STATUTORY INSTRUMENTS

1964 No. 1289

FOOD AND DRUGS

COMPOSITION

The Mineral Hydrocarbons in Food Regulations 1964

Made - - - - -	30*th July* 1964
Laid before Parliament	14*th August* 1964
Coming into Operation	15*th August* 1964

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, 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:—

Citation and commencement

1. These regulations may be cited as the Mineral Hydrocarbons in Food Regulations 1964; and shall come into operation on 15th August 1964.

Interpretation

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

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

"chewing compound" means chewing gum and other products of a like nature and use;

"dried fruit" means prunes, currants, sultanas and raisins;

"food" means food intended for sale for human consumption;

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

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

"mineral hydrocarbon" means any hydrocarbon product, whether liquid, semi-liquid or solid, derived from any substance of mineral origin and includes liquid paraffins, white oils, petroleum jellies, hard paraffins and microcrystalline waxes;

"mineral oil" means any hydrocarbon product, whether liquid, semi-liquid or solid, derived from any substance of mineral origin and includes liquid paraffins, white oils, petroleum jellies and hard paraffins;

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

AND other expressions have the same meaning as in the Act.

(a) 4 & 5 Eliz. 2. c. 16.

(2) The Interpretation Act 1889(a) 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 and regulations hereby revoked were Acts of Parliament.

Exemptions

3.—(1) Regulation 5 of these regulations shall not apply in relation to—

(*a*) any dried fruit containing not more than 0·5 part by weight of mineral hydrocarbon per 100 parts by weight of dried fruit;

(*b*) any citrus fruit containing not more than 0·1 part by weight of mineral hydrocarbon per 100 parts by weight of citrus fruit;

(*c*) any sugar confectionery containing mineral hydrocarbon by reason of the use of mineral hydrocarbon as a polishing or glazing agent for confectionery if such confectionery contains by reason thereof not more than 0·2 part by weight of mineral hydrocarbon per 100 parts by weight of such confectionery;

(*d*) any food containing mineral hydrocarbon—

(i) by reason of the use in the composition of such food of dried fruit, citrus fruit or sugar confectionery, or any one or more of these commodities, containing mineral hydrocarbon not in excess of the relevant quantities permitted in accordance with sub-paragraphs (*a*), (*b*) and (*c*) of this paragraph;

(ii) by reason not of the inclusion of mineral hydrocarbon as an ingredient in such food but because of the use of mineral hydrocarbon as a lubricant or greasing agent on some surface with which such food has necessarily to come into contact during the course of preparation if such food contains by reason thereof not more than 0·2 part by weight of mineral hydrocarbon per 100 parts by weight of the food;

(*e*) any chewing compound which contains no more than 60 parts by weight of paraffin or microcrystalline wax per 100 parts by weight of chewing compound and otherwise contains no mineral hydrocarbon;

(*f*) any whole pressed cheese or part thereof containing mineral hydrocarbon by reason of the use of mineral hydrocarbon on the rind;

(*g*) any eggs, laid by domestic fowls or domestic ducks, which contain mineral hydrocarbon by reason of their having been subjected to a process of preservation consisting of being dipped in, sprayed with or otherwise treated with mineral hydrocarbon and which before sale or exposure for sale are required (by section 3 of the Agricultural Produce (Grading and Marking) Act 1928(b) and orders thereunder(c)) to be marked on the shell with the word "SEALED":

(*h*) any food intended for exportation to any place outside the United Kingdom.

(2) Any reference in paragraph (1) of this regulation to mineral hydrocarbon means liquid mineral hydrocarbon or semi-liquid mineral hydrocarbon, or paraffin or microcrystalline wax, which complies with the specification therefor set forth respectively in paragraphs 1, 2 and 3 of Part I of Schedule 1 to these regulations or a mixture of such liquid, or semi-liquid mineral hydrocarbons, or paraffin or microcrystalline wax; and the

(a) 52 & 53 Vict. c. 63. (b) 18 & 19 Geo. 5. c. 19.
(c) S.R. & O. 1936/1027 (Rev. I, p. 431: 1936 I, p. 39); S.I. 1950/211 (1950 I, p. 19).

reference in paragraph (1)(*e*) of this regulation to paraffin or microcrystalline wax means paraffin or microcrystalline wax which complies with the specifications set forth in paragraphs 3 and 4 of the said Part of the said Schedule.

