



Ministry of  
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Fisheries and Food  
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DANI/DHSS NI

*milk*  
HYGIENE

*A GUIDE TO THE  
DAIRY PRODUCTS  
(HYGIENE) REGULATIONS  
FOR DAIRY PRODUCT  
PROCESSORS*

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# *general*

## *INTRODUCTION*

### SECTION

1. This booklet provides guidance on the Dairy Products (Hygiene) Regulations 1995 and parallel legislation in Scotland and Northern Ireland. These Regulations implement Council Directive 92/46/EEC (as amended by Council Directive 94/71), laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products and Council Directive 92/47/EEC which permits the granting of temporary and limited derogations from some of the requirements in Directive 92/46.

2. This booklet is intended as a guide to the requirements of the Regulations for those who heat-treat or process milk or milk products (including those who manufacture, prepare, slice, pack, wrap or rewrap and bottle milk or milk products). It should not be regarded as a definitive statement of the law as contained in the Regulations and reference should also be made to them.

3. Businesses may need particular advice in order to comply with the requirements of the Regulations. Owners/managers/operators of dairies on farms or of processing establishments are therefore advised to keep in close touch with their local Environmental Health Department which is responsible for enforcement of provisions relating to processing. (In this paragraph and throughout this booklet reference to Environmental Health Department/Officer(s) includes as appropriate the Department of Agriculture for Northern Ireland.)

4. The Regulations provide, for the first time, harmonised rules in the raw milk and milk products sector and cover not just cows' milk but also goats', sheep and buffaloes' milk. They reflect much of what was in previous UK milk hygiene legislation relating to cows' milk.

5. The Regulations include a few provisions from previous legislation which following review have been retained on public health grounds. These provisions are those relating to heat-treatment of cream and ice cream, controls on sales of raw cows' drinking milk (and microbiological standards for such milk, which have also been extended to raw sheep and goats' milk). In addition, certain provisions in the Milk and Dairies (General) Regulations 1959, as amended, relating to communicable diseases have been retained on a short-term basis pending review of public health legislation. Apart from these Regulations and the Ice-Cream (Heat-Treatment) Regulations 1959, which now cover non-dairy ice cream only and the Drinking Milk Regulations 1976, all other dairy hygiene legislation has been revoked. In Scotland and in Northern Ireland a similar situation applies.

## SUMMARY

6. The Regulations apply to all premises which produce and place on the market raw milk, heat-treated drinking milk, milk for the manufacture of milk-based products and milk-based products intended for human consumption. However, (with one or two exceptions) they do not apply to most retail premises, including catering establishments, cafes and mobile vehicles, which sell milk and milk-based products e.g. to the ultimate consumer. Storage depots and wholesalers are subject to only minimal requirements. Member States also have some discretion to apply national rules to raw milk and raw milk-based products sold directly by the producer to the consumer and the UK has taken advantage of this (see Section 4, paragraphs 28 and 29). However all sales of raw cows' milk for drinking continue to be banned in Scotland.

7. The Regulations contain definitions for 'milk' and 'milk-based products'. In addition the EC Commission has advised that 'milk-based products' are as follows:

(a) *milk products* - whey, cream, cheese, butter, butteroil, buttermilk, anhydrous milk fat, yogurt, kephir, partly and wholly dehydrated milk products, caseins and caseinates and lactose *and*

(b) *composite milk products* - which are products where

(i) *no part replaces or is intended to replace any milk constituent*

AND

(ii) *milk or milk product is an essential part either in terms of quantity or for characterisation of the product.* The Commission has prepared a document which helps to clarify the type of composite milk products within the scope of the Directive (Document VI/8972/93-EN). According to this document, the crucial factor is the definition of 'essential part', so that products containing small amounts of milk or milk products are excluded (e.g. milk chocolate, biscuits containing butter, whisky cream). Examples of composite milk products are dairy ice cream, custard, cheesecake, rice pudding. Local Environmental Health Departments or MAFF/SOAFD should be able to advise on whether particular products are caught.

8. All premises with one or more cows, goats, sheep, and buffaloes need to be registered with ADAS in England/Wales (or licensed by the Environmental Health Department in Scotland and with the Department of Agriculture in Northern Ireland) if they are producing milk for sale. A separate leaflet - issued to all cows' milk producers - covers the requirements for these premises (known as '**production holdings**'). There is also a separate leaflet for goat and sheep milk producers and processors - see Section 8 for details of where to obtain these leaflets.

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9. All premises heat-treating milk or processing dairy products for sale (including those engaged in slicing, and/or packaging, bottling, wrapping or re-wrapping such products) or collecting raw milk or standardising the fat content of raw milk are known as '**dairy establishments**'. Such premises (which may be on farm) are subject to additional requirements to those applying to production holdings. In particular they need to be approved (or inspected in the case of direct sellers of raw milk or milk products where approval is not required - see Section 3, paragraph 2) by Environmental Health Departments, which have overall responsibility for supervising the necessary standards of hygiene in such premises. An approval number for the premises has to be shown on the commercial document (see Section 5, paragraph 15). From 1 January 1996 it must also appear as part of the health mark on milk and milk-based products produced and traded in both the UK and throughout the EC (see Section 5, paragraphs 3-11).

