

Therapeutic Goods

No. 29 of 1966

An Act to make provision for and in relation to Standards for Goods for Therapeutic Use, and for other purposes.

[Assented to 24 May, 1966]

BE it enacted by the Queen's Most Excellent Majesty, the Senate, and the House of Representatives of the Commonwealth of Australia, as follows:—

PART I.—PRELIMINARY.

1. This Act may be cited as the *Therapeutic Goods Act 1966*. Short title.
2. This Act shall come into operation on a date to be fixed by Proclamation. Commencement.

- Parts.** 3. This Act is divided into Parts, as follows:—
 Part I.—Preliminary (Sections 1–10).
 Part II.—Determination of Standards (Sections 11–18).
 Part III.—Goods to Conform to Standards (Sections 19–23).
 Part IV.—Miscellaneous (Sections 24–30).
- Repeal.** 4. The *Therapeutic Substances Act 1953* and the *Therapeutic Substances Act 1959* are repealed.
- Interpretation.** 5.—(1.) In this Act, unless the contrary intention appears—
 “general standard”, in relation to goods for therapeutic use, means a standard specified in an order made under section 13 of this Act that applies to a substance or article of which the goods consist, or are represented to consist, and—
 (a) if the goods are for human use—has effect in relation to goods for human use; or
 (b) if the goods are for veterinary use—has effect in relation to goods for veterinary use;
 “goods for therapeutic use” means goods that—
 (a) are (whether by writing or otherwise) represented to be, or are (whether by reason of the way in which the goods are put up or for any other reason) likely to be taken to be—
 (i) for therapeutic use;
 (ii) for use as an ingredient or component in the preparation or manufacture of a substance or article for therapeutic use; or
 (iii) for use as a container, or as part of a container, of a substance or article for therapeutic use or use of a kind referred to in the last preceding subparagraph; or
 (b) are included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or use of a kind referred to in subparagraph (ii) or (iii) of the last preceding paragraph,
 but does not include—
 (c) goods in respect of which a certificate has been issued under section 8 of this Act; or
 (d) goods consisting of a vaccine prepared from microscopic organisms from the body of a person or animal for use only in the treatment of that person or animal;
 “labelling and packaging requirements”, in relation to goods for therapeutic use, means requirements specified in an order made under section 15 of this Act that applies

to a substance or article of which the goods consist, or are represented to consist, and—

(a) if the goods are for human use—has effect in relation to goods for human use; or

(b) if the goods are for veterinary use—has effect in relation to goods for veterinary use;

“order” means an order made by the Minister under Part II.;

“specific standard”, in relation to goods for therapeutic use, means a standard for a substance or article of which the goods consist, or are represented to consist, that—

(a) if the goods are for human use—

(i) is specified in an order made under section 11 of this Act that has effect in relation to goods for human use;

(ii) where a standard for the substance or article is not specified in such an order but the substance or article is the subject of a monograph in the British Pharmacopoeia—is constituted by the statements in that monograph; or

(iii) where a standard for the substance or article is not specified in such an order and the substance or article is not the subject of a monograph in the British Pharmacopoeia but is the subject of a monograph in the British Pharmaceutical Codex—is constituted by the statements in the last-mentioned monograph; or

(b) if the goods are for veterinary use—

(i) is specified in an order made under section 11 of this Act that has effect in relation to goods for veterinary use; or

(ii) where a standard for the substance or article is not specified in such an order but the substance or article is the subject of a monograph in the British Veterinary Codex—is constituted by the statements in that monograph;

“substance” includes a mixture or compound of substances;

“the British Pharmaceutical Codex” means—

(a) the latest edition (being an edition that has taken effect for the purposes of this Act in accordance with sub-section (1.) of the next succeeding section) for the time being of the book called the British Pharmaceutical Codex published by direction of the Council of the Pharmaceutical Society of Great Britain; or

- (b) if that edition has been added to or amended by additions or amendments that have taken effect for the purposes of this Act in accordance with sub-section (1.) of the next succeeding section—that edition as affected by those additions or amendments;