(3) An exemption provided for in paragraph (1) of this regulation shall not apply if the food contains any mineral hydrocarbon other than mineral hydrocarbon of a kind defined in relation to that food in paragraph (2) of this regulation.

Continuation of the Mineral Oil in Food Order 1949

4. Until the Mineral Oil in Food Order 1949(**a**) as amended(**b**) ceases to have effect in accordance with regulation 10 hereof, regulation 5 of these regulations shall not apply in relation to—

(*a*) the use of any mineral oil in the composition or preparation of any food in accordance with the provisions of that order as amended ;

(*b*) the sale of any food containing mineral oil in accordance with such provisions.

Prohibition of mineral hydrocarbon in food

5. Subject to the provisions of these regulations—

(*a*) no person shall use or permit to be used any mineral hydrocarbon in the composition or preparation of any food ;

(*b*) no person shall sell any food containing any mineral hydrocarbon ;

(*c*) no person shall, on and after 15th February 1965, consign or deliver, or import into England and Wales, any food containing any mineral hydrocarbon.

Condemnation of food containing mineral hydrocarbon

6. Where any food is certified by a public analyst as being food in the composition or preparation of which any mineral hydrocarbon has been used which it is an offence against the foregoing provisions of these regulations to use, permit to be used, sell, consign or deliver, or import into England and Wales, that food 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

7. 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.

Enforcement

8. Each food and drugs authority shall enforce and execute these regulations in their area ;

Provided that each port health authority shall enforce and execute in their district the provisions of regulations 5 and 6 of these regulations in so far as they relate to importation.

(a) S.I. 1949/614 (1949 II, p. 14).
(b) S.I. 1950/1239, 1954/1044, 1955/1901 (1950 III, p. 41; 1954 I, p. 802 ; 1955 I, p. 917).

Application of various sections of the Act

9.—(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.

Revocation

10. The orders and regulations specified in Schedule 2 to these regulations shall cease to have effect on 15th February 1965.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 30th July 1964.

(L.S.) *Christopher Soames,*
Minister of Agriculture, Fisheries and Food.

Given under the Official Seal of the Minister of Health on 30th July 1964.

(L.S.) *Bernard Braine,*
Joint Parliamentary Secretary,
Ministry of Health.

Regulation 3(2)

SCHEDULE 1

PART I

SPECIFICATIONS FOR LIQUID MINERAL HYDROCARBON, SEMI-LIQUID MINERAL HYDROCARBON, AND PARAFFIN OR MICROCRYSTALLINE WAX

Specification for liquid mineral hydrocarbon

1. Liquid mineral hydrocarbon—

(*a*) shall be a transparent mixture of liquid hydrocarbons, almost colourless and tasteless;

(*b*) shall have an absorption intensity in iso-octane over the range 240–280 millimicrons not greater than $E\frac{1\%}{1\text{ cm.}}$ 0·4 (0·04 litre gm. cm.); and

(*c*) shall comply with the tests for acidity or alkalinity, carbonisable substances, solid paraffins, and sulphur compounds given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963.

Specification for semi-liquid mineral hydrocarbon

2. Semi-liquid mineral hydrocarbon—

(*a*) shall be a white translucent unctuous mixture of semi-liquid hydrocarbons barely fluorescent in daylight ;

(*b*) shall contain not more than 0·1 per cent. of sulphated ash ;

(*c*) shall have an absorption intensity in iso-octane at 290 millimicrons not greater than $E\ \frac{1\%}{1\ cm.}$ 10·0 (1·0 litre gm. cm.) ; and

(*d*) shall comply with the tests for acidity or alkalinity and sulphur compounds given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963.

