

Serial Number 1951/202

**THE STOCK REMEDIES (BIOLOGICAL PRODUCTS)
REGULATIONS 1951**

B. C. FREYBERG, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington, this 19th day of
September 1951

Present :

HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to the Stock Remedies Act 1934, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

Preliminary

1. (1) These regulations may be cited as the Stock Remedies (Biological Products) Regulations 1951.

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

2. (1) Unless the context otherwise requires, expressions used in these regulations shall have the same meaning as in the Stock Remedies Act 1934.

(2) In these regulations, unless the context otherwise requires,—

“Equipment” includes all apparatus, containers, instruments, machinery, piping, receptacles, thermometers, utensils, and other articles used in the preparation, handling, manufacture, bottling, or storage of biological products :

“Licence” includes a principal technician’s licence and a licence in respect of premises granted under these regulations :

“Principal technician”, in relation to the manufacture of a biological product, means the person who has the immediate direction, supervision, and control of the actual process of manufacturing that product in premises licensed under these regulations, and includes the owner or occupier of any such premises who himself exercises such immediate direction, supervision, and control :

“Proprietor”, in respect of a biological product manufactured in New Zealand, means the licensee in respect of premises licensed under these regulations, and in respect of a biological product not manufactured in New Zealand, means the importer thereof :

“Veterinary practitioner” means any person for the time being authorized to use in connection with his business the designation of veterinary practitioner pursuant to section 14 of the Veterinary Surgeons Act 1926 :

“Veterinary surgeon” means any person for the time being registered as a veterinary surgeon under the Veterinary Surgeons Act 1926.

3. Any approval or notice to be given, any licence or permit to be issued, any discretion to be exercised, or any thing or matter to be done, by the Board under these regulations shall be sufficient for the purposes of these regulations if given, issued, exercised, or done by the Registrar or any member of the Board duly authorized in that behalf by the Board.

Construction of or Alteration to Premises

4. Every person intending to build any premises for use in the manufacture of biological products, or to make substantial alterations, whether structurally or by way of additions, to any existing building or premises intended to be adapted for use in the manufacture of biological products, shall submit to the Board for approval particulars of the site of the proposed building and a description and plan of the proposed building or alterations.

5. No person shall commence the erection of any such building or the making of any such alterations until he is notified in writing by the Board that the site, description, and plan of the building or alterations are approved by the Board.

6. No person erecting any such building or making any such alterations shall make any material departure from the description and plan as approved by the Board, either before or during the erection or alteration of the building or at any later time, without the previous permission in writing of the Board.

7. No licensee of any premises licensed under these regulations shall, during the currency of his licence, make any substantial structural reinstatement, alteration, or addition to the buildings comprised in his licensed premises except with the prior approval in writing of the Board :

Provided that, in the case of reinstatement consequent upon destruction or damage by fire, flood, or other disaster or upon dilapidation of buildings, the approval shall not be arbitrarily or unreasonably withheld.

Licensing of Principal Technicians

8. No person shall engage in the manufacture of any biological product unless he is the holder of a principal technician's licence in respect of the manufacture of that product granted under these regulations.

9. Every person desiring to obtain a principal technician's licence in respect of the manufacture of any biological product shall make application in writing to the Stock Remedies Registration Board in the form provided by the Board for the purpose, and shall set out in his application the particular biological product or products in respect of which a licence is sought and such further information or particulars as may be required by the said form.

10. If in the opinion of the Board any information or particulars required to be furnished in accordance with the form of application are insufficiently given, the Board may require the applicant to furnish such further details, information, and particulars as the Board thinks necessary and until such further details, information, and particulars are furnished to the Board the application shall not be further entertained by the Board.

11. No principal technician's licence in respect of the manufacture of any biological product shall be granted under these regulations unless the applicant for a licence—

- (a) Is in the opinion of the Board of good character and repute ; and
- (b) Satisfies the Board that by virtue of his qualifications, training, skill, and experience he is a fit and proper person to be granted a licence.

