

**RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR
DRIED MILK**

CAC/RCP 31-1983¹

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¹ Amended by the 18th Session of the Codex Alimentarius Commission in 1989.

RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR DRIED MILK

SECTION I - SCOPE

This Code of Practice applies to dried milk products as defined. It recommends general hygiene and technological practices for use in the handling (including the production, preparation, processing, packaging, storage, transport and distribution) of dried milk products for human consumption to ensure safe, sound and wholesome dried milk products.

SECTION II - DEFINITIONS

For the purposes of this Code the following expressions have the meaning stated:

- 2.1 "*adequate*": sufficient to accomplish the intended purpose of this Code;
- 2.2 "*cleaning*": the removal of food residues, soil, dirt, grease or other objectionable matter;
- 2.3 "*contamination*": the occurrence of any objectionable matter in the product;
- 2.4 "*disinfection*" the reduction, without adversely affecting the food by means of hygienically satisfactory chemical agents and/or physical methods, of the number of micro-organisms to a level that will not lead to harmful contamination of food;
- 2.5 "*dried milk*": roller dried or spray dried milk products or composite milk products as defined in Articles 2 and 3 respectively of the Code of Principles concerning Milk and Milk Products, Seventh Edition (CAC/MI-1973)² as follows:

"Article 2 MILK PRODUCTS

- 2.1 The terms used to designate milk products shall only be employed for those products which are exclusively derived from milk as defined in Article 1.
- 2.2 Notwithstanding Article 2.1, the terms used for each milk product may be employed when substances necessary for the manufacturing process are added, provided that these substances are not intended to take the place in part or in whole of any milk constituent.

² In the Codex General Standard for the Use of Dairy Terms (CODEX STAN 206-1999):

"2.2 Milk product is a product obtained by any processing of milk, which may contain food additives, and other ingredients functionally necessary for the processing.

2.3 Composite milk product is a product of which the milk, milk products or milk constituents are an essential part in terms of quantity in the final product, as consumed provided that the constituents not derived from milk are not intended to take the place in part or in whole of any milk constituent.";

"4.3 Use of the Names of Milk Products in Codex Commodity Standards

4.3.1 Only a product complying with the provisions in a Codex standard for a milk product may be named as specified in the Codex standard for the product concerned.

4.3.2 Notwithstanding the provisions of Section 4.3.1 of this Standard and Section 4.1.2 of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985, Rev. 1-1991), a milk product may be named as specified in the Codex standard for the relevant milk product when manufactured from milk, the fat and/or protein content of which has been adjusted, provided that the compositional criteria in the relevant standard are met.

4.3.3. Products that are modified through the addition and/or withdrawal of milk constituents may be named with the name of the relevant milk product in association with a clear description of the modification to which the milk product has been subjected provided that the essential product characteristics are maintained and that the limits of such compositional modifications shall be detailed in the standards concerned as appropriate.";

and

"4.5 Use of Terms for Composite Milk Products

A product complying with the description in Section 2.3 may be named with the term "milk" or the name specified for a milk product as appropriate, provided that a clear description of the other characterizing ingredient(s) (such as flavouring foods, spices, herbs and flavours) is given in close proximity to the name."

2.3 The terms used to designate milk products may also be used in association with a word or words to designate the type, grade, origin and/or intended use of such milk products or to describe physical treatment or the modification in composition to which they have been subjected in accordance with Articles 1.3 and 2.2."

"Article 3 COMPOSITE PRODUCTS

3. The term "milk" and the terms used for milk products may also be employed together with a word or words to designate composite products of which no part takes or is intended to take the place of any milk constituent and of which milk or a milk product as referred to in Articles 1 and 2 is an essential part either by quantity or for characterization. If such composite products are designated in terms which are suggestive of milk or milk products or the dairy industry, the label shall indicate the milk or milk product used as well as the other essential constituents.";

2.6 "*establishment*" any building(s) or area(s) in which dried milk products are prepared, processed, handled, packed or stored and the surroundings under the control of the same management;

2.7 "*food handling*": any operation in the production, preparation, processing, packaging, storage, transport and distribution and sale of food;

2.8 "*liquid milk products*": except for milk, the raw materials from which milk products are prepared, including intermediate evaporated or concentrated products used in the process of preparing dried milk products;

2.9 "*pasteurization*": a heat treatment process applied to a product with the aim of avoiding public health hazards arising from pathogenic microorganisms associated with milk. Pasteurization as a heat treatment process is intended to result in only minimal chemical, physical and organoleptic changes.

NOTE: Pasteurization is intended to avoid public health hazards in the sense that, although it may not destroy all the pathogenic microorganisms which may be present, it reduces the number of harmful microorganisms to a level at which they do not constitute a significant health hazard. Pasteurization also extends the keeping quality of some products by reducing the number of spoilage microorganisms in the product.

