Questions & Answers on licence application DIR 159 – field trials of genetically modified (GM) vaccines for farmed crocodiles

What is this application for?

The University of Queensland is seeking approval to trial, under limited and controlled conditions, two live genetically modified (GM) insect-specific viruses for the protection of crocodiles against *Kunjin virus*. *Kunjin virus* infection in crocodiles can produce skin lesions which impact the processing of crocodile skin for leather goods. The proposed trials would take place on two crocodile farms in the Northern Territory, over a five year period. A total of up to 2800 juvenile crocodiles are expected to be vaccinated during the trial.

The trial would assess the efficacy and safety of the GM vaccines for crocodiles under farm conditions.

What other regulatory processes apply to this trial?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulate agricultural and veterinary chemical products, including veterinary vaccines. For commercial products, the normal form of approval is through registration. The APVMA also issues permits to allow the limited use of an unregistered product in certain circumstances, for example to enable collection of data to support an application for registration (e.g. safety and efficacy). The APVMA can impose conditions on the use of veterinary products in registrations and permits. The applicant has indicated that they will apply to APVMA for a research permit.

How have the GM vaccines been created?

The parent organisms are two distinct insect-specific viruses normally associated with mosquitoes in northern Australia. These viruses are not known to cause disease in infected mosquitoes and are not able to replicate or cause disease in humans or other animals.

To generate the GM vaccine strains, two genes that code for *Kunjin virus* proteins were introduced in place of the corresponding genes of the parental viruses. The GMOs are intended stimulate an immune response in the crocodiles to protect against *Kunjin virus* infection.

Has the GM vaccine been previously tested or used?

These GM viral vaccine strains have undergone limited testing in the laboratory, demonstrating that they are not able to replicate in vertebrate cells. They have not previously been tested in the environment.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the proposed release poses negligible risks to people or the environment. However, a range of licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and its introduced genetic material. Proposed control measures include limiting access to the site to authorised staff; keeping vaccinated crocodiles physically separated from non-vaccinated crocodiles; and appropriate waste disposal. As is common in veterinary vaccine trials, vaccinated crocodiles could enter general commerce, including use in human food or animal feed, however this would only be permitted once testing confirms that the GM viruses are no longer present. Full details of the draft licence conditions are set out in the RARMP, which is now available for comment.

How can I comment on this application?

You are invited to submit your comments on the consultation version of the RARMP that has been prepared for application DIR 159. The full consultation RARMP and a summary are available on the What's New page of the OGTR website or via the Freecall number below. Your advice would be appreciated on any risks to the health and safety of people or to the environment that may be posed by the proposed release. Please note that the consultation period closes on **10 April 2018** and written submissions are required by that date.

Submissions relating to the protection of people or the environment in connection with the proposed release are taken into account in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.

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