

Notification

New Delhi, the 28th November, 2000

S.O. 2720—In exercise of the powers conferred by Section 17 of the Export (Quality Control and Inspection) Act, 1963 (22 of 1963) .The Central Government hereby makes the following rules, namely:

1. Short title and Commencement—(a) These rules may be called the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000.

(b) They shall come into force on the date of their publication in the official Gazette.

2. Definition.—In this notification unless the context other – wise requires, the following definitions shall be applicable

(a) “Act” means the Export (Quality Control and Inspection) Act, 1963 (22 of 1963);

(b) “Agency” means any one of the Export Inspection Agencies at Mumbai, Calcutta, Cochin, Delhi and Madras established under section 7 of the Act;

(c) “Batch” means a quantity of milk products which have been prepared under the same conditions and in particular treated in single continuous operation;

(d) “Certificate” means certificate issued under sub-section (3) of Section 7 of the Act stating that the commodity conforms to the conditions regarding Quantity Control and Inspection;

(e) “Collection Centre” means an establishment where raw milk may be Collected and possibly cooled and filtered.

(f) “Competent Authority” means any one of the Export Inspection Agencies at Bombay, Calcutta; Cochin, Delhi and Madras established under section 7 and Inspection of the Act.

(g) “Composite Milk Products” Composite Milk Product is a product of which the milk, milk products or milk constituents are an essential part either in term of quantity or for the characterisation of the product:

Provided that the constituents not derived from milk are not intended to take the place in part or in whole of any milk constituent.

(h) “Consignment” means a quantity of milk products for a single delivery to one destination for further processing by the food industry or intended for direct human consumption;

(i) “Council” means the export Inspection Council established under section 3 of the Act;

(j) “Country of Despatch” means India;

- (k) "Country of Destination" means the country to which milk products are dispatched from India:
- (l) "Heat Treatment" any treatment involving heating that causes, immediately after it has been applied, a negative reaction to the phosphates test.
- (m) "Hermetically sealed container" means container which, when sealed, is intended to protect the contents against the entry of micro-organisms during and after heat treatment and which is impervious;
- (n) "Holding" means an establishment at which one or more dairy animals and their followers are kept:
- (o) "Milk Products" means Milk products, namely products, namely Products exclusively derived from milk, it being accepted that substances necessary for their manufacture may be added, provided that these substances are not used to replace in part or in whole any milk constituents, and composite milk products of which not part replaces or is intended to replace any milk constituents and of which milk or a milk products is an essential part either in terms of quantity or for characterization of the product.
- (p) "Packing" means the placing of milk products in any form of package;
- (q) Packaging means the placing of one or more wrapped or unwrapped products as in a container, as well as the container itself;
- (r) "Placing on the market" means the stocking or display with a view to sale, offering for sale, delivery or any other manner of disposal with the exception of retail sale, which must be subject to the checks laid down by national rules for retail business.
- (s) "Plant" means any premises where milk products are processed and manufactured.
- (t) "Potable water" means water that has been approved by State Health Authority or other Agency or Laboratory acceptable to the Competent Authority as safe for drinking and suitable for food processing.
- (u) "Raw Milk" means the milk products by secretion of the mammary glands of one or more, cows, ewes, goats or buffaloes, which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect;
- (v) "Thermisation" is a heat treatment applied to raw milk aimed at reducing the number of organisms in milk and permitting longer storage of the milk prior to further processing. The heating conditions are 62° to 65° C for 15 to 20 seconds. Thermized milk must be phosphates positive.
- (w) "Treatment establishment" means an establishment or production holding where milk and/or products are treated, processed and packed;
- (x) "UHT (Ultra High Temperature) Treatment" treatment of milk of cream is a high-temperature/short time heat treatment aimed at producing a commercially sterile product, which can be stored at room temperature. The process aims to destroy all micro-organisms; any residual micro-organisms are unlikely to cause spoilage under normal storage conditions. UHT-treated

milk and cream are packaged aseptically into sterilized, hermetically sealed containers. The total heat treatment is equivalent. In terms of its effectiveness against heat-resistant spores, to a minimum F° value of 3 min.

As per S.O. 3719 dated 30th November 2002, the Clause (x) of rule 2, the following has been substituted;

- (a) for the word “residcal” the word “residual” shall be substituted;
- (b) the paragraph beginning with the words “A hermetically sealed container.....” and ending with the words “entry of micro-organisms” shall be omitted;

As per S.O. 999(E) dated 13th September 2004, the clause (x) of rule 2, the following has been substituted;

“(x) “Ultra High Temperature (UHT) Treatment” is treatment of milk or cream in a high temperature or short time heat treatment aimed at producing a commercially sterile product, which can be stored at room temperature.

Note: The UHT process aims to destroy all micro-organisms. Any residual micro-organism is unlikely to cause spoilage under normal storage conditions. The UHT-treated milk and cream are packaged aseptically into sterilized, hermetically sealed containers. The total heat treatment is equivalent, in terms of its effectiveness against heat resistant spores, to a minimum F° value of three minutes. The temperature for UHT treatment is in the range of 135 degree-150 degree C in combination with appropriate holding times such as 140 V for 2-3 seconds.”

The temperature for UHT treatment is in the range of 135 degree – 150 degree C in combination with appropriate holding times such as 140V for 2-3 seconds.

- *A hermetically sealed container is a container that is designed and intended to be secure against the entry of micro- organisms.
- (y) “Wrapping” is the protection of the products by the use of an initial wrapping or initial container in direct contact with the products concerned as well as the initial wrapper or initial container itself;

3. BASIS OF COMPLIANCE:

- (a) It shall be the responsibility of the processors to ensure that the milk products intended for exports are handled processed at all stages of production, storage and transported under proper hygienic conditions so as to meet the health requirement laid down under these rules and that the product conforms to the specifications given in the order by the Central Government under section 6 of the Act.
- (b) The Competent Authority shall ensure that all the processors comply with the requirement by regular monitoring of the plant as per the control measures prescribed in the Para of this part. For effective monitoring of the scheme, As per S.O. 3719 dated 30th November 2002 the clause (b) of rule 3, the following has been substituted;

“(b)The Competent Authority shall ensure that all the processors comply with the requirements by regular monitoring of the establishment as per the control measures prescribed in sub rule 4.18 of these rules. For effective monitoring of the scheme, the Council shall issue necessary instructions in this regard from time to time.”

