1976/68

THE FOOD AND DRUG REGULATIONS 1973, AMENDMENT NO. 2

DENIS BLUNDELL, Governor-General

ORDER IN COUNCIL

At the Government Buildings at Wellington this 1st day of March 1976

Present:

THE RIGHT HON. R. D. MULDOON PRESIDING IN COUNCIL

PURSUANT to the Food and Drug Act 1969, His Excellency the Governor-General, acting by and with the advice and consent of the Executive Council, hereby makes the following regulations.

ANALYSIS

REGULATIONS

1. Title and commencement—(1) These regulations may be cited as the Food and Drug Regulations 1973, Amendment No. 2, and shall be

read together with and deemed part of the Food and Drug Regulations 1973* (hereinafter referred to as the principal regulations).

(2) Except as provided in subclauses (3) and (4) of this regulation, these regulations shall come into force on the day after the date of their notification in the *Gazette*.

(3) Without limiting section 46 (5) of the Act, regulations 3, 4, 6, 7, 8 (1), 13, 14, 15, 16, 22, 25 (2), 31, 33, 34, and 35 of these regulations shall come into force on the day 6 months after the date of the notification of these regulations in the *Gazette*.

(4) Without limiting section 46 (5) of the Act, regulations 36 and 37 of these regulations shall come into force—

(a) So far as they are applicable to manufacturers of therapeutic drugs, on the 1st day of September 1977:

(b) So far as they are applicable to pharmaceutical wholesalers and to persons conducting pharmacies, on the 1st day of December 1977.

2. Exemptions from regulation 3 of principal regulations—Regulation 4 of the principal regulations is hereby amended by revoking paragraph (c).

3. Additional requirements as to labelling of non-standard foods—Regulation 6 of the principal regulations is hereby amended by revoking subclause (2), and substituting the following subclauses:

"(2) Where such a food consists of 2 or more ingredients the label shall specify in descending order the amounts of those ingredients in the package, such amounts being expressed either as a proportion of the whole contents of the package or as the amounts present in named units within the package.

"(2A) Notwithstanding anything in these regulations, where such a food contains as an ingredient a food for which a standard is prescribed, it shall not be necessary to specify the ingredients of that ingredient food."

4. Form and manner of labelling—(1) Regulation 9 of the principal regulations is hereby amended by revoking subclause (1), and substituting the following subclause:

"(1) The particulars that are required by regulations 5, 238, 239, and 244 of these regulations to appear on a label shall appear in the principal display panel, except that—

"(a) The statement of the volume of the contents of a bottle of wine, fruit wine, or vegetable wine may appear on a label affixed to the neck of the bottle:

"(b) All or any of the particulars specified in—

"(i) Paragraph (c) of subclause (1) of regulation 5; and

"(ii) Paragraph (c) of subclause (1) of regulation 238; and

"(iii) Paragraphs (b) and (c) of subclause (4) of regulation 239; and

"(iv) Subparagraphs (ii) and (iii) of paragraph (b) of subclause (5) of regulation 239; and

"(v) Paragraphs (b) and (c) of subclause (3) of regulation 244—

*S.R. 1973/79
Amendment No. 1: S.R. 1974/188

of these regulations may appear on one other label or panel of the label."

(2) Subclauses (1) and (2) of regulation 4 of the Food and Drug Regulations 1973, Amendment No. 1* are hereby consequentially revoked.

5. Labelling of food not sold in suitable packages—Regulation 11 of the principal regulations is hereby amended by omitting from subclause (2) the expression "12 mm", and substituting the expression "4 mm".

6. Claims as to presence of vitamins—Regulation 13 of the principal regulations is hereby amended by adding to subclause (2) the words "If the food requires dilution or preparation before consumption the quantity of each vitamin shall be calculated for the purposes of this regulation in relation to the food after such dilution or preparation."

7. Claims as to presence of minerals—Regulation 14 of the principal regulations is hereby amended by adding the words "If the food requires dilution or preparation before consumption the proportion of each mineral shall be calculated for the purposes of this regulation in relation to the food after such dilution or preparation."

