Australian Government
Department of Health
Office of the Gene Technology Regulator

18 December 2014

Summary of the Risk Assessment and Risk Management Plan for Licence Application No. DIR 125

Decision

The Gene Technology Regulator (the Regulator) has decided to issue a licence for this application for dealings with a genetically modified (GM) *E. coli* chicken vaccine. Zoetis Australia Research & Manufacturing Pty Ltd (Zoetis) has been approved under the *Gene Technology Act 2000* (the Act) to commercially release the GM chicken vaccine for the purposes of import, transport, storage and disposal within Australia. Subject to approval by other relevant authorities as set out below, Zoetis is permitted to import the GM chicken vaccine into Australia, and distribute it to commercial poultry farms.

Every veterinary vaccine for sale in Australia is required to be assessed for quality, safety and efficacy. The Australian Pesticide and Veterinary Medicines Authority (APVMA) administers the *Agricultural and Veterinary Chemicals Code Act 1994* to regulate agriculture and veterinary chemical products, including vaccines. Therefore, in addition to approval by the Regulator, Zoetis will require approval from APVMA for use of the GM vaccine.

Furthermore, import of the GM chicken vaccine is also subject to regulation by the Department of Agriculture which 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 vaccines). Therefore, in addition to approval by the Regulator, Zoetis will require approval from the Department of Agriculture for import of the GM vaccine.

The Regulator has released a science based Risk Assessment and Risk Management Plan (RARMP) in accordance with the requirements of the Act and corresponding state and territory legislation, that was finalised following consultation with a wide range of experts, agencies and authorities, and the public. The RARMP concludes that this commercial release poses negligible risks to human health and safety and the environment. General licence conditions have been imposed for the release to ensure that there is ongoing oversight of the licence.

The application

Application number	DIR 125
Applicant	Zoetis Australia Research & Manufacturing Pty Ltd (Zoetis)
Project title	Commercial release of genetically modified vaccine to protect chickens against pathogenic *Escherichia coli*
Parent organism	*Escherichia coli* serotype O78, strain EC34195
Introduced or modified genes and resulting modified traits	Partial deletion of *aroA* gene (impaired biosynthesis of essential aromatic amino acids resulting in reduced spread and persistence of the GMO - attenuation)
Proposed locations	Commercial poultry farms in Australia
Proposed release date	Ongoing from date of approval
Proposed activities	Import, storage, transport and disposal of the GM chicken vaccine.

Risk assessment

The risk assessment concludes that there are negligible risks to the health and safety of people, or the environment, from the proposed commercial release, either in the short or long term. No controls are required to manage these negligible risks.

The risk assessment process considers how the genetic modification and proposed activities conducted with the GMOs might lead to harm to people or the environment. Risks are characterised in relation to both the seriousness and likelihood of harm, taking into account current scientific/technical knowledge, information in the application and relevant previous approvals. Both the short and long term impact are considered.

Credible pathways to potential harm that were considered included whether changes in gene expression due to gene deletions could: result in products that are toxic or allergenic to people or other organisms; alter characteristics that may impact on the disease burden due to the GM *E. coli*; or produce unintended changes in bacterial characteristics. The chance for unintended exposure to the vaccine and the GM bacteria it contains, and for gene flow was also considered.

The principal reasons for the conclusion of negligible risks are that the genetic modification is unlikely to cause harm to people and the environment; the extensive previous experience with the GM chicken vaccine overseas, and bacteria similar to the GMO are common in the environment.

Risk management plan

The risk management plan describes measures to protect the health and safety of people and to protect the environment by controlling or mitigating risk. The risk management plan is given effect through licence conditions.

As the level of risk is assessed as negligible, specific risk treatment is not required. However, the Regulator has imposed licence conditions under post-release review (PRR) to ensure that there is ongoing oversight of the release and to allow the

collection of information to verify the findings of the RARMP. The licence also contains a number of general conditions relating to ongoing licence holder suitability, auditing and monitoring, and reporting requirements which include an obligation to report any new information about risks or unintended effects associated with the authorised dealings.