12. Every principal technician's licence issued under these regulations shall be in the Form No. 1 in the Schedule hereto and shall authorize the licensee to engage or be employed in the manufacture only of the biological product or biological products specified in the licence.

13. Every such licence shall, unless sooner revoked or surrendered, continue in force until the 31st day of March next after the date on which it is issued, but may from time to time be renewed for a period ending on the 31st day of March in each subsequent year.

14. All the provisions of these regulations with respect to the grant of an application for a principal technician's licence shall apply, with the necessary modifications, to the grant of an application for the renewal of a licence.

15. On the renewal of a principal technician's licence there shall be issued to the licensee a certificate of renewal in the Form No. 2 in the Schedule hereto.

16. Any principal technician's licence (including a renewal thereof) may be revoked in any of the following events :—

- (a) If the licensee so requests ; or
- (b) If any biological product manufactured under his supervision is found to have deteriorated or to be dangerous or to be ineffective for its purpose ; or
- (c) If in the opinion of the Board the quality of any biological product manufactured under his supervision is inferior to the quality that could be attained, having regard to all relevant circumstances.

17. The revocation of any principal technician's licence shall be effected by a declaration of revocation in writing by the Board served upon the licensee or sent to the licensee by post in a registered letter addressed to him at his usual or last known place of abode.

Licensing of Premises

18. Subject to the provisions of regulations 21 and 22 hereof, no person shall carry on the manufacture of any biological product in any premises unless he is the holder of a licence in respect of those premises granted under these regulations.

19. Except as provided in regulation 20 hereof, no premises shall be licensed under these regulations unless—

- (a) They have been erected in compliance with regulations 4, 5, and 6 hereof; and
- (b) They comply with the requirements of regulation 33 hereof; and
- (c) The person to perform the duties of principal technician in respect of the manufacture of biological products in the premises is the holder of a principal technician's licence granted under these regulations.

20. Notwithstanding the provisions of paragraph (a) or paragraph (b) of regulation 19 hereof, any premises which are used at the date of the coming into force of these regulations for the manufacture of any biological product may be licensed under these regulations for the manufacture of that biological product if—

- (a) In the opinion of the Board the premises are sanitary, are in good repair and condition, and comply substantially with the requirements of regulation 33 hereof; and
- (b) A person claiming to be qualified to hold a principal technician's licence in respect of the biological product or products to be manufactured in the premises makes application for and is granted a principal technician's licence under these regulations.

21. Every person who at the date of the coming into force of these regulations uses any premises for the manufacture of any biological product shall forthwith after that date make application in writing to the Board for a licence in respect of those premises for the manufacture of the biological product or products specified in the application.

22. Every person who at any time after the date of the coming into force of these regulations proposes to use any premises for the manufacture of any biological product shall make application in writing to the Board for a licence in respect of those premises for the manufacture of the biological product or products specified in the application.

23. Every application for a licence in respect of any premises shall be in the form provided by the Board for the purpose and shall set out the particular biological product or products to be manufactured in the premises and such further information or particulars as may be required by the said form.

24. If in the opinion of the Board any information or particulars required to be furnished in accordance with the form of application are insufficiently given, the Board may require the applicant to furnish such further details, information, and particulars as the Board thinks necessary, and until such further details, information, and particulars are furnished to the Board the application shall not be further entertained by the Board.

25. On receipt of an application for a licence in respect of any premises the Board shall cause the premises described in the application to be inspected and reported on by the person authorized to make the inspection.

26. On receipt of the report referred to in regulation 25 hereof and on being satisfied that the requirements of these regulations in respect of the premises and its equipment have been complied with, the Board shall issue to the applicant a licence in respect of the premises in the Form No. 3 in the Schedule hereto.

27. Every licence in respect of any premises shall authorize the licensee to manufacture in the premises specified in the licence only the biological product or products specified in the licence.

28. (1) Every such licence shall, unless sooner revoked or surrendered, expire on the expiry date as hereinafter defined next following the date on which the licence was issued, but may from time to time be renewed for a period ending on the next ensuing expiry date as hereinafter defined.

