1988 No. 436

MILK

Milk (Amendment) Regulations (Northern Ireland) 1988

Made . . . . . *13th December 1988*

Coming into operation . . *1st January 1989*

The Department of Agriculture, in exercise of the powers conferred on it by Articles 4, 5(3), 6(1), 7 and 9(1) of the Milk (Northern Ireland) Order 1983(**a**) and of every other power enabling it in that behalf, with the concurrence of the Department of Health and Social Services(**b**) insofar as they relate to any process of direct heat treatment by steam, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Milk (Amendment) Regulations (Northern Ireland) 1988 and shall come into operation on 1st January 1989.

Amendment to the Milk Regulations (Northern Ireland) 1987

2. The Milk Regulations (Northern Ireland) 1987(**c**) shall be amended as follows:—

(1) for regulation 20 there shall be substituted—

"*Interpretation*

20. In this Part, in Parts VII and VIII, the Seventh Schedule, Eighth Schedule and the Ninth Schedule "milk" includes milk-based drink except—

(*a*) where otherwise specified; and

(*b*) in regulations 23(1), 37(2), (3) and (5) and in the Seventh Schedule paragraph 1(1) and (2).";

(2) in regulation 21(2)(*a*) the word "raw" shall be omitted;

(3) after regulation 21 there shall be inserted—

"*Raw Milk Standard*

21A.—(1) Raw milk shall not be accepted for heat treatment by the holder of a distributor's licence unless—

(*a*) over the preceding two months not less than two samples each month of the milk licence holder's raw milk have been submitted to the total viable bacterial count test in accordance with the

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(**a**) S.I. 1983/148 (N.I. 2)
(**b**) *See* S.I. 1983/148 (N.I. 2), Article 9(2)
(**c**) S.R. 1987 No. 229

procedure set out in the Eighth Schedule, and the geometric mean of the results of such tests is not more than 100,000 bacteria per millilitre; or

(*b*) the milk has been purchased as milk which complies with the requirements of sub-paragraph (*a*) and with a written warranty to that effect.

(2) Raw milk which is not heat treated within 36 hours of its admission to the heat treatment establishment shall not be subjected to heat treatment unless—

(*a*) the holder of a distributor's licence has, in the handling and storage of the milk, taken steps to ensure that a sample of that milk submitted to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule, contains not more than 200,000 bacteria per millilitre; and

(*b*) a sample of that milk has been submitted to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule.

(3) The holder of a distributor's licence who heat treats milk shall retain for a period of not less than 3 months any warranty referred to in paragraph 1(*b*).

(4) The holder of a distributor's licence who heat treats milk shall keep a record of the result of any test carried out in compliance with this regulation and shall retain the record for a period of not less than 3 months.

(5) In this regulation references to a sample of milk are references to a sample which has been taken, transported and stored in accordance with the procedure set out in the Seventh Schedule.";

(4) after regulation 22 there shall be inserted—

"*Heat treated milk which is to undergo further heat treatment*

22A.—(1) Milk which has already been heat treated in another heat treatment establishment shall not be accepted for further heat treatment unless, on its admission to the heat treatment establishment for further heat treatment, the temperature of that milk is checked by the holder of a distributor's licence, and it does not exceed 6°C.

(2) Milk accepted for further heat treatment in accordance with paragraph (1) shall be retained at a temperature of not more than 6°C until it is subjected to further heat treatment and the temperature of such milk shall be checked by the holder of a distributor's licence immediately before such further heat treatment.

(3) Milk which has been heat treated in another Member State of the European Economic Community shall not be admitted to a heat treatment establishment for further heat treatment unless it is accompanied by the certificate required under the Importation of Milk Regulations (Northern Ireland) 1988(**a**).

(**a**) S.R. 1988 No. 420

(4) The holder of a distributor's licence who heat treats milk shall retain the certificate referred to in paragraph (3) for a period of not less than 3 months from the date of further heat treatment.

