Questions & Answers on licence application DIR 193 – Commercial supply of a genetically modified (GM) vaccine for chickens

What is this application for?

Bioproperties Pty Ltd is seeking approval for the commercial supply of a genetically modified (GM) vaccine for chickens, Vaxsafe® ILT, to protect chickens against infectious laryngotracheitis (ILT) virus. This virus causes a highly contagious lung disease mainly affecting chickens. Although ILT virus can potentially infect some other bird species such as turkeys, peafowl and pheasants, it does not infect people or other animals. The proposed vaccination would take place in chicken farms throughout Australia and would be ongoing from the date of issue of the licence.

What other regulatory processes apply to this commercial vaccine?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) administers the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code) to regulate agricultural and veterinary chemical products, including veterinary vaccines. For commercial products, the normal form of approval is through registration. The APVMA can impose conditions on the use of veterinary products in registrations and permits.

How has the GM vaccine been created?

The GM vaccine was produced through the removal of one gene from the ILT virus. Removal of this gene is intended to weaken the virus, so that the vaccine does not cause disease in vaccinated chickens but is still able to produce an immune response which can protect against later infection by the ILT virus.

Has the GM vaccine been previously tested or used?

The GM vaccine has been previously approved for trials to vaccinate broiler chickens against the ILT virus in selected chicken farms in rural Victoria and New South Wales.

Laboratory studies found that the GM virus produced milder symptoms than the ILT virus, and vaccination with the GM virus protected chickens from later ILT infection.

What is the process for considering this application?

The licence application will be subject to comprehensive, science-based risk analysis. The process includes two rounds of stakeholder consultation. In the first round, the Regulator will seek advice from prescribed experts, agencies and authorities prior to preparing a draft Risk Assessment and Risk Management Plan (RARMP). The RARMP focuses on identifying risks to people and to the environment that may be posed by the commercial release. Following public release of the draft RARMP, submissions will again be sought from stakeholders, this time including the public. The RARMP will then be finalised, taking into account submissions received, and will inform the Regulator's decision whether or not to issue a licence.

How can I comment on this application?

The comprehensive RARMP for this application is expected to be released for public comment in **October 2022**. Its release will be advertised in newspapers, and it will be available on the OGTR website along with a range of supporting information. While comment is not being sought from the public at this stage, you can obtain a copy of the full application by contacting the OGTR. Please quote the application number DIR 193. A summary of the application is available on the OGTR website under 'DIR 193' or by contacting the OGTR.

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