“ the British Pharmacopoeia ” means—

- (a) the latest edition (being an edition that has taken effect for the purposes of this Act in accordance with sub-section (2.) of the next succeeding section) for the time being of the book called the British Pharmacopoeia published under the direction of the General Medical Council of the United Kingdom; or
- (b) if that edition has been added to or amended by additions or amendments that have taken effect for the purposes of this Act in accordance with sub-section (2.) of the next succeeding section—that edition as affected by those additions or amendments;

“ the British Veterinary Codex ” means—

- (a) the latest edition (being an edition that has taken effect for the purposes of this Act in accordance with sub-section (3.) of the next succeeding section) for the time being of the book called the British Veterinary Codex published by direction of the Council of the Pharmaceutical Society of Great Britain; or
- (b) if that edition has been added to or amended by additions or amendments that have taken effect for the purposes of this Act in accordance with sub-section (3.) of the next succeeding section—that edition as affected by those additions or amendments;

“ therapeutic use ” means use in or in connexion with—

- (a) the preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or animals;
- (b) the influencing, inhibiting or modifying of a physiological process in persons or animals; or
- (c) the testing of the susceptibility of persons or animals to a disease or ailment.

(2.) For the purposes of this Act, goods for therapeutic use shall be deemed to be represented to consist, either in whole or in part, of a particular substance or a particular article if—

- (a) the goods bear a name or description—
 - (i) that is, or is likely to be taken for, a name or description of the substance or article; or
 - (ii) that is likely to cause the goods to be taken to consist, in whole or in part, of that substance or article;
- (b) the Minister or another person is informed, in pursuance of a notice under section 9 of this Act, that the goods consist, in whole or in part, of that substance or article; or
- (c) the goods are otherwise represented, by writing or otherwise, or otherwise purport, to consist, in whole or in part, of that substance or article.

(3.) For the purposes of this Act—

- (a) goods shall be deemed to be for veterinary use if—
 - (i) the goods bear any particulars that constitute, or are likely to be taken for, a statement that the goods are intended for veterinary use and are not intended for human use; or
 - (ii) the goods are otherwise represented, by writing or otherwise, or otherwise purport, to be intended for veterinary use and not to be intended for human use; and
- (b) goods shall be deemed to be for human use if they are not for veterinary use.

(4.) For the purposes of the last two preceding sub-sections, goods shall be deemed to bear a name, description or other particulars if that name, that description or those particulars, as the case may be, are set out on—

- (a) the goods or any part of the goods;
- (b) a container or package containing the goods or any part of the goods;
- (c) a label affixed or attached to the goods or any part of the goods; or
- (d) a label affixed or attached to, or inserted in, a container or package containing the goods or any part of the goods.

6.—(1.) The edition of the British Pharmaceutical Codex that was published in the year One thousand nine hundred and sixty-three shall be deemed to have taken effect for the purposes of this Act on the commencement of this Act, and any additions to, or amendments of, that edition, any subsequent edition of the British Pharmaceutical Codex and any additions to, or amendments of,

**Editions of
British
Pharmaceutical
Codex, &c.,
having effect
for purposes
this Act.**

any subsequent edition shall take effect for the purposes of this Act upon such dates as are respectively fixed by the Minister by notices published in the *Gazette*.

(2.) The edition of the British Pharmacopoeia that was published in the year One thousand nine hundred and sixty-three, and the additions to, and amendments of, that edition contained in the Addendum to that edition published in the year One thousand nine hundred and sixty-four, shall be deemed to have taken effect for the purposes of this Act on the commencement of this Act, and any further additions to, or further amendments of, that edition, any subsequent edition of the British Pharmacopoeia and any additions to, or amendments of, any such subsequent edition shall take effect for the purposes of this Act upon such dates as are respectively fixed by the Minister by notices published in the *Gazette*.

(3.) The edition of the British Veterinary Codex that was published in the year One thousand nine hundred and sixty-five shall be deemed to have taken effect for the purposes of this Act on the commencement of this Act, and any additions to, or amendments of, that edition, any subsequent edition of the British Veterinary Codex and any additions to, or amendments of, any such subsequent edition shall take effect for the purposes of this Act upon such dates as are respectively fixed by the Minister by notices published in the *Gazette*.

Mixtures.

