Australian Government
Australian Pesticides and Veterinary Medicines Authority

24 November 2016

Dr Raj Bhula
Gene Technology Regulator
Office of the Gene Technology Regulator
MDP 54 GPO Box 9848
CANBERRA ACT 2601

Dear Dr Bhula Raj

Submission to the Review of the Gene Technology Regulations 2001: Invitation to comment on discussion paper

Thank you for your letter of 17 October 2016 inviting the Australian Pesticides and Veterinary Medicines Authority (APVMA) to make a submission on a discussion paper for options for regulating new technologies.

The APVMA's legislation requires consultation with the Office of the Gene Technology Regulator (OGTR) where applications relate to genetically modified (GM) products[1]. As such, the APVMA welcomes this review, which will assist in improving clarity regarding which organisms meet the definition of 'genetically modified organism' and therefore what products meet the definition of a 'GM product'.

While it is not the APVMA's role to comment on the regulatory scope of the OGTR, the APVMA takes this opportunity to highlight the importance of the collaborative working relationship between the agencies to:

- leverage assessments to avoid duplication,
- ensure no duplication with emerging science, and
- reduce regulatory burden and delays for agricultural industries.

Leveraging assessments to avoid duplication

The APVMA will continue to leverage OGTR assessments when applicable to avoid duplication. While the APVMA is required to be satisfied in relation to the safety, efficacy and trade implications for agvet chemicals, we are focussed on minimising duplication of assessments undertaken. To this end, we are working with applicants to make better use of assessments undertaken by the OGTR.

I note the registration process for the APVMA to assess a GM product includes consideration of matters where there is no regulatory overlap, such as crop safety, label claims such as efficacy statements, and trade impacts. The APVMA will continue

[1] Section 8A of the Agricultural and Veterinary Chemicals (Administration) Act 1992

to seek advice from OGTR on these issues where required. In addition, where it is possible to leverage OGTR processes, for example, in the area of research permits, there is no duplication of assessment as the APVMA uses the controlled release licence issued by OGTR.

Collaboration to ensure no duplication with emerging science

The main GM products for which the APVMA receives registration applications for are products that contain recombinant DNA. The APVMA will continue to consult and seek OGTR advice on GM questions and issues about agvet products. Furthermore, the APVMA will continue to work with OGTR on areas of emerging science to minimise duplication in assessment, or delays in the registration of new technologies.

Reduction in regulatory burden for the agricultural industries

The APVMA is aware of the Department of Agriculture and Water Resources reform process around the potential removal of viable seeds from the scope of regulation under the *Agricultural and Veterinary Chemicals Code 1994*. The APVMA notes the seeds for plants, genetically modified to be more resistant to pest pressures, are regulated by the APVMA as an agricultural chemical product and also by the OGTR. In the event this reform is adopted by government to reduce the regulatory burden on the agricultural industry, the APVMA will work with the Department and OGTR to provide clarity for industry.

The APVMA is also supportive of any ideas to achieve regulatory excellence between our agencies and reduce the regulatory burden for agricultural industries that may arise from this consultation process.

I look forward to continuing to work together and provide support for industry on regulating new technologies. If you require further information, please contact Dr Phil Reeves, Chief Scientist on or .

Yours sincerely

KAREENA ARTHY
Chief Executive Officer