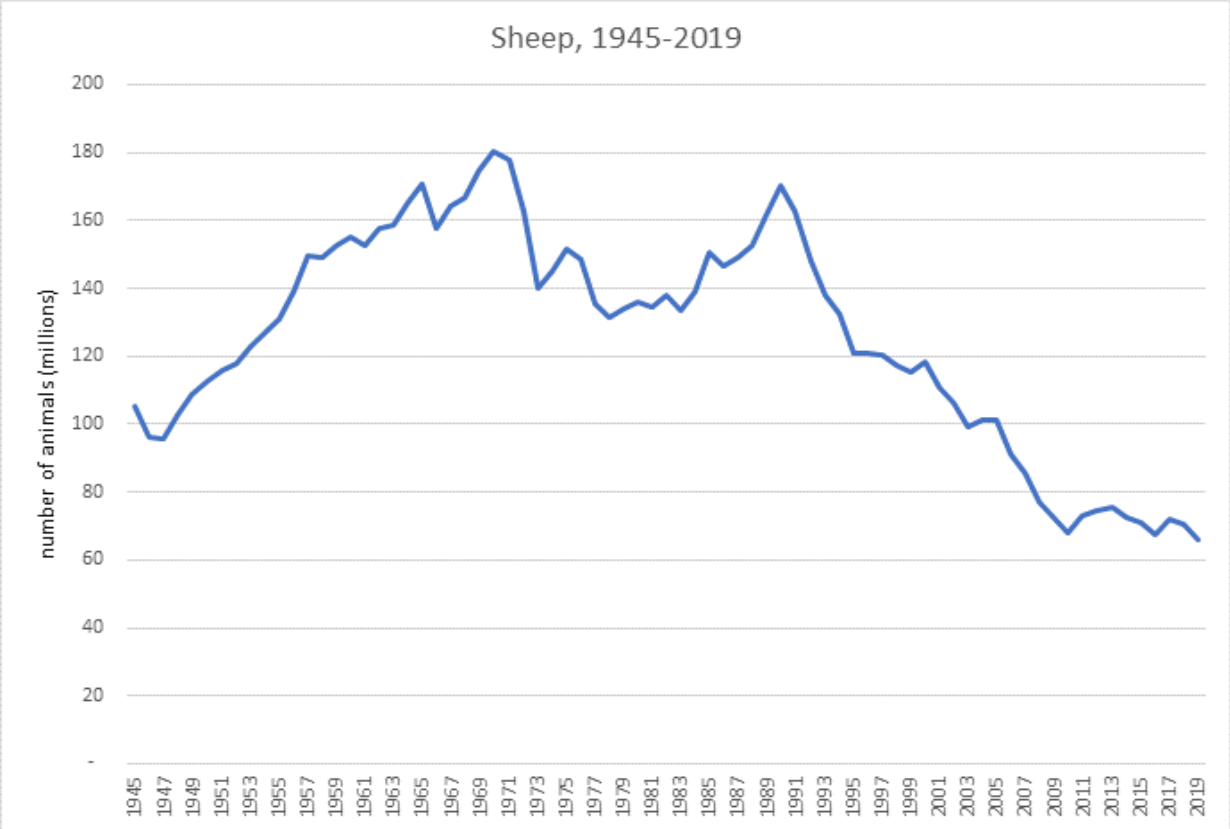
Compilation of historic agricultural livestock trends

