

Commonwealth of Australia

Gene Technology Act 2000

DETERMINATION UNDER SECTION 72B

I, Brett Mason, Parliamentary Secretary to the Minister for Health and Ageing, hereby make the following determination pursuant to section 72B of the *Gene Technology Act 2000*.

1. Citation

This determination may be cited as the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007*.

2. Commencement and period of effect

This determination takes effect on the latest of the following days:

- (a) the day the APVMA permit commences;
- (b) the day the AQIS import permit commences; and
- (c) the day following the day this legislative instrument is registered;

and ceases to have effect at the end of the period of 6 months starting when the determination takes effect.

3. Interpretation

In this determination, unless the contrary intention appears, the following definitions apply:

‘*AgVet Code*’ means the Code contained in the Schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*.

‘*APVMA*’ means the Australian Pesticides and Veterinary Medicines Authority continued in existence by section 6 of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*.

‘*APVMA permit*’ means the permit, if any, issued in respect of the GMO by the APVMA.

‘*AQIS*’ means the Australian Quarantine and Inspection Service.

‘*AQIS permit*’ means the permit, if any, issued in respect of the importation of the GMO by AQIS.

‘*the GMO*’ means the genetically modified organism specified at clause 4 of this determination.

4. Genetically modified organism (GMO)

Subject to this determination, this determination authorises the dealings referred to in clause 5 with Influenza A/equi-2/Kentucky/94[H3N8] recombinant Canarypox virus (vCP1529) and Influenza A/equi-2/Newmarket/2/93[H3N8] recombinant Canarypox virus (vCP1533), which are contained in the vaccines PROTEQFLU, PROTEQFLU TE and RECOMBITEK FLU EQUINE INFLUENZA VIRUS vaccines.

5. Dealings with the GMO authorised by this determination

This determination authorises the following dealings with the GMO:

- (a) The GMO may be imported into Australia.
- (b) The GMO may be transported within Australia.
- (c) The GMO may be disposed of.
- (d) The GMO may be possessed, supplied or used for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (c).

Note: The scope of this clause is limited by section 13 of the Act. The only dealings that are authorised by this determination are dealings that are covered by the Act, and the Act only applies to the extent described in section 13, namely:

- *To things done or omitted to be done by constitutional corporations;*
- *To things done or omitted to be done in the course of constitutional trade or commerce;*
- *To things done or omitted to be done by a person that may cause the spread of diseases or pests;*
- *For purposes relating to the collection, compilation, analysis and dissemination of statistics;*
- *To the Commonwealth and Commonwealth authorities; and*
- *To any things authorised by the legislative power contained in paragraph 51(xxxix) of the Constitution insofar as it relates to the matters mentioned above.*

6. Condition: informing the Regulator

A person engaging in any of the dealings with the GMO listed in clause 5 must inform the Regulator as soon as practicable if:

- (a) the person becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings specified in the emergency dealing determination; or
- (b) the person becomes aware of any contraventions of the conditions to which the emergency dealing determination is subject by any person; or
- (c) the person becomes aware of any unintended effects of the dealings specified in the emergency dealing determination.

7. Condition: informing people of obligations

A person engaging in any of the dealings with the GMO listed in clause 5 must inform any other person, who possesses or is supplied with the GMO in the course of the first person's dealings, of any conditions (including any variations of the conditions) of this determination applying to that other person by virtue of dealings engaged in by that other person.

8. Condition: record-keeping

The following persons must keep records in relation to the following dealings, and provide the records to the Regulator upon request:

- (a) A person importing the GMO must keep records of the quantity of the GMO imported, the date of importation, and the date of on-supply.
- (b) A person transporting the GMO must keep records of the quantity of the GMO transported, the dates of transportation and on-supply, the vehicle or other means of transport used, and the manner of storage during transportation.
- (c) A person possessing the GMO for the purposes of importation or transportation must keep records of the quantity of the GMO stored, the dates of storage, and the manner of storage.
- (d) A person supplying the GMO for the purposes of importation or transportation must keep records of quantity of the GMO supplied, the date of supply and the name, address and telephone number of the person to whom the GMO is supplied.

9. Condition: access to premises

If:

- (a) a dealing with a GMO is specified in the emergency dealing determination; and
- (b) a particular condition of the emergency dealing determination applies to the dealing by a person;

the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Note: this condition is imposed upon the determination by section 72D(4) of the Act.

10. Condition: approved container

A person importing the GMO, transporting the GMO or possessing or supplying the GMO for the purposes of importation or transportation must keep the GMO in a container that complies with the requirements of the AgVet Code.

11. Condition of importation: Directed to premises on arrival

The GMO may only be imported into premises listed on the AQIS import permit. The vaccine may only be moved from the premises under the direction of the Chief Veterinary Officer, or his or her delegate, of the State or Territory in which the vaccine is to be used.

12. Condition of disposal: manner of disposal

If a person disposes of the GMO, the GMO must be disposed of as hazardous waste.

13. Condition: items to be disposed of

Contaminated waste (including syringes, needles and vials, unused vaccine, gloves and any other material associated with any dealing with the GMO or that has otherwise been exposed to the GMO) must be collected and treated as hazardous waste and disposed of as soon as reasonably practicable, and disposal must be by incineration. The waste must be collected by a hazardous waste contractor and transported and disposed of in a way to prevent dissemination.

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BRETT MASON

Parliamentary Secretary to the Minister for Health and Ageing

18/9/2007