Minimum Temperature/Time Combinations for Pasteurization

Pasteurized milk and skimmed milk	63°C for 30 min 72°C for 15 s
Pasteurized cream (18% fat) (35% fat or more)	75°C for 15 s 80°C for 15 s
Pasteurized concentrated milk	80°C for 25 s

NOTE: The temperature/time combinations given are typical examples of many combinations of temperature and time having an equivalent and minimum bactericidal effect necessary for pasteurization. The combinations depend on such factors as the nature of the product, solid content, viscosity, etc. Temperature/time tables may be found in the following references: Enright, J.B., W.W. Sadler and R.C. Thomas: Thermal inactivation of *Coxiella burnetti* in Milk Pasteurization. Pub. Hlth Monograph No. 47. Pub. Hlth Service Pub. No. 517, US Supt Doc., Washington, DC, 1957; Enright, J.B.: The Pasteurization of Cream, Chocolate Milk and Ice Cream Mixes containing the Organism of Q Fever. Journal of Milk and Food Technology Vol. 24, No. 11, Nov. 1961.2.10

2.10 "*pests*": any animals capable of directly or indirectly contaminating food.

SECTION III - HYGIENE REQUIREMENTS IN THE MILK PRODUCTION AREA

Hygienic considerations in regard to milk production are not covered in this Code

For Raw Material Requirements, see Section VII of this Code

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

4.1 LOCATION

Establishment should be located, in areas which are free from objectionable odours, smoke, dust or other contaminants and are not subject to flooding.

4.2 ROADWAYS AND YARDS

Roadways and yards serving the establishment and which are within its boundaries or in its immediate vicinity should have a hard paved surface suitable for wheeled traffic. There should be adequate drainage and provision should be made to allow for cleaning.

4.3 BUILDINGS AND FACILITIES

4.3.1 Buildings and facilities should be of sound construction and maintained in good repair.

4.3.2 Adequate working space should be provided to allow for satisfactory performance of all operations.

4.3.3 The design should be such as to permit easy and adequate cleaning and to facilitate proper supervision of food hygiene.

4.3.4 The buildings and facilities should be designed to prevent the entrance and harbouring of pests and the entry of environmental contaminants such as smoke, dust, etc.

4.3.5 Buildings and facilities should be designed to provide separation, by partition, location or other effective means, between those operations which may cause cross-contamination.

4.3.6 Buildings and facilities should be designed to secure hygienic operations by means of a regulated flow in the process from the arrival of the raw material at the premises to the finished product, and should provide for appropriate temperature conditions for the process and the product.

4.3.7 In food handling areas:

- *Floors*, where appropriate, should be of waterproof, non-absorbent, washable, non-slip and non-toxic materials, without crevices, and should be easy to clean and disinfect. Where appropriate, floors should slope sufficiently for liquids to drain to trapped outlets
- *Walls*, where appropriate, should be of waterproof, non-absorbent, washable and non-toxic materials and should be light coloured. Up to a height appropriate for the operation they should be smooth and without crevices, and should be easy to clean and disinfect.
- *Ceilings* should be so designed, constructed and finished as to prevent the accumulation of dirt and minimize condensation, mould development and flaking, and should be easy to clean.
- *Windows* and other openings should be so constructed as to avoid accumulation of dirt and those which open should be fitted with screens. Screens should be easily movable for cleaning and kept in good repair. Internal window sills, if present, should be sloped to prevent use as shelves.
- *Doors* should have smooth, non-absorbent surfaces, and, where appropriate, be self-closing and closefitting.
- *Stairs*, lift cages and auxiliary structures such as platforms, ladders, chutes should be so situated and constructed as not to cause contamination to food. Chutes should be constructed with inspection and cleaning hatches.

4.3.8 In food handling areas all overhead structures and fittings should be installed in such a manner as to avoid contamination directly or indirectly of food and raw materials by condensation and drip, and should not hamper cleaning operations. They should be insulated where appropriate and be so designed and finished as to prevent the accumulation of dirt and to minimize condensation, mould development and flaking. They should be easy to clean.

4.3.9 Living quarters, toilets and areas where animals are kept, should be completely separated from and should not open directly on to food handling areas.

4.3.10 Where appropriate, establishments should be so designed that access can be controlled.

4.3.11 The use of material which cannot be adequately cleaned and disinfected, such as wood, should be avoided, unless its use would clearly not be a source of contamination.

4.4 HYGIENIC FACILITIES

4.4.1 Water supply

4.4.1.1 An ample supply of water in compliance with Sub-Section 7.3 of this Code under adequate pressure and of suitable temperature should be available with adequate facilities for its storage where necessary and distribution, and with adequate protection against contamination. The standards of potability should not be less than those contained in the latest edition of "International Standards of Drinking Water" (WHO).