4. The milk products for Exports shall be subjected to the following conditions:
- 4.1 Any statutory restriction imposed by any State/ Central Government with respect to commercial/environment conservation measures from time to time shall strictly be adhered.
 - 4.2 They must have been obtained from milk of diary animals which meet the requirements given in items 1 to 4 of Annexure A.
 - 4.3 They must contain only the permissible food additives/processing aids, other than milk, which are fit for human consumption.
 - 4.4 They must have been treated and prepared in an approved plant which complies with Chapter 1 and II, V and VI of the Annexure B and satisfy the requirements of these rules.
 - 4.5 They must have been processed and/or manufactured under hygienic conditions complying with Items 2 and 5 of Annexure B from milk meeting the requirement laid down in Annexure C.
 - 4.6 They must have undergone a processing treatment which enables them to meet inter alia the analytical specifications laid down in item 3 of the Annexure C.
 - 4.7 They must have undergone a health marking and levelling in accordance with item 5 of the Annexure C.

As per S.O. 3719 dated 30th November 2002 the paragraph 4.7, the following has been substituted;
(a) For the word “lavelling” the word “labelling” shall be substituted;
 - 4.8 They must have been packed in accordance with item 4 of Annexure C.
 - 4.9 They must be stored and transported in accordance with item 6 of the annexure C.
 - 4.10 The period during which the milk products are fit for human consumption and storage shall be indicated by the processor.
 - 4.11 The results of the various checks and tests are recorded and kept for presentation to the competent authority for a period of two years.
 - 4.12 To detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances should not be present in milk which might alter the sensory characteristics of milk products or make their consumption dangerous or harmful to human health.

As per S.O. 3719 dated 30th November 2002 the paragraph 4.12, the following has been substituted;

(b) “4.12 There shall not have any residue of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents in excess of the permitted levels fixed so as to make them harmful or which might alter their organoleptic characteristics or make their consumption dangerous or harmful to human health.”

- 4.13 If the milk products examined show traces of residues in excess of the permitted levels fixed, they must not be allowed either for the manufacture of foodstuffs or for direct human consumption.
- 4.14 Tests for residues must be carried out in accordance with National/Internationally recognised methods.
- 4.15 Having satisfied itself that the plant meets the requirements with regard to the nature of the activities if carries out, the competent authority shall accord approval to such plant for a period of one year.
- 4.16 The Competent Authority may take the assistance of a representative each from EIC, APEDA, Ministry of Food Processing Industries, National Dairy Development Board, and Representative of Industry and co-operatives and experts from National Dairy Research Institute etc. in the matter of approval of processing plants.

As per S.O. 3719 dated 30th November 2002 the paragraph 4.16, the following has been substituted;

(c) “4.16 The Competent Authority may take the assistance of representatives from Export Inspection Council, Agricultural and Processed Food Products Export Development Authority, Ministry of Agriculture, Ministry of Food Processing Industries, National Dairy Development Board, National Dairy Research Institute, industry, co-operatives in the matter of approval of establishment.”

- 4.17 The competent authority shall draw up a list of the approved plants, each of which have an official number and the competent authority shall furnish to appropriate authorities the list of approved plants and subsequent change thereof.
- 4.18 The inspection and monitoring of plant and packaging centres shall be carried out regularly by the competent authority, which shall at all times have free access to all parts of the plants, in order to ensure that these rules are being observed. The health checks and supervision of production shall be carried out as per the elements given in Annexure D.

As per S.O. 1397 dated 24th April 2007 the sub rule 4.18 of rule 4, the following has been substituted;

“4.18. The inspection and monitoring of plant and packaging centres shall be carried out at least once in three months by the competent authority, which shall at all times have free access to all parts of the plants, in order to ensure that these rules are being observed. The health checks and supervision of production shall be carried out as per the elements given in Annexure D.”

5. CERTIFICATION:

- (a) On request from the plant, the competent authority shall issue health certificate in the prescribed proforma after satisfying itself that the milk

products are processed in approved processing plants having valid approval number and after satisfying the relevant requirement.

- (b) The Competent Authority shall also issue vague certificates on request from the processor or exporter after satisfying itself that the requirements of the relevant standards are met;

As per S.O. 3719 dated 30th November 2002 the clause (b) of rule 5, the following has been substituted;

“(b) The Competent Authority shall also issue any other certificates on request from the processor or exporter after satisfying itself that the requirements of the relevant standards are met.”

6. FEE:

- (a) A fee of Rs. 5,000 shall be paid by the processor along with the application for approval of the milk processing plant.
- (b) A fee at the rate of 0.2 percent of F.O.B. value shall be paid by the processor or exporter to the Competent Authority:

As per S.O. 1515 dated 16th June 2008 the sub rule (b) of rule 6, the following has been substituted;

(b) A monitoring fee @ 0.20% of free on board (F.O.B.) value shall be paid by the processor or the exporter to the concerned Export Inspection Agency with a maximum of Rs.15 lakhs per annum per exporter or processor.

Note: The amount of monitoring fee for each consignment payable by the exporter shall be rounded off to the nearest rupee and, for this purpose, where such amount contains a part of a rupee consisting of paise, then, if such part is fifty paise or more, it shall be increased to one rupee and if each part is less than fifty paise, it shall be ignored.”

NOTE:

The amount of fee for each consignment payable by the processor/exporter shall be bounded off to the nearest rupee and, for this purpose, where such amount contains a part of a rupee then if such a part is 50 paise or more, it shall be increased to one rupee and, if such part is less than 50 paise, it shall be ignored.

7. Competent Authority shall take actions if the requirement means to be met.

8. APPEAL :

8.1 Any person aggrieved by the

- (i) Decision of the competent authority not according the approval as per rule 4.15.
- (ii) Refusal of competent authority to issue veterinary Health Certificate as per rule 5 of this notification;
- (iii) Decision of the competent authority to denotify processor/exporter as per rule 7 of this notification;

- 8.2 Any person aggrieved by the decision of the competent Authority may prefer an appeal within 10 days of receipt of such decision to an Appellate Authority appointed by the Central Government.
- 8.3 The Appellate Authority shall consist of five members appointed for the purpose by the Central government;
- 8.4 The appeal shall be disposed of within 15 days of its receipt and its decisions shall be final.