Specification for paraffin or microcrystalline wax

3. Paraffin or microcrystalline wax—

(*a*) shall be an almost odourless and tasteless mixture of solid hydrocarbons ;

(*b*) shall contain not more than 0·1 per cent. of sulphated ash ;

(*c*) shall have an iodine value of not more than 4·0 ;

(*d*) shall have an absorption intensity in iso-octane at 290 millimicrons not greater than $E\ \frac{1\%}{1\ cm.}$ 0·4 (0·04 litre gm. cm.) ; and

(*e*) shall comply with the tests for acidity or alkalinity, and sulphur compounds given in the monograph for Liquid Paraffin in the British Pharmacopoeia 1963.

Specification for paraffin or microcrystalline wax in chewing compounds

4. Paraffin or microcrystalline wax in chewing compounds—

(*a*) shall comply with the specification set forth in paragraph 3 of this Part of this Schedule ; and

(*b*) shall have been tested for the presence of polycyclic hydrocarbons by the method set forth in Part II of this Schedule with the result described in paragraph 5 of the said Part II.

PART II

METHOD OF TESTING PARAFFIN OR MICROCRYSTALLINE WAX FOR THE PRESENCE OF POLYCYCLIC HYDROCARBONS

Principle of method

1. The method is based on the maximum absorbance within four wavelength ranges of an extract prepared by chromatography on silica gel and partition of the adsorbate between cyclohexane and nitromethane followed by a second chromatography on silica gel impregnated with nitromethane. Some of the polynuclear hydrocarbons are susceptible to photo-oxidation. The entire procedure subsequent to the addition of the wax to the chromatographic column must therefore be carried out under subdued light. No grease is to be used on stopcocks or joints.

Apparatus to be used

2. The following apparatus shall be used—

(*a*) a spectrophotometer capable of accurate measurement over the range 280–400 millimicrons ;

(*b*) fused quartz cells 10 mm. optical path length ; and

(*c*) chromatographic apparatus consisting of—

(i) a glass tube, approximately 35 cm. by 3·5 cm., constricted at the lower end to fit a suction flask and capable of being heated to 85° C.; and

(ii) a glass tube, approximately 115 cm. by 1·7 cm., sealed to a stopcock at the lower end and fitted with a solvent reservoir of approximately 500 ml. capacity.

Reagents to be used

3. The following reagents shall be used—

(*a*) solvents—namely iso-octane (2,2,4 trimethylpentane), benzene cyclohexane, n-hexadecane, methanol, and nitro-methane freshly distilled under reduced pressure in a current of nitrogen on the day of use;

(*b*) silica gel—which shall pass a 100 B.S. sieve and be retained on a 200 B.S. sieve, washed with methanol, and activated by heating at 150° C. for 16 hours in a current of clean air or nitrogen; and

(*c*) nitrogen—which shall be oxygen free.

Method of conducting test

4. Any person conducting this test shall proceed as follows—

Dissolve 100 gm. ± 0·5 gm. of the molten sample in 500 ml. of hot iso-octane. Prepare a dry column (about 125 gm.) of silica gel in the tube mentioned in paragraph 2(*c*)(i) of this Part of this Schedule, retaining it by a glass wool plug at the constricted lower end. Heat the column to about 15° C. above the melting point of the wax, and pass through it 200 ml. of hot iso-octane, at the rate of about 12 ml. per minute, using suction. A layer of solvent must cover the silica gel from this point until the elution of the column is completed. Pass the wax solution through the column and follow it with 500 ml. of hot iso-octane. Discontinue the heating and suction and let the column cool. Pass a further 50 ml. of iso-octane at room temperature through the column. Change the receiver at the bottom of the column and elute adsorbed material from the silica gel with 200 ml. of benzene. To the benzene eluate add 1 ml. of n-hexadecane and evaporate the benzene in a stream of nitrogen under reduced pressure. Transfer the residue to a separating funnel with 50 ml. of cyclohexane, add 25 ml. of nitromethane saturated with cyclohexane, and shake vigorously for three minutes. Draw off the lower layer into a second separating funnel and repeat the extraction with four separate portions of 25 ml. of nitromethane saturated with cyclohexane. To the combined nitromethane extracts add 20 ml. of cyclohexane and shake as before. Draw off the lower layer into an evaporation flask, add 1 ml. of n-hexadecane and remove the solvent in a stream of nitrogen under reduced pressure. Allow the flask to cool and dissolve the residue in 10 ml. of iso-octane.

