1970

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

THE SENATE

THIRTY-SECOND REPORT

from the

STANDING COMMITTEE

on

REGULATIONS AND ORDINANCES

(Being a report upon Statutory Rules, 1970, No.8, Amendments of the Customs (Prohibited Imports) Regulations).

PERSONNEL OF COMMITTEE

Chairman:

Senator I.A.C. Wood.

Members:

Senator Cavanagh

Senator Davidson

Senator Devitt

Senator Greenwood

Senator Lawrie

Senator Wheeldon

FUNCTIONS OF THE COMMITTEE - Since 1932, when the Committee was first established, the principle has been followed that the functions of the Committee are to scrutinize regulations and ordinances to ascertain-

(a) that they are in accordance with the Statute;

(b) that they do not trespass unduly on personal rights and liberties;

(c) that they do not unduly make the rights and liberties of citizens dependent upon administrative rather than upon judicial decisions; and

(d) that they are concerned with administrative detail and do not amount to substantive legislation which should be a matter for parliamentary enactment.

SENATE STANDING COMMITTEE ON REGULATIONS AND ORDINANCES

THIRTY-SECOND REPORT OF THE COMMITTEE

The Senate Standing Committee on Regulations and Ordinances has the honour to present its Thirty-second Report to the Senate.

Statutory Rules, 1970, No.8
Amendments of the Customs (Prohibited Imports) Regulations

2. The purpose of this Report is to acquaint the Senate with the results of the Committee's inquiries concerning the amendments of the Customs (Prohibited Imports) Regulations contained in Statutory Rules, 1970, No.8.

3. The new regulations 5A ~~of~~ to 5G, contained in regulation 2 of these amendments, provide, among other things, that the importation of therapeutic substances is prohibited except by licensed importers or in accordance with a specific written permission of the Director-General of Health. The Director-General may, in his discretion, grant or refuse to grant a licence to an importer, and may, in his discretion, grant or refuse to grant permission for a lincensed importer to import a designated therapeutic substance.

~~Paragraph~~ Sub-regulation (4.) of ~~proposed~~ new Regulation 5A provides that a permission to import shall be subject to such conditions imposing requirements or prohibitions "as the Director-General of Health thinks necessary" to ensure that the substance is only used for the permitted purpose. Thus, the power of imposition of conditions in a permission may extend beyond whose which are, in fact, necessary to those which may be thought to be necessary. Regulation 5B empowers the Director-General "in his discretion" to grant or refuse to grant a licence to import substances. The words quoted imply a consideration of circumstances in the making of a decision which in themselves may be so wide as to preclude any challenge of the decision. The same observation is made in respect of ~~paragraph~~ sub-regulation (3.) of Regulation 5E.

~~Paragraph~~ Sub-regulation (1.) of Regulation 5F requires the Director-General where he has refused permission to import or refused to grant a licence or has revoked a licence, to furnish to the person concerned a statement in writing setting out his reasons. A person aggrieved by such a refusal or revocation may appeal to the Minister of Health who would

have the advice of the Drug Evaluation Committee in deciding such an appeal.

4. The Director-General is not bound by any criteria when exercising his discretion to determine whom he shall licence and to whom he shall grant permission to import. With respect to objective factors to be taken into account by the Director-General and the Minister in making their decisions, the Regulations are completely silent. There is no provision in the Regulations to prevent the Director-General and/or the Minister exercising their powers in a way which may amount to an unjust discrimination between importers and, thereby, subjecting individual rights and liberties unduly to administrative rather than judicial decisions.

5. The Committee realises that the purpose of the regulations is to protect the public from the importation and sale of untested or potentially dangerous drugs, but this purpose is nowhere expressed in terms of objective criteria in the regulations. The Committee considers that where executive bodies are given power to make administrative decisions affecting the rights and livelihood of individuals, there ought to be embodied in the empowering regulations objective criteria upon which those decisions are to be based. Such criteria provide a safeguard against arbitrary or unjustly discriminatory decisions. Reliance upon the Minister or other official acting "reasonably or fairly" is not a sufficient safeguard.

6. It was stated in evidence before the Committee that one of the reasons for not including objective criteria in these regulations was that this would confer a right of appeal to a court, which right, it was said, would not be appropriate in this case because the decisions in question would be of an administrative and not a judicial character.