4.4.1.2 *Non-potable water* should be carried in completely separate lines, identifiable preferably by colour, and with no cross-connect ion with or backsiphonage into the system carrying potable water (see also Sub-Section 7.3.2). It should not be possible to connect lines carrying non-potablewater to any equipment or cleaning/disinfection apparatus used in handling food. The facilities for non-potable water should be approved by the official agency having jurisdiction.

4.4.2 Steam

4.4.2.1 An adequate supply of steam, or other heating medium, should be provided to ensure satisfactory operation of all heat treatment, evaporating and drying equipment during the production of dried milk products, and also provide the necessary heat for cleaning, disinfection and other operations.

4.4.2.2 Steam used in direct contact with food or food contact surfaces should contain no substances including volatile boiler water compounds which may be hazardous to health or may contaminate the food.

4.4.3 Refrigeration

Sufficient refrigeration capacity should be available to chill and maintain raw and pasteurizedmilk and liquid milk products at a temperature sufficiently low to ensure no adverse effect onthe hygienic quality of the product (see Sub-Section 7.4.3).

4.4.4 Air

An adequate supply of air should be provided for the drying, conveying, cooling or air-sweeping of the product. Where necessary, precautions should be taken to remove oil, moisture, dirt, micro-organisms, insects, odours and all other objectionable matter, from such air. Compressed air which comes into contact with milk products or product contact surfaces should also conform to these requirements.

4.4.5 Effluent and waste disposal

Establishments should have an efficient effluent and waste disposal system which should at all times be maintained in good order and repair. All effluent lines (including sewer systems) should be large enough to carry peak loads and should be so constructed as to avoid contamination of potable water supplies.

4.4.6 Changing facilities and toilets

Adequate, suitable and conveniently located changing facilities and toilets should be provided inall establishments. Toilets should be so designed as to ensure hygienic removal of waste matter. These areas should be well lit, ventilated and where appropriate heated and should not open directly on to food handling areas. Hand washing facilities with warm or hot and cold water, a suitable hand cleaning preparation, and with suitable hygienic means of drying hands should be provided adjacent to toilets, and in such a position that the employee must pass them when returning to the processing area. Where hot and cold water are available, mixing taps should be provided. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided near to each washing facility. Taps of a non-hand operable type are desirable. Notices should be posted directing personnel to wash hands after using the toilet.

4.4.7 Hand washing facilities in processing areas

Adequate and conveniently located facilities for hand washing and drying should be provided wherever the process demands. Where appropriate, facilities for hand disinfection should also be provided. Warm or hot and cold water and a suitable hand cleaning preparation should be provided. Where hot and cold water are

available, mixing taps should be provided. There should be suitable hygienic means of drying hands. Where paper towels are used, a sufficient number of dispensers and receptacles should be provided adjacent to each washing facility. Taps of non-hand operable type are desirable. The facilities should be furnished with properly trapped waste pipes leading to drains.

4.4.8 Disinfection facilities

Where appropriate, adequate facilities for cleaning and disinfection of working implements and equipment should be provided. These facilities should be constructed of corrosion-resistant materials, capable of being easily cleaned, and should be fitted with suitable means of supplying warm and cold water in sufficient quantities.

4.4.9 Lighting

Adequate natural or artificial lighting should be provided throughout the establishment. Where appropriate, the lighting should not alter colours and the intensity should not be less than:

- 540 lux (50 foot candles) at all inspection points
- 220 lux (20 foot candles) in work rooms
- 110lux (10 foot candles) in other areas.

Light bulbs and fixtures suspended over food materials in any stage of production should be of a safety type and protected to prevent contamination of food in case of breakage.

4.4.10 Ventilation

Adequate ventilation should be provided to prevent excessive heat, steam, condensation and dust and to remove contaminated air. The direction of the air flow should never be from a dirty area to a clean area. Ventilation openings should be provided with a screen or other protecting enclosure of non-corrodible material. Screens should be easily removable for clearing.

4.4.11 Facilities for storage and disposal of waste and inedible material

Facilities should be provided for the storage of waste and inedible material prior to removal from the establishment. These facilities should be designed to prevent access to waste or inedible material by pests and to avoid contamination of food, potable water, equipment, building or roadways.

4.5 EQUIPMENT AND UTENSILS

4.5.1 Materials

All equipment and utensils used in food handling areas and which may contact food should be made of material which does not transmit toxic substances, odour or taste, is non-absorbent, is resistant to corrosion and is capable of withstanding repeated cleaning and disinfection. Surfaces should be smooth and free from pits and crevices. The use of wood and other materials which cannot be adequately cleaned and disinfected should be avoided except when their use would clearly not be a source of contamination. The use of different materials in such a way that contact corrosion can occur should be avoided.

4.5.2 Sanitary design, construction and installation

4.5.2.1 *All equipment and utensils* should be so designed and constructed as to prevent hygienic hazards and permit easy and thorough cleaning and disinfection and, where practicable, be visible for inspection. Stationary equipment should be installed in such a manner as to permit easy access and thorough cleaning.

