## 1967 No. 1119

## FOOD AND DRUGS

## COMPOSITION AND LABELLING

# The Artificial Sweeteners in Food Regulations 1967

Made - - - 24th July 1967 Laid before Parliament 31st July 1967

Coming into Operation:

Regulations 10 and 16 1st December 1967 Remainder - 1st August 1967

The Minister of Agriculture, Fisheries and Food and the Minister of Health, acting jointly, in exercise of the powers conferred on them by sections 4, 7, 123 and 136(2) of, and paragraph 2(2) of Schedule 12 to, the Food and Drugs Act 1955(a) and of all other powers enabling them in that behalf, hereby make the following regulations after consultation with such organisations as appear to them to be representative of interests substantially affected by the regulations and reference to the Food Hygiene Advisory Council under section 82 of the said Act (insofar as the regulations relate to the labelling of food):—

### PART I

### **PRELIMINARY**

### Citation and commencement

- 1. These regulations may be cited as the Artificial Sweeteners in Food Regulations 1967; and shall come into operation as follows:—
  - (a) regulations 10 and 16 shall come into operation on 1st December 1967;
  - (b) in all other respects, these regulations shall come into operation on 1st August 1967.

## Interpretation

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

"the Act" means the Food and Drugs Act 1955;

"artificial sweetener" means any chemical compound which is sweet to the taste, but does not include any sugar or any polyhydric alcohol;

"artificial sweetening tablet" means any tablet which contains an artificial sweetener and which is intended for sale with a view to its use in the preparation of food;

"calcium cyclamate" means the substance conforming to the description, specifications and requirements for calcium cyclamate contained in the Addendum 1964 to the British Pharmacopoeia 1963 and containing not more than 100 parts per million by weight cyclohexylamine;

"carbohydrate" means a substance containing carbon, hydrogen and oxygen only in which the hydrogen and oxygen occur in the same proportion as in water;

"cyclamate" means calcium cyclamate, sodium cyclamate or cyclamic acid, or a mixture of two or all of these substances;

"cyclamic acid" means the substance conforming to the description, specifications and requirements for cyclamic acid contained in the Addendum 1964 to the British Pharmacopoeia 1963 and containing not more than 100 parts per million by weight cyclohexylamine;

"food" means food intended for sale for human consumption and includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products, but does not include—

- (a) water, live animals or birds,
- (b) fodder or feeding stuffs for animals, birds or fish, or
- (c) articles or substances used only as drugs;

"food and drugs authority" has the meaning assigned to it by section 83 of the Act;

"full strength tablets" means artificial sweetening tablets which comply with the requirements as to composition set out in Part I of Schedule 2 to these regulations;

"half strength tablets" means artificial sweetening tablets which comply with the requirements as to composition set out in Part II of Schedule 2 to these regulations;

"human consumption" includes use in the preparation of food for human consumption;

"permitted artificial sweetener" means saccharin, saccharin calcium, saccharin sodium, cyclamic acid, calcium cyclamate or sodium cyclamate;

"polyhydric alcohol" means an alcohol with three or more free hydroxyl groups;

"saccharin" means the substance conforming to the description, specifications and requirements for saccharin contained in the British Pharmacopoeia 1963;

"saccharin calcium" means the substance conforming to the description, specifications and requirements for saccharin calcium contained in Schedule 1 to these regulations;

"saccharin sodium" means the substance conforming to the description, specifications and requirements for saccharin sodium contained in the British Pharmacopoeia 1963;

"sell" includes offer or expose for sale or have in possession for sale; and "sale" and "sold" shall be construed accordingly;

"sodium cyclamate" means the substance conforming to the description, specifications and requirements for sodium cyclamate contained in the Addendum 1964 to the British Pharmacopoeia 1963 and containing not more than 100 parts per million by weight cyclohexylamine;

"sugar" means any soluble carbohydrate sweetening matter; AND other expressions have the same meaning as in the Act.

(2) For the purposes of these regulations, the supply of any artificial sweetener or any food containing any artificial sweetener otherwise than by sale, at, in or from any place where artificial sweeteners or such food are or is supplied in the course of a business shall be deemed to be a sale of that

artificial sweetener or that food, as the case may be; and references to purchasing and purchaser shall be construed accordingly.

- (3) For the purposes of the Labelling of Food Order 1953(a), as amended(b), these regulations, insofar as they prescribe requirements as to composition for artificial sweetening tablets, shall be taken to prescribe standards for such tablets.
- (4) Any reference in these regulations to a label borne on a container shall be construed as including a reference to any legible marking on the container however effected.
- (5) Any reference in these regulations to any order or other regulations shall be construed as a reference to such order or regulations as amended by any subsequent order or regulations.
- (6) The Interpretation Act 1889(c) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament, and as if these regulations and the orders hereby revoked were Acts of Parliament.