(5) The holder of a distributor's licence who heat treats milk shall—

(*a*) in accordance with the procedure set out in the Seventh Schedule take samples of any milk which has already been heat treated in another heat treatment establishment before the milk is subjected to any further heat treatment;

(*b*) transport and store such samples in accordance with the procedure set out in the Seventh Schedule; and

(*c*) submit such samples to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule.

(6) The holder of a distributor's licence who heat treats milk shall keep a record of the result of any check carried out in compliance with paragraph (1) or (2) and of any test carried out in compliance with paragraph (5) and shall retain the record for a period of not less than 3 months.'';

(5) in regulation 23(1) for ''5°C'' there shall be substituted ''6°C'';

(6) in regulation 23 for ''71.75°C'' wherever it occurs there shall be substituted ''71.7°C'';

(7) after regulation 23(1) there shall be inserted—

''(1A) Milk-based drink shall be pasteurised by being retained at a temperature of not less than 72°C for at least 15 seconds, and then cooled immediately to a temperature not exceeding 6°C.'';

(8) regulation 23(5) shall be revoked;

(9) in regulation 24 for ''132.2°C'' wherever it occurs there shall be substituted ''135°C'';

(10) in regulation 29—

(*a*) after paragraph (4)(*a*) there shall be inserted—

''(*aa*) particulars of the place of origin or provenance of the milk if failure to give such particulars might mislead a purchaser to a material degree as to the true origin or provenance of the milk;'';

(*b*) paragraph 4(*c*)(iv) shall be revoked;

(11) in regulation 30(2) for ''5°C'' wherever it occurs there shall be substituted ''6°C'';

(12) for regulation 37 there shall be substituted—

''*Quality requirements for milk*

37.—(1) Milk shall be regarded as being of the required quality if samples of the milk are taken, transported and stored in accordance with the procedure set out in the Seventh Schedule and are found to comply with the standards of quality set out in paragraphs (2), (3), (4), (5), (6), (7) and (8).

(2) Samples of milk produced for sale by the holder of an untreated milk licence shall contain not more than 50,000 bacteria per millilitre

when subjected to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule.

(3) In the case of milk which has already been heat treated in another heat treatment establishment samples of that milk taken before any further heat treatment shall, when subjected to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule, contain not more than 100,000 bacteria per millilitre.

(4) Samples of milk which has been pasteurised by the holder of a distributor's licence shall, when subjected to the coliform test in accordance with the procedure set out in the Ninth Schedule, contain less than one coliform bacterium per millilitre.

(5) Samples of milk which has been pasteurised by the holder of a distributor's licence shall—

(*a*) when subjected to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule, contain not more than 30,000 bacteria per millilitre; and

(*b*) when subjected to the total viable bacterial count test in accordance with the procedure set out in the Tenth Schedule contain not more than 100,000 bacteria per millilitre.

(6) Samples of pasteurised milk, pasteurised semi-skimmed milk and pasteurised skimmed milk which have been pasteurised by the holder of a distributor's licence shall—

(*a*) when subjected to the phosphatase test in accordance with the procedure set out in the Eleventh Schedule, give a reading of not more than 10 microgrammes p-nitrophenol per millilitre; and

(*b*) when subjected to the peroxidase test in accordance with the procedure set out in the Twelfth Schedule, give a positive result.

(7) Samples of milk which has been ultra-heat treated by the holder of a distributor's licence shall contain not more than 100 bacteria per millilitre when subjected to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule.

(8) Samples of milk which has been sterilised by the holder of a distributor's licence shall contain not more than 100 bacteria per millilitre when subjected to the total viable bacterial count test in accordance with the procedure set out in the Eighth Schedule and except in the case of sterilised milk-based drink, shall give a negative result when subjected to the turbidity test in accordance with the procedure set out in the Fifth Schedule.";

(13) for the Seventh Schedule there shall be substituted—

"SEVENTH SCHEDULE regulations 20, 21A(5), 22A(5) and 37(1)

The Taking, Transport and Storage of Samples of Milk for Testing

Taking of samples

1.—(1) Samples of milk produced by the holder of an untreated milk licence may be taken at any time when the milk is in the possession of the licence holder or at any subsequent time before delivery to the consumer.

