1965/67

THE FOOD AND DRUG REGULATIONS 1946, AMENDMENT NO. 14

BERNARD FERGUSSON, Governor-General

ORDER IN COUNCIL

At the Government House at Wellington this 12th day of May 1965

Present:
HIS EXCELLENCY THE GOVERNOR-GENERAL IN COUNCIL

PURSUANT to the Food and Drugs Act 1947, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

REGULATIONS

1. (1) These regulations may be cited as the Food and Drug Regulations 1946, Amendment No. 14, and shall be read together with and deemed part of the Food and Drug Regulations 1946* (hereinafter referred to as the principal regulations).

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

2. (1) Regulation 24 of the principal regulations and regulation 11 of the Food and Drug Regulations 1946, Amendment No. 1, are hereby revoked.

(2) All exemptions granted under the said regulation 24 or any predecessor thereof and in force at the commencement of these regulations shall, subject to the provisions of clauses (5) and (6) of that regulation, enure until the expiration of the 31st day of December 1969, with which day all such exemptions then in force shall expire.

3. The principal regulations are hereby further amended by inserting, after regulation 49B (as inserted by clause (1) of regulation 7 of the Food and Drug Regulations 1946, Amendment No. 12), the following heading and regulation:

"UNPASTEURISED MILK

"49C. (1) Where a Medical Officer of Health knows or has reasonable grounds to suspect that any unpasteurised milk is infected with organisms capable of causing a communicable disease within the meaning of the

*S.R. 1946/136 (Reprinted with Amendments Nos. 1 to 13: S.R. 1963/209)
See also the Food and Drug Temporary Regulations 1946 (S.R. 1946/162), (*regulations 5, 7, 8, 9, and 11 of which were revoked by* S.R. 1947/152, 1949/158, 1950/138, and 1956/29.)

Health Act 1956 he may give to any person who has or may have any such milk in his possession for sale, written notice of his knowledge or suspicion describing, by postal address or otherwise, the source from which the Medical Officer of Health believes such milk to be supplied.

"(2) Any notice given under clause (1) of this regulation shall, unless it is sooner withdrawn, continue in force for any period, not exceeding one month, specified therein, but may from time to time be renewed by the Medical Officer of Health for further periods not exceeding one month at any one time.

"(3) Every notice given under clause (1) of this regulation shall be withdrawn forthwith upon a Medical Officer of Health being satisfied that the milk in respect of which it was given is not so infected.

"(4) While any such notice continues in force no person knowing of the notice shall sell any unpasteurised milk which he knows or has reason to believe has been obtained by him or some other person at or from the source described in the notice."

4. The principal regulations are hereby amended by inserting, after regulation 102, the following heading and regulation:

"STANDARD MILK

"102A. (1) Standard milk shall be milk which has had only milk solids added to it. It shall contain not less than $3\frac{1}{4}$ parts per cent of milk fat and not less than $8\frac{1}{2}$ parts per cent of milk solids other than milk fat.

"(2) Standard milk, if homogenised, shall be homogenised so that the fat globules are broken up to such an extent that after 48 hours of quiescent storage at a temperature of 4°C–10°C no visible cream separation occurs and the fat percentage of the top 50 ml of milk in a quantity of 500 ml, or of proportionate volumes, does not differ by more than 10 per cent of itself from the fat percentage of the remaining milk as determined after thorough mixing.

"(3) Standard milk shall be pasteurised in accordance with the requirements of regulation 100 hereof.

"(4) The bacterial condition of standard milk shall be that prescribed for milk in regulation 99 hereof.

"(5) In respect of every package of less than 2 gallons capacity containing standard milk the following requirements shall apply—

"(a) The date in the month on which the package was filled with standard milk or the date of the next succeeding day shall be legibly written or embossed on the disc, cap, or device used for sealing the package:

"(b) The word 'Standard' shall be legibly written in letters of not less than $\frac{1}{4}$ in. on a label attached to the package or shall be legibly written or embossed in letters of not less than $\frac{1}{12}$ in. on the disc, cap, or device used for sealing the package.

"(6) The word 'Standard' shall be legibly written in letters of not less than 1 in. on a label attached to every package of 2 gallons capacity or more used in the sale or distribution of standard milk.

"(7) The name and address of the packer shall be written or embossed on every package containing standard milk. The requirements of this clause as to the statement of the address of the packer shall be satisfied in the case of a bottle if the name of the town alone is written or embossed, either separately or in the trading name of the packer, on the disc, cap, or other device used for sealing the bottle.

"(8) No words or marking other than the words required by clauses 5 to 7 of this regulation shall be written or embossed on the disc, cap, or device used for sealing any package of standard milk.

