Commonwealth of Australia Gazette

Published by the Commonwealth of Australia

GOVERNMENT NOTICES

Australian Government

Department of Health

Office of the Gene Technology Regulator

6 March 2018

Invitation to comment on field trials of genetically modified (GM) vaccines for farmed crocodiles

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is currently assessing licence application DIR 159 from the University of Queensland. The application is for field trials, under limited and controlled conditions, of two insect-specific viruses, genetically modified as potential vaccines against *Kunjin virus* infection in farmed crocodiles. The purpose of the trials is to assess the efficacy and safety of the vaccine under farm conditions.

The trials are proposed to take place in two crocodile farms in the Northern Territory, over a five year period. The applicant proposes a number of control measures to restrict the spread and persistence of the GMOs and their genetic material. As is common in veterinary vaccine trials, the vaccinated crocodiles could enter general commerce, including use in human food or animal feed.

Use of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The University of Queensland will need to apply to the APVMA for a permit to allow the supply and limited use of the GM vaccine for the purpose of conducting research.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment. A range of draft licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and the introduced genetic material.

The Regulator welcomes written submissions in order to finalise the RARMP, which will then inform the decision on whether or not to issue the licence. The consultation RARMP and related documents can be obtained from the OGTR website under What's New or by contacting the Office. Please quote application DIR 159 in any correspondence.

Submissions should be received by close of business on **10 April 2018**.

Office of the Gene Technology Regulator, MDP 54, GPO BOX 9848 CANBERRA ACT 2601
Telephone: 1800 181 030 Facsimile: 02 62894044 E-mail: ogtr@health.gov.au
OGTR website www.ogtr.gov.au