(2) Samples of milk produced by the holder of a milk licence may be taken at any time when the milk is:

(*a*) in the possession of the licence holder;

(*b*) in the course of delivery to any distributor or manufacturer;

(*c*) in the possession of such distributor or manufacturer provided that the milk has not been mixed with any other milk.

(3) Subject to sub-paragraph (4) samples of milk which has been pasteurised or ultra-heat treated or sterilised may be taken at any time after heat treatment and before delivery to the consumer.

(4) Samples of milk which has been pasteurised shall only be subjected to microbiological testing if they have been taken in the heat treatment establishment as soon as possible after processing.

(5) For the purposes of this paragraph microbiological tests are those detailed in the Eighth, Ninth and Tenth Schedules.

2. When the milk is in containers not exceeding two litres in capacity, the sample shall consist of one such container which shall be delivered intact to the testing laboratory.

3. When the milk is in containers exceeding two litres in capacity a representative sample shall be taken of the milk in that container by aseptic means and transferred to a bottle or test tube, which shall be immediately stoppered, or closed with a close fitting overlapping metal cap.

4. The sampling containers and appliances shall be sterile.

Transport and holding of samples

5.—(1) Samples of milk except milk which has been ultra-heat treated or sterilised shall be transported to the testing laboratory with the least possible delay.

(2) Samples of milk which has been ultra-heat treated or sterilised shall be transported promptly to the testing laboratory.

(3) Samples of milk produced by the holder of a milk licence, untreated milk and milk which has been pasteurised shall with the least possible delay be placed in an insulated box containing an adequate quantity of suitable refrigerant capable of cooling the samples to a temperature of 5°C and maintaining them at a temperature of not more than 5°C until arrival at the testing laboratory.

(4) Samples of milk shall, on arrival at the testing laboratory, be removed from the carrying box and, if stored, shall be placed in a refrigerator capable of maintaining them at a temperature of not more than 5°C. Any sample of milk which has been pasteurised which does not arrive at the testing laboratory on the day on which it is taken shall be discarded.

Identification of samples

6. For the purposes of the identification of the sample, the person taking it shall mark or label the container at the time of sampling with the following particulars:—

(*a*) a number or other suitable identification mark; and

(*b*) the name of the licence holder by whom the milk was consigned, or by whom it was being delivered, or on whose premises the sample was taken.

Pre-incubation of samples of milk which has been ultra-heat treated or sterilised

7. Samples of milk which has been ultra-heat treated or sterilised shall be placed in an incubator at a temperature of 30°C and retained at that temperature for 15 days. If testing does not commence immediately the sample shall be placed in a refrigerator and held at a temperature of not more than 5°C until testing commences.'';

(14) for the Ninth Schedule there shall be substituted—

''NINTH SCHEDULE regulations 20 and 37(4)

The Coliform Test

Apparatus

1. The apparatus shall consist of:

(*a*) culture medium tubes which shall be test tubes complying with British Standard 3218: 1982(**a**) nominal size 150/16 and shall be closed with closely fitting metal caps; each tube shall contain an inverted Durham tube conforming to British Standard 3218: 1982;

(*b*) dilution tubes or flasks which shall be stoppered by means of a solid stopper or tightly fitting cover;

(*c*) pipettes which shall be 1.0 ml straight-sided blow-out delivery pipettes.