## Exemptions

- 3. The provisions of these regulations shall not apply to any food or artificial sweetener intended at the time of sale, consignment, delivery or importation, as the case may be, for exportation to any place outside the United Kingdom.
- 4. Until the Food Standards (Saccharin Tablets) Order 1953(d) and the Artificial Sweeteners in Food Order 1953(e) are revoked in accordance with regulation 16 hereof, the provisions of these regulations shall not have effect in relation to any saccharin, saccharin calcium or saccharin sodium (whether in tablet or other form, or as an ingredient of any food) sold in compliance with the provisions of those orders; and the provisions of those orders shall not have effect (pending their revocation in accordance with regulation 16 hereof) in relation to any saccharin, saccharin calcium or saccharin sodium (whether in tablet or other form) sold in compliance with the provisions of these regulations or to which any of the exemptions in these regulations apply.

#### PART II

# REQUIREMENTS RELATING TO ARTIFICIAL SWEETENERS

Sale, etc., of artificial sweeteners

5. No person shall sell, consign, deliver or import into England and Wales any artificial sweetener for human consumption which is not a permitted artificial sweetener.

Requirements as to composition for tablets containing artificial sweeteners

6.—(1) Every artificial sweetening tablet containing either saccharin or cyclamate as the sole artificial sweetener shall conform to the requirements as to composition set forth in relation thereto in the appropriate paragraph of Part I or Part II of Schedule 2 to these regulations.

- (a) S.I. 1953/536 (1953 I, p. 665).
- (c) 1889 c. 63.
- (e) S.I. 1953/1311 (1953 I, p. 662).
- (b) The relevant amending instruments are S.I. 1953/1889, 1959/471 (1953 I. p. 685; 1959 I, p. 1326). (d) S.I. 1953/1310 (1953 I, p. 695).

- (2) Every artificial sweetening tablet containing a mixture of saccharin and cyclamate shall contain not less than 1 milligram of saccharin and not less than 15 milligrams of cyclamate.
- (3) No person shall sell, consign, deliver or import into England and Wales any artificial sweetening tablet which does not comply with this regulation.
- (4) For the purposes of this regulation, saccharin means saccharin, saccharin calcium or saccharin sodium or a mixture of two or all of those substances.

## Labelling of containers of artificial sweetening tablets

- 7.—(1) No person shall sell, consign, deliver or import into England and Wales any artificial sweetening tablets in a container unless such container bears a label on which there appears such one of the following descriptions as may be appropriate—
  - (a) the words "cyclamate tablets" or "half strength cyclamate tablets" for full strength or half strength tablets respectively, containing no permitted artificial sweetener other than cyclamic acid or a mixture of cyclamic acid and calcium cyclamate and sodium cyclamate or of any two of those substances;
  - (b) the words "calcium cyclamate tablets" or "half strength calcium cyclamate tablets" for full strength or half strength tablets respectively, containing no permitted artificial sweetener other than calcium cyclamate;
  - (c) the words "sodium cyclamate tablets" or "half strength sodium cyclamate tablets" for full strength or half strength tablets respectively, containing no permitted artificial sweetener other than sodium cyclamate;
  - (d) the words "saccharin tablets" or "half strength saccharin tablets" for full strength or half strength tablets respectively, containing no permitted artificial sweetener other than saccharin or a mixture of saccharin and saccharin calcium and saccharin sodium or of any two of those substances;
  - (e) the words "saccharin calcium tablets" or "half strength saccharin calcium tablets" for full strength or half strength tablets respectively, containing no permitted artificial sweetener other than saccharin calcium;
  - (f) the words "saccharin sodium tablets" or "soluble saccharin tablets" for full strength tablets, or the words "half strength saccharin sodium tablets" or "half strength soluble saccharin tablets" for half strength tablets, containing in each case no artificial sweetener other than saccharin sodium;
  - (g) the words "cyclamate and saccharin tablets" or "saccharin and cyclamate tablets" for any artificial sweetening tablet containing cyclamate and one or more of the following substances, namely saccharin, saccharin calcium and saccharin sodium:

Provided that any word of similar meaning may be substituted for the word "tablets" in any of the foregoing descriptions.

(2) Every letter in every word appearing on a label on a container which is required so to appear by virtue of this regulation shall appear conspicuously and legibly in a dark colour upon a light coloured ground or in a light colour upon a dark coloured ground and shall be of uniform colour and size.