8. Preservatives—(1) Regulation 16 of the principal regulations is hereby amended by revoking subparagraph (i) of paragraph (b) of subclause (6).

(2) Regulation 16 of the principal regulations is hereby further amended by inserting in the appropriate column of the table of specified preservatives set out in subclause (8), in respect of the maximum permitted proportion in parts per million of sorbic acid (or its sodium, calcium, or potassium salts calculated as sorbic acid) in drink flavour, drink concentrate, the figures "3,000".

(3) Regulation 16 of the principal regulations is hereby further amended by omitting from the first column of the said table in subclause (8) the words "All other wine and fruit wine", and substituting the words "All other wine, fruit wine, and vegetable wine".

(4) Regulation 16 of the principal regulations is hereby further amended by inserting in the appropriate column of the said table in subclause (8), in respect of the maximum permitted proportion in parts per million of benzoic acid (or sodium benzoate calculated as benzoic acid) in special purpose foods other than infants' foods, the figures "1,000".

9. Antioxidants—Regulation 17 of the principal regulations is hereby amended by adding the following subclause:

"(9) Where any antioxidant is permitted by these regulations to be added to food, it may contain phospholipids including lecithin from natural sources, citric acid, lactic acid, malic acid, phosphoric acid, or tartaric acid."

10. Colouring substances—(1) Regulation 18 of the principal regulations is hereby amended by inserting in the appropriate columns of the table of synthetic colours set out in paragraph (d) of subclause (2),

*S.R. 1974/188

after the item "19140/C.I. Food Yellow 4/Tartrazine", the item "42053/C.I. Food Green 3/Fast Green FCF".

(2) Regulation 18 of the principal regulations is hereby further amended by revoking paragraph (b) of subclause (5).

(3) The First Schedule to the principal regulations is hereby consequentially revoked.

11. Incidental constituents—(1) Regulation 24 of the principal regulations is hereby amended by inserting in the Second Table, in their appropriate alphabetical order, and in the appropriate columns, the following items:

"Anilazine	Bulb crops	10
	Small fruit	10
	Tomatoes	10
"Azinphos-methyl / " or / "Azinphos-ethyl	Vegetables	2
"Benzoximate	Pome fruit	0.2
"Bupirimate	Pome fruit	0.1
"Carboxin	Grain crops	0.2
"Chlorethephon	Stone fruit	2
	Tomatoes	1
	Pome fruit	2
"Chlorpyrifos and its metabolite 3, 5, 6—trichloro 2 pyridinol	Meat fat, in any food	1.5
"Cyhexatin	Citrus fruit	3
	Pome fruit	3
	Small fruit	3
	Stone fruit	3
"Dichlofluanid	Small fruit	10
"Dichlorvos	Small fruit	2
"Fenbutatin oxide	Pip and stone fruit	1
"Methamidophos	Tomatoes	0.1
"Methidathion	Citrus fruit	2
"Phenthoate	Brassica crops	0.7
"Propargite	Pome fruit	3
"Propyzamide	Leafy vegetables	1
"Propoxur	Root and tuber vegetables	3
"Sec-butylamine	Citrus fruit	30
"Temephos	Meat fat, in any food	2
"Triforine	Stone fruit	3
"2, 4-D	Stone fruit	1".

(2) Regulation 24 of the principal regulations is hereby further amended by omitting from the said Second Table the items "Tricyclohexyltin hydroxide/Fruit/3", and "Heptachlor/Milk fat, in any food/0.1".

12. Bakery products—Regulation 62 of the principal regulations is hereby amended by adding the following subclause:

"(5) A bakery product may contain not more than 50 ppm of polyglycerol polylinoleate or polyglycerol polyricinoleate."

13. Corned, cured, pickled, and salted meat—Regulation 86 (3) of the principal regulations is hereby amended by omitting all the words occurring after the words "alone or in combination,", and substituting the words "if the final product does not contain more than 200 ppm of total nitrate and nitrite, calculated together as sodium nitrite".