As per S.O. 715 dated 25th Feb 2005, in rule 8, for sub-rule 8.4, the following sub-rule shall be substituted, namely: -

“8.4 The appeal shall be disposed of within 30 days of its receipt”

ANNEXURE A

REQUIREMENTS RELATING TO THE ACCEPTANCE OF RAW MILK AT TREATMENT AND/OR PROCESING ESTABLISHMENTS

1. ANIMAL HEALTH REQUIREMENTS FOR RAW MILK

1.1 Raw milk shall originate from-

- (i) animals which are apparently healthy and do not show any visible symptoms of infectious disease likely to be transferable to humans through milk;
- (ii) dairy animals which do not give the milk of abnormal sensory characteristics;

- (iii) dairy animals which do not show any under wound likely to affect the milk quality;
- (iv) animals which have been treated with antibiotics or other veterinary drugs which can be transferred to milk shall not be brought to the collection centre, unless the retention period of drug following such treatment has been inspected

2. HYGIENE OF THE HOLDING

- (1) Holdings from which raw milk is coming shall be maintained in such a way as to ensure-
 - (a) good conditions of housing, hygiene, cleanliness and health of the animals and
 - (b) satisfactory hygiene conditions for milking, handling, storing and cooling (where applicable).
- (2) Premises where milking is performed or milk is stored, handled or cooled must be so said and/or constructed as to avoid all risk of contamination of the milk.

As per S.O. 3719 dated 30th November 2002 the sub item (2) of item 2 of Annexure A, the following has been substituted;

“(2) Premises where milking is performed or milk is stored, handled or cooled must be so made and / or constructed as to avoid all risk of contamination of the milk.”

- (3) All efforts shall be made to ensure proper cleanliness and ventilation in the Animal premises/shed with proper sunlight. There shall be sufficient drainage so as to avoid accumulation of filth.
- (4)(i)The animals shall be held in clean, dry environment,
 - (ii)On a regular basis, the manure and residual food materials shall be heaped away from the animal premises/shed.
- (5) Animal shed shall be free from flies.
- (6) Milking of the animals shall be carried out in a clean and as far as possible dry environment.
- (7) Where milk producing animals are kept untethered in the open, the holding must also have a milking area adequately separated from the housing area.
- (8) The isolation of animals which are infected or suspected of being infected, the separation of animals from the rest of the herd must be possible and effective.
- (9) Animals of all species must be kept away from premises and sites where milk is stored, handled or cooled.

- (10) Production holdings shall be regular checked to ensure that hygiene requirements are being complied with. The frequency of these checks must take account of the assessment of risk on the production holding concerned. If the inspection show that hygiene is inadequate, appropriate steps shall be taken to improve the hygienic conditions.

3. HYGIENE IN MILKING, THE COLLECTION OF RAW MILK AND ITS TRANSPORT FROM PRODUCTION HOLDING TO THE COLLECTION CENTRES OR PROCESSING ESTABLISHMENTS.

(1) Hygiene in Milking-Milking Equipments

- (i) Milking equipment/utensils shall be made of corrosion resistant metals with smooth surfaces and wide mouths which are easy to clean and do not affect the sensory quality of milk.
- (ii) Milking utensil must have a lid of cover.
- (iii) Milking utensils should be thoroughly washed by detergent such as washing soda followed by rinsing with potable water and preferably sun dried.

(2) Storage Condition at Farmer's level

- (i) Milk shall be brought to the milk collection point as soon as possible immediately after milking in closed containers.
- (ii) If the milk is not collected within four hours of milking, it must be cooled to a Temperature of 7°C or lower in the case of two consecutive collections or 4°C or lower in collection is not daily. While the milk is being transported to the treatment and/or processing establishment, its temperature must not exceed 8°C.

(3) Hygienic Milking Practices

(a) Feeding

The feed and fodder for milking animals shall be palatable, nutritious, safe and suitable for feeding and shall not present a risk of transferring residues of fertilizers, toxins. etc.

(b) Vermins

Vermins shall be combined in such a way that it does not result in residue, i.e., pesticides, insecticides, toxins, etc. in milk.

(c) Hygienic Milking

Before milking, the udder as well as surrounding area of the animals shall be properly cleaned with water and dried. Animal shall be groomed properly and hair removed from the body, so that the risk contamination of milk can be avoided. Further, animals should be washed regularly.

Before every milk, a sample of milk from each teat shall be checked for freedom of foul smell and any visible abnormalities like blood, pus, flakes, etc. Such milk shall not be used for human consumption.

(4) Personal Hygiene

- (i) Absolute cleanliness should be required of personnel of specifically Milking should be carried out under good personnel hygiene of the milker, i.e., he/she should not be suffering from diseases, especially cough and cold, should wear clean clothes. Wash hands properly and cut nails periodically before milking.

For this purpose, suitable hand washing facilities are required near the place of milking.

- (ii) Precautions may be taken to ensure that persons liable to contaminate raw milk shall not be allowed to handle it.

(5) Production Hygiene

A suitable mechanism shall be established to prevent water being added to raw milk.

(6) Milk Reception at Collection-cum-Chilling Centre

(a) Premises

Rooms in the milk collection centre must be clean and risks of contamination may be reduced to the minimum by providing satisfactory safeguards. Adequate provision must be made for cleaning and sterilisation of containers and utensils.

The floors of the rooms of the collection centre may be constructed of concrete or other impervious material so that it should be easily cleaned. It shall be suitably inclined to hasten rapid drainage of wash water.

The walls and ceilings of the rooms should have a smooth and non-absorbent surface so that they can be efficiently cleaned. The building should be well lighted and adequately ventilated.

The surroundings of the collection centre should be maintained clean and free from any water logging. Proper method should be employed for pest control.

(b) Milk Collection Equipment

After every shift for milk collection, all milk collection and testing equipment should be thoroughly cleaned with detergent and cleaned water.