Equipment should be designed to minimize build-up of moisture of dried product in dryers, lines, bins and packaging equipment.

4.5.2.2 *Containers for inedible materials and waste* should be leak-proof, constructed of metal or other suitable impervious material which should be easy to clean, or disposable and able to be closed securely.

4.5.2.3 *The equipment for pasteurizing milk and liquid milk products* should be provided with a thermometer and an automatic temperature recorder, a flow diversion valve or pump "cut-out" as well as a positive pump or timing device to ensure that the proper time/temperature combination is maintained.

4.5.2.4 Sensors of the temperature measuring devices should be so positioned as to measure the temperature of the milk or milk products on the completion of the holding section of the pasteurizing process.

4.5.2.5 *Facilities* for the convenient withdrawal of samples for the purpose of control of effective pasteurizing or heat-treatment should be provided where necessary.

4.5.2.6 *All refrigerated spaces* should be equipped with temperature measurement or recording devices.

4.5.3 Thermometers and recording devices

4.5.3.1 *Thermometers* which include glass in their construction should not be used in any application where glass may come into contact with milk or milk products.

4.5.3.2 *Thermometers, temperature recorders* and similar instruments should be calibrated against a reference instrument upon installation and periodically at adequate intervals to ensure effective operation.

4.5.4 Spray dryers

4.5.4.1 Where necessary, *spray dryers* should be equipped with adequate air intake filters. Air which is drawn into the dryer should comply with the requirements of Section 4.4.4. In direct gas-fired dryers, precautions should be taken to ensure complete combustion to prevent contamination of the product.

4.5.4.2 *Exhaust air* from dryers should be treated to remove milk solids to the extent that they will not seriously contaminate factory buildings and surroundings.

4.5.5 Equipment identification

Equipment and utensils used for inedible or discarded materials should be so identified and should not be used for edible products.

SECTION V - ESTABLISHMENT: HYGIENE REQUIREMENTS

5.1 MAINTENANCE

5.1.1 The buildings, equipment, utensils and all other physical facilities of the establishment, including drains, should be maintained in good repair and in an orderly condition. As far as practicable, rooms should be kept free from steam, vapour and surplus water. Storage rooms should be kept dry.

5.1.2 Special attention should be paid to the maintenance of roofs, guttering and drainage in the area surrounding the exhausts of dryers to prevent contamination of the area.

5.1.3 Spray dryers and processing equipment should be regularly inspected for cracks.

5.2 CLEANING AND DISINFECTION

5.2.1 Cleaning and disinfection should meet the requirements of this Code. For further information on cleaning and disinfection procedures see Annex 1 to the "*Recommended International Code of Practice – General Principles of Food Hygiene*"

5.2.2 To prevent contamination of food, all equipment and utensils should be cleaned as frequently as necessary and disinfected whenever circumstances demand.

All wet product contact surfaces should be cleaned immediately after use. Dry product contact surfaces should be dry-cleaned by a technique appropriate to the equipment concerned immediately after use, and should be wet-cleaned only as necessary. Where necessary, equipment should be disassembled for cleaning.

5.2.3 If possible, metallic cleaning materials such as steel wool should not be used in the cleaning of dairy equipment or utensils. Where this is however necessary, great care should be exercised to avoid contamination of the product with metallic particles.

5.2.4 Equipment and pipelines which are cleaned in place should first be rinsed with water. In certain cases the use of warm water in general with a temperature not exceeding 45°C may be recommended.

Spray nozzles should be examined periodically to ensure effective distribution of detergent and disinfectant.

Air filters should be checked and cleaned regularly to ensure effective performance.

5.2.5 Cleaned equipment and utensils should normally be disinfected immediately before use, by physical or chemical agents as appropriate to the equipment and the nature of the product. In the case of dry product equipment disinfection immediately before use may not always be necessary. Where chemical agents are used, the equipment should be drained and then rinsed with water in compliance with Sub-Section 7.3 of this Code (see also Sub-Section 7.4.11).

5.2.6 Special clean protective clothing and shoe covers should be used by any person entering the chamber of the spray dryer for the purpose of cleaning or maintenance.

5.2.7 Adequate precautions should be taken to prevent food from being contaminated during cleaning or disinfection of rooms, equipment or utensils by water and detergents or by disinfectants and their solutions. Detergents and disinfectants should be suitable for the purpose intended and should be acceptable to the official agency having jurisdiction. Any residues of these agents on a surface which may come into contact with food should be removed by thorough rinsing with water in compliance with Sub-Section 7.3 of this Code before the area or equipment is again used for handling foods.

5.2.8 Either immediately after cessation of work for the day or at such other times as may be appropriate, floors, including drains, auxiliary structures and walls of food handling areas should be thoroughly cleaned.