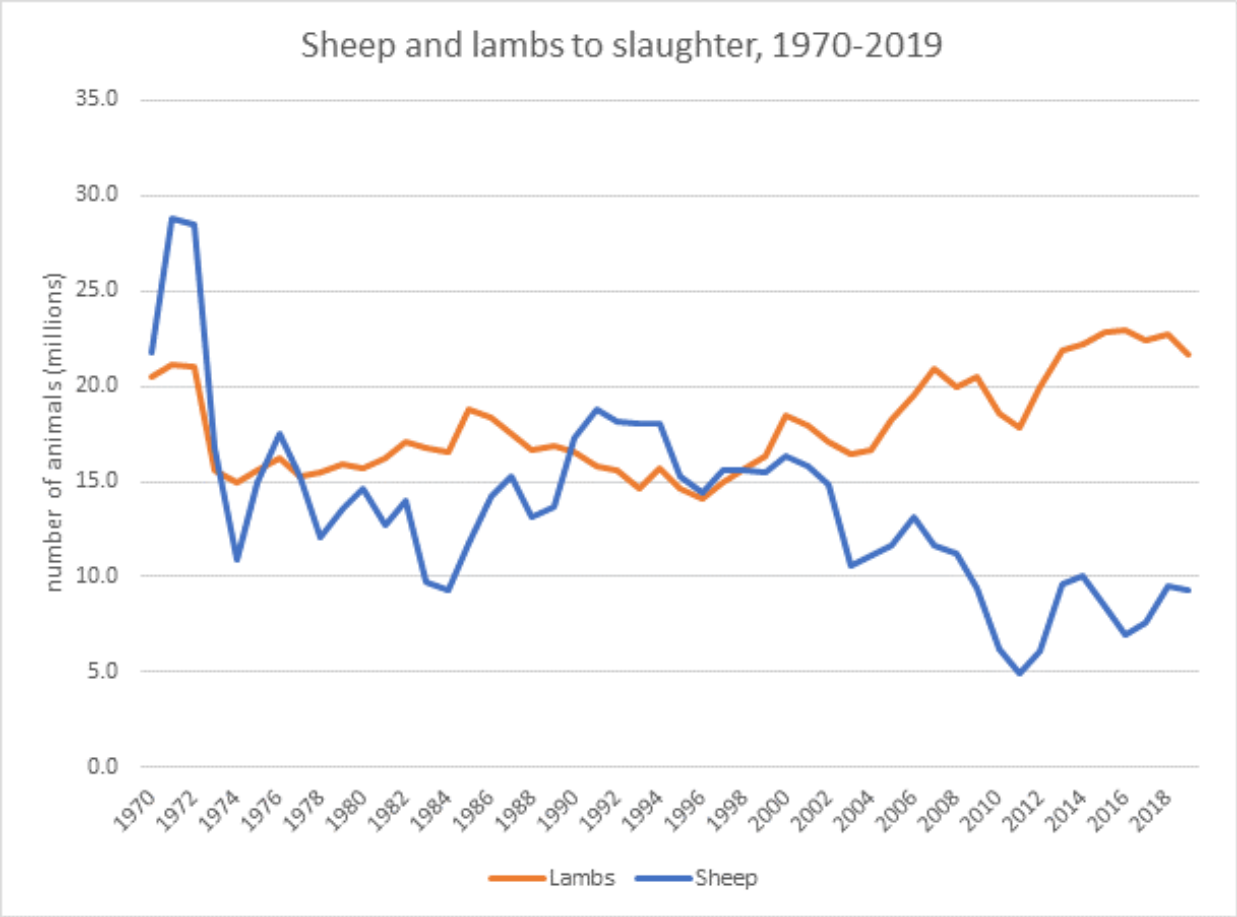
Historic agricultural livestock trends

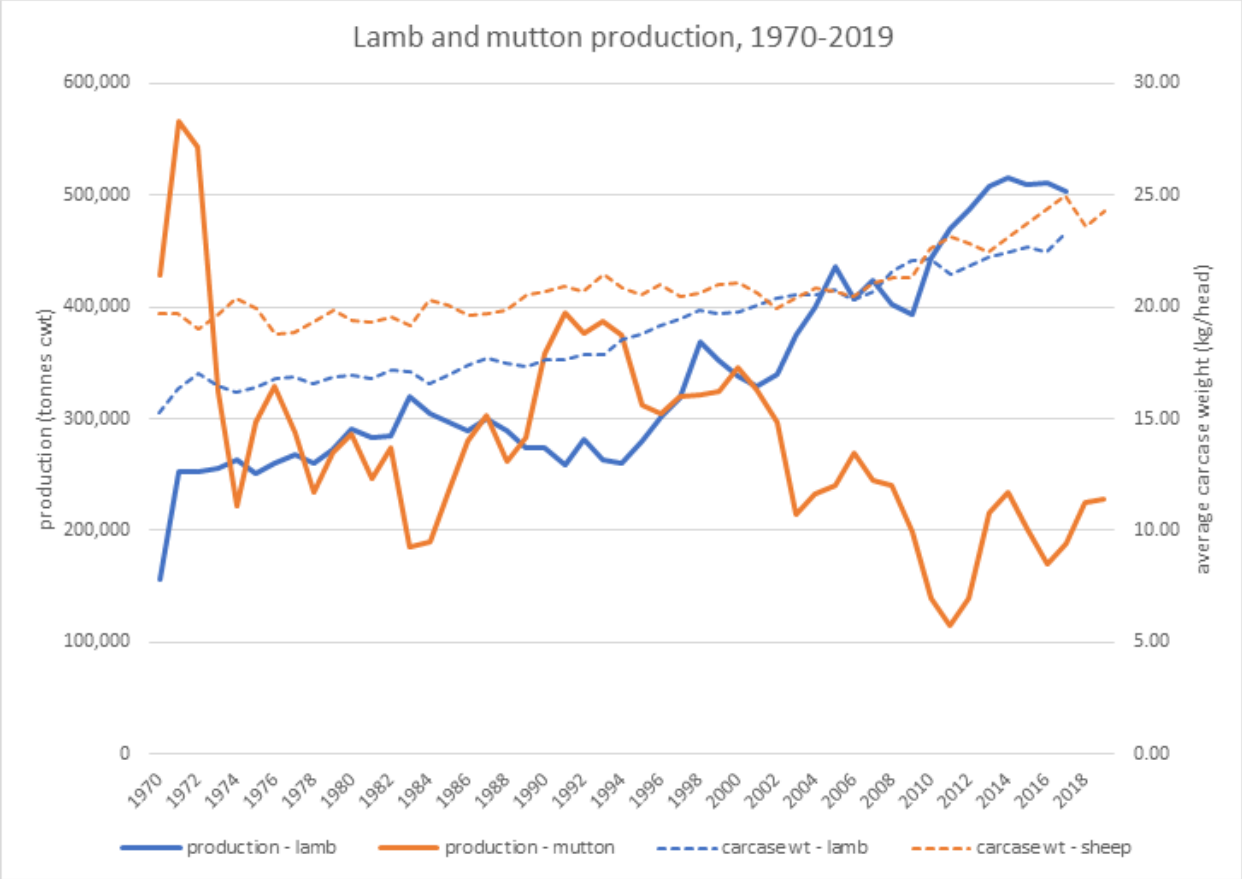
Note: the graphs are self-explanatory, so no specific commentary is provided.

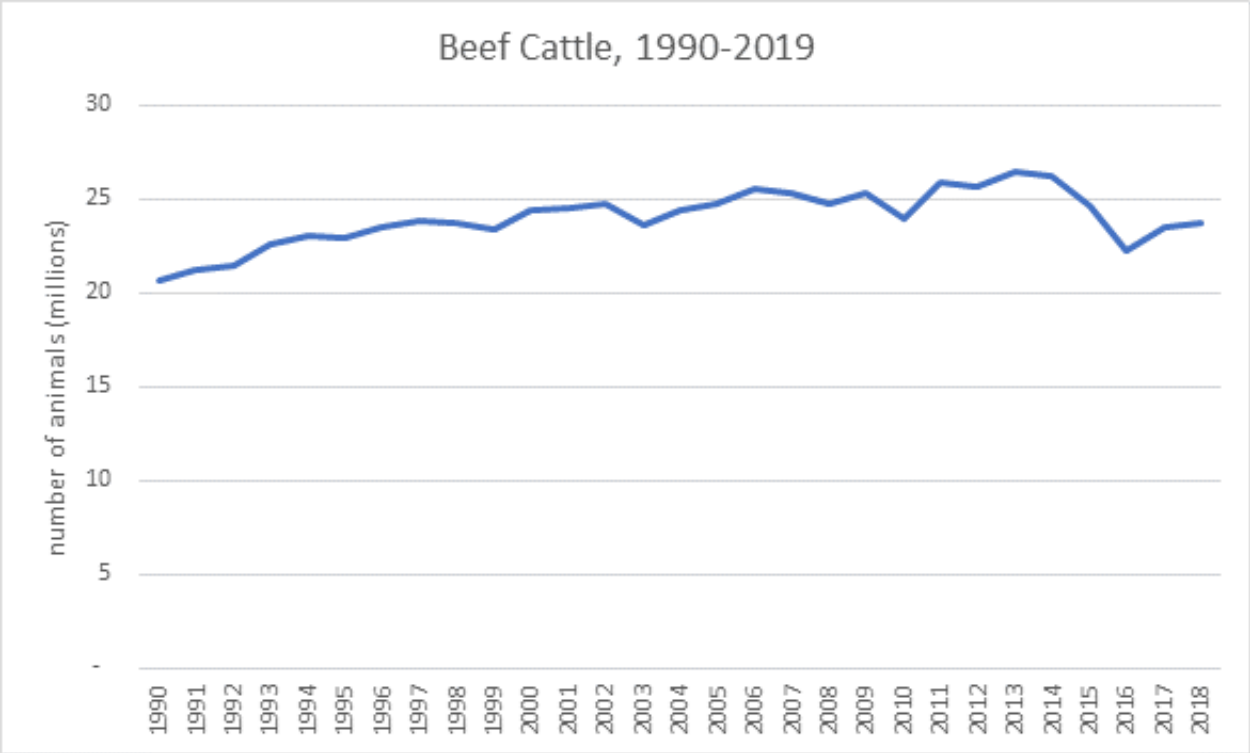
Source: MLA Market Information Statistics Database, August 2020

