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

What is this application for?

Bioproperties Pty Ltd is requesting a licence for the transport, storage and disposal of a GM vaccine against infectious laryngotracheitis virus (ILTV) in chickens, as part of its commercial supply in Australia. The application also would include testing the efficiency of various modes of administration of the vaccine in protecting chickens from ILT infection.

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 loses 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.

What other regulatory processes apply to this commercial supply?

The vaccine must also be authorised by the Australian Pesticides and Veterinary Medicines Authority (APVMA) prior to commercial supply. The APVMA regulates agricultural and veterinary chemical products, including veterinary vaccines.

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 Office of the Gene Technology Regulator (OGTR) regulates work with genetically modified organisms to protect people and the environment. The vaccine is also subject to authorisation from the APVMA. As the GM vaccine is yet to be registered with the APVMA, licence conditions drafted in the consultation RARMP ensure that any risks are managed and there is ongoing oversight of the release.

How can I comment on this application?

The full consultation RARMP and a summary of the RARMP for application DIR 193 are available on the OGTR website or via the contacts listed below. You are invited to submit your written comments (including email) on the consultation version of the RARMP, related to any risks to the health and safety of people or to the environment from the proposed release. Please note that issues such as **vaccine recipient safety, quality and efficacy of a veterinary product, and marketability and trade implications** do **NOT** fall within the scope of the evaluations conducted under the *Gene Technology Act 2000* as these are the responsibility of other agencies and authorities. Comments must be received by the close of the consultation period on **21 December 2022**.

What are the next steps in the evaluation process?

The RARMP will be finalised, taking into account submissions related to the protection of people or the environment. A de-identified summary of all comments received, and consideration of those comments is included in the Appendices to the final RARMP. The finalised RARMP will inform the Regulator's decision on whether or not to issue a licence.

The Office of the Gene Technology Regulator

OGTR Website

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