Cleaned, Sanitized, Empty cans provided by the dairy should be property, rechecked and if required may be washed with detergent and clean hot water.

(c) Collection of Milk

Before collection each individual farmer's milk should be examined for sensory test. At the time of collection, a strainer, or a cleaned cloth may be used to remove any suspended particle in the milk. The collection time at the centre be fixed as per the lorry/tanker timing of the processing plant.

As far as possible milk cans should be filled completely and the lid firmly placed on the can before using another can. This will increase the shelf life of milk, reduce the fat separation and also the risk of contamination during transportation.

(d) Despatch of Milk and Chilling

Milk should be despatched to dairy plants in such a manner that the interval between milking and the arrival at the processing plant does not exceed four hours, depending upon the local climatic conditions.

In case the distance between the processing plant and collection centre is large, then milk should be chilled to 10° C or below before despatch to the processing plant. Cleanliness of the milk-cooling equipment should be ensured. Further, the bulk coolers should be provided with metal shields for protection from air contamination.

(7) Transportation of Milk from the Farm and Villages to the Collection-cum-Chilling centres and processing plants.

During transportation of milk in cans from the farm and villages to the collection centre, adequate precautions should be taken enroute to ensure that the deterioration in quality of milk is minimised.

Cans should have close fitting lids. The filled cans should be adequately protected from sunshine. Rain or dirt should not be allowed to come in contact with the inner portion of the can. No packing such as jute, newspaper, straw etc. between can lids and the can neck should be used.

Water from dripping vegetation or splashes on the road should not be allowed to come in contact with cans.

No other material should be loaded on the same vehicle which carries milk cans.

When road or rail tankers are used to carry milk, they should be so designed that, as far as possible, agitation is prevented during transport.

All the hygienic practices for preservation of milk should be borne in mind while using the tanker system for transporting milk.

The edge of the manhole in the tanker should be flanged upwards so as to prevent dripping into the tank when lid is lifted. A special cover has to be provided over the lid for protection from dust or dirt from the road. Similarly, a cover should be provided over any valve or hose connector.

Tankers should be so constructed as to be easily cleanable and the design of tankers should conform to best technical and hygienic standards. The cleaning and sanitation of the tankers should be done at the end of operations.

The insulation material should be of such quality that the temperature of milk should not be allowed to rise more than 2^o C during transportation.

Violent agitation or surging in the tank should be minimised to avoid breaking of bacterial clumps or alteration of fat globules or admixture of air.

4. Raw Milk Standards

Raw milk collected for further processing shall conform to the following standards:

- | | | |
|----------------------------------|---|--|
| (a) Heavy Metals | - | The raw milk shall conform to the relevant National/International standards. |
| (b) Pesticides Residues | - | -Do- |
| (c) Aflatoxin | - | -Do- |
| (d) Antibiotic residues | - | -Do- |
| (e) Contaminants and Adulterants | - | -Do- |

ANNEXURE B

1. GENERAL CONDITIONS FOR APPROVAL OF TREATMENT ESTABLISHMENTS AND PROCESSING ESTABLISHMENTS

The processing plant shall meet the following requirements:

(a) Site

The processing plant/dairy shall preferably be situated in open, clean, and healthy surroundings away from roadside where lot of dust arises due to vehicular traffic; garbage dumps; cattle sheds; flies. It shall be free from sources of obnoxious fumes, smoke, odours of excessive dust. There shall not be accumulation of fresh, garbage or similar waste in the vicinity of the plant.

(b) Building

Structures housing the dairy shall be suitable in size, construction and design to facilitate maintenance and hygienic operations for processing purposes. It should provide sufficient space for housing of equipment and storage materials (raw as well as finished products) necessary for hygienic operations. The material of construction shall be of brick, plaster, cement, concrete, tile or any other equivalent materials which ensure cleanliness. Construction of the building shall be such that it shall be rodent proof, fly proof and bird proof. No portion of building shall be used for domestic purposes or other types of food operations unless separated by suitable partitions or locations or other effective means.

(c) Ventilation and Lighting

The processing plant/dairy shall be adequately lighted and ventilated keeping in mind the number of workers, their hours of work and nature of operation. Ventilation and lighting shall also be in accordance with Factory Act, 1948.

(d) Floors; Walls and Ceilings

The floor shall be smooth, washable, properly sloped to gullies connected to sewers or drains. It shall be impervious to water and not affected by weak acids, alkalis or stream. Hard, smooth and impervious flooring, such as cement concrete flooring shall be made for work room, store room and godown. Internal walls and ceilings shall be smooth non-absorbent, light-coloured surface, free from crevices and sharp angles, to facilitate their efficient cleaning. The junction of the floor with the walls and junction between the two walls shall be rounded to prevent accumulation of dust. The dairy floors, walls and ceilings shall be regularly cleaned.

(e) Repairs

The building shall be maintained in a proper state of repair and cleanliness at all times. Whenever required, it may be lime washed, painted, disinfected, and deodorised.

(f) Processing Room

The room shall be made fly proof and rodent-proof. The floor shall be impervious to water and shall have a sufficient slope to ensure drainage. Drains in processing rooms shall be cemented and covered with detachable covers. Drains shall be kept clean and shall be provided with traps at suitable places before they are connected with the municipal drain to avoid blocking or choking, or in the absence of any such arrangement, they shall be drained in soakage pits situated at a suitable distance from the dairy and also the source of water supply. Adequate facilities for washing the room shall be provided. Adequate number of wash basins and sinks shall be provided. Proper ventilation shall be maintained to prevent condensation and drippage. Exhaust fans shall be provided where necessary.

The processing rooms shall be provided with effective means to prevent the entry of flies and insects. Such effective means may be screens, fans, air curtains etc. The processing rooms should be provided with self-closing double doors. The doors and window should be covered with fly proof wire gauge, and they should be open outwards.

Effective drainage shall be provided to drain off a large quantity of water shed for washing the machinery, equipment, furniture, floor etc.; 15 to 30 cm half circular drains with glazed pipe at the bottom should be provided.