(2) For the purposes of this regulation the term "expiry date" means the 31st day of March in the year 1956, and in every fifth year thereafter.

(3) On the renewal of a licence in respect of any premises there shall be issued to the licensee a certificate of renewal in the Form No. 4 in the Schedule hereto.

29. All the provisions of these regulations with respect to the grant of a licence in respect of any premises shall apply, with the necessary modifications, to the grant of an application for the renewal of a licence.

30. On the application of the licensee of any premises the Board may, by notice in writing given to the licensee, amend or vary the licence in respect of his premises by authorizing the licensee to manufacture a biological product not specified in his licence, and may, on its own motion, by a like notice given to a licensee, amend or vary his licence by withdrawing the right conferred by the licence to manufacture any biological product specified in the licence, if the Board is satisfied on such grounds as it shall deem sufficient that the biological product manufactured under the licence has deteriorated or has become dangerous or has become ineffective for its purpose.

31. Any licence in respect of any premises (including a renewal thereof) may be revoked in any of the following events :—

- (a) If the licensee so requests ; or
- (b) If, during the period of twelve months immediately preceding the revocation, the licensee has been convicted of any offence under the Stock Remedies Act 1934 or any regulations made thereunder ; or
- (c) If the licensee fails or neglects to remedy within the time specified in the notice any defect in or about the licensed premises or its equipment when required by an Inspector so to do by notice in writing served on the licensee ; or
- (d) If any biological product manufactured in the licensed premises is found to have deteriorated or to be dangerous or to be ineffective for its purpose ; or
- (e) If in the opinion of the Board the quality of any biological product manufactured in the licensed premises is inferior to the quality that could be attained, having regard to all relevant circumstances ; or
- (f) If the licensed premises cease to comply with the requirements of regulation 33 hereof or are not at all times maintained as required by regulation 34 hereof.

32. The revocation of a licence in respect of any premises shall be effected by a declaration of revocation in writing by the Board served upon the licensee or delivered at his licensed premises to some person appearing to have the management thereof or sent to the licensee by post in a registered letter addressed to the licensee at his licensed premises.

Requirements as to Premises

33. All premises used or intended for use in the manufacture of any biological product shall comply with the following requirements:—

- (a) The premises shall be—
- (i) Suitably constructed to prevent the spread of disease :
 - (ii) Equipped with all necessary equipment for the preparation, manufacture, handling, bottling, and storage of biological products :
 - (iii) Provided with an adequate supply of clean water, both hot and cold, and be well and properly drained :
- (b) Adequate and suitable hygienic accommodation shall be provided for the proper management and effective control of animals used in the preparation, manufacture, or testing of biological products :
- (c) Incinerators or other suitable means shall be provided for the destruction of carcasses of animals and contaminated material of a dangerous character :
- (d) All floors shall be constructed of concrete or other impervious and easily cleaned materials, and shall be so finished as to be impervious to moisture, and faces of concrete shall be finished to a smooth, plane surface :
- (e) Interior walls and the interior surface of exterior walls shall be made of or lined with tiles, cement, or other material so finished by painting or otherwise as to present a smooth surface and to be impervious to moisture, and faces of concrete shall be finished to a smooth, plane surface :
- (f) Ceilings of rooms shall have a smooth surface capable of being washed without damage to the surface :
- (g) All rooms shall be provided with adequate ventilation and with adequate natural and artificial lighting :
- (h) Adequate privy accommodation shall be provided in rooms not opening directly into any room in which biological products are prepared, manufactured, handled, or stored :
- (i) Conveniently adjacent to any privy accommodation there shall be provided hand basins, which shall be furnished with waste pipes and with pipes to supply hot and cold water, and shall not be used for any other purpose than personal ablutions.

34. The licensee of every licensed premises shall at all times during the currency of his licence maintain his premises and all equipment used in connection with the manufacture of biological products in his licensed premises in a clean condition and in good order and repair.