"(9) The requirements of paragraph (b) of regulation 12 hereof as to the statement of the net contents shall be deemed to be satisfied in the case of a bottle if the statement of net contents is legibly embossed on the side of the bottle."

5. (1) The principal regulations are hereby amended by revoking regulation 179 (as substituted by regulation 22 (1) of the Food and Drug Regulations 1946, Amendment No. 12, and as amended by regulation 21 of the Food and Drug Regulations 1946, Amendment No. 13) and regulation 179A and the heading to that regulation (as inserted by regulation 10 of the Food and Drug Temporary Regulations 1946), and substituting the following regulation:

"179. (1) For the purposes of this Part of these regulations, unless the context otherwise requires,—

"'The *British Pharmacopoeia*' means the 1963 edition of the *British Pharmacopoeia*:

"'The *British Pharmaceutical Codex*' means the 1963 edition of the *British Pharmaceutical Codex*:

and includes in each case the addenda, supplements, and corrigenda thereto that have been published before the coming into force of this regulation.

"(2) Any drug within the meaning of paragraphs (a), (b), (c), or (i) of the definition of 'drug' in section 2 of the Act, other than a drug for which some other standard is prescribed by these regulations, shall—

"(a) If it is the subject of a monograph in the *British Pharmacopoeia,* conform to the descriptions and tests prescribed therein with respect to that drug:

"(b) If it is not the subject of a monograph in the *British Pharmacopoeia* but is the subject of a monograph in the *British Pharmaceutical Codex,* conform to the descriptions and tests prescribed therein with respect to that drug.

"(3) Any surgical dressing which is the subject of a monograph in the *British Pharmaceutical Codex* shall conform to the descriptions and tests prescribed therein with respect to that surgical dressing.

"(4) Wherever in the publications described in clauses (1) and (2) of this regulation it is required that a drug shall be compounded with olive oil or arachis oil, the drug, if intended solely for external use, may be compounded with olive oil, or arachis oil, or cotton seed oil, or maize oil, or soya bean oil.

"(5) Any drug within the meaning of paragraphs (a), (b), (c), or (i) of the definition of 'drug' in section 2 of the Act, not being a drug supplied with reference to the needs of a particular person and not being the subject of a monograph in the *British Pharmacopoeia* or the *British Pharmaceutical Codex,* shall bear on its package a label setting out:

"(a) (i) Its international non-proprietary name or a name approved by the United Kingdom General Medical Council or its true scientific name; and

"(ii) Its strength, quality, or purity; or

"(b) The information required by regulation 187 hereof."

(2) The following regulations are hereby revoked:

(a) Regulation 22 of the Food and Drug Regulations 1946, Amendment No. 12:

(b) Regulation 21 of the Food and Drug Regulations 1946, Amendment No. 13:

(c) Regulation 10 of the Food and Drug Temporary Regulations 1946.

6. Regulation 180 of the principal regulations is hereby amended by omitting from clause (4) the words "second addendum to the *British Pharmacopoeia* 1932", and substituting the words "*British Pharmacopoeia*".

7. The principal regulations are hereby amended by inserting, after regulation 186c, the following heading and regulation:

"OPHTHALMIC PREPARATIONS

"186D. Any drug used or recommended for application to the eye shall be sterile so as to pass the tests for sterility prescribed in the *British Pharmacopoeia*."

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 several amendments to the Food and Drug Regulations 1946.

Regulation 2 revokes regulation 24 of the principal regulations which at present enables the Director-General of Health to exempt packages which contain any food or drug and which bear a duly registered trademark or brand from the usual requirement that any package containing any food or drug must bear the name and address of the manufacturer or seller. Existing exemptions are to continue in force but will expire, unless sooner revoked, with 31 December 1969.

Regulation 3 inserts a new regulation which enables Medical Officers of Health to prevent the sale of unpasteurised milk where they know or have reasonable grounds to suspect that it is infected with organisms capable of causing a communicable disease within the meaning of the Health Act 1956.

Regulation 4 prescribes standards and labelling requirements for "standard" milk. "Standard" milk is milk which has had only milk solids added to it.

Regulation 5 substitutes a new regulation 179 for the existing regulations 179 and 179A. The new regulation is largely concerned with the application of the standards and specifications for drugs and surgical dressings set out in the latest editions of the *British Pharmacopoeia* and the *British Pharmaceutical Codex*.

Regulation 6 substitutes a reference to the latest edition of the *British Pharmacopoeia* for a reference to an addendum to the 1932 edition in regulation 180.

Regulation 7 inserts a new regulation 186D in the principal regulations. The new regulation imposes a requirement that drugs used or recommended for application to the eye must be sterile so as to pass the tests prescribed in the *British Pharmacopoeia*.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette:* 13 May 1965.
These regulations are administered in the Department of Health.