



15 October 2007

FACT SHEET

Conditions applying to an Emergency Dealing Determination for Genetically modified (GM) vaccines for Equine Influenza (Proteqflu, Proteqflu TE)

These GM vaccines are subject to regulation under the *Gene Technology Act 2000* (the Act).

Certain dealings with these vaccines have been temporarily authorised by an **Emergency Dealing Determination** (EDD) made under the Act. Import, supply and use of the GM vaccines have also been authorised by an Australian Quarantine and Inspection Service (AQIS) import permit and Australian Pesticides and Veterinary Medicines Authority (APVMA) emergency use permits.

The vaccines must only be **imported into premises listed on the AQIS import permit**.

Distribution and administration of the vaccines will be coordinated by the Australian Chief Veterinary Officer (ACVO) and the relevant State and Territory Chief Veterinary Officers, through local Disease Control Centres and Forward Control Posts.

CONDITIONS OF THE EDD MUST BE COMPLIED WITH

Any dealings with these vaccines must be in accordance with the conditions of the EDD (summarised over page), as well as with conditions imposed by the APVMA (specified in the emergency use permits and permit labels) and AQIS (specified in the import permit). The conditions of the EDD are consistent with the APVMA, AQIS and ACVO requirements (where they relate to the same activities) but you should also familiarise yourself with these other requirements.

Dealings authorised by the EDD include the **importation, transport and disposal** of the GM vaccines, and their possession and supply in the course of these dealings. Administration of the vaccines to horses is authorised by the ACVO and facilitated by the APVMA permits.

Under the Act, the Gene Technology Regulator has powers to **monitor compliance** with the conditions of the EDD.

If you have any questions about the conditions of the EDD please contact the Office of the Gene Technology Regulator (OGTR) on freecall 1800 181 030, facsimile 02 6271 4202 or email ogtr@health.gov.au.

SUMMARY OF EDD CONDITIONS*

Under the **Conditions** of the EDD, a person engaging in any dealings with the GM vaccine must:

- **inform** any other person to whom they supply the GM vaccine of any EDD conditions that apply to them.
- **store** the GM vaccine in accordance with APVMA requirements, including during importation and transport.
- if **disposing of the GM vaccine or other contaminated waste** (including syringes, needles and vials, gloves and any other material associated with the dealing), dispose of it as hazardous waste. The waste must, as soon as practical, be collected by a hazardous waste contractor and transported and disposed of in a way that prevents dissemination. The waste must be disposed of by incineration.
- if **importing**, only import into premises listed on the AQIS import permit. The GM vaccine may only be removed from the premises under the direction of the Chief Veterinary Officer (or their delegate) of the State or Territory in which the vaccine is to be used.
- **keep records** in relation to the dealings, and provide them to the Gene Technology Regulator on request, relating to:
 - if **importing**, the quantity of the GM vaccine imported, the date of importation, and the date of on-supply;
 - if **supplying** for the purposes of importation or transportation, the quantity of the GM vaccine supplied, the date of supply and the name, address and telephone number of the person to whom the GM vaccine is supplied;
 - if **transporting**, the quantity of the GM vaccine transported, the dates of transportation and on-supply, the vehicle or other means of transport used (e.g. registration details), and the manner of storage during transportation (e.g. in esky);
 - if **possessing** for the purposes of importation or transportation, the quantity of the GM vaccine stored, the dates of storage, and the manner of storage.
- **allow access** to persons authorised by the Gene Technology Regulator, for the purposes of auditing or monitoring, to premises where the dealing is being undertaken.
- **notify** the Gene Technology Regulator as soon as practicable if they become aware of:
 - additional **information about risks** to the health and safety of people or to the environment associated with the dealings specified in the EDD; or
 - any **breach of the conditions** of the EDD; or
 - any **unintended effects** of the dealings specified in the EDD.

* The full conditions of the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* can be found via the OGTR website at www.ogtr.gov.au.