7.—(1.) Where—

- (a) goods consist, or are represented to consist, of a mixture of substances; and
- (b) there is a specific standard applicable to the goods in relation to the mixture,

any specific standard that is applicable to the goods in relation to a substance included in the mixture shall be disregarded.

(2.) Where—

- (a) goods consist, or are represented to consist, of a mixture of substances;
- (b) there is no specific standard applicable to the goods in relation to the mixture but there is a specific standard applicable to the goods in relation to a substance included in the mixture; and
- (c) the Minister, by instrument in writing, has directed that this Act does not apply to that substance when it is part of a mixture of that kind,

the specific standard so applicable to the goods shall be disregarded.

(3.) Where—

(a) goods consist, or are represented to consist, of a mixture of substances; and

(b) there is, with respect to any matter, a general standard applicable to the goods in relation to the mixture,

any general standard with respect to that matter that is applicable to the goods in relation to a substance included in the mixture shall be disregarded.

(4.) In this section, “substance” includes article.

8.—(1.) Where a person satisfies a person authorized by the Minister to issue certificates under this section that goods are not intended for therapeutic use, the person so authorized may issue to the other person a certificate that this Act does not apply to the goods.

Certification of goods not intended for therapeutic use.

(2.) A certificate under the last preceding sub-section may be issued unconditionally or subject to conditions.

(3.) Where a condition subject to which a certificate under this section is issued is not complied with, the person to whom the certificate was issued shall be deemed to have committed an offence against this Act.

9.—(1.) The Minister may, by notice in writing served on a person who—

(a) has imported goods for therapeutic use into Australia;

(b) has caused goods for therapeutic use to become the subject of trade or commerce among the States;

(c) has, under a law of the Commonwealth relating to the provision of pharmaceutical benefits, supplied goods for therapeutic use as a pharmaceutical benefit; or

(d) has supplied goods for therapeutic use to the Commonwealth or to an authority of the Commonwealth or a Territory of the Commonwealth,

Furnishing of information with respect to composition of goods.

direct the person to furnish, in writing, to the Minister or another person specified in the notice, within such period as is so specified, such information with respect to the composition of the goods as is required by the notice.

(2.) A person shall not—

(a) fail to comply with a notice served on him under this section; or

(b) in purported compliance with such a notice, knowingly furnish information that is false or misleading.

(3.) A person is not excused from furnishing information in pursuance of a notice served on him under this section on the ground that the information might tend to incriminate him, but his furnishing of any information in pursuance of the notice is not admissible in evidence against him in any criminal proceedings, other than proceedings under this Act.

(4.) A notice under this section may be served on a person—

- (a) personally;
- (b) by sending the notice or a copy of the notice by post to the person at his last-known place of abode or employment; or
- (c) in the case of a body corporate—by sending the notice or a copy of the notice by post to the registered office, if any, of the body corporate or by serving the notice or a copy of the notice personally on the manager, secretary or other executive officer of the body corporate.

Labelling and
packing
requirements
in British
Pharmacopoeia,
&c.

10.—(1.) Subject to the next succeeding sub-section, where—

- (a) a specific standard applicable to goods for therapeutic use is a standard constituted by statements in a monograph in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex;
- (b) requirements applicable to the labelling or packing of the goods are specified in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex, as the case may be; and
- (c) the goods are not labelled or packed in accordance with those requirements,

the goods shall, for the purposes of this Act, be deemed not to conform to that standard.

(2.) Where—

- (a) an order made under section 15 of this Act applies to the labelling or packing of goods;
- (b) requirements applicable to the labelling or packing of the goods are specified in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex; and
- (c) the requirements referred to in the last preceding paragraph are inconsistent with the requirements specified in the order,

then, in relation to the goods, the requirements referred to in paragraph (b) of this sub-section shall, to the extent of the inconsistency, for the purposes of the section of this Act for the purposes of which the order was made, be disregarded.

PART II.—DETERMINATION OF STANDARDS.

11.—(1.) The Minister may, by order in writing, determine that the standard for a substance or article the name of which is specified in the order (including a substance or article that is the subject of a monograph in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex) is, for the purposes of this Act, the standard so specified.

Determination of standards for specific goods.

