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

7 October 2022

Legislation Reform
Agriculture Victoria
Submission via website only: Reforming Victoria's biosecurity legislation | Engage Victoria

Dear Legislation Reform team,

Re: Reforming Victoria's biosecurity legislation

Thank you for the opportunity to provide comment on the *Reforming Victoria's biosecurity legislation* Discussion Paper.

Animal Medicines Australia (AMA) is the peak industry association representing the registrants and approval holders of veterinary medicines and animal health products in Australia. They are the local divisions of global innovators, manufacturers, formulators and registrants that supply essential veterinary medicines and animal health products that are critical to supporting Australia's $34 billion livestock industry and the $30 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA member companies play a vital role in Australia's biosecurity as the producers of medicines that prevent, control and treat animal diseases across the livestock, equine and companion animal sectors. AMA members develop, register and supply innovative new medicines including vaccines and anti-infection medicines to prevent and control outbreaks of animal disease, as well as medicines and treatments that enable good health and wellbeing, and the production of food and fibre products that are safe for human consumption and use. Healthy animals are much less susceptible to disease and infection, and good animal health is essential to good animal welfare.

Australia is in a unique position because many of the world's most devastating and debilitating animal diseases are not present here. Our strict biosecurity measures and systems help maintain this disease-free status, protecting animal health and welfare, public health, environmental health, food quality and safety, and give Australia a competitive advantage in global markets. An outbreak of animal disease could have severe ramifications for the entire agricultural sector, as well as domestic animal health, food safety, public health and our environment.

We are pleased to provide the following comments on biosecurity for consideration by the Victorian State Government.

The Importance of Biosecurity

Animal disease outbreaks have catastrophic and far-reaching impacts on animal welfare, agricultural industries and our everyday lives. Strong biosecurity is critical to protect animal health and welfare, food safety and security, trade in agricultural products and to mitigate the significant costs of responding to and controlling a preventable disease outbreak. The agricultural sector is a multi-billion-dollar industry that is critical to Australia's economy. Australia's disease-free status for many debilitating animal diseases is rare and confers important market advantage for our producers through competitive costs of production, production of high-quality goods, industry sustainability and global reputation.

Australia's biosecurity is heavily dependent on the interconnectedness of many different systems in multiple locations, both within and outside our national borders, with multiple potential entry pathways of pathogens into and within Australia. A system is only as strong as its weakest link – a failure in one part of the biosecurity system could potentially place the entire system at risk and have far-reaching impacts. It is essential that actions in each state or territory prioritise effective and efficient communication, partnership, knowledge sharing and stakeholder engagement across all levels of the biosecurity system, both within and beyond state or territory borders.

AMA considers it essential that:

- The Victorian biosecurity legislation prioritises risk-based assessment and is underpinned by science,
- Response and control measures are proportionate to the risk posed by an activity or disease,
- State-level biosecurity activities and strategies are aligned with national activities and strategies, whilst allowing unique or location-specific risks to be appropriately addressed, and
- The biosecurity system considers both current and future biosecurity threats, with the agility to respond to sudden shocks (such as disease incursions or COVID-19-related disruptions to supply chains for important animal medicines).

The Purpose and Principles of Reformed Biosecurity Legislation

AMA supports the prioritisation of biosecurity on the Victorian Government's agenda with the reform of its biosecurity legislation to protect Victoria, and the rest of Australia, from the harmful impacts of exotic and established exotic pests, weeds and diseases.

AMA would expect that the consolidation of Victoria's biosecurity laws into a single new Biosecurity Act will deliver more efficient and effective administration, reduce duplication of regulation, clarify the respective roles and responsibilities of stakeholders, and support effective responses to direct and indirect biosecurity threats.

AMA supports legislative reform that will build a collective vision and purpose to enhance capability, support collaboration and build awareness of biosecurity in Victoria. The reformed legislation should embody the following principles:

- legislation and regulation that is agile, flexible and able to deliver the desired biosecurity outcomes;
- legislation and regulation that reflects both current and emerging biosecurity threats;
- regulation, compliance and enforcement activities that are based on science, proportionate to the biosecurity risk and that minimise the regulatory burden;
- communication, transparency and accountability is embedded in biosecurity systems, actions, processes and decision-making; and
- recognition that biosecurity is a shared responsibility that requires engagement and collaboration across a broad range of stakeholders.

The new legislation should not be overly prescriptive. The Primary Act should clearly identify the purpose and focus on high-level principles. Operational details are more appropriately captured by subordinate legislation, regulations, guidance and practice material that can be more readily adapted or updated to reflect changes in the operating environment and emerging biosecurity issues.

Successful implementation of the reformed legislation will depend on significant further consultation and engagement with stakeholders, particularly those who will be directed affected by biosecurity regulations and requirements. Regular and informative engagement with stakeholders, alongside genuine consultation on regulatory settings, is essential to ensure that the reformed legislation is able to deliver the intended outcomes.

Biosecurity systems must embed effective and efficient communication at the heart of all activities. Efficient and effective communication, collaboration and cooperation between local, regional, state/territory, national and international stakeholders is of paramount importance to ensure biosecurity and regulatory responses are timely, feasible, practical and effective.