2. The medium, diluent and all glassware, stoppers, covers and caps shall be sterile.

Medium

3. The medium shall be lactose bile brilliant green broth made according to the following formula and shall have a final pH of 7.2 ± 0.1:

Peptone	10g
Lactose	10g
Dehydrated Ox Bile	20g
Brilliant Green	0.0133g
Water	1000 ml

Diluent

4. The diluent shall be as specified for the total viable bacterial count test (paragraph 4 of the Eighth Schedule).

(a) *See* BSI Catalogue 1986 published in 1985 by the British Standards Institution, London ISBN 0 580 14963 3

Method of carrying out the test

5. Each dilution tube or flask shall contain sterile diluent of a volume not less than 8.9 ml and not more than 9.1 ml.

6. A 1 in 10 dilution and a 1 in 100 dilution of the milk sample shall be prepared in the manner described for the total viable bacterial count test in paragraphs 5(1) and 5(2) of the Eighth Schedule.

7. After mixing, a fresh pipette shall be introduced into the milk sample and a 1 ml portion transferred to each of 3 culture tubes containing about 10 ml of lactose bile brilliant green broth. A fresh pipette shall be taken and 1 ml of the 1 in 10 dilution shall be transferred to each of 3 culture tubes in a manner similar to that described for the transfer of the milk sample. A fresh pipette shall be taken and 1 ml of the 1 in 100 dilution shall be transferred to each of 3 culture tubes in a manner similar to that described for the transfer of the milk sample. The culture tubes shall be incubated at 30°C ± 1°C for 48 hours and examined for gas production.

Confirmatory test

8. Each tube showing gas production (presumptive positive) shall be inoculated into a fresh tube of lactose bile brilliant green broth. These tubes shall be incubated at 30°C ± 1°C for 48 hours and examined for gas production. The confirmed positive tubes shall be recorded.

Interpretation

9. The most probable number of coliforms per ml of milk shall be determined from the number of confirmed tubes in accordance with the following table:—

DETERMINATION OF MOST PROBABLE NUMBER OF COLIFORMS PER ML

Number of confirmed tubes			*MPN of coliforms per ml*	*Category**	*Confidence Limits*			
					95%		*99%*	
1 ml	1/10 ml	1/100 ml						
0	0	0	<0.3					
0	0	1		0				
0	1	0	0.3	2	<0.1	1.7	<0.1	<2.3
0	2	0		0				
1	0	0	0.4	1	0.1	2.1	<0.1	2.8
1	0	1	0.7	2	0.2	2.7	0.1	3.5
1	1	0	0.7	1	0.2	2.8	<0.1	3.6
1	1	1		0				
1	2	0	1.1	2	0.4	3.5	0.2	4.4
1	2	1		0				
1	3	0		0				
2	0	0	0.9	1	0.2	3.8	<0.1	5.0
2	0	1	1.4	2	0.5	4.8	0.2	6.2
2	1	0	1.5	1	0.5	5.0	0.2	6.4
2	1	1	2.0	2	0.7	6.0	0.4	7.6
2	1	0	2.1	1	0.8	6.2	0.5	7.9
2	2	1		0				
2	3	0		0				
3	0	0	2	1	< 1	13	< 1	18
3	0	1	4	1	1	18	< 1	23
3	0	2		0				
3	1	0	4	1	1	21	< 1	28
3	1	1	7	1	2	28	< 2	36
3	1	2		0				
3	2	0	9	1	3	38	1	51
3	2	1	15	1	5	50	3	66
3	2	2	21	2	8	64	5	82
3	2	3		0				
3	3	0	20	1	<10	140	<10	190
3	3	1	50	1	10	240	<10	320
3	3	2	110	1	30	480	20	640
3	3	3	> 110					

*Category 0: Unacceptable tube combinations, having, under normal conditions, the least chance of being obtained. Combinations not mentioned in the table also belong to this category.

When such a combination is obtained, it is probable that a mistake has been made, faulty technique has been used, or a bacteriostatic substance is present in the product.

Category 1: Most likely tube combinations. One of these should be obtained in 95% of cases.