(2.) The standard may be specified in such manner as the Minister thinks fit, and, without limiting the generality of the foregoing, may be specified by reference to any one or more of the following, that is to say, the composition, strength, potency, stability, sterility, quantity, quality or method of preparation of a substance or article.

12.—(1.) The Minister may, by order in writing, determine that a monograph in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex shall, for the purposes of this Act, be deemed to be modified in such manner as is specified in the order.

Modification of monographs by Minister.

(2.) A reference in this Act to a monograph in the British Pharmacopoeia, a monograph in the British Pharmaceutical Codex or a monograph in the British Veterinary Codex shall, if an order under the last preceding sub-section is in force in relation to the monograph, be read as a reference to the monograph as deemed to be modified in the manner specified in the order.

13.—(1.) The Minister may, by order in writing, determine that, with respect to a matter that is a prescribed matter, the standard for a substance or article to which the order applies is, for the purposes of this Act, the standard specified in the order.

Determination of general standards.

(2.) An order under the last preceding sub-section may be expressed to apply to substances generally, articles generally or to a class of substances or articles specified in the order.

(3.) Where a general standard applicable to goods is inconsistent with a specific standard applicable to the goods, the general standard, in relation to the goods, is, to the extent of the inconsistency, of no effect.

(4.) In this section, "prescribed matter" means composition, strength, potency, stability, sterility, quantity, quality, method of preparation or any other matter prescribed by the regulations.

14. Where an order made under section 11 or 13 of this Act provides that a matter relating to a standard is to be determined in accordance with a test specified by the Minister under this section, the Minister may, by order in writing, specify a test for the purposes of the first-mentioned order.

Tests.

Determination of requirements with respect to labelling, packing and containers.

15.—(1.) The Minister may, by order in writing, for the purposes of a section of this Act specified in the order, direct that goods consisting of a substance or article to which the order applies shall be labelled in such manner as is specified in the order.

(2.) The Minister may, by order in writing, for the purposes of a section of this Act specified in the order, direct that goods consisting of a substance or article to which the order applies shall be packed in such manner as is specified in the order.

(3.) The Minister may, by order in writing, for the purposes of a section of this Act specified in the order, direct that goods consisting of a substance or article to which the order applies shall be in containers that comply with such requirements as are specified in the order.

(4.) An order under this section may be expressed to apply to substances generally, articles generally, a class of substances or articles specified in the order or a substance or article the name of which is so specified.

(5.) Without limiting the generality of sub-section (1.) of this section, the Minister may, in an order made under that sub-section, direct that there shall, in such manner, if any, as is specified in the order, be set out on—

- (a) goods consisting of a substance or article to which the order applies;
- (b) a container or package containing goods consisting of a substance or article to which the order applies;
- (c) a label affixed or attached to goods consisting of a substance or article to which the order applies; or
- (d) a label affixed or attached to, or inserted in, a container or package containing goods consisting of a substance or article to which the order applies,

such particulars as are required by the order.

Effect of orders in relation to goods for human use or veterinary use.

16. Unless the contrary intention appears in an order, the order has effect in relation to goods for human use and goods for veterinary use.

Amendment and revocation of orders.

17. The Minister may, by order in writing, amend or revoke an order made under a preceding provision of this Part.

Notification of orders in *Gazette*, &c.

18.—(1.) The making of an order shall be notified in the *Gazette*.

(2.) An order takes effect from the date of notification of the making of the order in the *Gazette* or from such later date, if any, as is specified in the order.

(3.) The notification in the *Gazette* of the making of an order shall include a statement of the place where copies of the order can be obtained.

(4.) Orders are not Statutory Rules within the meaning of the *Rules Publication Act 1903–1964*.

PART III.—GOODS TO CONFORM TO STANDARDS.

19.—(1.) The importation into Australia is prohibited of goods for therapeutic use that—

Importation
of goods for
therapeutic
use.

- (a) do not conform to any specific standard applicable to the goods;
- (b) do not conform to any general standard applicable to the goods; or
- (c) do not comply with any labelling and packaging requirements applicable to the goods and having effect by virtue of an order made under section 15 of this Act for the purposes of this section.

(2.) Goods the importation of which is prohibited under the last preceding sub-section are prohibited imports for the purposes of the *Customs Act* 1901–1966, and the provisions of that Act relating to prohibited imports apply accordingly.