10. There will be further EC developments which will have a bearing on the Regulations e.g. on derogations for traditional products. Whilst these will be made known publicly, it may be helpful for businesses to keep in touch with their local Environmental Health Department.

# *conditions to be met on production holdings (dairy farms)*

## *ANIMAL HEALTH REQUIREMENTS*

1. Raw cows' and raw buffaloes' milk can only originate from production holdings with herds which are officially tuberculosis-free, and brucellosis-free or officially brucellosis-free. Milk from goats and sheep can only originate from holdings which are brucellosis-free or officially brucellosis-free (*Brucella melitensis*). However, milk from healthy animals in herds/flocks which are not officially tuberculosis-free or brucellosis-free or officially brucellosis-free can be used for the manufacture of heat-treated milk or for the manufacture of milk-based products following heat-treatment.

2. In addition, the animals should not show any symptoms of infectious diseases communicable to humans through milk nor should they give the milk any abnormal organoleptic characteristics. The animals should not have any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder (or udder wound likely to affect the milk). Regular veterinary inspections (by a farmer's private vet) should be undertaken to check compliance with these requirements. Frequency of inspections will depend on circumstances but they can take place when a farmer's private vet is present for other purposes. The extent of inspections/number of animals checked will be for the producer to decide. Records of visits by a farmer's private vet e.g. receipts/invoices should be kept to show to Environmental Health Officers.

## *HYGIENE REQUIREMENTS*

### ***The holding***

3. All holdings (except those used solely for producing milk for consumption by the owner/occupier) must be registered (or licensed in Scotland and Northern Ireland) provided that they meet the relevant hygiene requirements. Cows' milk producers who were registered or licensed under previous milk and dairies regulations are automatically regarded as registered/licensed under the new regulations. But producers of goats', sheep and buffaloes' milk must apply for registration/licensing under the new regulations from the relevant authority.

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4. If animals are housed, the premises must ensure good conditions:
  - of housing, hygiene, cleanliness and health of the animals;
  - of hygiene for milking, handling, cooling and storing the milk.
5. Where milking is carried out or milk is stored, handled or cooled the premises must:
  - be easy to clean and disinfect with easy-to-clean walls and flooring;
  - have flooring which allows draining of liquids and easy disposal of waste;
  - have adequate ventilation and lighting;
  - have a sufficient supply of potable water meeting current drinking water quality standards;†
  - be separate from contamination sources;
  - have fittings and equipment which are easy to clean and disinfect.
6. If milk is stored at the holding, those premises must have suitable milk refrigeration equipment, adequate vermin control and be adequately separated from animal housing.
7. If a moveable milk bail is used, there must be a sufficient supply of potable water and the fittings and equipment should be easy to clean and disinfect. In addition, the bail should be sited on fresh ground free from waste matter and milk should be protected. The construction of the bail should allow interior surfaces to be kept clean.
8. If the milk-producing animals are kept untethered in the open, the milking parlour/area must be adequately separated from any housing area.
9. The isolation of infected animals (see paragraphs 1 and 2 of this Section) should be effective.

### ***Milking***

10. Milking must be carried out hygienically and the milk must be placed in a clean place to avoid adverse effects on it.

† Directive 80/778/EEC

***Premises and equipment***

11. Utensils, containers, tanks etc., intended for milking, collection or transport must be of smooth material which resists corrosion, is easy to clean and disinfect and does not transfer to the milk substances which will endanger human health or affect the compositional or organoleptic characteristics of the milk.

12. After use, utensils or equipment which come into contact with the milk must be cleaned and disinfected. Containers and tanks used to transport milk must be cleaned and disinfected after use.

***Staff***

13. Staff must observe high standards of cleanliness and those milking and handling raw milk must wear suitable clean milking clothes. Hands must be washed before milking and should be kept as clean as possible during milking. Persons who may be liable to contaminate raw milk must not milk animals or handle raw milk.

# *conditions to be met by dairy processors (dairy establishments)*

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1. Dairy establishments (collection and standardisation centres, treatment or processing establishments) can only use milk that comes from registered/licensed production holdings or from other approved establishments. Except as indicated in paragraph 2 below, all establishments have to be approved. Those establishments which have been granted temporary derogations also have to be approved but cannot export to other Member States and are not able to use the EC health mark on products. Stand-alone storage depots and warehouses do not need to be approved, nor do retail establishments.
2. On farm processors of raw drinking milk or raw milk-based products processed on the premises from their own milk, and selling their products exclusively (or virtually exclusively) to the ultimate consumer are exempt from the need for approval, although they have to meet general hygiene conditions applicable to processing establishments set out below, HACCP checks (but not certain testing or record keeping requirements) and training requirements (see Section 6 paragraphs 1 and 3) and be subject to inspection. However, premises from which these products are sold can be given an approval number and their products can carry the health mark if they meet the necessary standards for approval.
3. Businesses should notify their local Environmental Health Department if they are planning to set up a new operation or change an existing one. If establishments are in any doubt as to whether approval is necessary, advice should be sought from the local Environmental Health Department.

## *TREATMENT AND PROCESSING ESTABLISHMENTS*

### ***Working areas***

4. These establishments must have working areas large enough for work to be carried out under hygienic conditions and, if the production of some products might pose a risk of contamination to other products covered by the Regulations, the production must be carried out in a physically separate working area or in the same working area but at different times.

