1985/102

THE ANIMAL REMEDIES REGULATIONS 1980, AMENDMENT NO. 2

DAVID BEATTIE, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington this 20th day of May 1985

Present:

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to section 65 of the Animal Remedies Act 1967, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Animal Remedies Regulations 1980, Amendment No. 2, and shall be read together with and deemed part of the Animal Remedies Regulations 1980* (hereinafter referred to as the principal regulations).

(2) These regulations shall come into force on the 14th day after the date of their notification in the *Gazette*.

2. Two regulations (relating to premises) substituted in principal regulations—The principal regulations are hereby amended by revoking regulations 20 and 21, and substituting the following regulations:

*S.R. 1980/145
Amendment No. 1: S.R. 1981/129

"20. **Construction or alteration of premises**—(1) Every person intending to construct any premises for use in the manufacture of any biochemical substance may submit to the Board for its approval an adequate plan and description of the intended premises, together with the prescribed fee.

"(2) If, in such a case, the Board approves the plan and description, it may, subject to the other requirements of this Part of these regulations, notify the applicant in writing that, on completion of the premises in accordance with the plan and description, it will issue to the applicant a licence in respect of the premises.

"(3) Every licensee intending to alter any existing premises used in the manufacture of any biochemical substance shall submit to the Board for its approval an adequate plan and description of the intended premises, together with the prescribed fee.

"(4) The licensee shall not commence any such alterations until the Board notifies him in writing that it approves of the proposed alterations.

"(5) No person, either before, during, or after the construction or alteration of the premises, shall, without prior permission in writing from the Board, in any material way depart from the description and plan approved by the Board.

"(6) Every person who fails to comply with or contravenes any of the provisions of this regulation commits an offence and is liable on summary conviction to a fine not exceeding $200.

"21. **Requirements as to premises**—(1) All premises used or intended for use in the manufacture of any biochemical substance shall comply in all respects with the following requirements:

"(a) They shall be suitably constructed and subdivided to prevent the spread of disease:

"(b) They shall be equipped with adequate and suitable equipment for quality control and the safe and hygienic preparation, manufacture, handling, container filling, and storage of biochemical substances:

"(c) They shall be provided with a conveniently located and adequate supply of clean water, both hot and cold, and be well and properly drained in accordance with the Drainage and Plumbing Regulations 1978:

"(d) They shall have adequate and suitable hygienic accommodation for the proper management and effective control of animals used in the preparation, manufacture, or testing of biochemical substances:

"(e) They shall have adequate and suitable incinerators or other means for the destruction of carcasses of animals and contaminated material of a dangerous character:

"(f) All floors shall be constructed of impervious and easily cleaned materials finished to a smooth, plane surface:

"(g) All interior walls shall be of impervious material finished to a smooth, plane surface:

"(h) All ceilings of rooms shall be of a smooth, impervious surface capable of being cleaned without damage to the surface:

"(i) All rooms shall be provided with adequate ventilation and with adequate natural or artificial lighting:

"(j) They shall have adequate toilet accommodation, none of which shall open directly into any room in which biochemical substances are prepared, manufactured, handled, or stored:

"(k) They shall have hand basins conveniently adjacent to any toilet accommodation, which basins shall be furnished with waste pipes and serviced with pipes to supply hot and cold water, and shall not be used for any other purpose than personal ablutions.

"(2) Notwithstanding paragraph (b) of subclause (1) of this regulation, the Board may in any particular case waive the requirements of that paragraph so far as it relates to quality control if—

"(a) The licensee has made arrangements for quality control measures to be undertaken on the licensee's behalf on other premises; and

"(b) The Board is satisfied that those other premises are equipped with adequate and suitable equipment for quality control."

3. Fees—Regulation 38 of the principal regulations is hereby amended by revoking subclause (1), and substituting the following subclause:

"(1) Every application for a licence to manufacture or import an animal remedy, whether made pursuant to section 19 of the Act for a full licence or to section 24 of the Act for a provisional licence, shall be accompanied by a fee of $250; but no fee shall be payable in respect of an application made pursuant to subsections (3) and (4) of section 24 of the Act for the conversion of a provisional licence into a full licence."

4. Second Schedule to principal regulations amended—The Second Schedule to the principal regulations is hereby amended by inserting, after the item relating to nitrovin, the item set out in the Schedule to these regulations.

Reg. 4

SCHEDULE

ADDITIONAL ITEM INSERTED IN SECOND SCHEDULE TO PRINCIPAL REGULATIONS

Antibiotic	Animal Species	Use level	Direction of Medication	Claim	Limitations to be shown on the label
Oestradiol 17β	Beef cattle (steers)	24 mg	One implant every 200 days	Growth promotion	Implant must be removed before or at slaughter
	Beef cattle (steers)	45 mg	One implant every 400 days	Growth promotion	Implant must be removed before or at slaughter

P. G. MILLEN,
Clerk of the Executive Council.

EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

Regulation 1 relates to the Title and commencement.

Regulation 2 rectifies an error that occurred in the printing of the principal regulations after they had been made. The provision that was intended to appear as paragraph (k) of regulation 21 (1) instead appeared between subclauses (1) and (2) of regulation 20.

Regulation 3 increases from $30 to $250 the fee payable for a licence to manufacture or import an animal remedy. The Act no longer provides for the renewal of such licences, and so the fee for that is omitted.

Regulation 4 relates to the use of oestradiol 17β, which is a biochemical substance within the meaning of the Act. Regulation 36 (1) of the principal regulations prohibits the use or supply of any biochemical substance the use of which is for the time being restricted under Part VI of the Act, except pursuant to a prescription from a veterinary surgeon, or as authorised in the Second Schedule to the principal regulations. These regulations add oestradiol 17β to the list of substances in that Schedule, and authorise its use on the type of animal, within the maximum dosage, during the period, for the purpose, and subject to the limitations, specified in the Schedule to these regulations.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette:* 23 May 1985.
These regulations are administered in the Ministry of Agriculture and Fisheries.