(3.) Where the Minister is satisfied that it is not against the public interest so to do, he may, by instrument in writing and subject to such conditions, if any, as are specified in the instrument, exempt from sub-section (1.) of this section the importation by a person specified in the instrument—

- (a) of goods specified in the instrument; or
- (b) of goods to be used for a purpose specified in the instrument.

(4.) Where a condition specified in an instrument of exemption under this section is not complied with, the person in whose favour the exemption was granted shall be deemed to have committed an offence against this Act.

20. Except with the consent in writing of the Minister, a person shall not cause, suffer or permit goods for therapeutic use to become the subject of trade or commerce among the States unless the goods—

Interstate trade.

- (a) conform to any specific standard applicable to the goods;
- (b) conform to any general standard applicable to the goods; and
- (c) comply with any labelling and packaging requirements applicable to the goods and having effect by virtue of an order made under section 15 of this Act for the purposes of this section.

Pharmaceutical
benefits.

21.—(1.) Except with the consent in writing of the Minister, a person shall not, under a law of the Commonwealth relating to the provision of pharmaceutical benefits, supply as a pharmaceutical benefit goods for therapeutic use unless—

(a) the goods—

- (i) conform to any specific standard applicable to the goods;
- (ii) conform to any general standard applicable to the goods; and
- (iii) comply with any labelling and packaging requirements applicable to the goods and having effect by virtue of an order made under section 15 of this Act for the purposes of this section; and

(b) goods used as an ingredient in the preparation of the goods—

- (i) conform to any specific standard applicable to the goods so used; and
- (ii) conform to any general standard applicable to the goods so used.

(2.) Where a person supplies goods as a pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits in contravention of this section, that supply shall, for the purposes of that law, be deemed not to be a supply of a pharmaceutical benefit in accordance with that law.

Supply to the
Commonwealth
of goods for
therapeutic use.

22. Except with the consent in writing of the Minister, a person shall not supply to the Commonwealth or to an authority of the Commonwealth or of a Territory of the Commonwealth goods for therapeutic use unless the goods—

- (a) conform to any specific standard applicable to the goods;
- (b) conform to any general standard applicable to the goods; and
- (c) comply with any labelling and packaging requirements applicable to the goods and having effect by virtue of an order made under section 15 of this Act for the purposes of this section.

Consent of
Minister.

23.—(1.) The consent of the Minister for the purposes of any of the last three preceding sections may be given either unconditionally or subject to conditions.

(2.) Where a condition subject to which such a consent is given is not complied with, the person in whose favour the consent was given shall be deemed to have committed an offence against this Act.

PART IV.—MISCELLANEOUS.

24.—(1.) The regulations may make provision for or in relation to the examination, testing and analysing of goods to which this section applies.

Regulations may provide for the examination, &c., of goods for therapeutic use.

(2.) Without limiting the generality of the last preceding sub-section, the regulations which may be made by virtue of that sub-section include regulations making provision—

- (a) for or in relation to the taking of samples of goods to which this section applies;
 - (b) for or in relation to the authorization of persons to take, and to enter upon premises for the purposes of taking, samples of goods to which this section applies and to make examinations and inquiries with respect to matters relating to goods to which this section applies;
 - (c) for or in relation to the appointment or establishment of laboratories for the examination, testing and analysing of goods to which this section applies;
 - (d) for the issue of certificates by persons who have examined, tested or analysed goods to which this section applies; and
 - (e) for prescribing the extent to which certificates issued under the regulations are evidence of matters stated in the certificates.
- (3.) The goods to which this section applies are goods for therapeutic use that—
- (a) are imported into Australia;
 - (b) are proposed to be exported from Australia;
 - (c) have been, are or are proposed to be, the subject of trade or commerce among the States;
 - (d) have been supplied as a pharmaceutical benefit under a law of the Commonwealth relating to the provision of pharmaceutical benefits or are in the possession of a person who is an approved pharmaceutical chemist under such a law at premises in respect of which he is so approved; or
 - (e) have been supplied to the Commonwealth or to an authority of the Commonwealth or of a Territory of the Commonwealth or are in the possession of a person who is a party to a subsisting contract for the supply of goods of that kind to the Commonwealth or to such an authority.