The Committee believes, however, that the right of appeal to a judicial body is entirely appropriate ~~where~~ in this case and criteria for the decision making ~~are~~ should be embodied in the regulations. If the above-quoted reasoning was applied consistently, the citizen's right of appeal against administrative acts affecting his rights and liberties would be severely limited.

7. For these reasons, the Committee recommends the disallowance of the amendments of the Customs (Prohibited Imports) Regulations, as contained in Statutory Rules, 1970, No.8, and made under the Customs Act, 1901-1968.

Regulations and Ordinances
Committee Room,
Wednesday, 3 June, 1970.

IAN WOOD,
CHAIRMAN

APPENDIX

STATUTORY RULES

1970 No. 8

REGULATIONS UNDER THE CUSTOMS ACT 1901-1968.*

I, THE GOVERNOR-GENERAL in and over the Commonwealth of Australia, acting with the advice of the Federal Executive Council, hereby make the following Regulations under the *Customs Act* 1901-1968.

Dated this twenty-second day of January, 1970.

PAUL HASLUCK
Governor-General.

By His Excellency's Command,

D. L. CHIPP
Minister of State for Customs and Excise.

AMENDMENTS OF THE CUSTOMS (PROHIBITED IMPORTS) REGULATIONS†

Definitions.

1. Regulation 2 of the Customs (Prohibited Imports) Regulations is amended—

(*a*) by inserting before the definition of "flash point" the following definition:—

"'designated therapeutic substance', in relation to a licensed importer, means a therapeutic substance that is a designated therapeutic substance in relation to the importer under regulation 5c of these Regulations;";

(*b*) by inserting after the definition of "flash point" the following definition:—

"'licensed importer' means a person who holds a licence granted under regulation 5B of these Regulations, being a licence that is in force;";

(*c*) by adding after the definition of "the British Pharmacopoeia" the following definitions:—

"'therapeutic substance' means a substance, including a mixture or compound of substances, that has a therapeutic use and includes a surgical ligature, suture or dressing, but does not include a vaccine prepared from microscopic organisms from the body of a person or animal for use in the treatment of that person or animal only;

"'therapeutic use' means a use for the purpose of—

(*a*) the preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or animals;

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* Notified in the *Commonwealth Gazette* on 5 February 1970.

† Statutory Rules 1956, No. 90; as amended by Statutory Rules 1958, Nos. 6 and 67; 1959, Nos. 17, 31 and 93; 1960, No. 22; 1961, No. 147; 1962, No. 82; 1963, No. 26; 1964, Nos. 25 and 39; 1965, Nos. 81, 91, 135, 167 and 190; 1966, No. 95; 1967, Nos. 41, 58, 114 and 178; 1968, Nos. 100, 141 and 161; and 1969, Nos. 2, 7, 10, 39, 43 and 218.

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(*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."; and

(*d*) by adding at the end thereof the following sub-regulation:—

"(2.) For the purpose of regulations 5A to 5G (inclusive) of these Regulations—

(*a*) each form of a therapeutic substance shall be taken to be a separate and distinct therapeutic substance;

(*b*) if a therapeutic substance is manufactured according to two or more formulations—the substance manufactured according to a particular formulation shall be taken to be a different therapeutic substance from the substance manufactured according to the other or each other formulation; and

(*c*) a therapeutic substance having a particular strength shall be taken to be a different therapeutic substance from the substance having a different strength.".

2. After regulation 5 of the Customs (Prohibited Imports) Regulations the following regulations are inserted:—

Importation of therapeutic substances.

"5A.—(1.) The importation into Australia of any of the following therapeutic substances, that is to say—

(*a*) sera, toxoids, toxins, anti-toxins, vaccines, antigens or glandular extracts; or

(*b*) antibiotic substances,

is prohibited unless a permission, in writing, to import the substances has been granted by the Director-General of Health.

"(2.) The next succeeding sub-regulation applies to a therapeutic substance other than—

(*a*) a therapeutic substance specified in the last preceding sub-regulation;

(*b*) a drug specified in the Fourth Schedule to these Regulations; and

(*c*) a therapeutic substance imported by a passenger in a ship or aircraft, being a substance that is brought to Australia on the same ship or aircraft and is for the personal use of the passenger or a member of his family.