5. In working areas there should be:
- solid waterproof flooring (of any form) which is easy to clean and disinfect and which has good drainage;
  - easy to clean walls, ceilings or roof linings;
  - easy to clean non-corrodible doors;
  - adequate natural or artificial lighting and ventilation with, if appropriate, good steam and water vapour extraction facilities.
6. In these areas (or close by) there should be hot and cold running water in order to clean and disinfect hands and toilets where the taps used for hand washing must be designed to be non-hand-operable (elbow-operated or normal taps with elbow operated extensions or automatic cut off taps are permitted). In these facilities there should be a hygienic means of drying hands and suitable cleaning and disinfecting materials. There should also be facilities for cleaning tools, equipment and installations.

#### ***Storage areas***

7. All areas where raw materials and dairy products are stored must meet the same hygiene standards as working areas except that separate facilities for hand washing and cleaning equipment are not necessary.
8. In chilling and refrigeration rooms, a floor which is easy to clean and disinfect and which is well-drained is sufficient. Providing they were built before 1.1.93, wooden walls in chilling and refrigeration rooms are acceptable. In freezing and deep-freezing rooms, easy to clean, waterproof and rot-proof flooring is sufficient.

#### ***General***

9. There should be facilities for the hygienic handling and protection of raw materials and exposed final products during loading and unloading. There should be protection against pests.
10. All equipment in direct contact with raw materials should be of corrosion-resistant material and be easy to clean and disinfect. Raw materials or products not intended for human consumption should be placed in special watertight non-corrodible containers.
11. There should be a waste-water disposal system and a supply of potable water meeting current drinking water quality standards. Non-potable water can, however, be used for steam production, fire fighting and refrigeration equipment as long as the pipes are clearly distinguishable from those carrying the supply of potable water.

12. There must be adequate changing facilities with smooth, waterproof, washable walls and floors and with washbasins and flush lavatories (which should not open directly on to milk rooms). Taps fitted to wash hand basins must be designed to be non-hand-operable (elbow-operated taps or normal taps with elbow operated extensions or automatic cut off taps are permitted).

13. Processing establishments on farms need not provide changing rooms if the establishment is adjacent to the farmhouse or if the scale of the business or the risks associated with the operation does not warrant separate changing rooms e.g. a changing area might suffice.

14. There must be a room, cupboard, or a secure place for the storage of detergents, disinfectants, cleaning and maintenance material. Where appropriate, there should be facilities for cleaning and disinfecting tanks used for transporting milk and liquid or powdered milk-based products.

#### ***Equipment***

15. Treatment and processing establishments which package heat-treated drinking milk and liquid milk-based products e.g. cream/drinking yogurt, must have equipment for the mechanical filling and automatic sealing of containers. However this does not apply to churns and tanks (including bag in the box packs) and any container with a capacity of over 4 litres. In addition derogations from this requirement are available providing alternative filling and sealing methods are hygienic (see Section 7). The requirement does not apply to frozen milk-based products such as dairy ice cream.

16. Establishments must have equipment for the cooling and cold storage of raw milk, heat-treated milk and milk-based products. Cold stores must have correctly calibrated temperature measuring apparatus and businesses are therefore advised to arrange checks on accuracy of thermometers at suitable intervals.

17. When using disposable containers, establishments must have an area for their storage and for materials used in their manufacture. When using reusable containers, there should be a special storage area for them and equipment to clean and disinfect them mechanically.

18. Where appropriate, establishments must have containers for storing raw and standardised milk and standardisation equipment and centrifuges or other suitable means for physically purifying milk.

19. Where appropriate, establishments must have equipment for the cooling, wrapping and storage of frozen milk-based products and for the drying and wrapping of powdered milk-based products.

20. Where installed heat-treatment equipment must have:

- (a) an automatic temperature control,
- (b) a recording thermometer,
- (c) an automatic safety device preventing insufficient heating,
- (d) an adequate safety system preventing the mixture of heat-treated milk with incompletely heated milk, and
- (e) an automatic recording device for the safety system referred to in (d) above or a procedure for monitoring the safety system effectiveness.

However, Environmental Health Departments may accept different equipment which provides equivalent performance with the same health guarantees. Batch pasteurisers (used in some dairies and by some ice cream manufacturers) can therefore continue to be used as at present provided that authorisation is given by Environmental Health Departments.

21. Businesses will need to have means of monitoring the effectiveness of heat-treatment and preventing post pasteurisation contamination and Environmental Health Officers will pay particular attention to this. As an example, it is recommended practice that all equipment for heat-treating milk is properly calibrated and that the temperature shown on thermographs matches the temperature measured by a certified accurate indicating thermometer. Frequency of checks will depend on use, but businesses will need to have evidence that the equipment is functioning correctly and maintain records of thermographs so that they can show these to Environmental Health Officers, when required to do so. Failure by businesses to maintain control over heat-treatment and corresponding records will be regarded as a serious matter.

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**Hygiene conditions:****(a) Premises and equipment**

22. All equipment and instruments must be kept clean and in good condition in order to prevent contamination of raw materials or products. Animals are prohibited in working and storage areas and substances used for controlling vermin must be stored in lockable cupboards or rooms.

23. Disinfectants and similar substances need to be acceptable to the food authority on the basis that they are suitable for the purpose and used in such a way that they do not have adverse effects on machinery, equipment and products.