14. Canned meat—Regulation 96 (2) of the principal regulations is hereby amended by omitting all the words occurring after the words "alone or in combination,", and substituting the words "if the final product does not contain more than 200 ppm of total nitrate and nitrite, calculated together as sodium nitrite".

15. Canned manufactured meat—Regulation 97 (2) of the principal regulations is hereby amended by omitting all the words occurring after the words "alone or in combination,", and substituting the words "if the final product does not contain more than 200 ppm of total nitrate and nitrite, calculated together as sodium nitrite".

16. Canned meat with cereals, vegetables, or pastry—Regulation 98 (3) of the principal regulations is hereby amended by omitting all the words occurring after the words "alone or in combination,", and substituting the words "if the final product does not contain more than 200 ppm of total nitrate and nitrite, calculated together as sodium nitrite".

17. Lard—Regulation 113 of the principal regulations is hereby amended by omitting the word "at", and substituting the word "as".

18. Cheese—Regulation 132 of the principal regulations is hereby amended by inserting in the table set out in subclause (4), in its appropriate alphabetical order, and in the appropriate columns, the item "Egmont/45/40".

19. Tomato and apple sauce or tomato chutney sauce—Regulation 150 (2) of the principal regulations is hereby amended by omitting the words "The words shall form the first line of the label, and no other words shall appear in the same line.".

20. Raw sugar—The principal regulations are hereby amended by inserting, after regulation 156, the following regulation:

"156A. Raw sugar shall be a clean, granulated product obtained from sugar cane or sugar beet before refining."

21. Chocolate—Regulation 182 of the principal regulations is hereby amended by adding the following subclause:

"(5) Chocolate described as 'coverture' shall contain not more than 0.125% polyglycerol polyricinoleate."

22. Raw vegetables—Regulation 184 of the principal regulations is hereby amended by adding the following subclause:

"(4) Raw potatoes shall be packed in bags sufficiently opaque to protect the potatoes from the greening effect of light."

23. Frozen fruit—Regulation 193 (3) of the principal regulations is hereby amended by omitting the words "and ascorbic acid", and substituting the words ", ascorbic acid, and any acidulant that is a specified food conditioner".

24. Fruit juice—Regulation 197 of the principal regulations is hereby amended by adding the following subclause:

"(9) In these regulations 'essential oil' means the oil recoverable by distillation using the Official Method of Analysis of the Association of Official Analytical Chemists, 11th Edition 1970, 22.098 to 22.101."

25. Jam, fruit jelly, and marmalade—(1) Regulation 199 of the principal regulations is hereby amended by inserting in subclause (1), after the words "and spices.", the words "There may be added, during manufacture, invert sugar, and any emulsifier, surfactant, acidulant, alkali, or buffer that is a specified food conditioner.".

(2) Regulation 199 of the principal regulations is hereby further amended by omitting the table set out in subclause (1), and substituting the following table:

"Description of jam or fruit jelly	Minimum fruit content as a percentage
"Blackberry	35
"Blackcurrant	35
"Gooseberry	35
"Gooseberry and raspberry	35
"Gooseberry and strawberry	35
"Greengage	35
"Loganberry	35
"Plum	35
"Raspberry	35
"Raspberry and loganberry	35
"Raspberry and redcurrant	35
"Redcurrant	35
"Strawberry	35
"All other varieties	40".

(3) Regulation 199 of the principal regulations is hereby further amended by inserting in subclause (3), after the words "and spices.", the words "There may be added, during manufacture, invert sugar, and any emulsifier, surfactant, acidulant, alkali, or buffer that is a specified food conditioner.".

26. Culinary essences, extracts, and flavourings—Regulation 212 (1) of the principal regulations is hereby amended by omitting the words "and sucrose acetate isobutyrate", and substituting the words ". Dioctyl sodium sulphosuccinate, in a proportion not exceeding 5 ppm, and sucrose acetate isobutyrate may be added".

27. Artificial culinary essences, extracts, and flavourings—Regulation 213 (1) of the principal regulations is hereby amended by omitting the words "and sucrose acetate isobutyrate", and substituting the words ". Dioctyl sodium sulphosuccinate, in a proportion not exceeding 5 ppm, and sucrose acetate isobutyrate may be added".