Prepare by shaking together for one hour a mixture of 100 gm. of silica gel, and 40 ml. of nitromethane. Plug the stopcock end of the tube mentioned in paragraph 2(*c*)(ii) of this Part of this Schedule with glass wool and fill with nitromethane silica gel mixture. Transfer the solution of the residue to the column and wash with 160 ml. of iso-octane saturated with nitromethane, discarding the first 90 ml. of eluate. Percolation through the column can be accelerated if necessary by the application of a pressure of nitrogen gas on the reservoir. Add 250 ml. of benzene to the solvent reservoir and continue the elution collecting the whole eluate. Add 1 ml. of n-hexadecane to the eluate and remove the solvents in a stream of nitrogen under reduced pressure. A residue of about 1 ml. should remain. Dissolve this residue in iso-octane and dilute to 100 ml. Determine the absorbance of the solution against pure iso-octane in a 1 cm. cell over the range 280-400 millimicrons. Correct the absorbance values for any cell differences and for any absorbance derived from reagents as determined by carrying out the procedure without a wax sample.

Result of test

5. The tested paraffin or microcrystalline wax shall be deemed to have satisfied the test if the following result is obtained, namely if the light absorbance of the extract in a 1 cm. cell is below the following limits:—

Wavelength range (millimicrons)			
280-289	290-299	300-359	360-400
Absorbance Limit			
0·50	0·42	0·27	0·07

Check of test

6. The efficacy of the test shall be checked by determining the recovery of the polycyclic aromatic hydrocarbon Pyrene added at the level of 0·5 p.p.m. to a wax. The recovery should be not less than 40 per cent. of the amount added.

SCHEDULE 2

Regulation 10

ORDERS AND REGULATIONS REVOKED AS FROM 15TH FEBRUARY 1965

The Mineral Oil in Food Order 1949	S.I. 1949/614 (1949 II, p. 14).
The Mineral Oil in Food (Amendment) Order 1950	S.I. 1950/1239 (1950 III, p. 41).
The Mineral Oil in Food (Amendment) Order 1954	S.I. 1954/1044 (1954 I, p. 802).
The Mineral Oil in Food (Amendment) Regulations 1955	S.I. 1955/1901 (1955 I, p. 917).

EXPLANATORY NOTE

(This Note is not part of the regulations, but is intended to indicate their general purport.)

These regulations, which apply in England and Wales only, prohibit (subject to certain exemptions relating to dried fruit, citrus fruit, sugar confectionery, lubricants, cheese, eggs and chewing compounds) the use of any mineral hydrocarbon in the composition or preparation of food, the sale of food containing any mineral hydrocarbon and, on and after 15th February 1965, the consignment, delivery or importation of any food containing any mineral hydrocarbon (regulation 5).

The regulations lay down specifications for mineral hydrocarbons the use of which is regulated in relation to the permitted exemptions, including a test for limits of content of certain polycyclic aromatic hydrocarbons (regulation 3(2) and Schedule 1).

The regulations also make provision for the following:—

(*a*) the condemnation of food containing mineral hydrocarbon in contravention of the regulations (regulation 6);

(*b*) penalties for infringement of the regulations (regulation 7);

(*c*) enforcement by food and drugs authorities or (as regards the provisions of regulations 5 and 6 in so far as they relate to importation) by port health authorities (regulation 8); and

(*d*) application of certain sections of the Food and Drugs Act 1955 relating to legal proceedings (regulation 9).

The regulations come into operation on 15th August 1964, but the use of mineral oil in the preparation of food, and the sale of food containing mineral oil, in compliance with the Mineral Oil in Food Order 1949 (as amended) is permitted until that order is revoked on 15th February 1965.