The slope of the floor should be towards the drains and the farthest end of the floor from the drain should not be more than 5 meters. The drain openings should be provided with screen taps to prevent solid matter from clogging the drains. The ends of the drains leading to the outside of the factory should be made rodent proof by providing screens. The screens shall be examined periodically and replaced or cleaned, if necessary. The

drains should have water seals of minimum 5 cm. At least 50 percent of the length of the drain should be covered to facilitate the movement of trolleys. Mesh type for the drain should be better to prevent habitation of cockroaches and rodents in closed area of the drain.

Instruments and working equipment intended to come into direct contact with raw materials and products shall be made of corrosion-resistant material and easy to clean and disinfect.

The processing plant shall have

- an appropriate number of changing rooms with smooth, water proof, washable walls and floors, wash basins and flush lavatories. The latter must not open directly on to the work rooms. Wash basins must be equipped for hand-washing and have hygienic means of drying hands; wash-basin taps must not be hand operable;
- a room or a cupboard secure place for the storage of detergents, disinfectants and similar substances;
- a room or cupboard storing, cleaning and maintenance material;
- adequate facilities for cleaning and disinfecting tanks used for transporting milk and liquid or powdered milk-based products. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected in installations officially approved by the competent authority.

2. GENERAL CONDITIONS OF HYGIENE IN TREATMENT ESTABLISHMENTS AND PROCESSING ESTABLISHMENTS

(a) General Dairy Hygiene

Waste and refuse shall be collected in covered receptacles and shall not be allowed to scatter on the floor of the unit. It should be disposed of in a manner which is not detrimental to the hygiene of the surroundings of the disposal.

Adequate measures shall be taken to prevent mould growth on equipment and internal structures of processing and storage rooms. Adequate steps shall be taken to prevent infestation of cockroaches and other household pests.

When pesticides are used, due care shall be exercised to prevent contamination of equipment, raw materials and packing materials. Under no circumstances shall these be used during processing.

Floors and drains shall be kept clean. On no account shall the process room be used or converted to a store room for raw materials or used as eating room. Only the items required for processing on a particular day shall be kept in the process room. No lavatory, sink, cesspool or garbage shall be so situated or maintained that odours or fumes there from pervade any room where the milk is stored or processed. Proper places shall be provided for storage of brooms, brushes, buckets and other cleaning gear.

The dairy effluents duly treated so as to conform to local statutory norms shall be disposed in a manner which is not detrimental to the hygiene of the dairy and its surroundings. The effluents shall not be let off on road or in the open outside the dairy premises. Window glass and light fittings shall be maintained clean and dust-free all times.

There shall be no cobwebs in any part of the dairy Birds and domestic animals shall not be allowed in any part of the dairy.

All pumping and waste disposal lines should be large enough to carry peak loads. All lines should be watertight and the waste disposal should be affected in such a manner as not to cause contamination with potable water-supplies.

Premises should be well lit and ventilated. Special attention should be given to equipment producing excessive heat, steam, obnoxious fumes or vapours. Good ventilation should be provided and mould growth in overhead structures should be prevented. Light bulbs and fixtures suspended above should be of safety type.

(b) Plant and Equipment Hygiene

Material for equipment-All surfaces coming into contact with the milk shall be smooth, free from pits, crevices and loose scale and shall be non-absorbent. Furthermore, the surface shall be non-toxic and unaffected by milk and cleaning compounds. The finish of corrosion-resistance (stainless steel, etc.) surface shall be smooth.

All gasketing materials shall be food grade quality and non-porous, non-absorbent, and fitted in a manner such as to prevent its protruding into the milk or creating recesses or ledges between the gasketed joints which will interfere with proper cleaning.

(c) Installation of Equipment

All equipment shall be installed on a foundation of durable, easily cleanable material. Equipment shall be placed at least 45 cm from wall and ceiling, or sealed watertight thereto. All positions of the equipment shall be installed sufficiently spaced above the floor on a minimum number of supporting members to provide access for inspection and cleaning, or be installed completely sealed (water tight) to the floor. Whenever equipment passes through wall or floors, it shall be sealed thereto or sufficient clearance shall be allowed to permit inspection, cleaning and maintenance.

Where necessary, drains and catch pans shall be provided. These shall be of such dimensions as to collect all spill and drip, and readily accessible or readily removable for cleaning. Where pipes pass through ceilings into the floor of the processing area above, pipe sleeves shall be inserted in the floor above so that their upper periphery is at least 5 cm above the floor.

All electrical connections, such as switch boxes, control boxes, conduit and cables, shall be installed at least 45 cm away from the equipment walls to facilitate cleaning, or be completely sealed to the equipment or wall.

All equipment coming into contact with milk shall be kept clean. An ample supply of steam and water, hose, brushes, detergents and other equipment necessary for the proper cleaning of machinery and equipment shall be available. All equipment should be cleaned and sanitized. All parts of equipments coming into contact with milk shall be sterilized by steam or any other suitable sterilizing agent after each processing run. The entire processing system shall be cleaned at the close of operation and flushed out with potable water prior to use. Contaminating stores and spare parts of machinery shall be kept separate from the processing areas.

Bottles, pails, cans and other containers used to transport or store milk shall be kept clean and not used for any other purpose.

It shall be ensured that containers for milk are kept clean. The containers shall not be stacked in a manner which allows the contamination of the product.

(d) Water supply-

There shall be an adequate supply of safe and potable water. Running water under pressure shall be easily accessible to all rooms and areas in which milk is handled and equipment were washed. The equipment shall be so installed and used that back siphonage of liquid into the potable water lines is precluded.

Hot and cold water in ample supply shall be provided for plant clean-up needs where necessary. The storage tanks for water should unless completely sealed, be kept covered with tight fitting lids, examined regularly and cleaned out at least once every six months. The date of the last cleaning and next cleaning shall be prominently displayed on the storage tanks. The water shall be periodically examined as desired by the licensing authority chemically and bacteriologically. A rerecord of such examination shall be maintained.