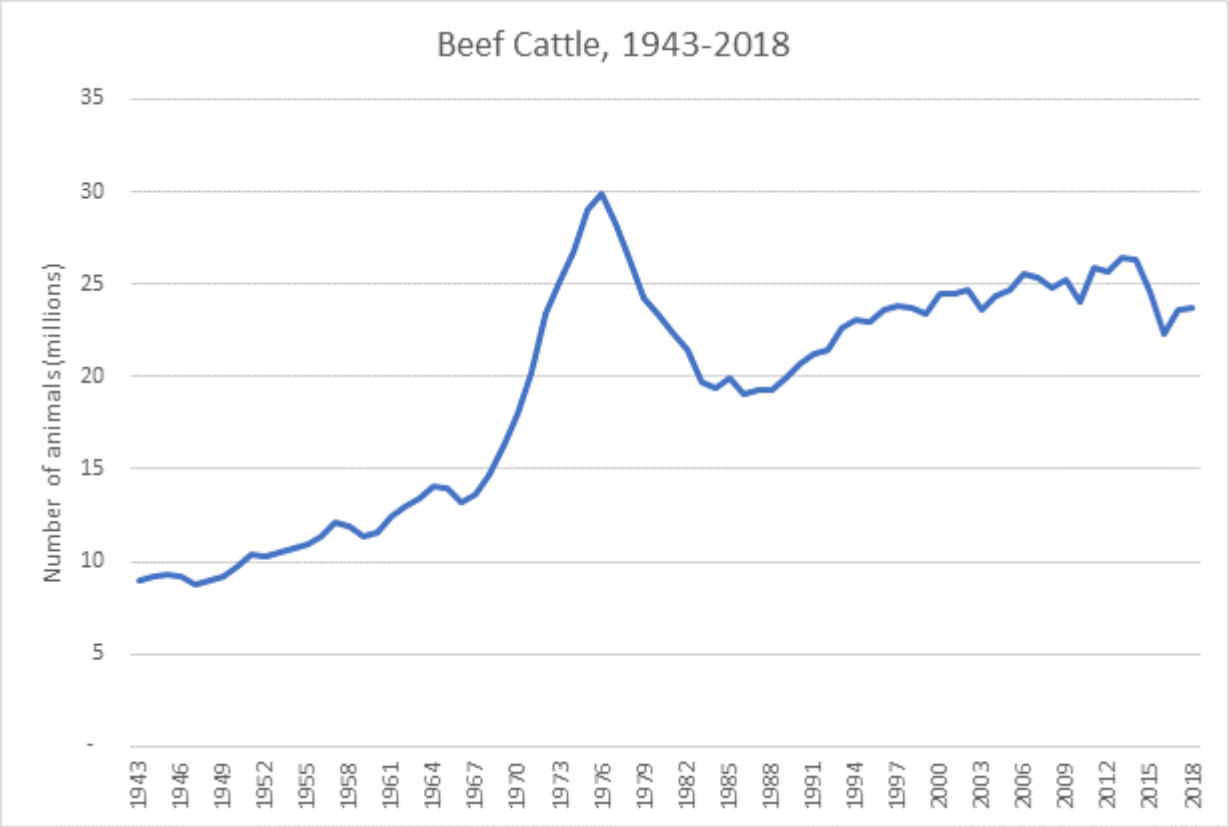


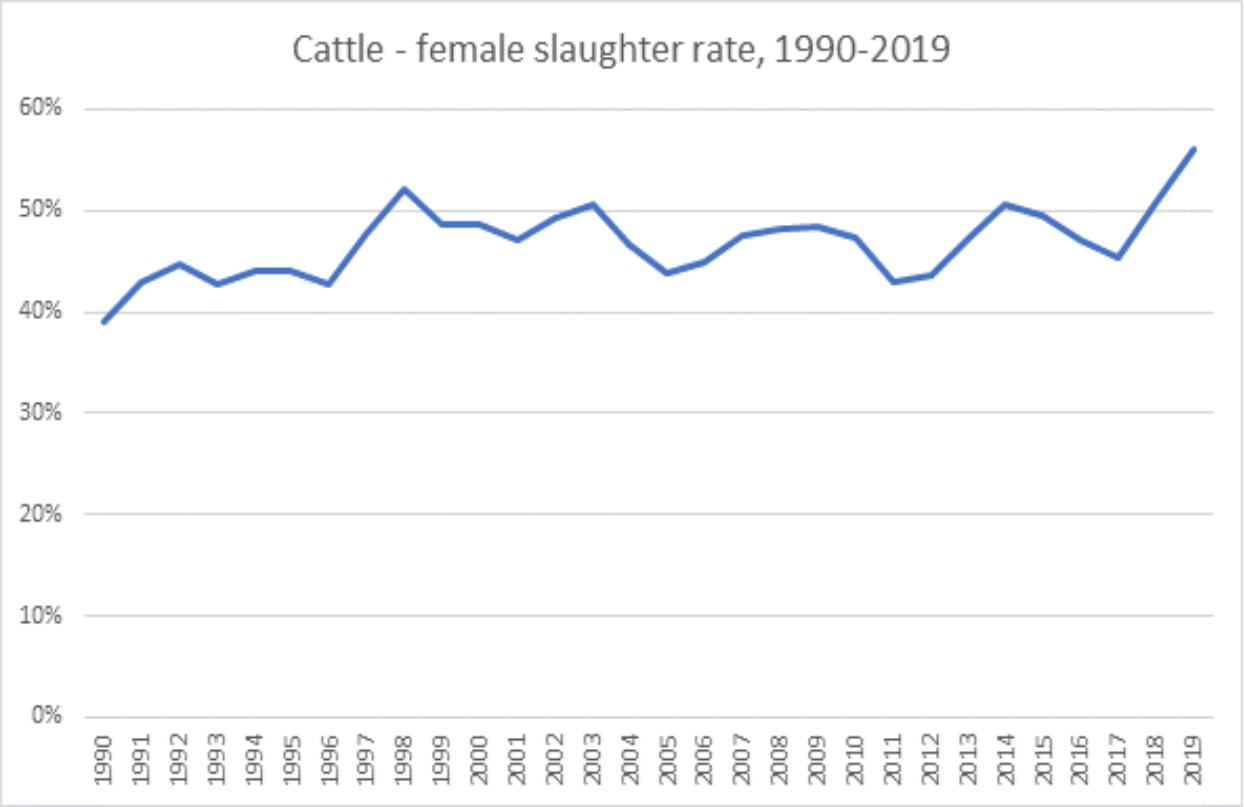


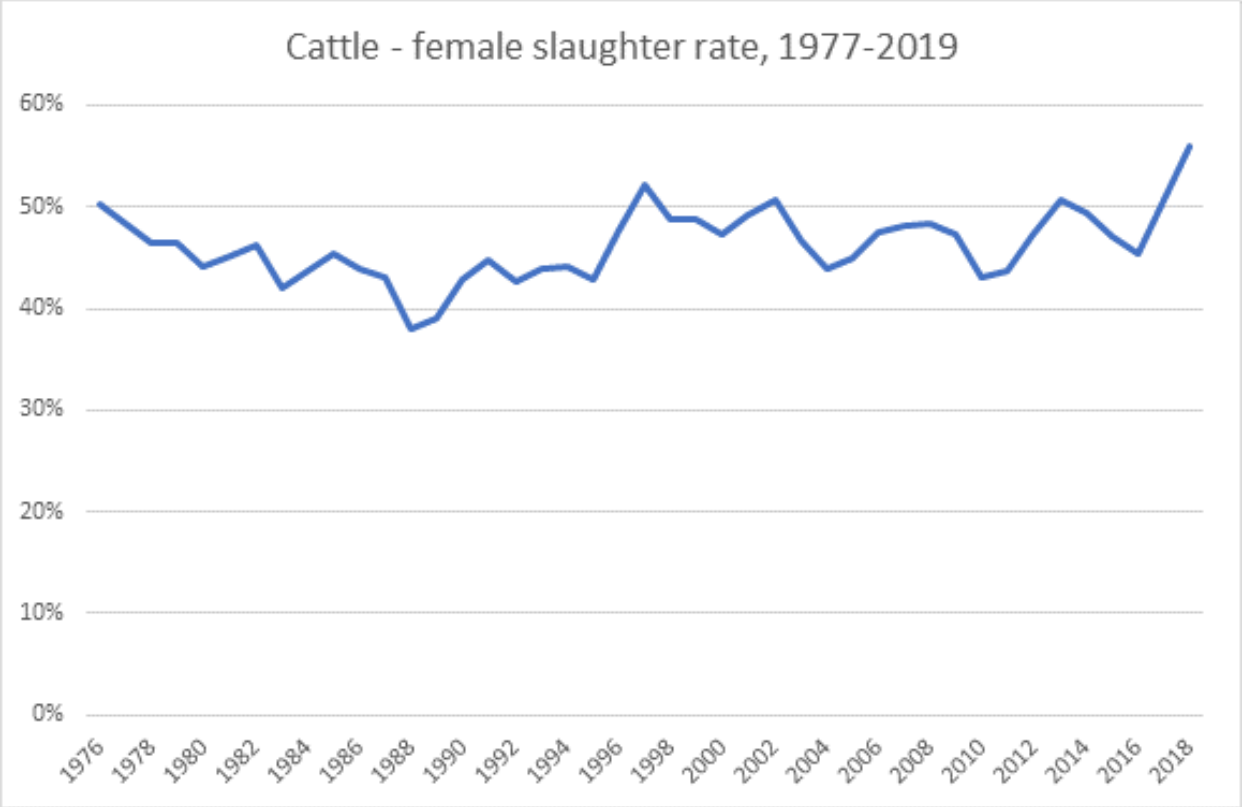

Sheep and lambs to slaughter, 1970-2019
number of animals (millions)
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016 2018
Lambs
Sheep