24. In order to achieve high standards of food safety an appropriate risk analysis programme should be drawn up (see Section 6).

25. Measures should be taken to prevent cross contamination. Rooms used for production should have separate wet and dry areas, each with their own operating conditions. It may be appropriate that these activities should be separated in time to avoid risks of contamination. After each journey, or each series of journeys where there is only a very short period of time between unloading and the subsequent loading, containers and tankers used to transport milk to an establishment must be cleaned and disinfected before re-use.

26. The cleaning programmes for equipment, containers and installations which come into contact with perishable milk or milk-based products during production and for equipment, containers and installations which come into contact with microbiologically stable milk-based products and rooms in which they are stored must be based on risk analysis principles.

27. The treatment premises must also be cleaned in accordance with procedures based on risk analysis principles. It must be remembered that the condition of premises and equipment must never be such as to compromise the hygiene of raw or heat-treated products.

**(b) Staff**

28. A high standard of cleanliness is required of all staff. Suitable clean working clothes and clean head gear which completely encloses the hair must be worn.

29. Staff working with raw materials and dairy products must wash their hands at least each time work is resumed and/or when contamination has occurred. Any wounds to the skin must be covered with a waterproof dressing.

30. There should be no smoking, spitting, eating or drinking in work or storage areas.

31. All food handlers being recruited to work in establishments will need to demonstrate, through a medical certificate, that there is no medical impediment to such employment. However employers have discretion in some circumstances to accept medical certificates issued in respect of a previous period of employment. Separate guidance is available on medical certification from the Department of Health and Scottish Office and Department of Health and Social Services for Northern Ireland.

### *COLLECTION AND STANDARDISATION CENTRES*

32. These establishments must meet the requirements specified in paragraphs 4-14. In addition, collection centres must have cooling equipment or appropriate means for cooling milk and, if milk is stored at the collection centre, a cold-storage installation. If milk is purified at the collection centre there must be centrifuges or any other apparatus suitable for the physical purification of milk.

33. Standardisation centres must have containers for the cold storage of raw milk, standardisation equipment and containers for the storage of standardised milk, and centrifuges or any other apparatus suitable for the physical purification of milk.

SECTION

# *standards for raw milk, heat-treated milk and milk-based products*

## SECTION

1. Hygiene standards are laid down relating to raw milk (when collected from the production holding for acceptance at the treatment or processing establishment). There are also hygiene requirements for the manufacture of heat-treated milk and milk-based products, and microbiological criteria for milk-based products and drinking milk.

### *RAW MILK*

2. *Raw cows' milk* to be used for the production of heat-treated drinking milk, fermented milk, junket, flavoured milk or cream must have a:

Plate count at 30°C (per ml)	≤ 100,000
Somatic cell count (per ml)	≤ 400,000

3. *Raw cows' milk* for the production of other milk-based products must have a:

Plate count at 30°C (per ml)	-	from 1.1.94 ≤ 400,000
	-	from 1.1.98 ≤ 100,000
Somatic cell count (per ml)	-	from 1.1.94 ≤ 500,000
	-	from 1.1.98 ≤ 400,000

4. Where *raw cows' milk* is to be used for the manufacture of raw milk-based products whose manufacture does not involve any heat-treatment i.e. at least equal to pasteurisation, such milk must meet the standard in paragraph 2 and the following standard for *Staphylococcus aureus* (per ml): n=5 c=2 m=500 M=2000 (see paragraphs 21 and 22 for an explanation of n, c, m and M).

5. *Raw goats' and sheep milk* to be used for the production of heat-treated drinking milk or heat-treated milk-based products must have a plate count at 30°C (per ml) of ≤ 3,000,000 from 1.1.95 and < 1,500,000 from 1.12.99. Standards relating to somatic cell counts may be specified at a later date.

6. Where *raw goats' or sheep milk* is to be used for manufacturing a milk-based product without any heat-treatment, such milk must have a plate count at 30°C (per ml) of ≤ 1,000,000 from 1.1.95 and < 500,000 from 1.12.99 and meet the *S. aureus* (per ml) standard for raw cows' milk (ie. n=5 c=2 m=500 M=2000).

7. *Raw buffaloes' milk* is subject to the same standards as raw sheep and goats' milk.
8. Plate count figures should be based on a geometric average over a period of two months, with at least two samples a month, and somatic cell count figures should be based on a geometric average over three months, with at least one sample a month. Standards apply to raw milk collected from the production holding (except in the case of somatic cell counts where until 1.7.97 the standards can alternatively be checked on bulk milk arriving at a treatment or processing establishment or with the first buyer.) Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.
9. Limits for antibiotic residues in milk laid down in Annex I and III to EC Regulation 2377/90† (as amended) and limits for pesticides and other residues also apply. In addition milk should not contain any added water and checks on the freezing point of milk are required.
10. *It is the responsibility of operator/managers to ensure that raw milk is checked against standards in the Regulations including animal health standards. Where raw milk is purchased direct from a production holding by a person/company which is not itself going to process or treat the milk, that first buyer is responsible for undertaking these checks.*

## REQUIREMENTS FOR THE PRODUCTION OF HEAT-TREATED DRINKING MILK

11. *Raw cows' milk* to be used for the manufacture of heat-treated drinking milk must meet the standards in paragraph 2 above. If treatment of the raw milk has not begun within 36 hours of the milk's acceptance at the dairy, the plate count at 30°C must not exceed 300,000 per ml if the milk is to be heat-treated.
12. *Pasteurised milk* must be obtained by means of a heat-treatment involving a high temperature for a short time (at least 71.7°C for 15 seconds or any equivalent combination) or a pasteurisation process using different time and temperature combinations to obtain an equivalent effect, and must show a negative reaction to the phosphatase test and a positive reaction to the peroxidase test or, in the case of high-temperature pasteurised milk, show a negative reaction to both tests and be labelled as 'high temperature pasteurised'.
13. *UHT milk* must be obtained by applying heat to a continuous flow of raw milk entailing the application of a high temperature for a short time (not less than +135°C for not less than one second).