EMPLOYEE HYGIENE

Every person employed in connection with production, handling, processing and distribution of milk shall be medically examined by an authorized registered medical practitioner and the examination shall include X-Ray of the chest for tuberculosis. The examination shall also include, examination of stool for protozoal and helminthic infestation for those parasites which are transmitted by ingestion and for the presence of Salmonella, Shigella species and Vibrio cholerae; urine and blood examination for venereal diseases. Subsequently, the employee shall be medically examined once in a year or more frequently; if necessary to ensure that he/she is medically fit and free from communicable diseases. A record of such examination shall be maintained.

It shall be impressed on all employees that they should notify to the medical officer or management, cases of fever, vomiting, diarrhea, typhoid, dypentery, boils, cuts and ulcers (however small), discharging ears and notifiable diseases occurring in their own homes and families.

No worker who is suspected to be suffering from any of the disorders listed above shall be permitted to work inside the dairy. The supervisor shall check the personal hygiene of the workers before the start of work and whenever they enter any processing room after any absence.

Employees shall keep their finger nails short and clean and wash their hands with soap or detergent and water before commencing work and after each absence, specially after using sanitary conveniences. Towels used for drying hands should be clean. No worker shall allow his hands or any part of his body or clothing to come in contact with the milk. He should adopt strict hygienic practices so as to avoid adding any microbial contamination to the milk.

All employees shall be inoculated and vaccinated against the enteric groups of diseases once a year and against small pox once in two years. In case of an epidemic all workers shall be inoculated. A record shall be maintained. No worker shall be allowed to work without proper clothing and foot wear.

Employees shall be provided with clean uniforms (preferably white) or aprons or both and clean washable caps, wherever necessary. Separate room or place for changing the clothes shall be provided. The clothes shall not be hung in any processing room. The uniforms shall not be worn outside the dairy but put on just before starting the work and changed when leaving.

Eating, spitting, nose cleaning or the use of tobacco in any form including smoking or chewing betel leaves shall be prohibited within the processing, packing and storage area of the dairy. Notice to this effect shall be prominently displayed and enforced.

Sufficient and suitable sanitary conveniences shall be provided, maintained and kept clean. The conveniences shall be properly lighted. Separated conveniences shall be provided for each sex. No conveniences shall open directly into any work room in the dairy. The conveniences shall always be maintained clean and in good repairs.

Sufficient number of wash basins with adequate provision of nail brushes, soap and towels, latrines and urinals in the prescribed manner should be provided, conveniently situated and accessible to workers at all times while they are the dairy. The wash basins shall be installed in or alongside the sanitary conveniences.

The importance of hygienic and aesthetic standards should be indicated to the personnel, since carelessness at any stage will endanger the health of the consumers.

3. Special Requirements for registration of collection securities-In addition to the general requirements laid down at item 1 above, the collection centres must have at least:-

- (i) cooling facilities if milk is stored at the collection centre.
- (ii) Testing facilities to check fat and SNF content. These should include milk testing equipment.
- (iii) Milk collection equipment which should be properly sanitized.

4. Special requirements for the approval of Treatment Establishments and Processing Establishments-In addition to the general requirements laid down in 1 above, treatment establishments and processing establishment must have at least:

- (i) equipment for the cooling and cold storage of heat treated milk, liquid milk-based products. Cold Stores must be equipped with correctly calibrated temperature measuring apparatus;

- (ii) -in the case of wrapping in disposable containers, an area for the storage of such containers and for storage of the raw materials intended for their manufacture:
 - in the case of wrapping in re-usable containers, a special area for their storage and equipment designed to clean and disinfect them mechanically;
- (iii) containers for storing raw milk, standardization equipment and containers for storing standardized milk;
- (iv) if appropriate, centrifuges or any other suitable means for removal of extraneous matters from milk;
- (v) heat-treatment equipment fitted with :
 - an automatic temperature control,
 - A recording thermometer
 - An automatic safety device preventing insufficient heating, or cooling medium, and
 - An adequate safety system preventing the mixture of pasteurized or sterilized milk with incompletely heated milk, and
 - A recording device for the safety system referred to in the preceding indent;
- (vi) equipment for the cooling, packing and storage of frozen milk products if such operations are carried out there;
- (vii) equipment for drying and packing powdered milk products if such operation are carried out there.

5. Hygiene requirements relating to the premises equipment and staff of Treatment Establishments and Processing Establishments- In addition to the general requirements laid down above establishments must comply with the following conditions:

- (i) Cross-contamination between operations by equipment, ventilation or staff must be avoided. If appropriate, and in the light of the assessment of risk, rooms intended for production processes shall be divided into wet and dry areas, each having its own operating conditions.
- (ii) As soon as possible after each journey, or after each series of journeys where there is only a very short space of time between unloading and the following loading, but in any event at least once each working day, containers and tanks used for transporting raw milk to the milk collection or standardization centre or to the milk treatment or processing establishment must be cleaned and disinfected before reuse.
- (iii) Equipment, containers and installation which come into contact with milk or milk-based products or other perishable raw materials during production must be cleaned and disinfected at the end of each work phase and at least once each working day.

- (iv) The treatment premises should, if necessary, be cleaned at least once each working day.
- (v) For the cleaning of other equipment, containers and installations which come into contact with microbiologically stable milk-based products and with rooms in which such substances are placed, the operator or manager of the establishment shall draw up a cleaning programme based on the assessment of risk. The programme must meet the requirement referred to in item 1 and must also ensure that the product does not become unsafe and a health risk to the consumer as a result of inadequate cleaning methods.

ANNEXURE C

1. REQUIREMENTS FOR MILK FOR THE MANUFACTURE OF MILK PRODUCTS

- (i) The operator or manager of the processing establishment must take all necessary steps to ensure that the raw milk is treated (within 36 hours of acceptance), if the milk is kept at a temperature not exceeding 6⁰ C, or within 48 hours of acceptance if the milk is kept at a temperature of 4⁰ C or lower.
- (ii) Heat-treated milk intended for the manufacture of milk products must be obtained from raw milk, which complies with the standards, laid down in Annex A.
- (iii) Heat-treated milk must meet the following requirements
 - (a) pasteurized ,milk must comply with Clause 2(a) of this Annex.
 - (b) UHT milk must have been obtained by the treatment as defined under the item on definition and shall comply with the requirements given therein.