Roles and responsibilities in managing biosecurity risks

AMA member companies play a vital role in Australia's biosecurity as the producers of medicines that prevent, control and treat animal diseases, across the livestock, equine and companion animal sectors. AMA members develop, register and supply innovative new medicines, including vaccines and anti-infection medicines to prevent and control outbreaks of animal diseases, as well as medicines and treatments that enable good health and wellbeing.

In the event of an exotic animal disease detection in Victoria, it is critical that veterinary medicines can be obtained quickly and efficiently. It is important that Victoria's biosecurity legislation provides the capability and flexibility to respond quickly to emerging threats and emergency situations, including coordination and collaboration with federal-level frameworks and stakeholders. This could include streamlining the process for emergency use approvals and permits, fast-track systems to source essential veterinary medicines across international, federal and state borders, and risk-based flexibility in satisfying non-critical regulatory requirements.

It is important to seek harmonisation and alignment of state/territory biosecurity arrangements wherever possible and appropriate, to improve understanding and consistent application. However, AMA acknowledges the need for a degree of flexibility and variation to address specific local and

regional-scale biosecurity issues. Effective and efficient communication, collaboration and cooperation between stakeholders at all levels and across jurisdictions is critical to ensure risks are clearly identified and communicated to affected parties, thereby supporting efficient and effective responses that deliver the desired outcomes.

Victorian biosecurity will benefit from active engagement with key industry associations and organisations (such as the Australian Veterinary Association, Animal Health Australia and the Victorian Farmers Federation), as these organisations are conduits for the dissemination of trusted advice. Local authorities and communities are also valuable sources of local knowledge and understanding of potential risks in a specific area.

Individual actions are an essential component of 'on the ground' activities that support everyday management of biosecurity risks, such as on-farm biosecurity protocols and knowledge of disease reporting mechanisms. Engagement and understanding by individuals also facilitates disease surveillance, compliance, and other practical biosecurity measures that may be required. Farmers and local veterinarians are often the first to notice unusual disease activity, so it is critical that they are engaged in and well informed about local biosecurity activities and risks, and their role and responsibilities if a disease occurs, such as notifying authorities, isolating affected animals, and enacting strict biosecurity protocols for entering/leaving properties.

Managing biosecurity risks with reformed legislation

Biosecurity must include effective surveillance of animal disease within state borders, as well as nationally. This will enable responsible authorities and affected stakeholders to detect and track endemic, exotic and emerging diseases that threaten animal health. Surveillance is critically important for diseases that can be transmitted to humans (such as brucellosis or Hendra virus), and for diseases that can persist in the environment to pose a disease threat in the future (such as anthrax).

Wild animals can be important disease reservoirs and vectors and it is important to include surveillance of wild animal populations as well as domestic animals. For example, migratory water birds can carry various strains of avian influenza, fruit bats are known vectors for Hendra virus, and wild pigs could become a reservoir for African swine fever if it enters Australia.

Climate change will pose diverse and growing threats to biosecurity. Most notably, changing environmental conditions will alter the distribution and behaviour of many animal and insect species, in turn leading to changing distributions of vector-borne diseases. Flies, ticks, mosquitoes and rodents are common animal disease vectors that can quickly spread into new areas in favourable environmental conditions where they have not been previously detected or routinely looked for, and where the animal (and human) population may be immunologically naïve. Environmental stressors can result in altered disease transmission routes (if the preferential target species for a mosquito is not found in the new environment, it may feed on a new species) as well as increased infectivity and pathogen virulence. Biosecurity risks posed by changing disease distributions may be subtle and not immediately apparent, hence there is a need to ensure systems are capable of detecting both direct and indirect risks to biosecurity.

A shared biosecurity culture implies a level of trust, stewardship and responsibility for all stakeholders. Care must be taken to ensure that this does not devolve to burdensome regulations that do not

address the problem. Adherence to government guidelines on best practice regulation[1] and close engagement with stakeholders in the animal health industry will help to ensure that regulatory actions and responses are appropriate, realistic, feasible and effective.

Regulatory settings are an important component of biosecurity. The ability of animal health companies to maintain business continuity and the capacity to develop and provide critically important veterinary medicines depends on a regulatory environment that is reliable, efficient and predictable. Disruptions in supply chains related to the COVID-19 pandemic illustrate the need for flexibility and adaptability in the biosecurity system to mitigate the impacts of external stressors when 'business as usual' is not possible. In the case of an exotic animal disease incursion, Australia's ability to respond quickly and effectively (for example, by approving and distributing a new vaccine or treatment, or streamlined import procedures for animal medicines (or ingredients) manufactured overseas) will be critical. Flexibility and adaptability is also needed to ensure the biosecurity workforce is appropriately engaged, trained, resourced, connected and integrated to identify, detect and respond effectively and efficiently to both direct and indirect biosecurity threats, now and in the future.

Summary

AMA recognises that climate change, shifting and unpredictable trade and travel patterns, and changes in land use pose multiple, emerging and complex risks to Australia's animals, people, environment, economy, livelihoods and way of life. Strong biosecurity at international, national, regional and local levels, and industry-led disease preparedness and response processes, including access to disease prevention tools such as vaccines, are central to maintaining animal health and keeping devastating animal diseases out of Australia.

We look forward to further consultation opportunities as the reform process continues. If we can provide further information at any time, please do not hesitate to contact me.

Yours Sincerely,

Dr Charmian Bennett

Director, Science and Policy

(unsigned for electronic submission)

[1] The Office of Best Practice Regulation | OBPR (pmc.gov.au)