Questions & Answers on licence DIR 193 – Commercial supply of a genetically modified (GM) vaccine against infectious laryngotracheitis virus in chickens

What does this licence allow?

Bioproperties Pty Ltd received an approval under the *Gene Technology Act 2000* to transport, store, dispose and test various modes of administration associated with the commercial supply of a GM vaccine against infectious laryngotracheitis virus (ILTV) in chickens within Australia.

What is infectious laryngotracheitis virus?

Infectious laryngotracheitis virus causes infectious laryngotracheitis (ILT). ILT is an acute respiratory disease mainly affecting chickens. Infection with ILTV can result in severe production loss due to weight loss, decreased egg production and death of infected chickens. Although ILTV can potentially infect some other bird species such as turkeys, peafowls and pheasants, it does not infect people or other animals.

How has the GM vaccine been made?

The GM vaccine strain was produced through the removal of one gene from an Australian strain of ILTV. Removal of this gene stops the virus causing severe disease in vaccinated chickens, but it is still able to stimulate an immune response which can protect against later infection by ILTV.

What is the purpose of the commercial supply?

The commercial supply of the GM vaccine is for the vaccination of chickens to protect them from ILTV infection. Chickens would usually only be vaccinated if there is an outbreak of ILTV in the area.

Has the GM vaccine been previously tested or used?

Field trials of the GM vaccine were approved under DIR-154 and APVMA permits. Field trials showed that the vaccine was able to protect chickens from ILT disease and it did not harm people or the environment.

What is the role of OGTR in approving the vaccine?

The Gene Technology Regulator (Regulator) has a specific responsibility to protect the health and safety of people, and to protect the environment by identifying any risks posed by or as a result of gene technology, and by managing those risks through regulating dealings with genetically modified organisms. The Regulator must issue an approval before the vaccine can be distributed.

What controls have been imposed for this GM vaccine against ILTV?

The licence is for an ongoing commercial release. The vaccine is also subject to authorisation from the APVMA. As the GM vaccine is yet to be registered with the APVMA, the Regulator has imposed specific measures to manage risk, as the risk assessment concluded that this release of the GM vaccine against ILTV poses negligible risks to the health and safety of people and low to moderate risks to the environment. Additionally, general conditions have been imposed to ensure that there is ongoing oversight of the release.

Want more information?

A number of documents relating to this decision are available on the DIR-193 page of the OGTR website or via Freecall 1800 181 030. These documents include the finalised Risk Assessment and Risk Management Plan (RARMP), a summary of the RARMP and the licence.

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OGTR Website