

QUESTIONS & ANSWERS ON DECISION ON LICENCE APPLICATION DIR 050/2004: VACCINATION OF CATTLE WITH GENETICALLY MODIFIED BOVINE HERPESVIRUS VACCINES

What is this decision ?

The Queensland Department of Primary Industries and Fisheries has been issued a licence to conduct a trial of genetically modified (GM) bovine herpesvirus vaccines in live cows under limited and controlled conditions.

What is the purpose of the trial?

The purpose of the trial is to evaluate the safety and effectiveness of the GM vaccines in protecting cattle from infection by type 1 *Bovine herpesvirus* (BoHV-1) and from the bovine pestivirus *Bovine viral diarrhoea virus* (BVDV), and from secondary infections.

BoHV-1 can cause both respiratory and reproductive tract infections, while BVDV is one of the most common viral diseases of cattle in Australia, causing symptoms such as pneumonia and diarrhoea. Both viruses can cause bovine respiratory disease, commonly known as 'shipping fever', which renders the animals susceptible to debilitating and sometimes fatal viral or bacterial infections.

When and where will the release occur ?

The trial will be conducted over 5 years from July 2005 in a certified animal containment facility in Queensland and will involve the inoculation of up to 180 cattle of 4-6 months of age with the vaccines. The vaccinated cattle will be held in the facility for up to 6 weeks to enable their immune response to the vaccines to be tested.

How have the GM bovine herpesvirus vaccines been modified ?

The GM bovine herpesvirus vaccines have been modified by the introduction of one of two genes from BVDV and/or by the introduction of a gene from jellyfish. As with conventional vaccines, the proteins produced by the BVDV genes are expected to stimulate the immune system of the vaccinated cattle to produce protective antibodies. The jellyfish protein (green fluorescent protein) will enable vaccinated animals to be distinguished from naturally infected animals.

Is this the first release of these GM vaccines ?

Yes, they were developed by the applicant. However, similar non-GM vaccines have been approved for release in Australia and in other countries.

Will any of the cattle from this trial be used for human or animal food ?

No. The cattle will be euthanased and incinerated.

What controls have been imposed for this release ?

A range of licence conditions have been imposed to minimise the exposure of people and other organisms to the GM vaccines and to prevent the GMOs or their introduced genetic material leaving the trial site. These conditions include:

- limiting the size and duration of the release;
- conducting the release in approved animal containment facilities;
- wearing personal protective equipment;
- transport and storage in accordance with OGTR guidelines;
- monitoring the trial site to ensure that GMOs do not persist.

Full details of the imposed licence conditions are set out in the final version of the Risk Assessment & Risk Management Plan that was prepared for this application and formed the basis of the Regulator's decision to issue this licence.

The finalised RARMP, which also includes a summary of the submissions received through the consultation process with expert groups and the public, and/or an Executive Summary are available on the OGTR website (www.ogtr.gov.au under 'What's New?') or via Freecall 1800 181 030.