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Department of Health

Office of the Gene Technology Regulator

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Invitation to comment on field trials of a genetically modified (GM) vaccine for chickens

Australia's gene technology regulatory system is designed to protect the health and safety of people and the environment by identifying risks posed by, or as a result of, gene technology and managing those risks.

The Gene Technology Regulator is currently assessing licence application DIR 154 from Bioproperties Pty Ltd. The application is for field trials, under limited and controlled conditions, of a live attenuated GM vaccine, Vaxsafe® ILT, for the protection of chickens against infectious laryngotracheitis virus. The purpose of the trials is to assess the efficacy and safety of the vaccine under farm conditions.

The trials are proposed to take place on selected chicken farms in New South Wales and Victoria, over a 5 year period. As is common in veterinary vaccine trials, the vaccinated chickens could enter general commerce, including use in human food or animal feed.

Use of veterinary products also requires approval by the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA has issued a permit to Bioproperties Pty Ltd to allow the supply and limited use of the GM vaccine for the purposes of conducting research.

A consultation Risk Assessment and Risk Management Plan (RARMP) has been prepared, which concludes that the proposed release would pose negligible risk to human health and safety or to the environment. A range of draft licence conditions would limit the scale, location and duration of the release, as well as restrict the spread and persistence of the GMO and the introduced genetic material.

The Regulator welcomes written submissions in order to finalise the RARMP, which will then inform the decision on whether or not to issue the licence. The consultation RARMP and related documents can be obtained from the OGTR website under What's New or by contacting the Office. Please quote application DIR 154 in any correspondence.

Submissions should be received by close of business on **27 June 2017**.

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