† Council Regulation (EEC) No. 2377/90 of 26 June 1990 laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

14. *Sterilised milk* must have been heated and sterilised in hermetically sealed wrappings or containers, the seal of which must remain intact. Alternatively, the continuous flow process may be used.

## *REQUIREMENTS FOR MILK FOR THE MANUFACTURE OF MILK-BASED PRODUCTS*

15. For the manufacture of all milk-based products use of the *raw milk* must start

- as soon as possible after acceptance at the establishment if the milk has not been refrigerated or
- within 36 hours of acceptance at the dairy if the milk is kept at a temperature not exceeding 6°C; or
- within 48 hours of acceptance at the dairy if the milk is kept at a temperature not exceeding 4°C; and
- within 72 hours in the case of buffaloes', sheep or goats' milk.

Environmental Health Departments may authorise these time and temperature limits to be exceeded for technological reasons.

16. *Heat-treated milk* to be used in the manufacture of milk-based products must have come from raw milk meeting the standards laid down in paragraphs 2, 3, 5 and 7 (as appropriate) of this section.

17. If *thermised milk* is to be used for the manufacture of milk-based products it must have come from raw milk treated for at least 15 seconds at a temperature between 57°C and 68°C. It should only be made from raw milk of a specified standard. There are also requirements relating to thermised milk used for the production of pasteurised, UHT or sterilised milk intended for the manufacture of milk-based products.

18. If *pasteurised or UHT milks* are to be used, the milk must meet the requirements laid down in paragraphs 12 and 13 of this section as appropriate.

## *MICROBIOLOGICAL CRITERIA FOR MILK-BASED PRODUCTS*

19. Schedule 6, Part 1 of the Regulations lays down microbiological standards for milk-based products. These standards apply on removal from the processing establishment. They do not apply to retail sales.

20. The Schedule gives standards for compulsory criteria (for pathogens) and analytical criteria (for organisms indicating poor hygiene). The action required if standards are exceeded varies. The Directive also includes guidelines for indicator organisms which are not compulsory and so not in the Regulations but which operators may find it helpful to follow. Local Environmental Health Departments can provide details.

21. The sampling plans laid down in the Schedule are to be used for enforcement purposes. Manufacturers do, however, have to carry out their own sampling (in accordance with a risk analysis programme) in order to demonstrate that their production meets the standards laid down in Schedule 6.

22. The sampling plans in Schedule 6 use the ICMSF (International Commission of Microbiological Specifications for Foods) format i.e. 'n' 'c' 'm' 'M'. These are defined in the Regulations. Briefly, the level of test organism which is acceptable in the product is denoted by 'm', and 'M' is the hazardous or unacceptable level of contamination. 'n' defines the number of sample units required for testing. Microbial counts between 'm' and 'M' are undesirable but some will be accepted, the number acceptable is denoted by 'c' i.e.  $n = 5$ ,  $c = 2$ ,  $m = 100$ ,  $M = 10,000$  means that no more than two samples out of the 5 can contain a level of the organism between  $m$  and  $M$ .

## *MICROBIOLOGICAL CRITERIA FOR DRINKING MILK*

23. Schedule 4 of the Regulations lays down the microbiological criteria for drinking milk, both raw and heat-treated. In the case of raw cows' milk for drinking (paragraph 1 of Part I of Schedule 4) the standards apply only where milk is being imported or exported.

24. In addition there are other microbiological standards for heat-treated milks and these have to be assessed in accordance with the principles described in paragraph 21 of this Section.

25. Raw milk for drinking for direct sale to consumers in the UK is subject to different requirements (see paragraphs 28-31 below).

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26. In addition, heat-treated drinking milk must not contain pharmacologically active substances in quantities higher than the limits laid down in Annexes I and III to Regulation 2377/90 (as amended) or any added water.

### *METHODS OF ANALYSIS*

27. Manufacturers can continue to use methods of analysis that are not internationally recognised for routine quality purposes. However any legal action taken by enforcement officers will be based on the results of reference methods laid down in Schedule 11 or other internationally accepted methods of analysis.

### *DIRECT SALES OF RAW DRINKING MILK*

28. As indicated in Section 1, the Directive allows Member States to maintain their national rules relating to direct sales of raw drinking milk to consumers. In England and Wales (and in Northern Ireland) raw cows' drinking milk can only be sold at the farm gate by a registered (licensed in Northern Ireland) producer or a farmhouse caterer (or via a distributor).

