Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

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Summary of the Risk Assessment and Risk Management Plan (Consultation Version)

for

Licence Application No. DIR 195

Introduction

The Gene Technology Regulator (the Regulator) has received a licence application to conduct a trial using a genetically modified organism (GMO). It qualifies as Dealings involving the Intentional Release (DIR) of genetically modified organisms into the Australian environment under the *Gene Technology Act 2000*.

The applicant, University of Tasmania (UTAS), proposes to conduct a trial with a GM vaccine in Tasmanian devils. The GM vaccine consists of a replication defective human adenovirus serotype 5 (HAdV-5) vector that has been genetically modified to produce proteins capable of inducing an immune response against devil facial tumour cells.

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

Veterinary medicines must be approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA), which provides a national registration scheme for agricultural and veterinary chemical products under the *Agricultural and Veterinary Chemicals Code Act 1994* (AgVet Code), including vaccines. Therefore, in addition to approval by the Regulator, the University of Tasmania would require a permit from APVMA to use this GM vaccine.

The Regulator has prepared a draft Risk Assessment and Risk Management Plan (RARMP) for this application, which concludes that the proposed trial poses negligible risk to the health and safety of people and the environment. Licence conditions have been drafted for the proposed trial. The Regulator invites submissions on the RARMP, including draft licence conditions, to inform the decision on whether or not to issue a licence.

The application

Project Title	Trial of a genetically modified vaccine against devil facial tumour disease in Tasmanian devils[1]
Parent organism	Human adenovirus serotype 5 (HAdV-5)
Genetic modifications	• 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 GM vaccine in Tasmanian devils for prevention and/or treatment of devil facial tumour disease
Previous trial	The proposed study would be the first trial to be conducted with the GM vaccine.
Proposed limits and controls	
Proposed duration	5 years
Proposed trial size	22 Tasmanian devils
Proposed locations	Two contained trial sites in Tasmania
Proposed controls	• only registered veterinarians would administer the GMO • only trained and authorised personnel would access the trial sites • personnel would use personal protective equipment (PPE) • transport, storage and disposal of the GMO would be carried out according to the OGTR *Guidelines for the* T*ransport, Storage and Disposal of* GMOs.

Risk assessment

The risk assessment concludes that risks to the health and safety of people or the environment from the proposed trial are negligible. No specific risk treatment measures are required to manage these negligible risks.

The risk assessment process considers how the genetic modifications and proposed activities conducted with the GMO might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, considering information in the application (including proposed controls), relevant previous approvals and current scientific/technical knowledge. Both the short- and long-term impact are considered.

[1] The title of the project as supplied by the applicant is "*Limited and controlled release of a genetically modified adenoviral vaccine for Tasmanian devils*"

Credible pathways to potential harm that were considered include the; potential exposure of people and animals other than the Tasmanian devils to the GMO; and the potential for the GMO to transfer or acquire genetic material from other viruses. The potential for the GMO to be released into the environment and its effects were also considered.

Important factors in reaching the conclusions of the risk assessment included that the GMO is replication defective, and unintended exposure to the GMOs would be minimised by the proposed limits and controls measures.

As risks to the health and safety of people, or the environment, from the proposed trial of the GMO treatment have been assessed as negligible, the Regulator considers that the dealings involved do not pose a significant risk to either people or the environment.

Risk management

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions. Draft licence conditions are detailed in Chapter 4 of the RARMP.

As the level of risk is considered negligible, specific risk treatment is not required. However, since this is a trial, the draft licence includes limits on the number of animals included in the trial, types of facilities used, limits on the duration of the trial, as well as a range of controls to minimise the potential for the GMO to spread in the environment. In addition, there are several general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any unintended effects.