Category 2: Less likely tube combinations than those of category 1. One of these should be obtained in only 4% of cases.'';

(15) for the Tenth Schedule there shall be substituted—

''TENTH SCHEDULE regulation 37(5)(*b*)

Total Viable Bacterial Count Test at 21°C

Apparatus

1. The apparatus shall consist of:

(*a*) dilution tubes or flasks which shall be stoppered by means of a solid stopper or tightly fitting cover;

(*b*) pipettes which shall be 1.0 ml straight-sided blow-out delivery pipettes;

(*c*) Petri dishes complying with British Standard 611: Part 1 1978, Part 2: 1982(a); and

(*d*) incubator capable of maintaining a temperature of (*a*) 6°C ± 0.5°C and (*b*) 21°C ± 1°C.

2. The diluent, medium and all glassware and metal caps shall be sterile.

Medium

3. The culture medium shall be prepared in accordance with the following formula and have a final pH of 6.9 ± 0.1:

Tryptone	5.0g
Yeast extract	2.5g
D-glucose anhydrous	1.0g
Skimmed milk powder	1.0g
Agar	10-15g
depending on the Agar	
Water	1000 ml

Diluent

4. The diluent shall be peptone/salt solution made according to the following formula:

Peptone	1.0g
Sodium chloride	8.5g
Water	1000 ml

Method of carrying out the test

5.—(1) An unopened package of the milk to be tested or a representative sample of not less than 100 ml shall be incubated for 5 days at 6°C in an incubator.

(2) After incubation, a 1 in 10 dilution of the milk sample shall be prepared as follows:

(a) *See* B.S.I. Catalogue 1986 published in 1985 by the British Standards Institution, London ISBN 0 580 194963 3

The milk sample shall be thoroughly mixed. A 1 ml pipette shall be introduced into the sample container and 1 ml of the milk withdrawn and then be introduced into the dilution tube or flask. After the addition of the milk the contents of the dilution tube or flask shall be thoroughly mixed.

(3) A 1 in 100 dilution and a 1 in 1000 dilution shall be prepared in a similar manner, except that in the preparation of the 1 in 100 dilution, 1 ml of the 1 in 10 dilution shall be added to the dilution tube or flask, and for the 1 in 1000 dilution, 1 ml of the 1 in 100 dilution shall be added to the flask instead of 1 ml of the milk sample. A fresh pipette shall be used for the preparation of each dilution.

6. 1 ml of the 1 in 10 dilution shall be measured with a pipette held in a vertical position. The tip of the pipette shall be touched against the side of the dilution flask. The contents of the pipette shall be blown out gently into the centre of a Petri dish, the tip of the pipette being held about 15 mm above the level of the bottom of the dish. Three seconds shall be allowed to elapse, the tip of the pipette shall then be touched against the dish at a point some distance from the fluid already delivered, and the last drop blown out. A fresh pipette shall be taken and 1 ml of the 1 in 100 dilution shall be transferred to another Petri dish in a manner similar to that described for the transfer of the 1 in 10 dilution. A fresh pipette shall be taken and 1 ml of the 1 in 1000 dilution shall be transferred to another Petri dish in a manner similar to that described for the transfer of the 1 in 10 dilution.

7. 10-12 ml of the sterile culture medium which shall have been melted and cooled to about 45°C shall be delivered under aseptic conditions into each of the Petri dishes and immediately thereafter the contents of the dishes shall be mixed by means of a series of circular movements in a clockwise and anti-clockwise direction. The mixing procedure shall last from 5-10 seconds, the Petri dish being kept flat on the bench throughout the whole process. The time which shall elapse between the preparation of the dilution and the addition of such dilution and culture medium to the Petri dishes shall not exceed 15 minutes. The plates shall be incubated bottom upwards at 21°C ± 1°C for 25 hours.

Counting of bacteria

8. Colonies on the dish shall be counted within 1 hour of removal from the incubator. Colony counting equipment consisting of an illuminated base with a dark background fitted with a magnifying lens to be used at a magnification of 1.5 diameters and a mechanical or electronic digital counter shall be used.

