Commonwealth of Australia

Gene Technology Act 2000

Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007

EXPLANATORY STATEMENT

This legislative instrument is an emergency dealing determination made under Part 5A (in particular section 72B(1)) of the *Gene Technology Act 2000* (the Act). It 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).

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 this emergency dealing determination is 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.

Operation and scope

The determination will commence only when:

- The APVMA permit has commenced; and
- The AQIS import permit has commenced; and
- The determination has been registered in the Federal Register of Legislative Instruments.

The determination will operate initially for a period of 6 months from commencement. The Minister may (by legislative instrument) revoke the determination, or extend its effect, under sections 72E(2) and 72C(3) of the Act respectively.

An emergency dealing determination can only authorise 'dealings', consistently with the definition of 'deal with' in section 10 of the Act. That definition includes a number of possible actions a person might take with respect to a GMO. The dealings which the determination can cover are limited by section 13 of the Act, which provides that the Act only applies as follows:

- 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 statistics;
- to the Commonwealth and Commonwealth authorities; and
- to things authorised under the incidental power in paragraph 51(xxxix) of the Constitution.

These limits on the applicability of the Act reflect certain constitutional limitations on Commonwealth legislation, as well as the arrangements made under the Gene Technology Agreement 2001.

Within the scope of the Act, dealings with the GMO will be exempted from the offence provisions in the Act (sections 32 and 33). Outside of the scope of section 13, the corresponding State and Territory laws will apply to all persons, and all things done in, dealing with a GMO. In States which have not included an emergency dealing scheme in their own legislation, a person 'dealing with' the GMO outside the areas described above may be liable to penalties. This issue is discussed further in the notes on clause 5 of the determination below.

A person engaging in a dealing with the GMO covered by the determination who fails to comply with the conditions of the determination may be subject to penalties under sections 35A and 35B of the Act.

Notes on clauses

1. Citation

This clause provides that the name of the determination is the *Gene Technology (Equine Influenza Vaccine) Emergency Dealing Determination 2007*.

2. Commencement and period of effect

This clause provides for the period during which the determination is in force. The determination enters into force on the later of the following three dates:

- the date of commencement of the APVMA permit;
- the date of commencement of the AQIS permit; and
- the date of registration of the determination as a legislative instrument.

The determination ceases to have effect on 6 months after the determination takes effect.

3. Interpretation

This clause includes a number of standard general rules concerning the interpretation of words and phrases in the determination. The clause also defines a number of basic abbreviations, including 'the GMO' and terms relating to certain Commonwealth agencies, and any permits for the GMO issued by those agencies.

4. Genetically modified organism (GMO)

This clause provides a technical definition of the GMO. The GMO is referred to as "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 PROTEQFLU, PROTEQFLU TE and RECOMBITEK FLU equine influenza virus vaccines.

5. Dealings with the GMO authorised by this determination

This clause recites the 'dealings' with the GMO that are authorised by the determination. The dealings are importation, transport and disposal of the GMO, and any use, possession or supply of the GMO that is for the purposes of or in the course of one of the other authorised dealings.

The determination does not cover the actual use of the GMO, by way of the administration of the vaccine to animals. This is because use in general is not within the scope of the definition of 'deal with' in section 10 of the Act. For the same reason, administration of the vaccine to animals would not be an offence under the Act. Administration of the vaccine is, instead, regulated under the permit issued by APVMA.

The effect of section 13 of the Act is that the dealings authorised by the determination are only such dealings as are covered by the Act. Dealings with the equine influenza vaccine will not be things done or omitted to be done that may cause the spread of diseases or pests. For practical purposes there will be no statistical or other incidental activities involved. Consequently, in practice, the determination authorises the following persons to engage in the following dealings:

- Constitutional corporations may deal with the GMO – thus, those corporations may import, transport and dispose of the GMO, or use, supply or possess it for those purposes;
- The Commonwealth and Commonwealth authorities may deal with the GMO in the same ways;

- Persons may deal with the GMO in the course of constitutional trade or commerce – thus, in general, any person may import the GMO into Australia, and any person may transport the GMO so long as the transport is for the purposes of the importation, or the transportation occurs between different States or Territories.

A note to the clause discusses these issues.

6. Condition: informing the Regulator

This clause provides that a person dealing with the GMO must inform the Regulator as soon as practicable if the person becomes aware of any new information or events which suggest that the GMO may be posing a risk to the health and safety of people or to the environment.

7. Condition: informing people of obligations

This clause provides that a person dealing with the GMO 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 of this determination applying to that other person, including any variations of those conditions.

8. Condition: record-keeping

This clause provides that persons must keep certain records in relation to their dealings, and provide the records to the Regulator upon request. The persons required to keep records, and the records they are required to keep, are as follows:

(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

This clause replicates the condition imposed upon the determination by section 72D(4) of the Act, namely, that if:

- a dealing with a GMO is specified in the emergency dealing determination; and
- 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.

10. Condition: approved container

This clause imposes the condition that 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

This clause provides that 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

This clause provides that if a person disposes of the GMO, the GMO must be disposed of as hazardous waste.

13. Condition: items to be disposed of

This clause provides that all contaminated waste (including syringes, needles and vials, unused vaccine, gloves and any other material used in the administration of 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.