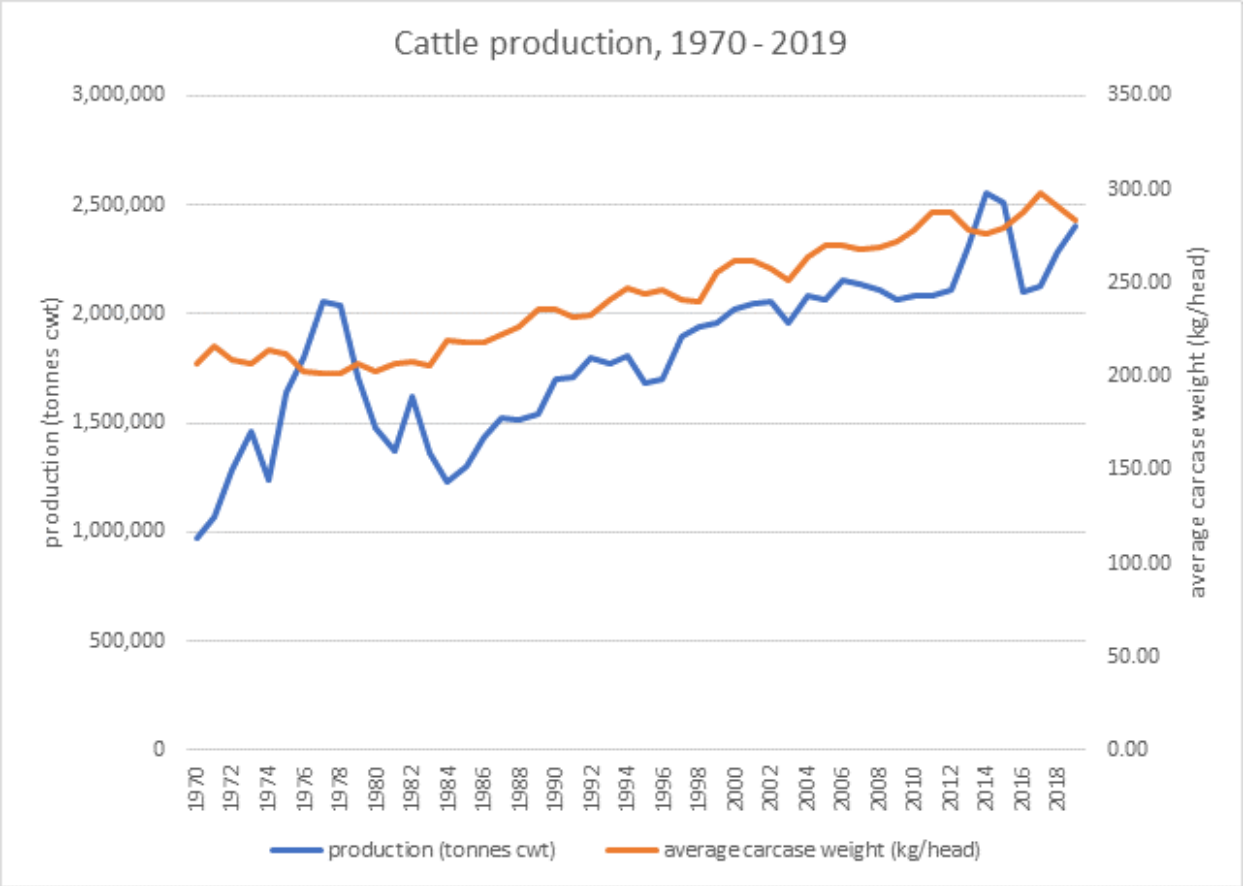

Lamb and mutton production, 1970-2019
production (tonnes cwt)
600,000
500,000
400,000
300,000
200,000
100,000
0
30.00
25.00
20.00
15.00
10.00
5.00
0.00
average carcase weight (kg/head)
1970 1972 1974 1976 1978 1980 1982 1984 1986 1988 1990 1992 1994 1996 1998 2000 2002 2004 2006 2008 2010 2012 2014 2016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

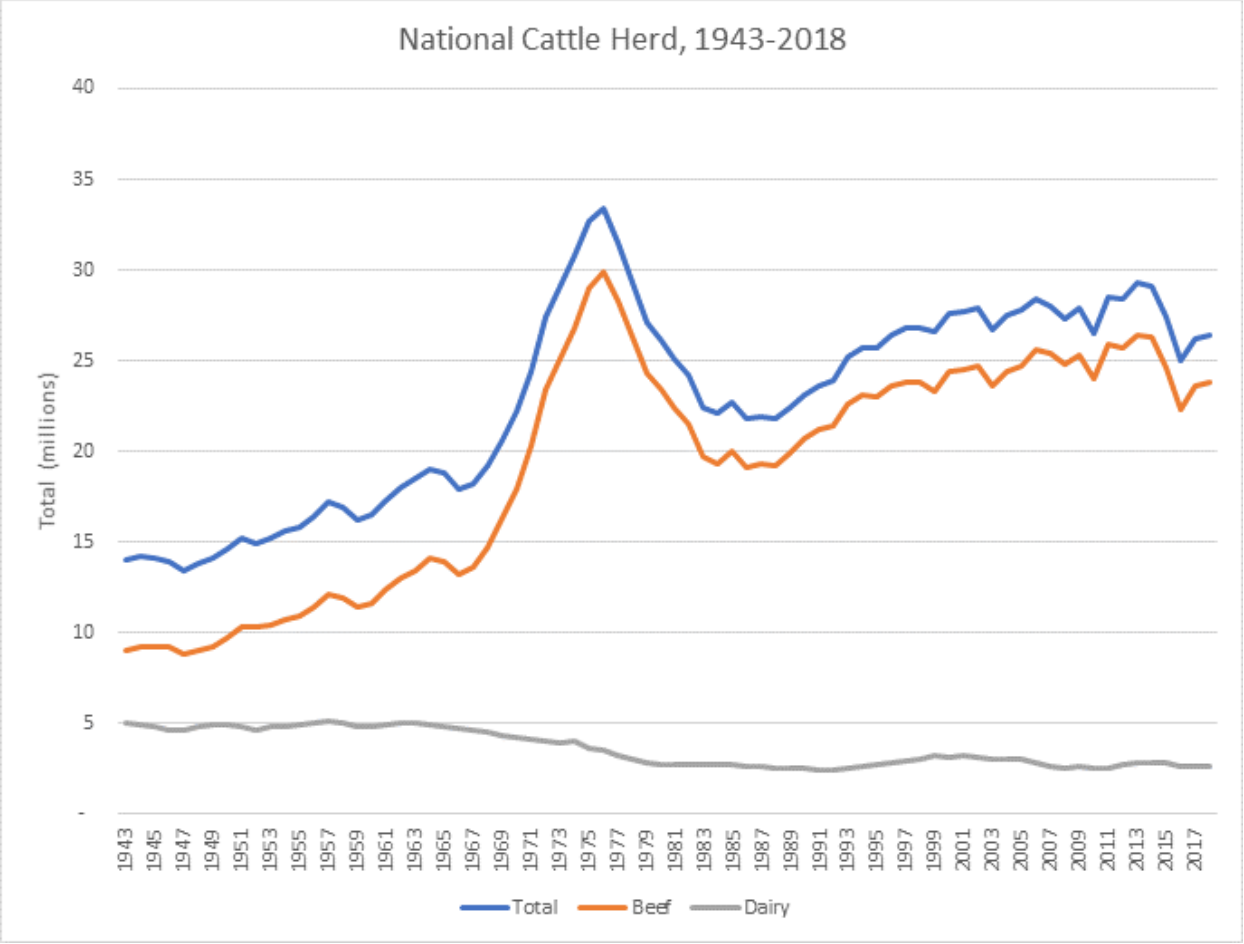

Beef Cattle, 1990-2019
number of animals (millions)
30
25
20
15
10
5
-
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018