29. It also has to meet certain microbiological standards (for plate count and coliforms). ADAS (and Department of Agriculture in Northern Ireland) are responsible for enforcing restrictions at farm level and for sampling/testing of raw cows' drinking milk. The microbiological standards have also been extended to raw goats' and sheep's milk for which Environmental Health Departments continue to have responsibility.

30. Under current Food Labelling Regulations all raw cows' milk has to carry a health warning indicating that the milk has not been heat-treated and may contain organisms harmful to health. This requirement is likely to be extended to raw sheep and goats' milk in revised Food Labelling Regulations (expected to take effect in January 1996).

31. In Scotland the ban on sales of raw cows' milk for drinking has been continued. Raw goats' and sheep's milk for drinking can continue to be sold but only direct to the ultimate consumer at the farm and must meet the microbiological standards (for plate count and coliforms).

## *TEMPERATURES*

32. Paragraph 15 refers to the temperature requirements for raw milk before treatment. In addition, on production holdings where cows' milk is not collected within 2 hours of milking, it must be cooled to a temperature of not more than 8°C if there is a daily collection, or not more than 6°C if collection is not daily.

33. During transport to the treatment establishment the temperature must not exceed 10°C. However these temperatures can be exceeded for technological or operational reasons, if agreed with Environmental Health Departments, provided that the microbiological criteria specified in Part I of Schedule 6 are met by the end product.

34. After acceptance at a treatment establishment, and if not treated within 4 hours, raw milk must be cooled to a temperature not exceeding 6°C and maintained at that temperature until heat-treated.

35. Other storage and transport requirements are set out in Schedules 7 and 8 of the Regulations.

SECTION

*rules on wrapping,  
packaging, health,  
marking, labelling,  
storage, transport and  
documentation*

**WRAPPING AND PACKAGING**

1. Wrapping and packaging material must comply with all the rules of hygiene and be strong enough to protect products effectively from physical damage and from contamination. Wrapping and packaging operations must take place under hygienic conditions and in rooms (or designated areas) provided for that purpose. However, product manufacturing and wrapping/packaging operations can take place in the same room provided that:

- the room is sufficiently large to ensure that the hygiene of the operations is assured;
- the wrapping and packaging material has been placed in protective covers immediately after its manufacture and is brought to the processing establishment whilst in such covers and stored there hygienically in a special room;
- the storage room referred to above is vermin and dust-free and is separated from rooms containing substances which could contaminate the products;
- the packaging is assembled hygienically before being brought in to the room (if not assembled automatically);
- the packaging is used without delay (and is not handled by staff handling unwrapped products if there is a risk of contamination); and
- immediately after packaging the products are placed in storage rooms/areas.

2. The sealing of containers of heat-treated milk and liquid milk-based products must take place in the treatment establishment where the last heat-treatment was carried out, immediately after filling, and with a sealing device which, once broken, can be easily seen and checked. Sealing must be carried out automatically except in the case of limited production where non-automatic sealing is acceptable (see Section 7).

## HEALTH MARKING AND LABELLING

3. Except where temporary derogations apply, all products covered by the Directive and originating from approved establishments must carry a health mark. Such marking, carried out during or immediately after manufacture, should be visible, legible, indelible and easily distinguishable. The intention of health marking is to enable enforcement authorities to trace products back to originating establishments where difficulties arise.

4. The health mark can be applied anywhere on the product or the wrapping (if the product is individually wrapped) or to a label on the wrapping. However, if a small dairy product is individually wrapped and subsequently packaged, e.g. a box of small individually wrapped cheese portions, the health mark need only be applied to the box. 'Small dairy products' means products of 10cm or less in accordance with provisions in the Food Labelling Regulations 1984. Individual ice creams e.g. choc ices, cornettos would not need to be health marked.

5. If products wrapped and/or packaged in accordance with paragraph 4 are further packaged e.g. in a cardboard box, the health mark must be applied to the further packaging. However, packaging would not include crates, wheeled trolleys or plastic trays. Also if packaging is of a shrink wrap type and the health mark was visible through the shrink wrap it would not be necessary for the packaging to be health marked.

6. The health mark must appear in one of the following forms within an oval surround:



\*\*\* = Approval number (for example) AA001M. (Letters AA vary depending on the local authority/region e.g. NI applies in Northern Ireland.) The M is optional subject to the agreement of the approving authority.

The 'United Kingdom' can be abbreviated to 'UK' when a product is sold on the UK market. 000 = Indication of where the approval number is printed outside the health mark. e.g. 'For approval numbers, see lid...'

7. There is an abbreviated form of health mark (involving only the letters 'UK' and the approval number) for reusable bottles or small packages of 10cm or less.

8. The health mark can be applied by an ink stamp or by branding or may be printed on or applied to a label or any part of a product provided it is visible. In the case of operations which arrange packaging centrally it would be acceptable for a number of approval numbers to be pre-printed within a health mark and for the numbers that are not applicable to be deleted.

9. Until 1 January 1996 milk and milk-based products (which are not health marked) can be traded with other Member States provided that the health mark/approval number is shown on the accompanying commercial document.

10. For heat-treated milk and liquid milk-based products the labelling on the packaging must also show (for the purpose of checks by enforcement authorities):

(a) the type of heat-treatment which the raw milk has undergone and

(b) information allowing the date of last heat-treatment to be established (which could be by means of the lot mark or 'use by' or 'best before' date) together with, for pasteurised milk, the temperature at which the product should be stored (i.e. 6°C or lower).