Sales by description

- 8. No person shall sell any food under such a description as to lead an intending purchaser to believe that he is purchasing a permitted artificial sweetener or artificial sweetening tablet if the food does not conform to the appropriate description, specifications and requirements prescribed by these regulations.
- 9. Where a person sells any article or substance to a purchaser in response to a request for an artificial sweetener to which these regulations apply, he shall be deemed to sell such article or substance as such an artificial sweetener and under such a description as is specified in relation to such an artificial sweetener in these regulations unless he clearly notifies the purchaser at the time of sale that the article or substance is not such an artificial sweetener.

## PART III

REQUIREMENTS RELATING TO FOOD CONTAINING ARTIFICIAL SWEETENERS

Sale, etc., of food containing artificial sweeteners

- 10.—(1) No food shall contain any artificial sweetener other than a permitted artificial sweetener.
- (2) No person shall sell, consign, deliver or import into England and Wales any food which does not comply with this regulation.

### PART IV

#### ADMINISTRATIVE PROVISIONS

## Condemnation of Food

11. Where any artificial sweetener or any other food is certified by a public analyst as being food which it is an offence against regulation 5 or 10 hereof to sell, consign, deliver or import into England and Wales, it may be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed on the order of a justice of the peace) as being unfit for human consumption.

## Penalties and enforcement

- 12.—(1) If any person contravenes or fails to comply with any of the foregoing provisions of these regulations he shall be guilty of an offence and shall be liable to a fine not exceeding one hundred pounds or to imprisonment for a term not exceeding three months, or to both, and, in the case of a continuing offence, to a further fine not exceeding five pounds for each day during which the offence continues after conviction.
- (2) Each food and drugs authority shall enforce and execute such provisions in their area:

Provided that each port health authority shall enforce and execute in their district the provisions of regulations 5, 6, 7 and 10 hereof insofar as these regulations relate to importation.

(3) The requirements of section 109(3) of the Act (which requires notice to be given to the Minister of Agriculture, Fisheries and Food of intention to institute proceedings for an offence against any provisions of these regulations

relating to labelling or marking) shall not apply as respects any proceedings instituted by a council for an offence against any such provisions of these regulations.

Application of various sections of the Act

- 13.—(1) Sections 108(3) and (4) (which relate to prosecutions), 110(1), (2) and (3) (which relate to evidence of analysis), 112 (which relates to the power of a court to require analysis by the Government Chemist), 113 (which relates to a contravention due to some person other than the person charged), 115(2) (which relates to the conditions under which a warranty may be pleaded as a defence) and 116 (which relates to offences in relation to warranties and certificates of analysis) of the Act shall apply for the purposes of these regulations as if references therein to proceedings, or a prosecution, under or taken or brought under the Act included references to proceedings, or a prosecution as the case may be, taken or brought for an offence under these regulations and as if the reference in the said section 112 to subsection (4) of section 108 included a reference to that subsection as applied by these regulations.
- (2) Paragraph (b) of the proviso to section 108(1) of the Act shall apply for the purposes of these regulations as if the reference therein to section 116 of the Act included a reference to that section as applied by these regulations.

Amendment of the Lead in Food Regulations 1961

- 14. The Lead in Food Regulations 1961(a) shall be amended as follows:—
  - (a) by deleting from regulation 2(1) thereof the definition of saccharin;
  - (b) by substituting in the said regulation 2(1) for the definition of sweetened the following definition:—
    - "'sweetened' means containing any added sugar or other soluble carbohydrate sweetening matter or added polyhydric alcohol or any artificial sweetener inasmuch as its use is permitted by the Artificial Sweeteners in Food Regulations 1967; and 'unsweetened' shall be construed accordingly."

Amendment of the Preservatives in Food Regulations 1962

- 15. The Preservatives in Food Regulations 1962(b) shall be amended as follows:—
  - (a) by deleting from regulation 2(1) thereof the definition of saccharin;
  - (b) by substituting in the said regulation 2(1) for the definition of sweetened the following definition:—
    - "'sweetened' means containing any added sugar or other soluble carbohydrate sweetening matter or added polyhydric alcohol or any artificial sweetener inasmuch as its use is permitted by the Artificial Sweeteners in Food Regulations 1967; and 'unsweetened' shall be construed accordingly."

#### Revocation

16. The Food Standards (Saccharin Tablets) Order 1953(c) and the Artificial Sweeteners in Food Order 1953(d) are hereby revoked.

(a) S.I. 1961/1931 (1961 III, p. 3631).

(b) S.I. 1962/1532 (1962 II, p. 1655).

