Questions & Answers on licence application DIR 195 – Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils

What is this application for?

The University of Tasmania is seeking approval for a trial with a genetically modified (GM) vaccine for the prevention and/or treatment of devil facial tumour disease (DFTD), a transmissible cancer that affects Tasmanian devils. The disease is transmitted from one devil to another by biting and leads to the development of tumours on the face or inside the mouth of affected animals. DFTD has caused a significant decline in the wild population of Tasmanian devils over the last decades.

The proposed trial would be conducted within contained trial sites in Tasmania. Up to 22 Tasmanian devils would receive the GM vaccine in the trial.

What other regulatory processes apply to this trial?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemical products, including animal vaccines. The APVMA issues permit to allow testing of a new product during its development. The APVMA can impose conditions on the use of veterinary products in their registrations and permits. The University of Tasmania would also require a permit from APVMA to conduct the trial with the GM vaccine if they are granted a licence by the Gene Technology Regulator. In addition, the University of Tasmania would require approval by the relevant Tasmanian authority, the Department of Natural Resources and Environment Tasmania, to conduct the trial.

How has the GM vaccine been produced?

The GM vaccine is based on an adenoviral vector. It has been modified by the deletion of genes so that it cannot multiply or cause disease. Additionally, the GM vaccine contains genes to produce proteins able to induce an immune response against devil facial tumour cells. The GM vaccine is expected to protect devils against future exposure to DFTD.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) prepared for this application concluded that the trial poses negligible risks to people or the environment. However, as this is a trial under limited and controlled conditions, a number of licence conditions have been drafted to restrict when and where the trial can take place, limit the size of the trial, and restrict the spread and persistence of the GM vaccine. For example, there are conditions relating to preparation and administration of the GM vaccine, secure transport and storage of the GM vaccine and appropriate waste disposal. Full details of the draft licence conditions are available in the consultation RARMP.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 195 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed trial. Please note that issues such as **target animal safety, quality and efficacy of a veterinary product, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **12 May 2023.**

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

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