Australian Government
Australian Pesticides and
Veterinary Medicines Authority

17/03/2021

Implementation Secretariat
National Gene Technology Scheme
Australian Department of Health
Via email: gene.technology.implementation@health.gov.au

APVMA Submission on the National Gene Technology Scheme Consultation Regulatory Impact Statement

Dear Implementation Secretariat

Thank you for the opportunity to contribute to this consultation process. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for the evaluation, registration and regulation of agricultural and veterinary (agvet) chemicals in Australia.

Live and viable genetically modified organisms (GMOs) that also meet the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) definition of an agvet chemical product fall under the regulatory framework of both the APVMA and the Office of the Gene Technology Regulator (OGTR). Examples of these products include live genetically modified (GM) veterinary vaccines, and GM insect-protected canola and cotton. The APVMA also evaluates the safety, efficacy and trade risk of herbicides used on GM herbicide tolerant crops.

The APVMA is supportive of a risk proportionate approach to the regulation of GMOs that is flexible enough to accommodate new technology while continuing to protect human health and the environment. The APVMA supports independent, science and evidence-based regulation, and considers that this can be delivered though a regulatory model comprised of primary and secondary legislation, including delegated legislation.

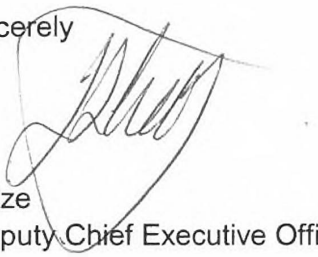
The Consultation Regulation Impact Statement (CRIS) puts forward two options in addition to the status quo. The APVMA notes that Option B (risk tiering model) appears to meet the objectives of the review of the scheme without the level of complexity proposed in Option C (matrix model). As such, Option B is consistent with government principles to reduce regulatory burden, and streamline and simplify legislation.

The APVMA notes that under the current framework, an OGTR licence is not required for a live GM veterinary vaccine (or any agvet chemical) before an application for registration can be made to the APVMA. In the hypothetical scenario on page 16 of the CRIS, applications could be made to the OGTR and the APVMA simultaneously. In this case, the 255 days for the OGTR assessment and the 12 months for the APVMA assessment would run concurrently.

The APVMA also notes the proposed changes to the Gene Technology Account and the purposes for which it can be credited.

Whatever option is chosen, the APVMA is committed to working collaboratively with the OGTR where our work intersects. If you have any questions please contact Bronwyn Battisson on 02 6770 2547 or by email at bronwyn.battisson@apvma.gov.au.

Yours sincerely



Jason Lutze
Acting Deputy Chief Executive Officer