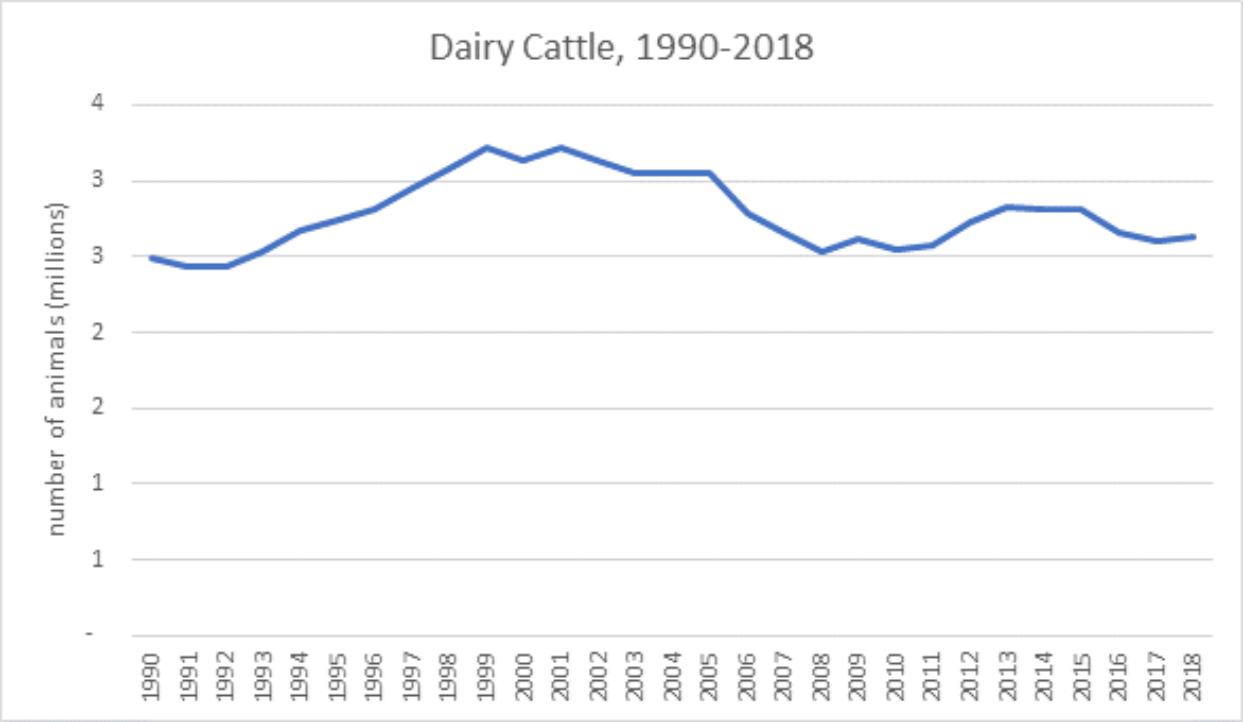

Beef Cattle, 1943-2018
Number of animals (millions)
35
30
25
20
15
10
5
-
1943
1946
1949
1952
1955
1958
1961
1964
1967
1970
1973
1976
1979
1982
1985
1988
1991
1994
1997
2000
2003
2006
2009
2012
2015
2018

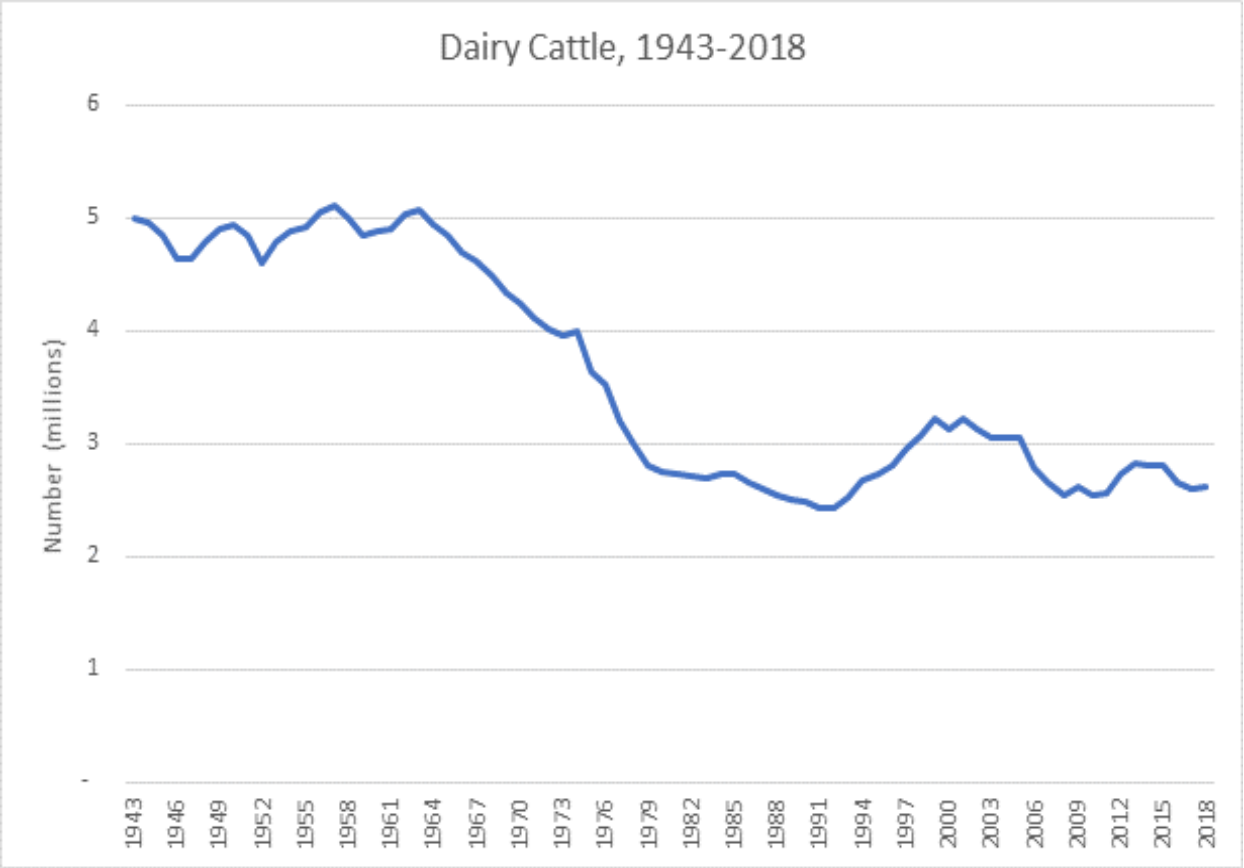

Cattle - female slaughter rate, 1990-2019
60%
50%
40%
30%
20%
10%
0%
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019