28. Beer, lager, ale, and stout—Regulation 227 (3) of the principal regulations is hereby amended by inserting, after the words "fining agents," the words "carbon dioxide,".

29. Wine—Regulation 228 (4) of the principal regulations is hereby amended by adding the words ", and such fermentation shall not take place in a package of a capacity exceeding 5 litres".

30. Fruit wine—(1) Regulation 229 of the principal regulations is hereby amended by revoking subclause (4), and substituting the following subclause:

"(4) No fruit wine shall be labelled with the word 'champagne'."

(2) Regulation 229 of the principal regulations is hereby further amended by omitting from subclause (11) the words "or fruit wine", and substituting the words ", fruit wine, or vegetable wine".

31. Vegetable wine—The principal regulations are hereby amended by inserting, after regulation 229, the following regulation:

"229A. (1) Vegetable wine shall be the product of the alcoholic fermentation of the juice, or of the juice and other portions, of any vegetable. Vegetable wine shall not contain more than 22.9 percent of alcohol.

"(2) Vegetable wine may contain caramel, yeast nutrients, tannins, and fining agents. There may be added during preparation sugar in a proportion of not more than 1 kg to every 5 litres of the juice, or of the juice and other portions of vegetables, as the case may be. There may also have been added fortifying spirit containing not less than 80 percent of alcohol (such spirit being wine distillate, or uncoloured, unflavoured potable-grade spirit) and not more than 200 ppm of diethyl pyrocarbonate. Vegetable wine may contain carbon dioxide, nitrogen, specified food conditioners, and any preservative specified in subclause (8) of regulation 16 of these regulations in relation to vegetable wine.

"(3) Vegetable wine shall be labelled, in 6 mm lettering, with the name of the vegetable wine and words indicating the vegetable from which the wine is derived.

"(4) No vegetable wine shall be labelled with the word 'wine' unless the name of the vegetable from which the wine is made immediately precedes the word 'wine'.

"(5) The requirements of this regulation are in addition to the requirements of section 161A of the Sale of Liquor Act 1962 (as inserted by section 13 of the Sale of Liquor Amendment (No. 2) Act 1971)."

32. Other alcoholic drinks—Regulation 232 of the principal regulations is hereby amended by omitting all the words occurring after the words "and any other foodstuffs.".

33. Labelling of alcoholic drinks—The principal regulations are hereby amended by inserting, after regulation 232, the following regulation:

"232A. All alcoholic drinks, except beer, lager, ale, and stout, shall be labelled on the principal display panel with a statement of the approximate percentage of alcohol in the drink. The approximate percentage so declared shall not differ from the actual percentage by more than one-tenth of the actual percentage."

34. General requirements for special-purpose foods—(1) Regulation 233 (3) of the principal regulations is hereby amended by adding to paragraph (c) the word "; and".

(2) Regulation 233 (3) of the principal regulations is hereby further amended by adding the following paragraph:

"(d) If the food requires dilution or preparation before consumption, the quantity or proportion referred to in paragraph (a) of this subclause shall be calculated in relation to the food after such dilution or preparation."

35. Diabetic food—(1) Regulation 234 (4) of the principal regulations is hereby amended by adding to paragraph (c) the word "; and".

(2) Regulation 234 (4) of the principal regulations is hereby further amended by adding the following paragraph:

"(d) If the food requires dilution or preparation before consumption, the weights and percentages referred to in paragraph (a) of this subclause shall be calculated in relation to the food after such dilution or preparation."

36. General requirements for labelling of drugs—Regulation 238 (1) (a) of the principal regulations is hereby amended by omitting the words "as required by these regulations".

37. Safety packaging for therapeutic drugs—The principal regulations are hereby amended by inserting, after regulation 239, the following regulation:

"239A. (1) In this regulation 'a safety package' means a package, whether or not part of a strip of packages, enclosing a single tablet or other single item of a solid therapeutic drug or class of therapeutic drugs, being a package that—

"(a) Is made of aluminium foil or opaque laminated plastic, or of such other opaque material as may be approved by the Director-General in relation to the packaging of any solid therapeutic drug to which this regulation applies, either by notice published in the *Gazette* or in writing addressed to a particular manufacturer, packer, importer, or seller of therapeutic drugs; and

"(b) Is reasonably resistant to attempts by young children to open it.