Punishment of offences.

25.—(1.) A person who contravenes, or fails to comply with, a provision of this Act is guilty of an offence against this Act.

(2.) An offence against this Act may be prosecuted either summarily or upon indictment, but an offender is not liable to be punished more than once in respect of the same offence.

(3.) The punishment for an offence against this Act is—

(a) if the offence is prosecuted summarily—a fine not exceeding Two hundred dollars or imprisonment for a term not exceeding six months; or

(b) if the offence is prosecuted upon indictment—a fine not exceeding One thousand dollars or imprisonment for a term not exceeding one year.

(4.) In addition to any other punishment, a court may, if it thinks fit, order the forfeiture of goods in respect of which an offence against this Act has been committed.

Courts to take judicial notice of British Pharmacopoeia and British Pharmaceutical Codex, &c.

26. All courts shall, for the purposes of proceedings arising under this Act, take judicial notice of the British Pharmacopoeia, the British Pharmaceutical Codex and the British Veterinary Codex.

Delegation.

27.—(1.) The Minister may, by instrument in writing, delegate to a person, either generally or otherwise as provided in the instrument of delegation, all or any of his powers and functions under this Act, except this power of delegation.

(2.) A power or function so delegated may be exercised or performed by the delegate in accordance with the instrument of delegation.

(3.) A delegation under this section is revocable at will and does not prevent the exercise of a power or the performance of a function by the Minister.

Saving of other laws.

28. This Act is not intended to exclude or limit the operation of any other law of the Commonwealth or of any law of a State or Territory of the Commonwealth.

Dangerous substances.

29.—(1.) Where the Governor-General is satisfied that a substance, or the use of a substance, is causing, or is likely to cause, the occurrence in Australia of a serious outbreak of disease in persons or animals or is endangering, or is likely to endanger, the life or health of persons or animals in Australia, the regulations—

(a) may prohibit the importation into Australia of goods consisting of the substance; and

(b) may declare that quarantine measures are necessary in relation to goods consisting of the substance.

(2.) The Minister may, by instrument in writing and subject to such conditions, if any, as are specified in the instrument, exempt from regulations made by virtue of paragraph (a) of the last preceding sub-section the importation by a person specified in the instrument of goods consisting of a substance so specified.

(3.) Where a condition specified in an instrument of exemption issued under the last preceding sub-section is not complied with, the person in whose favour the exemption was granted shall be deemed to have committed an offence against this Act.

(4.) Goods the importation of which is prohibited under regulations made by virtue of paragraph (a) of sub-section (1.) of this section are prohibited imports for the purposes of the *Customs Act* 1901–1966, and the provisions of that Act relating to prohibited imports apply accordingly.

(5.) Where regulations made by virtue of paragraph (b) of sub-section (1.) of this section are in force in relation to a substance, the Minister may, by order in writing, direct the person or persons to whom the order applies—

(a) to destroy, or to refrain from selling or distributing, goods consisting of the substance that are in his or their possession; or

(b) not to prepare goods consisting of or containing the substance.

(6.) An order under the last preceding sub-section may be expressed to apply to persons generally, to persons included in a class of persons specified in the order or to a person specified in the order.

(7.) An order under sub-section (5.) of this section does not have effect—

(a) in the case of an order expressed to apply to a person specified in the order—until the order has been served on the person either personally or by sending it by post to, or by leaving it at, his last-known address; and

(b) in any other case—until a copy of the order has been published in the *Gazette*.

(8.) A person to whom an order under sub-section (5.) of this section applies shall comply with the directions in the order.

30. The Governor-General may make regulations, not inconsistent with this Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are

Regulations.

necessary or convenient to be prescribed for carrying out or giving effect to this Act, and in particular—

- (a) for making provision for or in relation to—
 - (i) the establishment of committees to advise the Minister on matters relating to the importation into Australia of therapeutic substances and on such other matters as are prescribed, and the functions and powers of those committees; and
 - (ii) the payment of remuneration and allowances to members of committees established under the regulations; and
 - (b) for prescribing penalties not exceeding a fine of Two hundred dollars or imprisonment for six months for offences against the regulations.
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