



Australian Government  
Department of Health  
Office of the Gene Technology Regulator

5 September 2014

## Invitation to comment on a proposed commercial release of genetically modified (GM) *E. coli* chicken vaccine

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 125 from Zoetis Australia Research and Manufacturing Pty Ltd for a commercial release of Poulvac *E. coli*® poultry vaccine that has been genetically modified to provide immunity to *E. coli* infection and disease. Subject to any State government requirements imposed for marketing reasons and approvals by other regulatory authorities, the proposed release would be Australia wide.

The GM vaccine will be subject to any State government requirements imposed for marketing reasons as well as to approval by other relevant regulatory authorities, including the Australian Pesticides and Veterinary Medicines Authority, which regulates the use of vaccines in chickens.

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. Draft licence conditions are proposed to ensure ongoing oversight of the release.

The Regulator welcomes written submissions to inform the decision on whether or not to issue a 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 125 in any correspondence.

Submissions should be received by close of business on **31 October 2014**.

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