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

What does this licence allow?

Bioproperties Pty Ltd has received approval from the Gene Technology Regulator 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 trial 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 may protect against later infection by ILTV.

What controls are imposed on this release?

The Risk Assessment and Risk Management Plan (RARMP) for this application concluded 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. The control measures imposed include isolating the trial sites at least 1 km from poultry located on other poultry farms, administration of the GM vaccine only by trained and supervised personnel; limiting access to the site to authorised persons; shed exit procedures for people; not harvesting and transporting chickens to processing facilities until at least 14 days after treatment or if displaying virus symptoms; 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. A full list of the control measures is detailed in the licence.

Want more information?

A number of documents relating to this decision are available on the DIR 154 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised RARMP, a summary of the RARMP and the licence.

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