Interpretation

9. The bacterial count per millilitre of the sample shall be ascertained by multiplying the total colony count per Petri dish by the reciprocal of the dilution used in the test.''.

Sealed with the Official Seal of the Department of Agriculture on 13th December 1988.

(L.S.) *S. R. Armstrong*
Assistant Secretary

The Department of Health and Social Services hereby concurs with the foregoing Regulations insofar as they relate to any process of direct heat treatment by steam.

Sealed with the Official Seal of the Department of Health and Social Services on 13th December 1988.

(L.S.) *R. W. McQuiston*
Assistant Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations amend the Milk Regulations (Northern Ireland) 1987 and make the following changes of substance—

(*a*) as pre-conditions for heat treatment of raw milk it is required that—

(i) the milk licence-holder's milk shall have met a prescribed standard (regulation 2(3));

(ii) in the case of raw milk not heat treated within 36 hours, steps have been taken to ensure a prescribed total viable bacterial count is not exceeded (regulation 2(3));

(*b*) the Resazurin test for milk produced by the holder of a milk licence is omitted (regulation 2(12) and (14));

(*c*) the prohibition on the sale of milk as pasteurised milk if it has been subjected to a second heat treatment is removed (regulation 2(8));

(*d*) the requirement for separate raw milk reception accommodation at heat treatment establishments is removed (regulation 2(2));

(*e*) specified conditions as to temperature, sampling and tests are applied to milk which has already been heat treated in another heat treatment establishment and which is to undergo further heat treatment (regulation 2(4) and (12));

(*f*) milk which has been heat treated in another Member State of the European Economic Community shall not be admitted to a heat treatment establishment for further heat treatment unless accompanied by the certificate required under the Importation of Milk Regulations (Northern Ireland) 1988, which certificate is to be retained for a period of at least 3 months from the date of further heat treatment (regulation 2(4));

(*g*) new coliform and total viable bacterial count tests are introduced for pasteurised milk (regulation 2(12), (14) and (15));

(*h*) the total viable bacterial count test requirements and standards for ultra-heat treated milk and sterilised milk are altered (regulation 2(12) and (13));

(*i*) additional labelling requirements are provided in respect of milk filled into bottles (regulation 2(10)).

The Regulations also amend the pasteurisation temperatures for milk (regulation 2(6)) and milk based drink (regulation 2(7)), after the temperature to which milk and milk based drink must be cooled alter pasteurisation (regulation 2(5) and (7)), alter the temperature to which heat treatment establishments must be capable of cooling milk which has been pasteurised (regulation 2(11)), increase the temperature for ultra high temperature treatment (regulation 2(9)), require the retention of test results and other specific records (regulation 2(3) and (4)), alter the requirements for taking samples of milk which has been pasteurised and for handling samples of untreated milk and milk which has been pasteurised (regulation 2(13)), and alter the requirements for identifying samples (regulation 2(13)).

Regulation 2(10) alters one of the provisions implementing so far as concerns milk, certain requirements of Council Directive No. 79/112/EEC (O.J. No. L33, 8.2.79, p. 1) on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer.

A copy of the BSI Catalogue: 1986 is available from the Sales Department, British Standards Institution, Linford Way, Milton Keynes, London MK14 6LE or may be inspected in Northern Ireland at the Belfast Education and Library Board, Public Library Central Branch, Royal Avenue, Belfast BT1 1EA.

1988 No. 437

Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 1988

These Regulations have been made by the Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly as the Health Ministers in exercise of the powers conferred by sections 75(1), 76(1)(6), 129(2)(5) and 132(1) of the Medicines Act 1968.

In pursuance of paragraph 11 of Schedule 4 to that Act these Regulations have been registered as a Northern Ireland statutory rule under the Statutory Rules (Northern Ireland) Order 1979. They are printed in full in the volume of United Kingdom Statutory Instruments for 1988 and have been numbered 2113 in that series.