Reusable glass bottles are exempt from these requirements.

11. Again for enforcement purposes, raw milk intended for direct human consumption must be labelled 'raw milk'. Similarly, milk-based products made from raw milk without heat-treatment should be labelled 'made with raw milk'. These requirements *do not* apply at the retail stage. The Food Labelling Regulations which *do* apply at the retail level do not require any such labelling. (But see Section 4, paragraph 30 relating to health warning.)

## STORAGE AND TRANSPORT

12. Dairy products covered by the Directive which cannot be stored at ambient temperatures must be stored at temperatures established by the manufacturer to ensure their durability. Pasteurised milk, when kept in the establishment and when transported in tanks or packed in small containers and churns, must not exceed 6°C. In addition pasteurised milk when transported to retail businesses e.g.

supermarkets, must not exceed 8°C. However there is no temperature requirement where pasteurised milk is delivered by milk floats or other small delivery vehicles entirely to households or mainly to households with a small amount also to small retail outlets or institutions e.g. schools.

13. Tanks, churns and other containers used to transport pasteurised milk must:

- have inside surfaces made of smooth material which is easy to clean and disinfect, which resist corrosion and which do not transfer substances to the milk so as to endanger human health or impair the composition or organoleptic characteristics of the milk;
- be designed to allow milk to drain away completely and taps, if fitted, should be easy to remove, clean and disinfect;
- be cleaned and disinfected immediately after each use and at least once every 24 hours; and
- be sealed before and during transport with a water-tight sealing device.

14. Milk tankers must only be used for the transportation of foodstuffs. Other vehicles used for transporting heat-treated milk must not be used to transport any other product or object which could lead to contamination or deterioration of the milk. The internal surfaces of such vehicles must be smooth and easy to wash and disinfect.

## *DOCUMENTATION*

15. During transport in bulk heat-treated drinking milk and milk-based products must be accompanied by a commercial document which must show the details of the EC health mark of the establishment consigning the product and:

- for heat-treated drinking milk or milk-based products, allow the nature of the heat-treatment and the supervising competent authority to be identified; and
- be kept by the consignee for at least one year.

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16. However, this accompanying document is not required when milk and milk-based products are delivered direct by the producer/manufacturer to the ultimate consumer. In effect this will mean that any doorstep deliveries involving a small amount of products being delivered to local shops will be exempt from this requirement. In addition the requirement relating to retention of documents is not applicable to retail outlets as they are outside the scope of the Regulations. It would be acceptable for the information specified to be placed on sales or advice/invoice notes. Where consignments are split, copies of the commercial document will suffice.

17. As indicated in paragraph 9, the EC health mark/approval number on the commercial document will be the sole means of telling whether products can be traded - where products are not themselves health marked - during the transitional period.

# health checks/ inspections/training

## OPERATOR/MANAGER OF ESTABLISHMENT

1. The operator or manager of an establishment must ensure that checks are carried out which allow him to:

- identify points critical to the safety of food, based on a risk analysis programme in establishments on the basis of the processes used (MAFF/DH and DANI information leaflets entitled '*Hazard Analysis Critical Control Point (HACCP): Practical food safety for businesses*' are available from Environmental Health Departments);
- monitor and check these critical points appropriately;
- take samples for analysis in a recognised laboratory to check cleaning and disinfection methods and compliance with the standards in the Directive;
- keep a record of the above for at least two years (two months for milk-based products which cannot be stored at ambient temperatures);
- inform the competent authority if the laboratory examination reveals a serious health risk; and
- withdraw any products considered to be a risk which will then be under the supervision and control of the competent authority.

(However where raw milk is purchased for resale as milk for processing, it is the responsibility of the 'first buyer' to ensure that appropriate checks/tests are carried out to check compliance with raw milk standards and that relevant records are kept and any follow up action taken.)

2. The operator or manager must also ensure that health marking described in paragraph 6 of Section 5 is controlled and carried out properly.

## TRAINING

3. All workers should receive training in hygiene that is appropriate to their work activity.

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## COMPETENT AUTHORITY

4. All establishments must be supervised by the competent authority to ensure that they are meeting the requirements of the Regulations. This may include the taking of samples required for laboratory tests in some cases.
5. In order to carry out checks on compliance with the Regulations the competent authority must have free access at all reasonable times to the cold stores and all the working premises. Operators must supply the competent authority with such information and assistance as it reasonably requests.
6. There are procedures which enable businesses to complain where they disagree with enforcement action taken by an Environment Health Officer. (The booklet *'Food Law Inspections and your business'*, available from Environmental Health Departments, gives further details). In addition an appeals procedure is available to businesses wishing to question the decision of the competent authority.
7. The competent authority in England, Wales and Scotland is the Local Authority (LA) (Environmental Health Department or in some cases Trading Standards Department). In Northern Ireland this is the District Council or the Department of Agriculture for Northern Ireland.

# *derogations*

## *TEMPORARY*

1. In accordance with arrangements under EC Directive 92/47 establishments were able to apply for temporary derogations (applicable until 1 January 1998) from certain structural and equipment requirements (in Schedule 2 Parts I and II of the Regulations). The UK submitted applications to the European Commission in 1993 and the UK list of establishments granted temporary derogations has now been agreed and included in Commission Decision 94/695.

