

Commonwealth of Australia

Gene Technology Act 2000

Gene Technology (Equine Influenza Vaccine) Emergency Dealing Extension Determination 2008

EXPLANATORY STATEMENT

This legislative instrument will extend the period of effect of an emergency dealing determination made under section 72B(1)) of the *Gene Technology Act 2000* (the Act).

The *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007* (the 2007 Determination) authorises dealings with the genetically modified organism that comprises the vaccine for equine influenza which is marketed in the United States as 'RECOMBITEK FLU' and in Europe as 'PROTEQFLU' or 'PROTEQFLU TE' (the GMO).

This determination will extend the period of effect of the 2007 Determination for a further 6 months.

Purpose and legislative framework

The Act is the Australian Government's component of the nationally consistent regulatory scheme for gene technology. Under the Gene Technology Agreement 2001, all States and Territories have committed to maintaining corresponding legislation. The object of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

Part 5A was inserted into the Act by the *Gene Technology Amendment Act 2007* (the Amending Act). The purpose of the amendments made by the Amending Act was to increase the effectiveness of the gene technology regulatory system by increasing its responsiveness.

The emergency provisions give the Minister power to expedite an approval of dealings with a GMO in an emergency. This recognises that situations may arise in which approval of a dealing with a GMO may be required in a limited time. The emergency provisions also further the objects of the Act to protect the health and safety of people and to protect the environment.

The existence of emergency provisions in the Act is consistent with other regulatory schemes. Other relevant product regulators for vaccines, such as the Australian

Pesticides and Veterinary Medicines Authority, possess the ability to expedite approvals in an emergency.

The purpose of making the 2007 Determination was to permit administration of the GMO so as to address an actual threat to the horse population in various parts of Australia from the equine influenza virus. A threat to the horse population is a threat to the environment from an animal disease.

Under section 72C(3) of the Act, the Minister may extend the period of effect of an emergency declaration. The purpose of this determination is to extend the period of effect of the 2007 Determination.

Effect of this determination

This determination will extend the period of effect of the 2007 Determination until 19 September 2008.

This determination commences on 20 March 2008, being the time when the 2007 Determination would have ceased to have effect but for the extension (see section 72C(6)).