(c) S.I. 1953/1310 (1953 I, p. 695).

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 21st July 1967.

(L.S.) Frederick Peart,
Minister of Agriculture, Fisheries and Food.

Given under the official seal of the Minister of Health on 24th July 1967.

(L.S.) Kenneth Robinson,
Minister of Health.

### SCHEDULE 1

Regulation 2(1)

## Saccharin calcium

Saccharin calcium is the calcium derivative of 2—sulphobenzoic imide with  $3\frac{1}{2}$  molecules of water of crystallisation. It contains not less than 98 per cent. of  $C_{14}H_{8}$  Ca  $N_{2}O_{6}S_{2}$  calculated with reference to the substance dried to constant weight at  $105^{\circ}C$ .

Description ... ... White crystals or white crystalline powder, odour faintly aromatic, taste intensely sweet.

Solubility ... ... 1 g. dissolves in 1.5 g. water.

Loss on drying ... ... When dried to constant weight at 105°C. loses not less than 11 per cent, and not more than 15 per cent, of its weight.

Ammonium Compounds ... Complies with the test given under Saccharin in the British Pharmacopoeia 1963.

4—Sulphamoylbenzoates ... Complies with the test given under Saccharin Sodium in the British Pharmacopoeia 1963.

## SCHEDULE 2

Regulation 6

Requirements as to composition for tablets containing permitted artificial sweeteners

## PART I-Full strength tablets

### 1. Saccharin

An artificial sweetening tablet containing saccharin or saccharin calcium or saccharin sodium or a mixture of two or all of those substances but no other artificial sweetener shall, when dried to constant weight at 105°C., have a total quantity of saccharin free and combined calculated as C<sub>7</sub>H<sub>5</sub>NO<sub>3</sub>S, which shall be not less than 11 milligrams and not more than 14 milligrams.

#### 2. Cyclamate

An artificial sweetening tablet containing cyclamate but no other artificial sweetener shall when dried to constant weight at  $105^{\circ}$ C., have a total quantity of cyclamic acid free and combined calculated as  $C_6H_{13}NO_3S$ , which shall be not less than 183 milligrams and not more than 233 milligrams.

### PART II—Half strength tablets

#### 1. Saccharin

An artificial sweetening tablet containing saccharin or saccharin calcium or saccharin sodium or a mixture of two or all of those substances but no other artificial sweetener shall, if sold in a container bearing a label upon which there appears the description

"half strength," have when dried to constant weight at  $105^{\circ}$ C. a total quantity of saccharin free and combined calculated as  $C_7H_5NO_3S$ , which shall be not less than 5.5 milligrams and not more than 7 milligrams.

### 2. Cyclamate

An artificial sweetening tablet containing cyclamate but no other artificial sweetener shall, if sold in a container bearing a label upon which there appears the description "half strength," have when dried to constant weight at  $105^{\circ}$ C. a total quantity of cyclamic acid free and combined calculated as  $C_6H_{13}NO_3S$ , which shall be not less than 92 milligrams and not more than 117 milligrams.

### EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These regulations, which apply to England and Wales only, supersede the Food Standards (Saccharin Tablets) Order 1953, and the Artificial Sweeteners in Food Order 1953.

The principal changes are:—

- (a) those artificial sweeteners which may be sold for human consumption and which may be used in food intended for sale for human consumption are specified (regulations 2(1), 5, 10, and Schedule 1);
- (b) requirements are laid down as to the composition of artificial sweetening tablets containing permitted artificial sweeteners (regulation 6 and Schedule 2), and the names by which they are to be described on labels are prescribed (regulation 7);
- (c) the definitions of "sweetened" in the Lead in Food Regulations 1961 and the Preservatives in Food Regulations 1962 are amended (regulations 14 and 15); and
- (d) the regulations provide that where any food is certified by a public analyst as containing any artificial sweetener not permitted by the regulations, that food may be treated for the purposes of section 9 of the Food and Drugs Act 1955 as being unfit for human consumption (regulation 11).

The regulations do not apply to any food or artificial sweetener intended for export (regulation 3).

These regulations come into operation on 1st August 1967, except regulations 10 and 16 which come into operation on 1st December 1967. Until the revocation, by regulation 16, of the Food Standards (Saccharin Tablets) Order 1953 and the Artificial Sweeteners in Food Order 1953, certain artificial sweeteners are exempt from the requirements of these regulations provided they comply with the provisions of those orders (regulation 4), and until that date the restrictions of the Artificial Sweeteners in Food Order 1953 on the use of artificial sweeteners in food continue to apply.

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ONE SHILLING NET