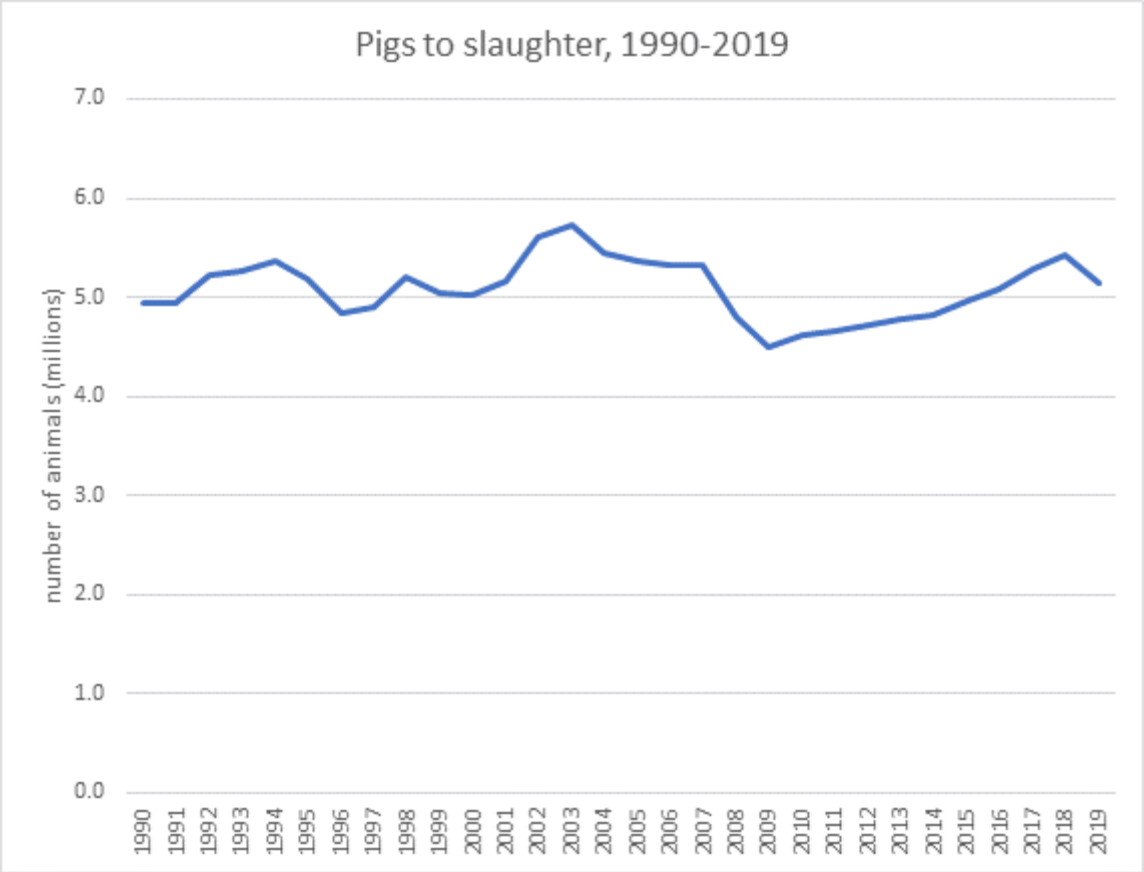

Cattle - female slaughter rate, 1977-2019
60%
50%
40%
30%
20%
10%
0%
1976
1978
1980
1982
1984
1986
1988
1990
1992
1994
1996
1998
2000
2002
2004
2006
2008
2010
2012
2014
2016
2018