5.2.9 Changing facilities and toilets should be kept clean at all times.

5.2.10 Roadways and yards in the immediate vicinity of and serving the premises should be kept clean.

5.3 HYGIENE CONTROL PROGRAMME

A permanent cleaning and disinfection schedule should be drawn up for each establishment to ensure that all areas are appropriately cleaned and that critical areas, equipment and material are designated for special attention. A single individual who should preferably be a permanent member of the staff of the establishment and whose duties should be independent of production, should be appointed to be responsible for the cleanliness of the establishment. He/she should have a thorough understanding of the significance of contamination and the hazards involved. All cleaning personnel should be well trained in cleaning techniques.

5.4 STORAGE AND DISPOSAL OF WASTE

Waste material should be handled in such a manner as to avoid contamination of food or potable water. Care should be taken to prevent access to waste by pests. Waste should be removed from the food handling and other working areas as often as necessary and at least daily. Immediately after disposal of the waste, receptacles used for storage and any equipment which has come into contact with the waste, should be cleaned and disinfected. The waste storage area should also be cleaned and disinfected.

5.5 EXCLUSION OF DOMESTIC ANIMALS

Animals that are uncontrolled or that could be a hazard to health should be excluded from establishments.

5.6 PEST CONTROL

5.6.1 There should be an effective and continuous programme for the control of pests. Establishments and surrounding areas should be regularly examined for evidence of infestation.

5.6.2 Should pests gain entrance to the establishment, eradication measures should be instituted. Control measures involving treatment with chemical, physical or biological agents should only be undertaken by or under direct supervision of personnel who have a thorough understanding of the potential hazards to health resulting from the use of these agents, particularly those hazards which may arise from residues retained in

the product. Such measures should only be carried out in accordance with the recommendations of the official agency having jurisdiction.

5.6.3 Pesticides should only be used if other precautionary measures cannot be used effectively. Before pesticides are applied, care should be taken to safeguard all food, equipment and utensils from contamination. After application, contaminated equipment and utensils should be thoroughly cleaned to remove residues prior to being used again.

5.7 STORAGE OF HAZARDOUS SUBSTANCES

5.7.1 Pesticides or other substances which may represent a hazard to health should be labelled with a warning about their toxicity and use. They should be stored in locked rooms or cabinets, used only for that purpose, and dispensed and handled only by authorized and properly trained personnel or by persons under strict supervision of trained personnel. Extreme care should be taken to avoid contaminating food.

5.7.2 Except when necessary for hygienic or processing purposes, no substance which could contaminate food should be used or stored in food handling areas.

5.8 PERSONAL EFFECTS AND CLOTHING

Personal effects and clothing should not be deposited in processing areas.

SECTION VI - PERSONNEL: HYGIENE AND HEALTH REQUIREMENTS

6.1 HYGIENE TRAINING

Managers of establishments should arrange for adequate and continuing training of every food handler in hygienic handling of food and in personal hygiene so that they understand the precautions necessary to prevent contamination of food. Instruction should include relevant parts of this Code.

6.2 MEDICAL EXAMINATION

Persons who come into contact with food in the course of their work should have a medical examination prior to their employment if the official agency having jurisdiction, acting on medical advice, considers that this is necessary, either because of epidemiological considerations, the nature of the food prepared in a particular establishment or the medical history of the prospective food handler. Medical examination of a food handler should be carried out at other times when clinically or epidemiologically indicated.

6.3 COMMUNICABLE DISEASES

The management should take care to ensure that no person, while known or suspected to be suffering from, or to be a carrier of a disease likely to be transmitted through food or while afflicted with infected wounds, skin infections, sores or with diarrhoea is permitted to work in any food handling area in any capacity in which there is any likelihood of such a person directly or indirectly contaminating food with pathogenic micro-organisms. Any person so affected should immediately report to the management that he/she is ill.

6.4 INJURIES

Any person who has a cut or wound should not continue to handle food or food contact surfaces until the injury is completely protected by a waterproof covering which is firmly secured, and which is conspicuous in colour. Adequate first-aid facilities should be provided for this purpose.

6.5 WASHING OF HANDS

Every person engaged in a food handling area should wash his/her hands frequently and thoroughly with a suitable hand cleaning preparation under running warm water in compliance with Sub-Section 7.3 of this Code while on duty. Hands should always be washed before commencing work, immediately after using the toilet, after handling contaminated material and whenever else necessary. After handling any material which might be capable of transmitting disease, hands should be washed and disinfected immediately. Notices requiring hand-washing should be displayed. There should be adequate supervision to ensure compliance with this requirement.

6.6 PERSONAL CLEANLINESS

Every person engaged in a food handling area should maintain a high degree of personal cleanliness while on duty, and should at all times while so engaged wear suitable protective clothing including head covering and footwear, all of which articles should be cleanable unless designed to be disposed of and should be maintained in a clean condition consistent with the nature of the work in which the person is engaged. Aprons and similar items should not be washed on the floor. During periods when food is manipulated by hand, any jewellery that cannot be adequately disinfected should be removed from the hands. Personnel should not wear any insecure jewellery when engaged in food handling.

