Questions & Answers on licence DIR 125 – Commercial release of genetically modified poultry vaccine

What does this licence allow?

Zoetis Australia Research & Manufacturing Pty Ltd (Zoetis) has received approval for the commercial release of a genetically modified (GM) poultry vaccine. The GM vaccine is intended for use on commercial poultry farms, to protect chickens from disease caused by *Escherichia coli* infection. The approval by the Gene Technology Regulator (the Regulator) enables Zoetis to import, transport, store and dispose of the GM chicken vaccine. Before it can be used on commercial chicken farms, Zoetis needs approval from other regulatory agencies and government departments as well.

What other regulatory approvals are required?

The Australian Pesticide and Veterinary Medicines Authority (APVMA) administers legislation to regulate agriculture and veterinary chemical products, including vaccines. The APVMA ensures that vaccines for use in Australia are suitably formulated, are of acceptable quality, are properly labelled and, when used according to the instructions, are safe, efficacious and do not unduly prejudice trade. If approval is granted by the APVMA, the vaccine is likely to be classified as a prescription animal remedy and would require supervision by a registered veterinarian to be used in commercial poultry farms. As part of the assessment of the GM chicken vaccine, the APVMA will consider the risk posed by the presence of residual vaccine in meat and eggs of chickens.

The Department of Agriculture administers Australian biosecurity conditions for the importation of biological products under the Quarantine Act, 1908. These products include animal or microbial derived products such as foods, therapeutics, laboratory materials and vaccines (including GM). An approval will also be required from the Department of Agriculture to import the GM vaccine.

How has the GM *Escherichia coli* been modified?

A disease causing *E. coli* was isolated from an infected chicken. This *E. coli* was genetically modified by deleting part of a gene, *aroA*. The resulting GM *E. coli* cannot make some essential nutrients and does not cause disease in chickens. Nevertheless, it can help provide immunity to some disease causing *E. coli* strains. The GM *E. coli* is sensitive to the same antibiotics as its parent.

Will the GM vaccine be harmful to people, birds, or other animals?

The risk assessment did not identify any substantive risks to people or the environment. The vaccine is already approved for use as a poultry vaccine in the USA, the EU and other countries. World-wide, approximately 5 billion doses of the vaccine have been applied to poultry without any confirmed adverse effects.

What controls have been imposed for this GM chicken vaccine?

The licence is for an ongoing commercial release. The Regulator has not imposed any specific measures to manage risk, as the risk assessment concluded that this release of GM *E. coli* poses negligible risks to the health and safety of people and the environment. However, 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 125 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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