2. Most of the temporary derogations granted to the UK relate to the requirement for establishments to have equipment for mechanically filling and automatically sealing containers of heat-treated milk and liquid milk-based products. But many of these derogations can now be made permanent (see paragraphs 3 and 4 below).

The remaining cases are those where establishments were undergoing major refurbishment and could demonstrate through work plans and a completion date that they would soon comply with the necessary requirements.

## *PERMANENT*

3. Under the Regulations Environmental Health Departments may grant derogations from Part I and II of Schedule 2 (see Section 3 paragraphs 4-21) to low capacity establishments making milk-based products. Establishments solely producing liquid milk as the end product are not currently eligible for these derogations.

4. Because most of the requirements relating to structure, hygiene and equipment were included in previous UK legislation, it is expected that there will be relatively few cases where Environmental Health Departments consider it necessary to give permanent derogations, although goats' and sheep's milk product processors may have more difficulty in meeting requirements and so may need derogations.

5. In the Regulations a low capacity establishment is defined as one using no more than 300,000 litres of milk (or its equivalent) each year. However EC harmonised criteria has now been agreed (in Commission Decision 95/165) which would enable derogations to be given to establishments processing up to 2 million litres of milk a year into products, assuming there is no health risk. The Regulations will be amended to reflect this development.

6. In addition establishments with limited production of heat-treated drinking milk by means of a separate circuit/production line may be granted a permanent exemption from the requirement to mechanically fill and automatically seal containers of heat-treated drinking milk provided alternative methods are hygienic.

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In the Regulations limited production means production not exceeding 300,000 litres per year but the new harmonised criteria with a limit of 2 million litres now applies and the Regulations will be amended in due course to reflect this.

7. Establishments making cheeses which, in their manufacture, require to be aged or ripened for at least 60 days have been granted permanent derogations from:

- the standards for raw milk (see Section 4, paragraphs 2-8);
- the structural, equipment and hygiene standards (see Section 3) and wrapping and packaging requirements (see Section 5, paragraphs 1 and 2)

8. Establishments producing milk-based products with traditional characteristics have been granted similar derogations and also derogations from microbiological standards in Schedule 6 Part I of the Regulations for the time being. In the longer term an EC exercise is underway to establish the harmonised criteria for derogations and the products that might benefit. MAFF, SOAFD and Department of Agriculture for Northern Ireland have sought applications from industry and manufacturers who have applied may wish to copy their applications to their local Environmental Health Department, so that they are aware of the situation. The Regulations will be amended in due course to reflect the outcome of the EC exercise.

9. Businesses should contact their local Environmental Health Departments for further information on the derogations available.

10. All products from establishments receiving permanent derogations are able to use the EC Health Mark and export their products to other Member States.

# *further information*

## *ENGLAND AND WALES*

For further information about the requirements of the Regulations in England and Wales, please contact your Local Authority's Environmental Health Department. Additional information is available by contacting:

The Ministry of Agriculture, Fisheries and Food  
Milk and Milk Products Division,  
Room 514  
Whitehall Place (East)  
London  
SW1A 2HH  
Telephone: 0171 270 8243

The Welsh Office Agriculture Department  
Cathays Park  
Cardiff  
CF1 3NQ  
Telephone: 01222 823624

The Department of Health  
Health Aspects of Environment & Food Division  
Skipton House, 80 London Road  
London  
SE1 6LW  
Telephone: 0171 972 5345

## *SCOTLAND*

For further information about the requirements of the Regulations in Scotland please contact your Local Authority Environmental Health Department or,

The Scottish Office Agriculture and Fisheries Department  
Meat, Fish and Milk Hygiene Branch  
Pentland House  
47 Robb's Loan  
Edinburgh  
EH14 1TY  
Telephone: 0131 244 6413

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## NORTHERN IRELAND

For further information about the requirements of the Regulations in Northern Ireland please contact:

The Department of Agriculture for Northern Ireland  
Milk and Milk Products Quality Assurance Division  
Dundonald House  
Upper Newtownards Road  
Belfast  
BT4 3SB  
Telephone: 01232 524685

DHSS (NI)  
Health Protection Policy  
Annex 4, Castle Buildings  
Stormont Estate  
Belfast  
BT4 3SS  
Telephone: 01232 521333

Further free copies of this leaflet may be obtained by writing to one of the Government Departments indicated above.

Free copies of the leaflets

'A Short Guide to the Dairy Products (Hygiene) Regulations for Dairy Farmers'.  
'A Short Guide to the Dairy Products (Hygiene) Regulations for Farmers producing and processing milk from Goats and Sheep'  
may be obtained by writing to:

MAFF Publications  
London SE99 7TP

Copies of the Regulations are available from HMSO Publication Centre, PO Box 276, London SW8 5DT or HMSO bookshops. Details of the Regulations are as follows:

The Dairy Products (Hygiene) Regulations SI 1995 No. 1086  
(ISBN 0-11-052883-2). Cost £8.10.

The Dairy Products (Hygiene) (Scotland) Regulations SI 1995 No. 1372 (S.101)  
(ISBN 0-11-054993-7). Cost £6.75.

Dairy Products (Hygiene) (Northern Ireland) Regulations 1995 SR No. 201  
(ISBN 0-337-91701-9) Cost £6.95.