"(3.) Subject to the next succeeding sub-regulation, the importation into Australia of a therapeutic substance in relation to which this sub-regulation applies is prohibited unless—

(*a*) a permission in writing to import the substance has been granted by the Director-General of Health; or

(*b*) the person importing the substance is a licensed importer.

"(4.) A permission under sub-regulation (1.) of this regulation or under the last preceding sub-regulation in respect of a therapeutic substance shall be subject to such conditions imposing requirements or prohibitions on the person to whom the permission is granted with respect to—

(*a*) the custody, use, disposal or distribution of the therapeutic substance; or

(*b*) the keeping of records relating to the therapeutic substance,

as the Director-General of Health thinks necessary to ensure that the substance is not used otherwise than for the purposes for which he grants the permission.

"(5.) Where a permission referred to in the last preceding sub-regulation is subject to a condition imposing requirements with respect to the keeping of records relating to a therapeutic substance, the permission shall be deemed to be granted subject to compliance by the person to whom it is granted with the following requirements with respect to any quantity of the therapeutic substance imported by him into Australia in accordance with the permission:—

(*a*) the person shall, when required to do so by an authorized officer at any reasonable time of the day, produce the records kept by him in relation to the substance for examination by the authorized officer, and permit that officer to take extracts from or copies of the records; and

(*b*) the person shall produce to an authorized officer, at any reasonable time of the day, the quantity of the therapeutic substance, or of a substance or mixture in the preparation of which any of the therapeutic substance has been used, that is in his possession, and permit the officer to examine the substance, to weigh or otherwise ascertain the quantity of the substance and to take a sample of the substance for further examination and analysis.

"(6.) In the last preceding sub-regulation, 'an authorized officer' means a person who is an officer authorized for the purposes of regulation 5D of these Regulations.

"(7.) Sub-regulation (4.) of regulation 5D of these Regulations applies in relation to an authorized officer who is acting under sub-regulation (5.) of this regulation in like manner as it applies in relation to an authorized officer who is acting under regulation 5D of these Regulations.

Licensed importers.

"5E.—(1.) The Director-General of Health may, in his discretion, grant or refuse to grant a person a licence to import therapeutic substances in relation to which sub-regulation (3.) of the last preceding regulation applies.

"(2.) Without limiting the generality of the last preceding sub-regulation, the Director-General of Health—

(*a*) may request an applicant for a licence to import therapeutic substances in relation to which sub-regulation (3.) of the last preceding regulation applies to furnish to the Director-General of Health a list, being a list certified by the applicant to be true and correct in every particular, of the therapeutic substances in relation to which sub-regulation (3.) of the last preceding regulation applies imported by the applicant during the period of two years immediately preceding his application for the licence; and

(*b*) may refuse to grant such a licence to an applicant who has been requested to furnish such a list to the Director-General of Health until the applicant has complied with the request.

"(3.) A licence granted under sub-regulation (1.) of this regulation remains in force, subject to the next succeeding sub-regulation, for such period as is specified in the licence.

"(4.) Where a licensed importer fails to comply with a condition of his licence, the Director-General of Health may, by notice in writing to the importer, revoke the licence.

Designated therapeutic substances.

"5C.—(1.) In this regulation—

'exempt therapeutic substance' means a substance declared, by an instrument that is in force, to be an exempt therapeutic substance for the purpose of this regulation;

'therapeutic substance' means a therapeutic substance in relation to which sub-regulation (3.) of regulation 5A of these Regulations applies.

"(2.) The Director-General of Health may, by instrument under his hand—

(*a*) declare a specified therapeutic substance, or the therapeutic substances included in a specified class of therapeutic substances, to be, for the purpose of these Regulations, a designated therapeutic substance or designated therapeutic substances, as the case may be, in relation to each licensed importer; or

(*b*) declare a specified therapeutic substance, or the therapeutic substances included in a specified class of therapeutic substances, to be an exempt therapeutic substance or exempt therapeutic substances, as the case may be, for the purpose of this regulation.

