ANALYSIS

1994, No. 126

An Act to amend the Animal Remedies Act 1967

[*9 December 1994*

BE IT ENACTED by the Parliament of New Zealand as follows:

1. Short Title and commencement—(1) This Act may be cited as the Animal Remedies Amendment Act 1994, and shall be read together with and deemed part of the Animal Remedies Act 1967 (hereinafter referred to as the principal Act).

(2) This Act shall come into force on a date to be appointed by the Governor-General by Order in Council; and one or more orders may be made bringing different provisions into force on different dates.

2. New Part inserted—The principal Act is hereby amended by inserting, after section 35, the following Part:

"PART IIA

"PROTECTION OF CERTAIN CONFIDENTIAL INFORMATION ABOUT INNOVATIVE ANIMAL REMEDIES

"35A. **Interpretation**—In this Part of this Act, unless the context otherwise requires,—

" 'Applicant' means—

"(a) A person who makes or has made, as the case may be, an application; and

"(b) A person on whose behalf an application is, or has been, made, as the case may be:

" 'Application' means an application for the issue under section 21 of this Act of a licence or a provisional licence to manufacture or import, as the case may be, an animal remedy:

" 'Commencement date' means the date on which this Part of this Act comes into force:

" 'Confidential information' includes—

"(a) Trade secrets; and

"(b) Information that has commercial value that would be, or would be likely to be, diminished by disclosure:

" 'Confidential supporting information' means confidential information given—

"(a) In, or in relation to, an innovative animal remedy application; and

"(b) About the animal remedy that is or was, as the case may be, the subject of that application:

" 'Ingredient' includes a chemical or biological entity:

" 'Innovative animal remedy application' means,—

"(a) In relation to an application made after the commencement date, an application that refers to an active ingredient—

"(i) That is an active ingredient of the animal remedy to which the application relates; and

"(ii) That has not, before that application is received by the Board, been referred to in any other application (except in an application by the applicant for a provisional licence for that animal remedy) as an active ingredient of an animal remedy; and

"(b) In relation to an application made before the commencement date, an application that referred to an active ingredient—

"(i) That is or was, as the case may be, an active ingredient of the animal remedy to which the application related; and

"(ii) That had not, before that application was received by the Board, been referred to in any other application (except in an

application by the applicant for a provisional licence for that animal remedy) as an active ingredient of an animal remedy:

" 'Protected period' means,—

"(a) In relation to confidential supporting information, relating to an innovative animal remedy application, received by the Board after the commencement date, a period commencing on the date that information is received by the Board and ending,—

"(i) Where—

"(A) The Board has either issued a licence, not being a provisional licence, under section 21 of this Act, or refused to grant such licence, in relation to the animal remedy that is the subject of the innovative animal remedy application; and

"(B) The date of that issue or refusal is not more than 5 years after the Board received an application in relation to that animal remedy,—

on the date 5 years after the date of that issue or refusal; or

"(ii) In any other case, on the date 5 years after the innovative animal remedy application to which that information relates is or was, as the case may be, received by the Board:

"(b) In relation to confidential supporting information, relating to an innovative animal remedy application, received by the Board not more than 5 years before the commencement date, a period commencing on the commencement date and ending,—

"(i) Where—

"(A) The Board has either issued or issues a licence, not being a provisional licence, under section 21 of this Act, or refused or refuses to grant such licence, in relation to the animal remedy that was the subject of the innovative animal remedy application; and

"(B) The date of that issue or refusal is or was, as the case may be, not more than 5 years after the Board received an

application in relation to that animal remedy,—

on the date 5 years after the date of that issue or refusal; or

"(ii) In any other case, on the date 5 years after the innovative animal remedy application to which that information related was received by the Board:

" 'WTO Country' means a country that is a party to the Agreement establishing the World Trade Organization adopted at Marrakesh on the 15th day of April 1994.

"35B. **Protection of confidential supporting information about innovative animal remedies**—Where the Board receives, or received not more than 5 years before the commencement date, an innovative animal remedy application and confidential supporting information, the Board, during the protected period in relation to that confidential supporting information,—

"(a) Shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Board; and

"(b) Shall not use that confidential supporting information for the purposes of determining whether to grant any other application.

"35C. **Circumstances where protection under section 35B does not apply**—(1) Notwithstanding section 35B of this Act, the Board may, during the protected period in relation to confidential supporting information,—

"(a) Disclose that confidential supporting information, or use that confidential supporting information for the purposes of determining whether to grant any application other than the application to which it relates or related, as the case may be,—

"(i) With the consent of the applicant who made the application to which the confidential supporting information relates or related; or

"(ii) If that disclosure or use is, in the opinion of the Board, necessary to protect the health or safety of members of the public; or

"(b) Disclose that confidential supporting information to—

"(i) A Government department or statutory body for the purposes of that Government department or statutory body:

"(ii) An adviser for the purposes of obtaining advice about the animal remedy to which the information relates,—

if, in the opinion of the Board, the Government department, statutory body, or adviser, as the case may be, will take reasonable steps to ensure the information is kept confidential; or

"(c) Disclose that confidential supporting information to any one or more of the following:

"(i) The World Health Organisation:

"(ii) The Food and Agriculture Organisation:

"(iii) The Office International des Epizooties:

"(iv) A regulatory agency of a WTO country:

"(v) A person or organisation, or a person or organisation within a class or classes of persons or organisations, approved by regulations made under this Act.

"(2) The power to grant consent under subsection (1) (a) (i) of this section may be exercised by a person other than the applicant referred to in that subsection if—

"(a) That applicant—

"(i) Has notified the Board in writing that that other person may grant that consent; and

"(ii) Has not notified the Board in writing that that person's authority to grant that consent has been withdrawn; or

"(b) That applicant's rights in respect of the relevant confidential supporting information have been transferred to that person and the applicant or that person has notified the Board of the transfer."

3. Publication of results of analyses and details of animal remedies—Section 55 of the principal Act is hereby amended by omitting the word "The", and substituting the words "Subject to Part IIA of this Act, the".

4. Regulations—Section 65 of the principal Act is hereby amended by inserting, after paragraph (g), the following paragraph:

"(ga) Approving persons or organisations, or classes of persons or organisations, for the purposes of section 35C (1) (c) (v) of this Act:".

This Act is administered in the Ministry of Agriculture and Fisheries.