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
2001
2002
2003
2004
2005
2006
2007
2008
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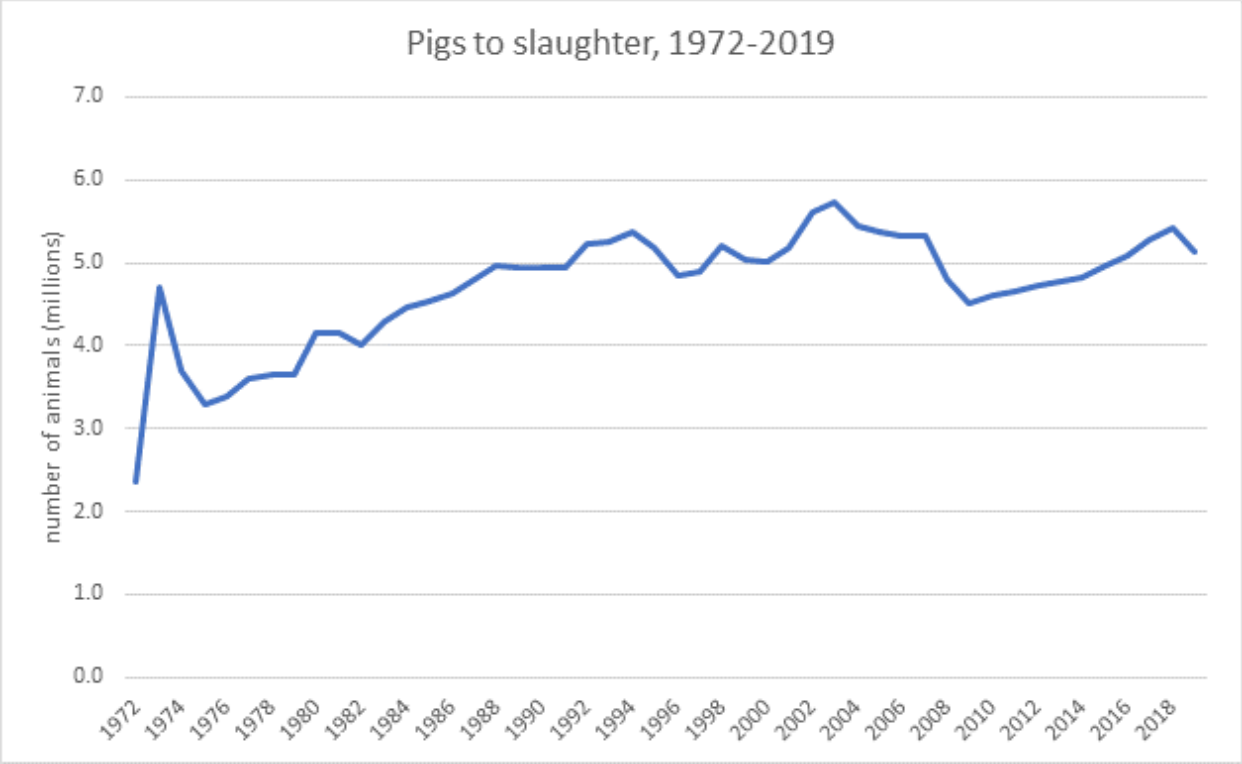
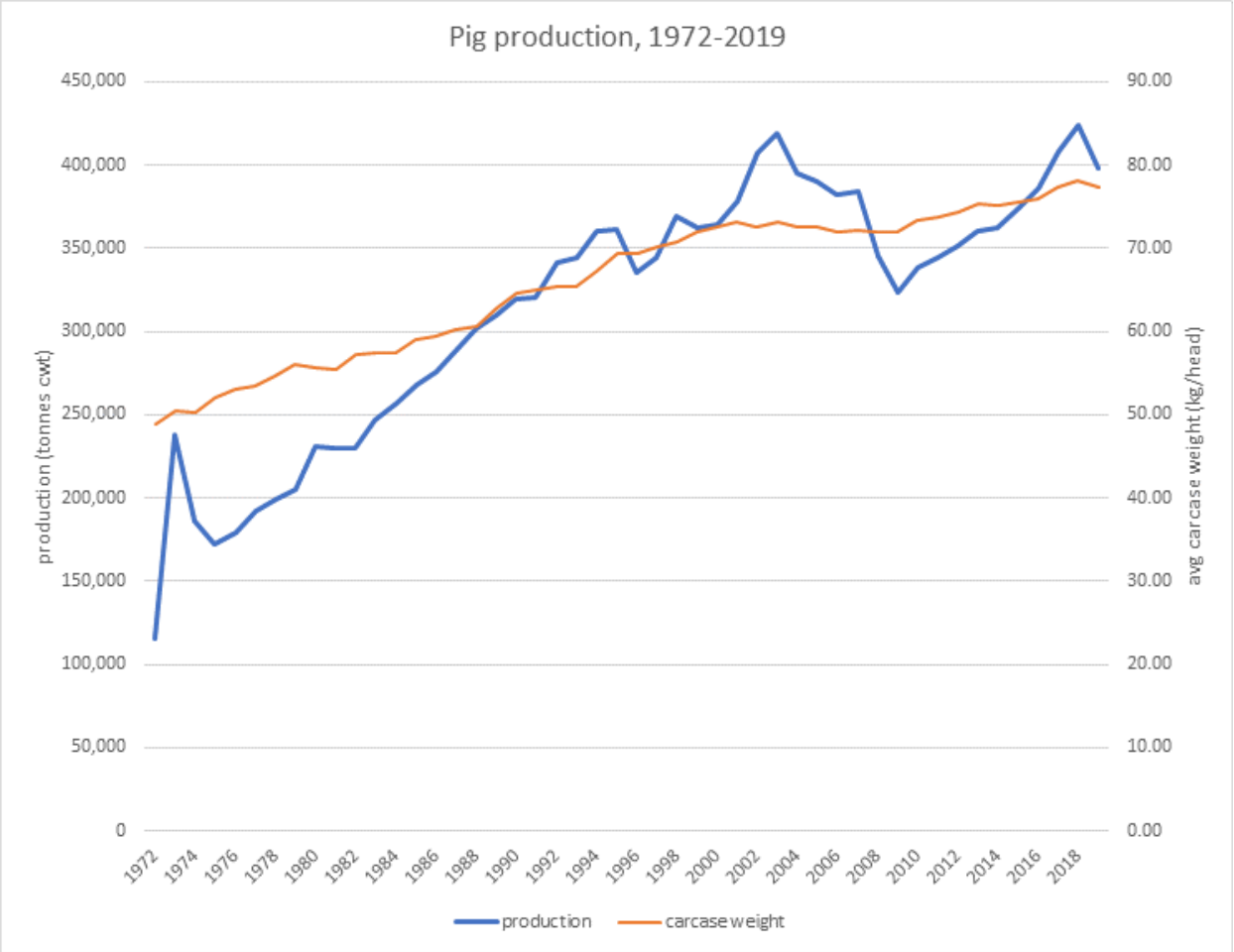
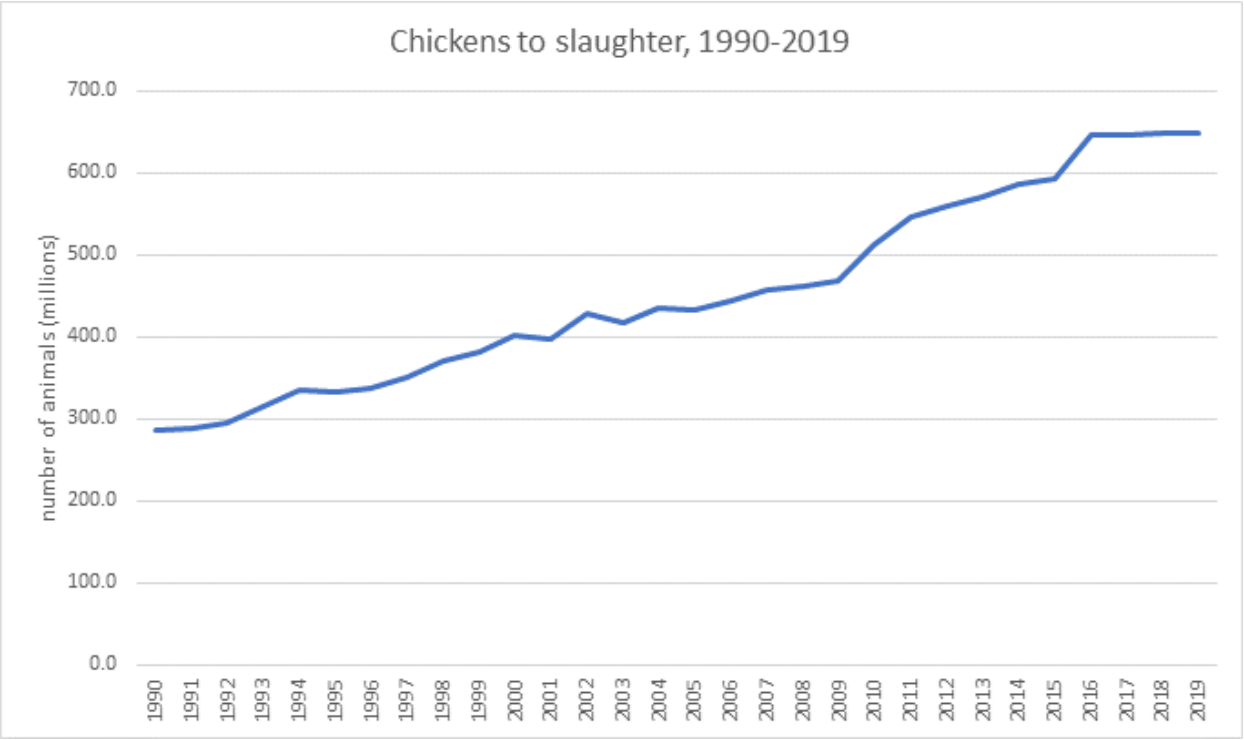
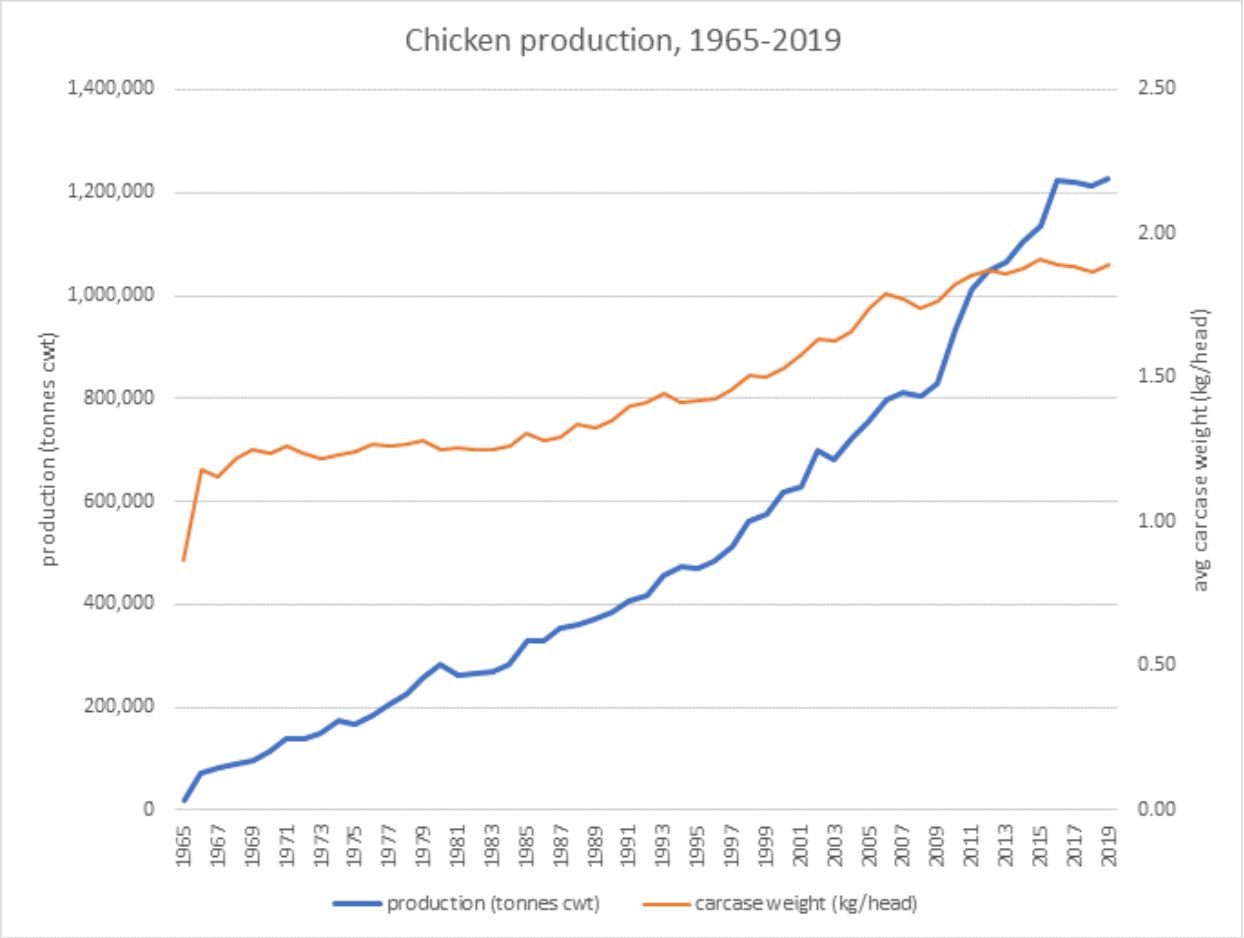
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019


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
1992
1994
1996
1998
2000
2002
2004
2006
2008
2010
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

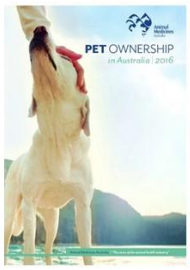
- Policy & Regulatory
- Political engagement
- Alliances, partnerships, research, and issues management