"(3.) Where—

(*a*) a licensed importer imports a therapeutic substance, other than—

(i) an exempt therapeutic substance; or

(ii) a therapeutic substance that is a designated therapeutic substance in relation to him by virtue of an instrument in force under paragraph (*a*) of the last preceding sub-regulation; and

(*b*) the therapeutic substance is a substance of a kind that the importer has not imported during the two years immediately preceding the importation of the substance,

the substance becomes, for the purpose of these Regulations, a designated therapeutic substance in relation to the licensed importer.

"(4.) A therapeutic substance that becomes a designated therapeutic substance in relation to a licensed importer by virtue of the last preceding sub-regulation continues to be a designated therapeutic substance in relation to the licensed importer until—

(*a*) the Director-General of Health approves the disposal of the substance by the licensed importer without restriction as to which persons to whom, or purposes for which, the substance may be disposed of; or

(*b*) the therapeutic substance becomes an exempt therapeutic substance,

whichever first occurs.

"(5.) The fact that a therapeutic substance that had, under sub-regulation (3.) of this regulation, become a designated therapeutic substance in relation to a licensed importer has, under the last preceding sub-regulation, ceased to be a designated therapeutic substance in relation to the importer shall not be taken to prevent the substance again becoming a designated therapeutic substance in relation to the licensed importer under sub-section (2.) or (3.) of this regulation.

"(6.) The fact that a therapeutic substance that had, under sub-regulation (2.) of this regulation, become a designated therapeutic substance, has ceased to be such a substance under that sub-regulation shall not be taken to prevent the substance again becoming a designated therapeutic substance

in relation to each licensed importer under that sub-regulation or a designated therapeutic substance under sub-regulation (3.) of this regulation in relation to a particular licensed importer.

"(7.) The Director-General of Health shall, from time to time, cause to be published in the *Gazette*—

(*a*) a list of therapeutic substances that are designated therapeutic substances in relation to all licensed importers; and

(*b*) a list of therapeutic substances that are exempt therapeutic substances for the purpose of this regulation.

Conditions of licences under regulation 5D.

"5D.—(1.) A licence granted under regulation 5B of these Regulations is subject to compliance by the person to whom it is granted with the following requirements with respect to any quantity of a designated therapeutic substance imported by him into Australia:—

(*a*) subject to sub-regulation (5.) of this regulation, the person shall, at least twenty-eight days before the importation of any quantity of the designated therapeutic substance, notify the Director-General of Health, in writing, of his intention to import the substance, of the quantity of the substance to be imported and of the name and address of the manufacturer of the substance;

(*b*) the person shall not dispose of a quantity of the designated therapeutic substance or of a substance or mixture in the preparation of which the designated therapeutic substance has been used except—

(i) with the approval of the Director-General of Health;

(ii) in accordance with that approval; and

(iii) after he has satisfied himself that the whole of that quantity of the substance will be used for the purpose specied in that approval;

(*c*) the person shall keep the designated therapeutic substance and any substance or mixture in the preparation of which the designated therapeutic substance has been used in safe custody until he disposes of it;

(*d*) the person shall keep, in books kept by him for the purpose, records of—

(i) the date on which he imports a quantity of the designated therapeutic substance and the quantity of the substance imported on that date;

(ii) the quantity of the designated therapeutic substance used by him in the preparation of another substance or a mixture, the date on which that quantity is so used and the quantity of that other substance or mixture then prepared;

(iii) the quantity of the designated therapeutic substance, or substance or mixture in the preparation of which the designated therapeutic substance has been used, that is supplied by him to another person, the name and address of the person to whom it is supplied and the date on which it is supplied;

(iv) the quantity of the designated therapeutic substance, or of a substance or mixture in the preparation of which the designated therapeutic substance has been used, that has been lost, destroyed or wasted or has evaporated, and the circumstances in which and date on which it was so lost, destroyed or wasted or it evaporated; and

(v) the quantity of the designated therapeutic substance, and of each substance or mixture in the preparation of which the designated therapeutic substance has been used, that remains in his possession;

(*e*) the person shall retain the books so kept by him until the Director-General of Health approves their destruction;

(*f*) the person shall, when required to do so by an authorized officer at any reasonable time of the day, produce the books for examination by the authorized officer, and permit that officer to take extracts from or copies of the books; and

(*g*) the person shall produce to an authorized officer, at any reasonable time of the day, the quantity of the designated therapeutic substance, or of a substance or mixture in the preparation of which the designated therapeutic substance has been used, that is in his possession, and permit the officer to examine the substance, to weigh or otherwise ascertain the quantity of the substance and to take a sample of the substance for further examination and analysis.

