



Summary of Licence Application DIR 195

The University of Tasmania (UTAS) has made an application under the *Gene Technology Act 2000* (the Act) to conduct a limited and controlled trial using a genetically modified organism (GMO).

Project Title	Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils
Parent organism	Human adenovirus serotype 5 (HAdV5)
Genetic modifications	<ul style="list-style-type: none">• Deletion of viral early-transcribed region 1 (E1) - to render virus unable to multiply• Deletion of viral early-transcribed region 3 (E3) - to increase host immune response to the virus• Insertion of antigen genes – to induce host immune response against tumour cells
Principal purpose	The proposed trial aims to evaluate the immunogenicity, safety and efficacy of a genetically modified (GM) vaccine in Tasmanian devils for the prevention and/or treatment of devil facial tumour disease
Previous trials	The proposed study would be the first trial to be conducted with the GMO
Proposed limits and controls	
Proposed duration	5 years
Proposed locations	Two contained trial sites in Tasmania
Proposed controls	<ul style="list-style-type: none">• only registered veterinarians would administer the GMO• only trained and authorised personnel would access the animal enclosures• personnel would use personal protective equipment (PPE)• transport, storage and disposal of the GMO would be carried out according to the OGTR <i>Guidelines for the Transport, Storage and Disposal of GMOs</i>

The application

Devil facial tumour disease (DFTD) is 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 University of Tasmania is seeking approval for a trial of a GM vaccine in Tasmanian devils. The GM vaccine consists of a replication defective human adenovirus serotype 5 (HAdV5) vector that has been genetically modified to produce proteins capable of inducing an immune response against devil facial tumour cells.

The purpose of the trial is to evaluate the immunogenicity, safety and efficacy of the GM vaccine for the prevention and/or treatment of devil facial tumour disease. The GM vaccine would be administered to Tasmanian devils kept in contained enclosures in Tasmania.

Supply of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). UTAS 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.

The application is for limited and controlled release under section 50A of the Act, as the Regulator was satisfied that its principal purpose is to enable the applicant to conduct the trial, and the proposed limits and controls are such that consultation with prescribed experts, agencies and jurisdictions is not required at this stage.

Next steps

The Gene Technology legislation sets out what the Regulator must do, as well as what the Regulator can or must consider, before deciding whether or not to issue a licence for this application.

The Regulator's staff will prepare a consultation version of the Risk Assessment and Risk Management Plan (RARMP) considering aspects of the application including the proposed limits and controls in accordance with the legislation.

The Regulator will seek comment on the consultation RARMP from the public, as well as a wide range of experts, agencies and authorities. The public and experts will be invited to provide submissions on the risks to human health and safety, and on risks to the environment from the proposed trial.

At this stage, the consultation RARMP is expected to be released for comment in **March 2023**.

After consultation, the Regulator's staff will finalise the RARMP, taking into account advice on relevant matters. The finalised RARMP will form the basis of the Regulator's decision whether or not to issue a licence. The consultation and final versions of the RARMP and associated documents will be available on the [OGTR website](#) when they are released.

Other information available from the [OGTR website](#):

- information on Australia's national scheme for regulation of gene technology and
- information on the DIR application process.

Please use the contact details below, if you

- would like a copy of the application. Please include the identifier DIR 195.
- have any questions about the application or the legislated evaluation process or
- wish to register on the mailing list.

The Office of the Gene Technology Regulator, MDP 54, GPO Box 9848, Canberra ACT 2601

Telephone: 1800 181 030

Email: ogtr@health.gov.au