Animal Medicines Australia

16/12/2019

Promoting Animal Care Benefits

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



Animal Medicines Australia

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

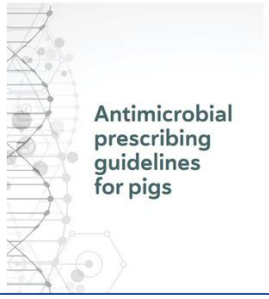
Animal Medicines Australia

16/12/2019

Issues Management Group

- Emerging issues
- Policy development
- Stewardship
- Industry engagement

RESPONSIBLE USE



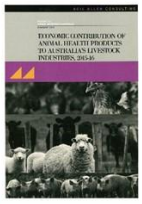
Animal Medicines Australia

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

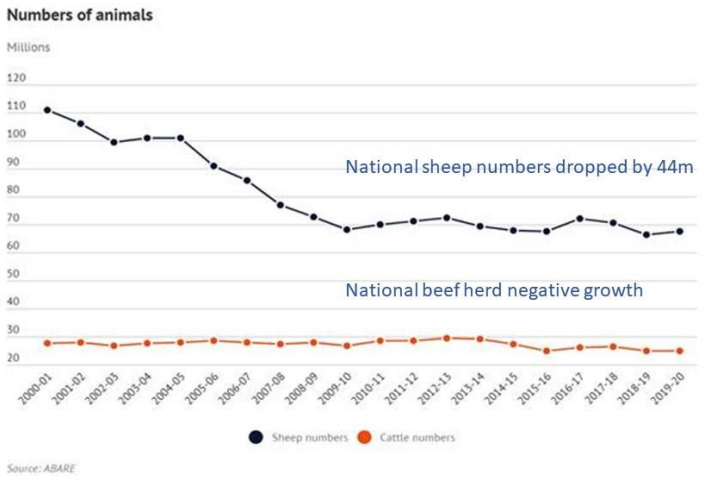
Regulatory roles and responsibilities

16/12/2019

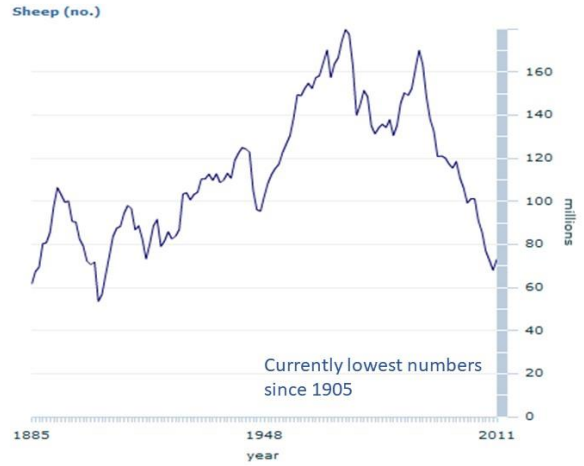
Animal Medicines Australia

16/12/2019

Business operating environment



Business operating environment



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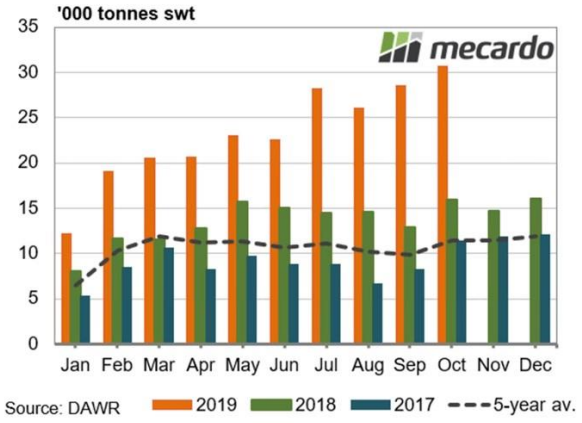
Business operating environment

Australian Beef Exports - China



Exports

Beef ↑ 122%

Lamb ↑ 69%

Mutton ↑ 118%

Reflective of ASF effects – alternate protein sources

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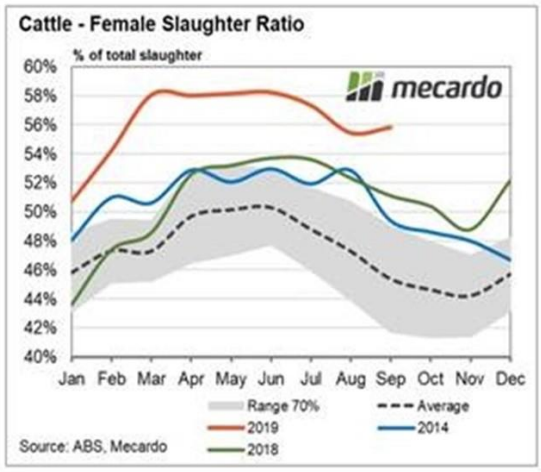
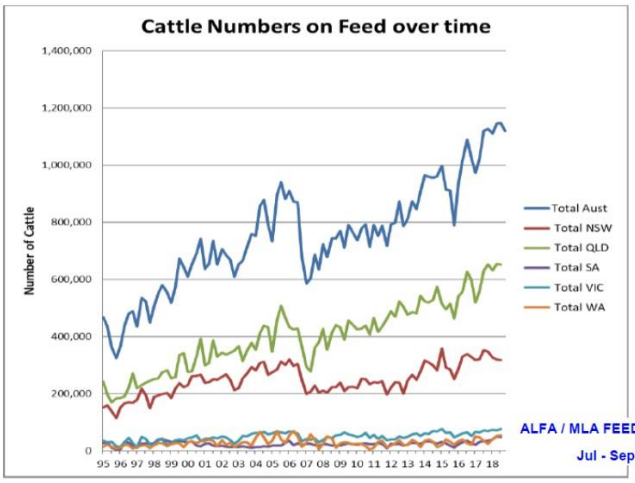
Business operating environment



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



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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!*

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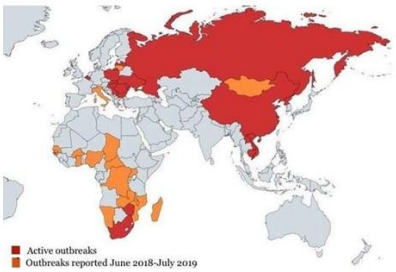
Case study: Market shocks

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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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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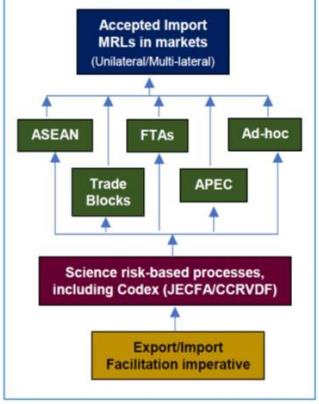
Case study: Importing Country MRLs (continued)

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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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

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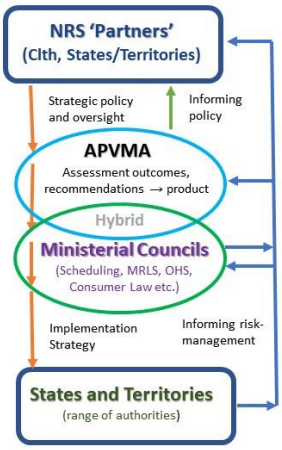
DRAFT Model for efficient and effective management of certain aspects of veterinary chemicals regulation

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

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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

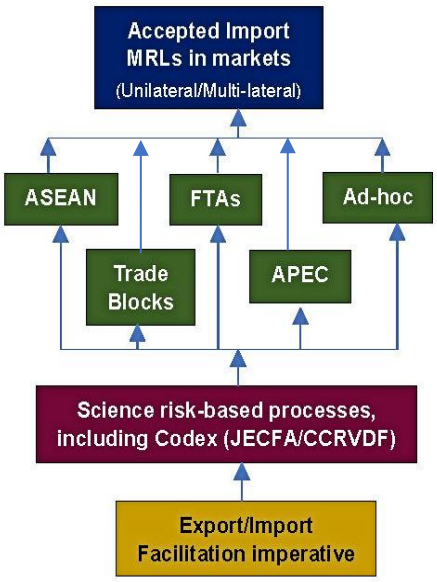
The goal is to achieve recognition of Australian and established internationally recognised standards, such as Codex, and accelerate harmonisation in regional trade fora. There is good opportunity for Australia to piggy-back the good work that has been undertaken in the pesticides field.

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.