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Submitted via email only: Gene.Technology.Implementation@health.gov.au

Regarding proposed regulatory framework to implement recommendations of the Third Review of the National Gene Technology Scheme

Animal Medicines Australia (AMA) is pleased to provide the following comments in response to the Consultation Regulation Impact Statement and Explanatory Paper on modernising and future-proofing the National Gene Technology Scheme.

Animal Medicines Australia (AMA) is the peak body representing the leading animal health companies in Australia. AMA member companies are the innovators, manufacturers, formulators and registrants of a broad range of veterinary medicine products that prevent, control and cure disease across the companion animal, livestock and equine sectors.

To date, interactions between AMA members and the Gene Technology Regulator have primarily concerned animal vaccines. However, gene technologies (GT) and genetic modification (GM) are becoming increasingly important tools in veterinary medicine, just as they are in human medicine. In the future, innovative new veterinary medicines developed using GT may be registered for use in Australia, such as antisera, vector vaccines, antivirals, immunoglobulins and monoclonal antibodies.

AMA supports the regulation of GT and genetically modified organisms (GMOs) in a way that reflects a true level of risk and is based on reliable scientific evidence. We support a science-based regulatory system that allows new technologies to be used to improve animal health and welfare, and protect public health, while preventing unacceptable risks to the health of animals, people or the environment.

Regulatory Principles

As indicated in our previous submissions, AMA supports **a regulatory system for GT that is outcome-focused**, rather than process-driven. The use of a process-based trigger for OGTR consideration is not scientifically justified and has a strong inhibitory effect on the development and commercialisation of potentially beneficial animal medicines in the future. The process-driven approach of the current system reflects the state of knowledge more than 20 years ago when GT was emerging and the National Gene Technology Scheme (NGTS) was first established. The science has advanced exponentially since then and this simplistic treatment of GT is no longer appropriate.

In contrast, a *product*-based classification offers a more balanced approach to risk assessment that is commensurate with the actual level of risk. Many GM products are genetically identical to, and thus indistinguishable from, the same products developed using 'traditional' ('non-GM') methods. For example, genetic modification of livestock has traditionally been achieved through selective breeding through successive generations to promote certain genetic traits, such as polled (hornless) cattle or particular fleece types in sheep. Gene editing techniques can achieve the same end point (i.e. a cow that lacks horn buds) relatively quickly, and with a much greater level of precision and control by targeting only the specific genes associated with the desired trait.

Regulatory Flexibility

An intention to 'future-proof' the gene technology regulatory system is one of the key drivers of this regulatory review, yet the proposal is heavily focused on GT that is already known. The science of GT is advancing rapidly and it is critical that the regulatory system is able to respond to scientific advances in a timely manner. A **'future-proofed' scheme must have the flexibility to accommodate new technologies** as-and-when they are discovered and enable them to be available quickly. This is facilitated most effectively, efficiently and appropriately through a science-based, risk-proportionate regulatory approach that is focused on the product or outcome.

It appears that Option B is most closely aligned with a risk-based, scientifically justified regulatory approach. However, as noted by other industries with considerable expertise and experience in this area, Option B does not offer sufficient scope for future innovation.

In particular, retaining a process-based trigger for consideration by the OGTR means that the system will continue to become outdated and will be in need of frequent updates to keep up with the rapid pace of scientific advances in this area. Delays in such updates will continue to act as a deterrent for investment in the Australian marketplace.

In relation to the other two Options:

> Option A (status quo) – as outlined in previous submissions, AMA supports the need for reform in this area. Maintaining the status quo would represent a lost opportunity to deliver valuable technological advances to Australia.
>
> Option C – this represents an overly complex and convoluted pathway to determining the appropriate regulatory authorisation. Some applications may also require multiple permits, which is a significant regulatory burden that will deter applicants. The system would be difficult to navigate for registrants, thus imposing greater administrative burden on the OGTR to screen applications and provide guidance. It is also unclear whether Option C would confer greater oversight or risk management ability. Option C is not supported by AMA.

Streamlined Regulation

AMA supports measures that will **streamline interactions and reduce duplicative regulation** between OGTR, APVMA and FSANZ. Regulatory duplication confers significant cost, time and uncertainty, thereby strongly discouraging innovation and investment in Australia and deferring the realisation of benefits for animal health and welfare, and agricultural productivity.

Veterinary products are highly specialised, defined-use products and are most appropriately regulated by APVMA as the primary authority. The APVMA has the required expertise to understand and assess the risks to people and the environment associated with the use of a veterinary product, and its registration process carefully considers these factors. There is no additional benefit conferred by the OGTR duplicating the assessment of human health and environmental risks associated with the use of veterinary products. AMA therefore suggests that in the case of veterinary medicines, **the APVMA should be the responsible regulator, with the OGTR providing specialist advice as required.**

If multiple regulatory approvals are required, some streamlining would be possible with the introduction of a **parallel assessment process** between (for example) APVMA and OGTR. At present, veterinary products involving GT must first be registered by OGTR before the APVMA assessment can begin. Mechanisms to support parallel processes by both regulators could offer important efficiencies and streamline the pathway from development to market.

Use of Delegated Legislation

In principle, AMA supports the use of delegated legislation to allow the NGTS to respond more rapidly to technological advances and scientific knowledge. Legislative change is a protracted process that does not support timely responses to emerging technologies and scientific advances. Further, legislative action can be strongly influenced by political pressures that take precedence over scientific evidence.

Further consultation will be needed to identify the broad parameters and principles about matters that are prone to change (most likely to be scientific/technical in nature) and therefore could be altered by the Scheme through this mechanism.

Summary

AMA notes that GT is a rapidly changing field where new technologies are expected to emerge in the future. The regulatory system must therefore be inherently agile and flexible enough to respond to scientific advances appropriately and in a timely manner.

AMA supports regulation that is consistent with the COAG Principles of Best Practice Regulation.[1] These principles ensure that regulatory responses are properly targeted and proportionate.

[1] https://www.pmc.gov.au/resource-centre/regulation/best-practice-regulation-guide-ministerial-councils-and-national-standard-setting-bodies

Principles of Best Practice Regulation

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:-
   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.

(Best Practice Regulation (2007)[1], pg 4)

Of the 3 proposed options, AMA generally supports Option B as this represents a risk-based approach to regulation and includes elements that aim to reduce regulatory burden and duplication. However, there appears to be a strong focus on technologies that are already known and understood, with little flexibility to accommodate future advances that are not yet known. The reform process is slow and it is critical that regulatory reforms remain relevant and effective over time (as in Principle 6 above). GT is highly dynamic and it is not clear that the options in this proposal will be able to satisfy Principle 6.

Overall, AMA is hopeful that reforms to the NGTS that focus on risk assessment and management will encourage the introduction of new innovations to the Australian market and deliver important animal health, welfare and productivity benefits for Australian animals and farmers.

Please let me know if we can provide any further information. We look forward to the next stage of consultation.

Yours sincerely,

(unsigned for electronic submission)

Dr Charmian Bennett
Director, Science and Policy