Manufacturing Methods

35. The licensee of every licensed premises shall—

- (a) Assign to each lot or batch of each biological product manufactured in his licensed premises a number by which each such lot or batch may be identified :
- (b) Adopt such methods and take such precautions as are necessary to prevent contamination during the course of the manufacture and bottling, or deterioration during the storage, of every biological product manufactured in his licensed premises :

- (c) Properly segregate and keep segregated all animals affected with or exposed to any infectious or contagious disease :
- (d) Effectively destroy forthwith the carcasses of all animals and all contaminated material of a dangerous character used in the manufacture of any biological product in his licensed premises ;
- (e) Not remove from his licensed premises any animal used in the preparation or testing of any biological product except with the permission in writing of the Board.

Records

36. The licensee of every licensed premises shall make and keep at his licensed premises an accurate record of the following particulars in respect of each biological product manufactured in his premises :—

- (a) The date of manufacture of each lot or batch of each biological product :
- (b) The serial number by which each lot or batch of each biological product may be identified :
- (c) The tests made for potency, sterility, and immunizing or other properties of each biological product :
- (d) The names and addresses of the persons to whom biological products have been sold or distributed, together with the identifying numbers of those products.

Inspection of Premises and Equipment

37. (1) The licensee of every licensed premises shall at all times permit any Inspector or other person authorized in writing by the Board to enter upon his licensed premises for the purpose of—

- (a) Inspecting the condition of the premises, its equipment and supplies (including chemicals and other materials), and of animals kept thereon ;
- (b) Inspecting the records kept by the licensee pursuant to regulation 36 hereof :
- (c) Examining the procedure adopted in the manufacture, storage, recording, sale, and distribution of biological products manufactured under his licence :
- (d) Taking samples of any biological product and of any cultures, media, chemicals, and other materials for examination and testing.

(2) The licensee shall afford all reasonable facilities and assistance in any such inspection, testing, and examination.

Sale, Distribution, and Use of Biological Products

38. (1) Where, as the result of the testing (whether by way of laboratory methods or otherwise) of any biological product, the Board is satisfied that any batch or lot of that product has deteriorated or has become dangerous or has become ineffective for its purpose the Board may, by notice in writing given to the proprietor of that product, require the proprietor to withdraw or recall from sale or use the batch or lot of that biological product specified in that behalf in the notice.

(2) Forthwith on receipt of any notice under subclause (1) of this regulation the proprietor shall withdraw or recall from sale or use the batch or lot of that biological product to which the notice relates, and shall destroy or otherwise dispose of that batch or lot in such manner as the Board may direct either in the notice given under subclause (1) of this regulation or in any subsequent notice given to the proprietor.

39. (1) This regulation applies with respect to the following biological products—namely, blackleg vaccine (for cattle), *Brucella abortus* vaccine (strain 19), contagious ecthyma vaccine (scabby mouth), distemper vaccine, fowl pox vaccine, strangles vaccine, tetanus toxoid vaccine, and tetanus anti-toxin serum.

(2) No person shall sell any biological product to which this regulation applies to any person who is not a veterinary surgeon or a veterinary practitioner.

(3) No person shall use any biological product to which this regulation applies unless he is a veterinary surgeon or a veterinary practitioner.

(4) Notwithstanding anything in subclause (2) or subclause (3) of this regulation—

(a) Contagious ecthyma vaccine for the prevention of scabby mouth in stock, and fowl pox vaccine for the prevention of fowl pox in poultry, may be sold by the proprietor thereof or a veterinary surgeon or veterinary practitioner directly to any person for the preventive treatment of his stock or poultry if the vendor is satisfied that the person is sufficiently instructed in the proper use of the vaccine in the treatment:

(b) Blackleg vaccine for the prevention of blackleg in cattle, and *Brucella abortus* vaccine (strain 19) for the prevention of contagious abortion in cattle, may be sold to the Department of Agriculture and used by any officer of the said Department duly authorized by the Director-General of the said Department.

40. (1) In their application to the treatment of animals the restrictions imposed by regulation 186B of the Food and Drug Regulations 1946, on the sale, dispensing, and prescribing of the antibiotic metabolites and other substances specified in the Sixth Schedule to the said regulations as set forth and contained in the Food and Drug Regulations 1946, Amendment No. 6,* shall apply to the sale, dispensing, and prescribing of those antibiotic metabolites or other substances as biological products for the treatment of stock, for the purposes of these regulations.