6.7 PERSONAL BEHAVIOUR

Any behaviour which could result in contamination of food, such as eating, use of tobacco, chewing (e.g., gum, sticks, betel nuts, etc.) or unhygienic practices such as spitting, should be prohibited in food handling areas.

6.8 GLOVES

Gloves, if used in the handling of food products, should be maintained in a sound, clean and sanitary condition. The wearing of gloves does not exempt the operator from having thoroughly washed hands.

6.9 VISITORS

Precautions should be taken to prevent visitors to food handling areas from contaminating food. These may include the use of protective clothing. Visitors should observe the provisions recommended in Sub-Sections 5.8, 6.7 and 6.8 of this Code.

6.10 SUPERVISION

Responsibility for ensuring compliance with all requirements of Sub-Sections 5.8-6.9 inclusive should be specifically allocated to competent supervisory personnel.

SECTION VII - ESTABLISHMENT: HYGIENIC PROCESSING REQUIREMENTS

7.1 RAW MATERIAL REQUIREMENTS

7.1.1 All milk used in the manufacture of dried milk products should have been produced under hygienic conditions in compliance with the provisions of the official agency having jurisdiction.

7.1.2 No milk which has been contaminated, or subjected to the addition of any harmful substances which render it unfit for human consumption, should be accepted for processing.

7.1.3 No milk or liquid milk product should be accepted by an establishment unless it has been derived from healthy animals. Milk from animals which have been treated with antibiotics and other drugs should be excluded for a period adequate to prevent contamination of the milk.

7.1.4 Inspection should be carried out on incoming milk and milk products to ensure that raw materials are satisfactory for processing.

7.1.5 Where necessary, laboratory tests should be made of the ingredients prior to their use.

7.1.6 Raw materials and other ingredients stored on the premises of the establishment should be maintained under conditions that will prevent spoilage, protect against contamination and minimize damage. Stocks of raw materials and ingredients should be properly rotated.

7.2 PREVENTION OF CROSS-CONTAMINATION

7.2.1 Effective measures should be taken to prevent contamination of pasteurized products by direct or indirect contact with material at an earlier stage of the process.

7.2.2 Persons handling raw milk or other raw materials or semi-processed products capable of contaminating the end-product should not come into contact with any end-product unless and until they discard all protective clothing worn by them during the handling of raw materials or semi-processed products which have come into contact with or have been soiled by raw materials or semi-processed products and they have changed into clean protective clothing.

7.2.3 If there is a likelihood of contamination, hands should be washed thoroughly between handling products at different stages of processing.

7.2.4 All equipment which has been in contact with raw materials or contaminated materials should be thoroughly cleaned and disinfected before being used for contact with pasteurized products.

7.2.5 Every department in which any dried milk product is prepared, processed or stored should be used at that time only for that purpose or for the preparation of other dried milk products or products subject to the same standard of hygiene.

7.3 USE OF WATER

7.3.1 As a general principle only potable water as defined in the latest edition of "International Standards of Drinking Water" (WHO) should be used in food handling.

7.3.2 Non-potable water may be used with the acceptance of the official agency having jurisdiction for steam production, refrigeration, fire control and other similar purposes not connected with food. However, non-potable water may, with specific acceptance by the official agency having jurisdiction, be used in certain food handling areas provided this does not constitute a hazard to health.

7.3.3 Water recirculated for re-use within the establishment should be treated and maintained in a condition so that no health hazard can result from its use. The treatment process should be kept under constant surveillance. Alternatively, recirculated water which has received no further treatment may be used in conditions where its use would not constitute a health hazard and will not contaminate either the raw material or the end-product. Recirculated water should have a separate distribution system which can be readily identified. The acceptance of the official agency having jurisdiction should be required for any treatment process and for the use of recirculated water in any food process.

7.4 PROCESSING

7.4.1 Processing should be supervised by technically competent personnel.

7.4.2 All steps in the production process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration, or the development of pathogenic and spoilage microorganisms.

7.4.3 After inspection and testing, incoming milk or liquid milk products should be processed directly or, if this is not possible, cooled to and held until processing at a temperature sufficiently low to prevent significant microbial growth. Milk which is in cans should be transferred to bulk holding tanks and cooled without delay.

7.4.4 Adequate heat-treatment facilities should be provided. All milk and liquid products should be pasteurized prior to concentrating.

7.4.5 The concentrated product leaving the evaporator should be fed directly to the dryer. If this is not possible for technical reasons it should be stored under such conditions of the time and temperature as will prevent development of micro-organisms and toxins during storage. If twin feed-balance tanks have to be used these should be used alternately. Feed-balance tanks should be cleaned and sterilized as often as necessary, depending on the conditions of their use.

