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

**What does this licence allow?**

The University of Tasmania is conducting a trial, under limited and controlled conditions, of a genetically modified (GM) vaccine for the prevention and/or treatment of devil facial tumour disease (DFTD) in Tasmanian devils. DFTD is a transmissible cancer that affects Tasmanian devils. It 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. This disease has caused a significant decline in the wild population of Tasmanian devils over the last decades.

The trial will be conducted within contained trial sites in Tasmania. Up to 22 Tasmanian devils will 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 will also require a permit from APVMA to conduct the trial with the GM vaccine. In addition, the University of Tasmania will 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 deleting genes so that it cannot multiply or cause disease. Additionally, the GM vaccine contains genes to produce proteins designed 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 imposed for this release?**

The 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 imposed 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 licence conditions are available in the licence.

**Want more information?**

A number of documents relating to this decision are available on the DIR 195 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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