"(2) No person shall sell any tablet or other single item in solid form, being or comprising a therapeutic drug or belonging to a class of therapeutic drugs to which this regulation applies, unless the tablet or item is enclosed in a safety package.

"(3) Subclause (2) of this regulation shall not apply—

"(a) Where a medical practitioner or dentist indicates in accordance with Regulation 7 (2) (b) (i) of the Social Security (Pharmaceutical Benefits) Regulations 1965* (as substituted by regulation 5 (1) of the Social Security (Pharmaceutical Benefits) Regulations 1965, Amendment No. 3†) that he does not wish the name of a therapeutic drug to appear on the label; or

*S.R. 1965/41
†S.R. 1974/40

"(b) Where a medical practitioner or dentist directs, either on the prescription or otherwise, that a therapeutic drug is not to be sold enclosed in a safety package; or

"(c) Where a pharmacist is of the opinion that, because of the age or infirmity of a particular person, a therapeutic drug to be used by that person and sold otherwise than on prescription should not be sold enclosed in a safety package.

"(4) In respect of a therapeutic drug packaged in a safety package forming part of a strip of safety packages it shall not be necessary to comply with the requirements of regulations 238 and 239 of these regulations if the strip bears its manufacturer's batch number, and each safety package is labelled with—

"(a) The name of the article; and

"(b) The appropriate designation, as defined in regulation 239 (6) (a) of these regulations, of the drug or of each of its active ingredients; and

"(c) The appropriate quantitative particulars, as defined in regulation 239 (6) (b) of these regulations, of each of its active ingredients:

"Provided that it shall not be necessary to comply with the requirements of paragraphs (b) and (c) of this subclause in respect of any item the size of which renders such compliance impracticable.

"(5) This regulation applies to the following therapeutic drugs:

"Aspirin, and its salts; and preparations containing aspirin or its salts.

"Iron, in preparations for human use containing more than 24 mg of elemental iron.

"Paracetamol, and preparations containing paracetamol.

"(6) This regulation applies to the following classes of therapeutic drugs:

"Barbiturates.

"Phenothiazine, and derivatives of phenothiazine and their salts, except dimethothiazine, methilazine, promethazine, and trimeprazine, and their salts and molecular compounds.

"Tricyclic, tetracyclic, and analogous antidepressants."

38. Transitional provision—Regulation 253 of the principal regulations is hereby amended by revoking subclause (1), and substituting the following subclause:

"(1) Where, in subclause (1) of regulation 85, subclause (1) of regulation 103, subclause (2) of regulation 187, or subclause (2) of regulation 193 of these regulations, a food is required to be maintained at a temperature below —18°C, it shall, until the 1st day of January 1981, be sufficient compliance with that requirement if the food is maintained at a temperature below —12°C."

39. Revocation—The Food Additives Notice 1975* is hereby revoked.

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

*S.R. 1975/22

EXPLANATORY NOTE

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

These regulations amend the Food and Drug Regulations 1973, the main purpose of which is to prescribe standards and labelling requirements for certain food and drugs. They make various changes to labelling requirements, and to restrictions applying to the use of nitrites in preserved meat. They also permit additional food additives, and prescribe a standard and labelling requirements for vegetable wine.

Regulation 37 inserts a new regulation 239A prohibiting the sale of specified therapeutic drugs and classes of drugs otherwise than in safety packages, except in the circumstances specified in the regulation.

Certain of the principal regulations require a food to be maintained at a temperature below —18°C in specified circumstances. Regulation 39 of these regulations provides that until the 1st day of January 1981 it shall be sufficient if such foods are maintained at a temperature below —12°C.

Issued under the authority of the Regulations Act 1936.
Date of notification in *Gazette*: 4 March 1976.
These regulations are administered in the Health Department.