2. MILK PROCESSING

Prior to processing raw milk shall be filtered or clarified to remove visible dirt and any other foreign material in it. The milk may be homogenized before pasteurization at appropriate pressure.

After completion of the day's run, the part of the homogenizer shall be dismantled and thoroughly washed with detergent solution followed by rinsing with hot water. Before using fresh batch of milk, the homogenizer shall be sterilized by pumping through it hot water or chlorine solution. The piston packing and leather gaskets of the homogenizer when worn out, shall be replaced as early as possible.

(a) Pasteurisation:

The milk shall be heated to at least 66⁰ C and held at 66 C continuously for at least 30 minutes, or it shall be heated to at least 74 C and held at 74 C continuously for at least 15 seconds in a standard and properly operated equipment. Other temperature and time combinations that enable the pasteurized milk to meet the hygienic requirements may also be adopted after approval by competent authority. To ensure that the bacteria present in the foam are killed, space heaters should be provided. The clear positioning and accuracy of the indicating and recording thermometers shall be checked regularly. The long stem indicating thermometer shall be accurate within +0.5 C. The recording thermometer shall be accurate

within 1 C between 63 and 64 C for holder pasteurization and within 1 C and between 71 and 72 C for high temperature short time (HTST) pasteurization.

After holding the milk, it should be cooled immediately in the standard and properly operated equipment to a temperature not exceeding 5 C. The pasteurized milk should be maintained at a temperature not exceeding 7 C until it leaves the milk plant for distribution.

All parts of the pasteurizer should be kept in a hygienic condition. Appropriate type of detergent sanitizers which do not adversely affect the quality of milk should be used for effective cleanliness and sterility of the pasteurization plant. The rubber gaskets of the pasteurizer need special attention in regard to cleaning operations because of the deposition of milk residues. All possible precautions shall be taken to avoid recontamination of raw milk after pasteurization through improperly designed or leaky equipment pumps, dirty bottles and bottling equipment, contaminated water, dust flies and from dirty habits of dairy plant personnel.

Pasteurized milk shall be filled in suitable package of standard quality. The package shall be so shaped as to permit effective cleaning operation. The package should not have inaccessible corners where milk deposits or scales are likely to accumulate or difficult to clean. The returned empty package shall be appropriately cleaned and sanitised using suitable detergent and sanitizer.

(b) Laboratory Control

The control dairy laboratory plays a vital role in checking the efficiency of milk processing. A well-equipped laboratory with competent quality control staff is essential for an efficient operation of milk processing plant. Depending upon the quantity of milk handled by each dairy, appropriate layout plant may be formulated.

(c) Milk Products

All the milk products manufactured in the processing plants should conform to the hygienic requirements outlines above. Wherever applicable the milk products should also conform to the national/international standards.

3. MICROBIOLOGICAL CRITERIA FOR MILK PRODUCTS

A. Microbiological criteria for certain milk-based products on removal from the processing establishments.

(i) Compulsory criteria: Pathogenic micro-organisms

Type of Micro-organism	Products	Standard (ml, g)
-Listeria mono-cytogenes	Cheese, other than hard	Absent in 25 g
	Cheese	Absent in 1 g
	Other products	
-Salmonella spp	All milk products except	Absent in 25 g
	Milk Powder	
	Milk Powder	Absent in 25 g
-Shigella	All milk products	Absent in 25 g

In addition, pathogenic micro-organisms and their toxins must not be present in quantities such as to affect the health of consumers

If these standards are exceeded, the foodstuffs must be excluded from human consumption and withdrawn from the market.

Sampling programmes will be drawn up in the light of the nature of the products and the assessment of risk.

(ii) Analytical criteria: organisms indicating poor hygiene

Type of Micro-organism	Products	Standard (ml, g)
-Staphylococcus aureus	Soft cheese (made from heat-treated milk)	m = 100 M = 1 000 n = 5 c = 2
	Fresh cheese	m = 10 M = 100
	Frozen milk products (in- cluding ice- cream)	n = 5 c = 2
	Milk Powder	Absent in 0.1/g
	Other Dairy Products	Less than 100/g
-Escherichia coli	Soft Cheese and other dairy products	m = 100 M = 1000 n = 5 c = 2
	Milk powder	Absent in 0.1 g

In all cases where these standards are exceeded there must be a review of the implementation of the methods for monitoring and checking critical points applied in the processing establishment. The competent authority shall be informed of the corrective procedures included in the production monitoring system to prevent any repetition of the occurrence.

If strains of enterotoxinogenic Staphylococcus aureus or strains of Escherichia coli that are presumed to be pathogenic are identified, all the batches involved shall be withdrawn from the market. In this case the competent authority shall be informed of the findings and of the action taken to withdraw the suspect batches and the corrective procedures introduced into the production monitoring system.

(iii) Indicator organisms guidelines

Type of Micro-organism	Products	Standard (ml, g)
-Coliforms	Liquid Milk Products	m = 0 M = 5

		n = 5
		c = 2
	Butter made from Pasteurized milk or Cream	m = 0 M = 10
		n = 5
		c = 2
	Frozen milk products (including ice-cream)	m = 0 M = 10
		n = 5
		c = 2
	Milk powders	Absent in 0.1 g
	Other Dairy Products	Less than 200/g
Plate Count	Pasteurised Milk	Less than 30,000/ml
	Ice cream	Less than 2,50,000/ml
	Milk Powders	Less than 40,000/g

These guidelines should help producers in ensuring proper operation of their establishments and in implementing the system and the procedure for carrying out their own check on their production.

Where ;

n = number of sample units comprising the sample;

m= threshold value for the number of bacteria; the result is considered satisfactory if the number of bacterial in all sample units does not exceed 'm';

M= Maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is 'M' or more;

c = number of sample units where the bacteria count may be between 'm' and 'M' the same being considered acceptable if the bacterial count of the other sample units is 'm' or less.

4. WRAPPING AND PACKAGING

- (i) Wrapping and packaging must take place under satisfactory hygiene conditions in rooms provided for that purpose.
- (ii) Bottling, filling of containers with liquid milk products and sealing of containers and of packaging must be carries out automatically.
- (iii) Wrapping or packaging may not be reused for the products with the exception of certain types of containers which may be reused after thorough cleaning and disinfecting.