"(2.) In the last preceding sub-regulation, 'authorized officer' means an officer authorized by the Director-General of Health by writing under his hand to be an authorized officer for the purposes of this regulation.

"(3.) The Director-General of Health shall issue to an officer whom he authorizes to be an authorized officer for the purposes of this regulation a certificate, under his hand, stating that the officer is an authorized officer.

"(4.) An authorized officer who enters upon land or into premises for the purposes of exercising a power conferred on him by sub-regulation (1.) of this regulation is not authorized to remain on the land or in the premises if, upon request by the occupier of the land or premises for the production of the certificate so issued to him, he does not produce the certificate.

"(5.) Where—

(*a*) the Director-General of Health has, by instrument in writing, authorized a licensed importer to give the notification that he is required to give under the condition of his licence specified in paragraph (*a*) of sub-regulation (1.) of this regulation in respect of the importation of a quantity of a specified designated therapeutic substance not less than a specified number of days, being less than twenty-eight days, before the importation of such a quantity; and

(*b*) that instrument is in force,

the reference in paragraph (*a*) of that sub-regulation to twenty-eight days shall, for the purpose of the application of the condition of the licence specified in that paragraph to and in relation to the importation by that licensed importer of a quantity of that designated therapeutic substance, be read as a reference to the number of days so specified.

Disposal of designated therapeutic substances.

"5E.—(1.) A licensed importer may, from time to time, apply, in writing, to the Director-General of Health for permission—

(*a*) to dispose of a quantity of a designated therapeutic substance to a person and for a purpose specified in the application; or

(*b*) to dispose of quantities of a designated therapeutic substance without restriction as to the person to whom or purpose for which it may be disposed of.

"(2.) The Director-General of Health may request an applicant under the last preceding sub-regulation to furnish him with such information.

not being information furnished by the licensed importer in connexion with a previous application under this regulation relating to the designated therapeutic substance to which the application relates, with respect to—

(*a*) the method of manufacture of the designated therapeutic substance;

(*b*) the investigations that have been carried out by the applicant and by other persons concerning the safe use of the substance; and

(*c*) if the substance is to be used for experimental purposes only—the investigations into the use of the substance that are proposed to be carried out,

and may defer consideration of the application until the information is furnished to him.

"(3.) The Director-General of Health may, in his discretion, grant or refuse to grant an application under this regulation.

"(4.) Where the Director-General of Health has refused permission for a licensed importer to dispose of a quantity of a designated therapeutic substance to a particular person or for a particular purpose, or to dispose of quantities of a designated therapeutic substance without restriction, or the Minister of State for Health, upon reviewing such a refusal by the Director-General of Health, has confirmed the decision of the Director-General of Health, the licensed importer shall not, within three months after the decision of the Director-General of Health or the Minister of State for Health, as the case may be, make a like application to the Director-General of Health for permission so to dispose of a quantity or quantities of the designated therapeutic substance unless the application is accompanied by information with respect to investigations carried out by the applicant or by other persons concerning the safe use of the substance that was not available when the previous application was considered by the Director-General of Health.

"(5.) In this regulation, references to a designated therapeutic substance shall be read as including references to a substance or mixture in the preparation of which a designated therapeutic substance has been used.

"5F.—(1.) Where the Director-General of Health— Director-General to give reasons for refusal.

(*a*) refuses a person permission to import a therapeutic substance specified in sub-regulation (1.) of regulation 5A of these Regulations;

(*b*) refuses a person permission to import a substance in relation to which sub-regulation (3.) of that regulation applies;

(*c*) refuses to grant a person a licence under regulation 5B of these Regulations;

(*d*) revokes such a licence that has been granted to a person;

(*e*) refuses a licensed importer who has applied for approval to dispose of a designated therapeutic substance without restriction as to the persons to whom or purpose for which the substance may be disposed of approval so to dispose of the substance; or

(*f*) refuses a licensed importer who has applied for approval to dispose of a quantity of a designated therapeutic substance to a specified person or for a specified purpose approval so to dispose of the quantity,

the Director-General of Health shall furnish to the person or licensed importer, as the case may be, a statement, in writing, setting out his reasons for the refusal or revocation, as the case may be.