(2) In their application to the treatment of animals the provisions of the said regulation 186B* of the Food and Drug Regulations 1946 shall apply, with the necessary modifications, to the sale, dispensing, and prescribing of any preparation containing any hormone as a biological product for the treatment of stock for the purpose of these regulations as if the hormone were a substance specified in the Sixth Schedule to the Food and Drug Regulations 1946.†

(3) Notwithstanding the provisions of subclause (2) of this regulation the Board may, by notice published in the *Gazette*, declare that the provisions of that subclause shall not apply to any biological product specified in the notice that contains as an ingredient thereof any hormone.

* Statutory Regulations 1951, Serial number 1951/68, page 255.

† Statutory Regulations 1946, Serial number 1946/136, page 327.

Offences

41. (1) Every person commits an offence against these regulations who acts in contravention of or fails to comply in any respect with any provision of these regulations or any requirement, stipulation, direction, or condition given, issued, or imposed under these regulations.

(2) Every person who commits an offence against these regulations shall be liable on summary conviction to a fine not exceeding £20.

SCHEDULE

Reg. 12]

[Form No. 1

Licence No.

PRINCIPAL TECHNICIAN'S LICENCE

PURSUANT to the application of [*Full name*], of [*Address*], dated the day of, 19..., the said [*Full name*], is hereby licensed under the Stock Remedies (Biological Products) Regulations 1951 as a principal technician for the purposes of the said regulations in respect of the manufacture of the following biological products—namely,, This licence is subject to the provisions of the said regulations and shall continue in force until the 31st day of March, next, unless sooner revoked or surrendered.

Dated at Wellington, this day of, 19..

....., Registrar,
Stock Remedies Registration Board.

Reg. 15]

[Form No. 2

CERTIFICATE OF RENEWAL OF PRINCIPAL TECHNICIAN'S LICENCE

PURSUANT to the application of [*Full name*], of [*Address*], dated the day of, 19.., the principal technician's licence issued to the said [*Full name*] and numbered is hereby renewed subject to the provisions of the Stock Remedies (Biological Products) Regulations 1951 until the 31st day of March, 19.., unless sooner revoked or surrendered.

....., Registrar,
Stock Remedies Registration Board.

Reg. 26]

[Form No. 3

Licence No.

LICENCE IN RESPECT OF PREMISES

THE premises of [*Name of owner or occupier*] of [*Address*], situate at, and described in application dated the day of, 19.., are hereby licensed under the Stock Remedies (Biological Products) Regulations 1951 for the manufacture in the said premises of the following biological products—namely,, This licence is subject to the provisions of the said regulations and shall continue in force until the 31st day of March, 19.., unless sooner revoked or surrendered.

Dated at Wellington, this day of, 19..

....., Registrar,
Stock Remedies Registration Board.

Reg. 28 (3)]

[Form No. 4

CERTIFICATE OF RENEWAL OF LICENCE IN RESPECT OF PREMISES

PURSUANT to the application of [*Name of owner or occupier*], of [*Address*], dated the day of, 19.., the licence numbered issued to the said [*Name of owner or occupier*] in respect of premises situate at is hereby renewed subject to the provisions of the Stock Remedies (Biological Products) Regulations 1951 until the 31st day of March, 19.., unless sooner revoked or surrendered.

Dated at Wellington, this day of, 19..

....., Registrar,
Stock Remedies Registration Board.

T. J. SHERRARD,
Clerk of the Executive Council.

EXPLANATORY NOTE

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

These regulations make provision for the licensing of persons in charge of the process of manufacturing biological products as stock remedies, and the licensing of premises used for the manufacture of any such products. They restrict the sale, distribution, and use of specified biological products.

Issued under the authority of the Regulations Act 1936.

Date of notification in *Gazette*: 20th day of September 1951.

These regulations are administered in the Department of Agriculture.

(Notice No. Ag. 5129.)