Sealing must be carried out in the treatment establishment in which the heat treatment has been carried out immediately after filling, by means of sealing devices which ensure that the milk is protected from any adverse effects of external origin on its characteristics. The sealing system must be so designed that once the container has been opened, the evidence that it has been opened remains clear and easy to check.

- (iv) The operator and manager of the establishment must ensure for control purposes, the following information is visibly and legibly displayed on the packaging of the milk products.

Milk Products made from pasteurized milk, the temperature at which the products must be stored.

- (v) Product manufacture and packaging operations may take place in the same room, notwithstanding point 1, subject to the following conditions:
 - (a) The room must be sufficiently large and so equipped that the hygiene of the operation is assured;
 - (b) The packaging material must have been brought to the treatment or processing establishment in a protective cover in which they were placed immediately after manufacture and which protects them from any damage during transport to the establishment and must have been stored there under hygiene conditions in a room intended for that purpose.
 - (c) The rooms for storing the packaging material must be free from dust and vermin and separated from rooms containing substances which might contaminate the products. Packaging material must not be placed directly on the floor;
 - (d) packaging material must be assembled under hygienic conditions before being brought into the room. A derogation from this requirement may be granted in the case of the automatic assembly of packaging, provided there is no risk of contamination of the products;
 - (e) packaging material must be brought into the room under hygienic conditions and used without delay. It may not be handled by staff handling unwrapped products;
 - (f) immediately after packaging, the products must be placed in the storage rooms provided for the purpose.

5. CONDITIONS GOVERNING HEALTH MARKING AND LABELLING

A. Conditions governing health marking

- (i) In case the importing country requires health certificate or health mark on the label, the same may be provided. Health marking must be carried out during or immediately after manufacture in the establishment, in an easily visible place. The mark shall be legible, indelible and its characters easily distinguishable. The health mark may be applied to the product or to the wrapping, if the product is individually wrapped or to a label affixed to this wrapping. However, where a product is individually wrapped and packaged, it will suffice for the health mark to be applied to the packaging.

- (ii) Where products marked in accordance with point 1 are subsequently placed in a packaging, the health mark must also be applied to the packaging.
- (iii) (a) The health mark shall give the following particulars;
 - the name of the consigning country in capitals,
 - the approval number of the establishment
- (b) the health mark may be applied to the product, wrapping or packaging by an ink stamp or by branding, or it may be printed on or applied to a label. In the case of products in hermetically-sealed containers, the mark must be indelibly applied either to the lid or to the container;
- (c) the health mark may also consist of an irremovable plate of resistant material complying with all the hygiene requirements and bearing the information specified in (a).

B. Conditions governing labelling

The labelling for milk products must clearly show for inspection purposes:

1. the nature of any neat treatment applied at the end of the manufacturing process;
2. for milk products in which growth of micro-organisms can occur, the use by or minimum durability date along with storage condition.

6. STORAGE AND TRANSPORT REQUIREMENTS

- (i) Products which cannot be stored at ambient temperature must be stored at the temperature established by the manufacturer to ensure their durability. In particular, the maximum temperature at which pasteurized milk may be kept until it leaves the establishment and during transport must be 6° C. When stored under cooled conditions the storage temperatures must be registered and the cooling rate must be such that the product reaches the required temperature as quickly as possible.
- (ii) Tanks, cans and other containers which are used for the transport of pasteurized milk must comply with all the rules of hygiene and in particular the following:
 - their inside surfaces and any other part which may come into contact with the milk must be made of SS 304 smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the milk in such quantities as to endanger human health, impair the composition of the milk or adversely affect its sensory characteristics;
 - they must be designed so that the milk can drain away completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect;
 - they must be washed, cleaned and disinfected immediately after each use and as necessary before further use;

- they must be hermetically sealed before and during transport by means of a watertight sealing device.
- (iii) Vehicles and containers used for transporting pasteurized milk must be designed and equipped in such a way that the required temperature can be maintained throughout the period of transport.
- (iv) Vehicles used for transporting heat-treated drinking milk and milk in small containers or in churns must be in good conditions. They may not be used to transport any other product or object likely to cause the milk to deteriorate. Their internal surfaces must be smooth and easy to wash, clean and disinfect. The interiors of vehicles intended for transporting milk must comply with all the rules of hygiene. Vehicles intended for the transport of heat-treated milk in small containers or churns must be so designed as to give the containers or churns adequate protection against all contamination and atmospheric influences and may not be used to transport animals.
- (v) To that end, the competent authority must regularly check that the means of transport and loading conditions meet the hygienic requirements.
- (vi) The products covered by this order must be dispatched in such a way that they are protected from anything liable to contaminate them or to cause them to deteriorate, having regard to the duration and conditions of transport and the means of transport employed.

ANNEXURE-D

1. HEALTH CHECKS AND SUPERVISION OF PRODUCTION

- (i) Establishments shall be subject to supervision by the competent authority, which must ensure that the requirements of this Order are met and in particular;
 - (a) check
 - (i) the cleanliness of the premises and equipment and staff hygiene;
 - (ii) the efficacy of the checks carried out by the establishment, notably by examining the results and taking samples;
 - (iii) the microbiological and hygiene conditions of the milk-based products;
 - (iv) the efficiency of the treatment of the milk-based products;
 - (v) the hermetically sealed containers by means of random sampling;
 - (vi) the appropriate health marking of the milk-based products whenever applicable;
 - (vii) storage and transport conditions;
 - (b) take any samples required for laboratory tests;

- (c) make any other checks it considers necessary to ensure compliance with this Order.
- (ii) The Competent Authority must have free access at all time to the cold stores and all working premises to check that these provisions are being strictly complied with.

[F.No. 6/1/2000-EIQEP]
P.K. DAS, Director

The Principal rules were published in the Gazette of India vide Notification No. S.O. 2720 dated 28th November 2000 and subsequently amended vide Notification No.S.O.3719 dated 30th November 2002 and S.O. 999 (E) dated the 13th September 2004, S.O. 715 dated 25th February 2005, S.O. 1397 dated 24th April 2007 and S.O. 1515 dated 16th June 2008