Questions & Answers on licence application DIR 154 – field trials of genetically modified (GM) vaccine for chickens

What is this application for?

Bioproperties Pty Ltd is seeking approval to trial, under limited and controlled conditions, a live attenuated GM vaccine, Vaxsafe® ILT, for the protection of chickens against infectious laryngotracheitis virus. The proposed trials would take place on selected chicken farms in New South Wales and Victoria, over a five year period. Up to 2 million broiler chickens would be vaccinated during the trial.

What is the purpose of the trial?

The purpose of the trial is to assess the efficacy and safety of the vaccine for chickens raised under farm conditions.

What other regulatory processes apply to this trial?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) regulates agricultural and veterinary chemical products, including veterinary vaccines. The APVMA has issued a permit to Bioproperties Pty Ltd to allow the supply and limited use of the GM vaccine to inoculate broiler chickens for the purpose of conducting research. The permit includes instructions for the use, storage and disposal of the vaccine, and imposes biosecurity measures for poultry production.

How has the GM vaccine been created?

The parent organism is Infectious laryngotracheitis virus (ILTV), the causative agent for infectious laryngotracheitis (ILT), an acute respiratory disease mainly affecting chickens. Although ILTV can potentially infect some other bird species such as turkeys, peafowls and pheasants, it does not infect people or other animals.

The GM vaccine strain was created through the removal of one gene from an Australian isolate of ILTV. Removal of this gene is intended to attenuate the virus, such that it does not cause severe disease in vaccinated chickens, but is still able to stimulate an immune response which can protect against later infection by ILTV.

Has the GM vaccine been previously tested or used?

This GM vaccine has not previously been released into the environment in Australia or elsewhere. However laboratory studies found that the GM virus produced milder symptoms than the unmodified ILTV strain, and inoculation with the GM virus protected chickens from later infection by the unmodified strain.

What controls are proposed for this release?

The consultation Risk Assessment and Risk Management Plan (RARMP) for this application concludes that the proposed release poses negligible risks to people or the environment. However, a range of licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and its introduced genetic material. Proposed control measures include administration of the GM vaccine only by trained staff under supervision of a registered veterinarian; limiting access to the site to authorised staff; shed entry and exit procedures for staff; not harvesting chickens until at least 28 days after treatment; decontamination of sheds and equipment; and appropriate waste disposal. As is common in veterinary vaccine trials, the vaccinated chickens could enter general commerce, including use in human food or animal feed. Full details of the draft licence conditions are set out in the RARMP, which is now available for comment.

How can I comment on this application?

You are invited to submit your comments on the consultation version of the RARMP that has been prepared for application DIR 154. The full consultation RARMP and a summary are available on the What's New page of the OGTR website or via the Freecall number below. Your advice would be appreciated on any risks to the health and safety of people or to the environment that may be posed by the proposed release. Please note that the consultation period closes on **27 June 2017** and written submissions are required by that date.

What are the next steps in the evaluation process?

Submissions relating to the protection of people or the environment in connection with the proposed release are taken into account in finalising the RARMP, which will then inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

Tel: 1800 181 030 E-mail: ogtr@health.gov.au

OGTR Website