7.4.6 Concentrated products may be transported to the drying plant, provided that, where necessary, they are pasteurized before drying. It should be recognized however that pasteurization reduces the number of viable micro-organisms, but may not destroy some toxins.

7.4.7 A continuous chart recording should be made of all pasteurization steps, and these charts should be dated and kept available for inspection for a period that exceeds the shelf life of the product, but unless a specific need exists they need not be kept for more than two years.

7.4.8 When breakdowns or unplanned discontinuities in processing occur which disrupt the normal flow of the product, the batch should not be released for human consumption unless it is of acceptable hygienic quality. Re-processing, diversion to non-human use or additional testing may be required.

7.4.9 Dried milk products recovered from equipment and which are not obtained from the normal continuous process should not be incorporated in the end-product, unless the recovery process is such that the hygienic quality of these products is maintained.

7.4.10 Dried milk products should not come into contact with wet surfaces and equipment.

7.5 PACKAGING

7.5.1 All packaging material should be stored in a clean and sanitary manner. The material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product objectionable substances beyond the limits acceptable to the official agency-having jurisdiction. The packaging material should be sound and should provide appropriate protection from contamination.

7.5.2 Product containers should not have been used for any purpose which may lead to contamination of the product. Where practicable, containers should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary cleaned and/or disinfected; when washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.

7.5.3 Precautions should be taken to minimise product dust and spillage. The packages should be closed immediately after filling or gassing, and the exteriors should be cleaned where necessary to remove any product dust.

7.5.4 Packaging should be done under conditions that preclude the introduction of contamination into the product.

7.5.5 Lot identification

Each container shall be permanently marked in code or in clear to identify the producing factory and the lot. A lot is a quantity of food produced under identical conditions, all packages of which should bear a lot number that identifies the production during a particular time interval, and usually from a particular "line" or other critical processing unit.

7.5.6 Processing and production records

Permanent, legible and dated records of pertinent processing and production details should be kept concerning each lot. These records should be retained for a period that exceeds the shelf-life of the product, but unless a specific need exists they need not be kept for more than two years. Records should also be kept of the initial distribution by lot.

7.6 STORAGE AND TRANSPORT OF THE END-PRODUCT

7.6.1 The end-product should be stored and transported under such conditions as will preclude contamination with and/or proliferation of micro-organisms and protect against deterioration of the product or damage to the container.

7.6.2 Storage should be in such a manner and in such containers as to prevent moisture absorption. During storage, periodic inspection of the product should take place to ensure that only food which is fit for human consumption is despatched and that end-product specifications should be complied with. The product should be despatched in the sequence of lot numbers.

7.7 SAMPLING AND LABORATORY CONTROL PROCEDURES

7.7.1 The establishment should have access to adequate laboratory facilities to carry out routine testing needed to effect continuous control of all operations.

7.7.2 Where appropriate, representative samples of the production should be taken to assess the safety and quality of the product.

7.7.3 The following should be monitored by a laboratory:

- (i) incoming milk and liquid milk products;
- (ii) other ingredients;
- (iii) processing and manufacturing stages, including pasteurization by means of phosphatase test; *
- (iv) cleaning and disinfection in the plant;
- (v) finished products;
- (vi) water quality;
- (vii) calibration of instruments, for example, gauges, thermometers, etc.;
- (viii) packaging materials;
- (ix) air quality;
- (x) steam quality; and
- (xi) microbiological monitoring of the environment within and immediately outside the plant.

7.7.4 Laboratory analytical procedures should preferably follow recognized or standard methods in order that the results may be readily interpreted. In many cases Codex methods are available.

7.7.5 Testing for pathogenic micro-organisms should be done within the confines of the establishment only when adequate precautions have been taken to ensure that no contamination of the product arising from the laboratory is possible.

7.7.6 The results of examination should be consistently monitored and in the event of a significant deviation from the normal characteristics appropriate action, including more detailed investigation, should be undertaken immediately.

7.7.7 The records of the examination should be kept at each establishment for a period that exceeds the shelf-life of the product, but unless a specific need exists they need not be kept for more than two years. It would also be appropriate to retain the records of examinations relating to the various manufacturing processes. All records should be available for inspection if so required. Means of identifying batches with samples should also be provided.

7.7.8 The person in charge of hygiene control should have authority commensurate with the responsibilities associated with planning, coordinating, executing and maintaining the establishment hygiene control programme and he should have a thorough understanding of the significance of contamination and the hazards involved.

SECTION VIII - END-PRODUCT SPECIFICATIONS

Standard methods should be used for sampling and examination to determine the compliance with the following specifications:

8.1 To the extent possible in good manufacturing practice, the products should be free from objectionable matter.

They should not contain any substances in amounts which may represent a hazard to health.