"(2.) *The last preceding sub-regulation applies*—

(*a*) to a licensed importer who has applied for approval to dispose of a designated therapeutic substance without restriction as to the persons to whom or purpose for which the substance may be disposed of whether or not the Director-General of Health approves, or indicates his willingness to approve, the disposal of a quantity of the substance to a specified person for a specified purpose; and

(*b*) to a licensed importer who has applied for approval to dispose of a quantity of a designated therapeutic substance to a specified person or for a specified purpose—whether or not the Director-General of Health approves, or indicates his willingness to approve, the disposal of a different quantity of the substance to that person for that purpose or the disposal of a quantity of the substance to another person or for another purpose.

Appeals.

"5B.—(1.) Subject to sub-regulation (4.) of this regulation, a person who is aggrieved by a decision of the Director-General of Health—

(*a*) refusing him permission to import any of the therapeutic substances specified in sub-regulation (1.) of regulation 5A of these Regulations;

(*b*) refusing him permission to import a substance in relation to which sub-regulation (3.) of that regulation applies;

(*c*) refusing to grant him a licence under regulation 5D of these Regulations; or

(*d*) revoking such a licence that had been granted to him,

may, within three months after notice of the decision is given to him, request the Minister of State for Health to review the decision.

"(2.) Subject to sub-regulation (4.) of this regulation, a licensed importer who is aggrieved by a decision of the Director-General of Health—

(*a*) refusing him permission to dispose of a quantity of a designated therapeutic substance to a specified person for a specified purpose; or

(*b*) refusing him permission to dispose of quantities of a designated therapeutic substance without restriction as to the person to whom or purpose for which they may be disposed of,

may, within three months after notice of the decision is given to him, request the Minister of State for Health to review the decision.

"(3.) A request under either of the last two preceding sub-regulations shall be in writing, shall state the grounds of the request and shall state, or be accompanied by, any information, additional to any information furnished by him to the Director-General of Health in connexion with the matter to which the decision relates, that the person wishes to furnish in support of the request.

"(4.) A person aggrieved by a decision of the Director-General of Health shall be taken not to have duly made a request under sub-regulation (1.) or (2.) of this regulation unless the person has, within twenty-eight days after notice of the decision was given to him, furnished to the Director-General of Health notice of his intention to request the Minister of State for Health to review the decision.

"(5.) Where a person requests the Minister of State for Health under this regulation to review a decision of the Director-General of Health, the Minister, after considering the grounds of the request, the information

furnished in support of the request, any information furnished by the person to the Director-General of Health in connexion with the matter to which the request relates, the report of the Director-General of Health concerning the matter to which the request relates and, if the request relates to the importation or disposal of a designated therapeutic substance, any advice relating to the importation or disposal of the substance that is furnished to the Minister by the Australian Drug Evaluation Committee established under the *Therapeutic Substances Act* 1953-1959, may, in his discretion, confirm, reverse or modify the decision.

"(6.) Where the request to the Minister of State for Health under this regulation relates to the importation or disposal of a designated therapeutic substance, the Minister of State for Health shall not determine the request until he has afforded the Australian Drug Evaluation Committee established under the *Therapeutic Substances Act* 1953-1959 an opportunity of considering the application to which the request relates and of furnishing advice to the Minister relating to the importation or disposal of the substance.

"(7.) The Australian Drug Evaluation Committee may, for the purpose of enabling it to furnish advice to the Minister of State for Health in relation to the importation or disposal of a designated therapeutic substance, request the person who applied to the Director-General of Health for permission to import the substance or for approval to dispose of the substance to furnish it with such information, relevant to the question whether the application should be granted, as it thinks fit.

"(8.) Where the Minister of State for Health reverses or modifies a decision of the Director-General of Health, he may give such decision as the Director-General of Health might have given under these Regulations, and his decision has effect for the purposes of these Regulations as if it were a decision of the Director-General of Health.".

3. The Third Schedule to the Customs (Prohibited Imports) Regulations is amended by omitting items 3, 22, 28A and 29. Third Schedule.

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