Australian Government
Department of Health
Office of the Gene Technology Regulator

18 December 2014

Issue of licence DIR 125 to Zoetis Australia Research and Manufacturing Pty Ltd for the commercial release of GM *E. coli* chicken vaccine

On 5 September 2014, the Gene Technology Regulator (the Regulator) invited submissions on the consultation version of the Risk Assessment and Risk Management Plan (RARMP) for licence application DIR 125 from Zoetis Australia Research and Manufacturing Pty Ltd (Zoetis).

The Regulator has now issued a licence in respect of application DIR 125, authorising the commercial release of *E. coli* chicken vaccine genetically modified to provide immunity to *E. coli* infection and disease for the purpose of import, transport, storage and disposal.

The GM vaccine is 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.

The decision to issue the licence was made after extensive consultation on the RARMP with the public, State and Territory governments, Australian Government agencies, the Minister for the Environment, the Gene Technology Technical Advisory Committee, and local councils, as required by the *Gene Technology Act 2000* and the corresponding State and Territory legislation.

Issues raised relating to the health and safety of people and the protection of the environment were considered in the context of current scientific information in reaching the conclusions in the finalised RARMP and in making the decision to issue the licence.

The finalised RARMP concludes that this commercial release poses negligible risks to people and the environment and does not require specific risk treatment measures. However, general licence conditions have been imposed to ensure ongoing oversight of the release.

Appendices A and B of the RARMP summarises the advice that was received from prescribed experts, agencies and authorities in the two rounds of consultation, and indicate how issues raised relating to risks to human health and safety or the environment were considered in the document. Three submissions were received from the public on the consultation RARMP, and the issues raised are summarised in Appendix C of the RARMP.

A Summary and the complete finalised RARMP, together with a set of Questions and Answers on this decision and a copy of the licence, can be obtained on-line from the DIR 125 page of the Office of the Gene Technology Regulator's website or requested via the contacts detailed below.

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