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Department of Health and Aged Care
Office of the Gene Technology Regulator

Email: ogtr@health.gov.au

Online Submission only.

Dear Sir/Madam,

Re: Proposed minor and technical amendments to the Gene Technology Regulations 2001

Thank you for the opportunity to provide comment on the proposal (the Proposal) to amend the *Gene Technology Regulations 2001*.

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 \$33 billion pet industry. Our members represent more than 90% of registered veterinary medicine sales in Australia.

AMA and its members have a long-standing commitment to an animal health industry that is responsible and sustainable. Our members' products are essential tools that can help meet economic, environmental and social challenges.

AMA member companies play a vital role in Australia's food production, agricultural trade and biosecurity preparedness, as well as ensuring the health and wellbeing of our pets, wildlife and competition animals. 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.

Ensuring access to animal health products is vital to maintaining not only the health and wellbeing of the animals in our care, but also Australia's rigorous biosecurity systems, public health and access to safe, nutritious, affordable food.

Animal Medicines Australia is pleased to provide the following comments on the proposed amendments to the *Gene Technology Regulations 2001* (the Regulations).

Proposed amendments

Administrative proposals

AMA has no objection to the proposed administrative amendments outlined in the Proposal. The proposed amendments improve clarity for stakeholders and ensure alignment with other regulatory frameworks.

Techniques that are not gene technology and organisms that are not GMOs

AMA supports the proposed amendments to Sections 1A and 1, which clarify the techniques and organisms excluded from regulation. The proposed amendments improve alignment between the Regulations and scientific advancements in biotechnology, while ensuring a risk-based approach to the regulation of these technologies.

Transfer of chloroplasts, mitochondria and nuclei

AMA supports the proposal to extend item 11 of Section 1A to include techniques that transfer unmodified nuclei, mitochondria and plastids that do not involve any genetically modified material. The proposed amendment provides clarity for registrants that these techniques are not considered gene technology and will facilitate the use of these techniques, similar to somatic cell nuclear transfer.

Introduction of nucleic acids

AMA supports the proposal to extend item 11 of Section 1A to include technologies such as mRNA vaccines. Clarifying that the application of an mRNA vaccine to an animal is not gene technology, provided that it cannot give rise to an infectious agent, does not alter the organism's genome sequence and, if DNA, cannot be transcribed provides certainty to registrants and veterinarians. As highlighted in the Proposal, introducing RNA that can be transcribed to a protein via a vaccine has an effect equivalent to introducing the expressed protein into an organism by other means and, as mRNAs and their expressed proteins degrade, they have a time-limited effect. Hence, AMA agrees that it is appropriate to regulate this technology in an equivalent manner to applying protein to an organism.

To avoid setting an unrealistic threshold for demonstration of compliance with the conditions associated with this clause, however, AMA recommends that the Regulation be amended to indicate that the technology *is not expected to* or *is not likely to* alter the organism's genome sequence.

The current Regulation requires that:

The introduction of the RNA cannot result in an alteration of the organism's genome sequence.

Amending the condition in a similar manner to that proposed in the *Draft Gene Technology Amendment Bill* in relation to somatic gene therapy, such that the therapy '*does not produce genetic changes in cells that can be inherited by the next generation*' could provide clarity that gene technology resulting in temporary modification where replication is self-limiting.

AMA notes the continued regulation of dealings with RNAs that are, themselves, GMOs. It is, however, unclear whether animals administered a self-amplifying (sa) mRNA vaccine would be considered a GMO. Previous advice received from the Office of the Gene Technology Regulator (OGTR) indicated that sa-mRNA vaccines were considered to be GMOs and requires a DIR (dealing involving intentional release of a GMO) license, as they are 'capable of transferring genetic material.' Further clarity regarding organisms that have been administered sa-mRNA vaccines would be welcome.

AMA supports the proposal to include application of antisense oligonucleotides (ASOs) to item 11 of Schedule 1A (not gene technology).

Exchange of DNA

AMA understands that the Proposal is to clarify that item 6 of Schedule 1 – which describes organisms that are not GMOs that are the result of an exchange of DNA within a species – relates only to microorganisms. The amendment makes clear that this item does not provide an exclusion for higher

organisms with cisgenic and intragenic modification. Nevertheless, AMA recommends that consideration is given to including cisgenic and intragenic organisms in item 6 of Schedule 1. Both of these processes can be achieved through conventional breeding techniques and the risks associated with cisgenic or intragenic modification is similarly negligible to those associated with DNA exchange in microorganisms.

Epigenetic modifications

As outlined in the Proposal, epigenetic modifications do not modify the DNA sequence and can result in changes to the level of gene expression similar to that seen following application of ASOs. While gene technology techniques can induce epigenetic modifications, so can natural environmental stimuli. Consequently, AMA supports the proposal to list organisms with epigenetic modifications as organisms that are not GMOs, provided that the organism has no other modifications that occurred because of gene technology.

Implementation approach

AMA notes that the government intends that amendments to items of Schedule 1A and 1 of the Regulations would commence the day after the Regulations are made and registered. AMA does not have any objections to this implementation approach.

In Summary:

AMA supports:

- The proposal to extend item 11 of Section 1A to include technologies such as mRNA vaccines. Clarifying that the application of an mRNA vaccine to an animal is not gene technology, provided that it cannot give rise to an infectious agent, does not alter the organism's genome sequence and, if DNA, cannot be transcribed provides certainty to registrants and veterinarians.

AMA recommends:

- That the Regulation be amended to indicate that the introduction of nucleic acids is not considered gene technology, providing that it *is not expected to or is not likely to* alter the organism's genome sequence.
- Further clarity regarding whether animals administered a self-amplifying (sa) mRNA vaccine would be considered a GMO.
- That consideration is given to including cisgenic and intragenic organisms in item 6 of Schedule 1. Both of these processes can be achieved through conventional breeding techniques and the risks associated with cisgenic or intragenic modification is similarly negligible to those associated with DNA exchange in microorganisms.

If we can provide further information at any time, please do not hesitate to contact me.

Yours Sincerely,



Dr Katie Asplin

Director, Animal Health Policy and Engagement