8.2 a) When tested by appropriate methods of sampling and examination the products should be free from micro-organisms in amounts which may represent a hazard to health.

b) Should not contain any substances originating from micro-organisms, particularly aflatoxins, in amounts which exceed the tolerances or criteria established by the official agency having jurisdiction.

8.3 MICROBIOLOGICAL CRITERIA

Dried milk should comply with the microbiological criteria in Section IX.

* *Methods:* (a) IDF-63 Phosphatase Activity-reference method for milk ISO-3356, 1975. Milk and dried milk, buttermilk and buttermilk powder, whey and whey powder—Determination of phosphatase activity (Reference Method); (b) AOAC (1983) Official Methods of Analysis of the AOAC, 14th Ed., Phosphatase (residual) in milk. Final Action, Method II, 16.112-16.114.

SECTION IX - MICROBIOLOGICAL CRITERIA FOR DRIED MILK PRODUCTS

This proposed Section for microbiological criteria for dried milk products contains:

- Microbiological End-product Specifications; and
- Microbiological Guidelines

Note: This proposed Section does not apply to dried milk products intended for use by high risk populations such as infants and children.

9.1 MICROBIOLOGICAL END-PRODUCT SPECIFICATIONS

A *microbiological end-product specification* serves as a guide to the official agency having jurisdiction and is intended to increase assurance that the provisions of hygienic significance in the Code have been met. It may include micro-organisms which are not of direct public health significance.

9.1.1 *Sampling plans and microbiological limits*

Salmonellae: *Salmonella* organisms should not be recovered from any of 15 sample units examined when the test is carried out according to the method described³. (n = 15, c = 0, m = 0).

Mesophilic Aerobic Bacteria: When examined by the method described, mesophilic aerobic bacteria should not be recovered:

- a) in a number exceeding 200,000 per gramme from any of the five samples tested; and
- b) in a number exceeding 50,000 per gramme from more than two of the five samples tested.

(n = 5, c = 2, m = 50,000, M = 200,000).

Coliform Bacteria: When examined by the method described, coliform bacteria should not be recovered:

- a) in a number exceeding 100 per gramme from any of the five samples tested; and
- b) in a number exceeding 10 per gramme from more than one of the five samples tested.

(n = 5, c = 1, m = 10, M = 100).

9.1.2 *Number of field samples from a lot*⁴

Take 15 field samples, all of which are used for detection of *salmonellae* and select at random 5 of these field samples to be examined also for mesophilic aerobic bacteria and coliform bacteria.

9.1.3 *Sampling methods*

For all dried milk products take field samples of at least 200 grammes.

Equipment for aseptic sampling: Sterile trier long enough to reach to the bottom of containers to be sampled. Sterile sample containers with tight closure, sterile spoon, alcohol lamp or other burner, cotton, clean cloth or towel and water pail. Where possible, the container should be cleaned before sampling.

Methods: For small packages, randomly take one unopened package for each of the field samples required. If the net weight of the package is less than 200 g. take as many unopened packages as required to make at least 200 g for each field sample. For larger containers, such as boxes, bags, etc., remove top layer with sterile spoon or other sterile implement, and with a sterile trier remove at least three cores from the centre, midway between the centre and the periphery, and from the periphery respectively. Aseptically transfer the cores to a sterile container. Samples should be stored tightly sealed at ambient temperature and analysis should take place as soon as possible after collection.

³ The method described requires sample units of 25 g.

⁴ A lot is a quantity of food manufactured under essentially identical conditions, all packages of which should bear a marking that will allow the identification of the source(s) of raw material(s), conditions of manufacture and day of final packing.

9.1.4 Reference methods

9.1.4.1 Detection of *Salmonellae*

Dried whole milk, dried skim milk, dried whey and similar products. The method is that of ISO (DIS 6779).

9.1.4.2 Enumeration of mesophilic aerobic bacteria

Dried whole milk, dried skim milk, dried whey and similar products. The method is the reference method of the International Dairy Federation; Ref. FIL-IDF 49:1970.

9.1.4.3 Enumeration of coliform bacteria

Dried whole milk, dried skim milk, dried whey and similar products. The method is the reference method of the International Dairy Federation; Ref. FIL-IDF 64:1971.

9.2 MICROBIOLOGICAL GUIDELINES

Microbiological Guideline is applied at the establishment at a specified point during or after processing to monitor hygiene. It is intended to guide the manufacturer and is not to be used for official control purposes. It may include micro-organisms other than those regarded in the criteria for microbiological standards and end-product specifications.

9.2.1 Sampling plans and microbiological limits

The manufacturer should define his own sampling plan for microbiological purposes and establish limits that will ensure that limits in microbiological end-product specifications will be, as a minimum, achieved and preferably bettered.

Special consideration should be given to monitoring the establishment samples for *Salmonella* spp. and susceptible intermediate process stages for the build-up of *Staphylococcus aureus*.

The latter may be done either by monitoring for *Staphylococcus aureus* or possible for thermonuclease.