

# EXECUTIVE INSTRUCTIONS

APPROVAL AND MONITORING  
OF  
PROCESSING ESTABLISHMENTS  
FOR EXPORT

## MILK PRODUCTS



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## 1. INTRODUCTION

- 1.1. The requirements for the approval of the establishments to process Milk products meant for export have been notified vide GOI Order and Notification S.O. 2719 and S.O 2720 both dated 28.11.2000, on the basis of which the establishments processing milk products meant for export are being approved by the Competent Authority (Export Inspection Agencies established under Section 7 of the Export (Quality Control and Inspection) Act, 1963).
- 1.2. The Primary responsibility for meeting the health requirements of importing countries and also those specified in the GOI Notifications lies with the processing establishments themselves, for which these establishments are required to plan and implement detailed HACCP based process control (own check system) and to maintain necessary records. The role of Export Inspection Council of India (EIC)/EIAs is to exercise official control by approving the units and implementing an effective surveillance system to ensure compliance to requirements as per clause 3 of the Notification No. S.O. 2720 dated 28 November 2000.

These instructions are framed also taking into consideration of the requirements of Regulation(EC)No. 178/2002, Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004, Regulation (EC) No. 2377/90, Directive 96/23/EC, Regulation EC/2073 of 2005 and Commission Decision 2004/438/EC.

## 2. PROCEDURE FOR APPROVAL OF ESTABLISHMENT

### 2.1. Application for approval

- 2.1.1. The establishment intending to process milk products for export shall submit the application for approval in the prescribed format placed at Annexure I in duplicate along with documents given at 2.1.3 to the nearest office of EIA under whose jurisdiction the establishment is situated.
- 2.1.2. Application fee as given in clause 17 shall be paid by the applicant by way of demand draft drawn in favour of the Export Inspection Agency concerned along with the application form.
- 2.1.3. The application shall be accompanied by the following documents:
  - a) HACCP Manual (including the Sanitary Standard Operating Procedures, process flow chart (s) with product description, manufacturing details in each step , Self-Residue Monitoring Plan.)
  - b) In the case of establishments meant for export to the EU, attested/certified copy of test report from EIA lab/EIC approved lab in respect of water complying with EC directive No.98/83/EC dated 3.11.1998 used during processing activities.(not later than 6 months).

However, in the case of establishments meant for export to countries other than EU, the water needs to be tested as per IS: 4251, not later than 6 months. (other than radiological parameters) from EIA Lab/EIC approved laboratory

- c) Location and Layout plan of the establishment (site plan and building plan in A-4 size), showing all infrastructure and equipment facilities.
- d) Layout showing the process/product flow, personnel flow, water flow (Indicating serially numbered water taps) and effluent flow, on A4 size paper separately, in evidence of meeting food safety requirements
- e) Attested/ Certified copies of documents proving legal identity of the applicant establishment and scope of their operations.
- f) Attested/ Certified copy of lease agreement for the premises and building, where ever necessary.
- g) List of identified farms, chilling centres and milk production holding, meeting the minimum requirements specified at Annexure IC from which the establishment intend to procure milk for processing along with details like address, and distance from the processing establishment. In case the units are not using liquid milk, then identified suppliers of milk products e.g. SMP, WMP, cream etc.

- h) Bio-data of the Veterinarian/technologist(s) with attested copies of degree certificate(s) experience certificate(s) and appointment letter/certificate of employment from the establishment and certificate of approval of EIAs if the same is available.
- i) An Undertaking and Guarantee in the formats placed at Annexure IA and Annexure IB
- j) Attested/ Certified copy of consent letter issued by Pollution Control Board concerned. (in case the consent letter is not available at the time of applying for approval this shall be submitted before the grant of final approval. However in such cases copy of the application made to Pollution Control Board (PCB) shall be submitted at the time of filing application for approval to EIA concerned).
- k) Attested/ Certified copy of the order allotting Importer Exporter Code number (IEC).
- l) Attested /certified copy of MMPO 92 registration certificate along with undertaking that sanitation and Hygiene inspection under MMPO 92 has been conducted.

**Note:** In case where a non-EU approved establishment submits application for the approval to process milk products for exports to the EU countries, the documents, which were submitted earlier, need not be submitted again, if there is no change.

## 2.2 Processing applications for approval

- 2.2.1 Applications received shall be scrutinised by the EIA office where it has been received and the discrepancies/ shortcomings observed should immediately be communicated to the applicants for rectification. A copy of application along with relevant documents and comments of the Officer In-charge of Sub-Office or Officer In-charge of Food Scheme (as applicable) shall be forwarded to In-charge of the Agency within seven working days after receiving it complete in all respect.

Adequacy audit of the HACCP manual and SSOPs shall be carried out by an EIA officer, having adequate knowledge of HACCP authorised by In-charge of the Agency. The adequacy audit report as per Annexure IIA along with the Audit Observation sheet (Annexure IIB) and the documents shall be forwarded to the In-charge of the Agency within five working days.

The application shall further be scrutinised by In-Charge of Food Scheme or a suitable officer authorised by him and deficiencies, if any, shall be communicated to the applicant for rectification.

- 2.2.2 When the application is complete in all respect, In-charge of the Agency shall depute a suitable officer as required by Clause 2.3.2 as Convener of Inter Departmental Panel (IDP) for assessment of the establishment.

- 2.2.3 Application pending for more than one year due to non-compliance by the establishment shall be rejected. However, the unit may apply afresh with all required documents and fees.

## 2.3 Assessment of the establishment

- 2.3.1. The Convener of IDP shall ensure that assessment of applicant establishment is carried out within fifteen working days of receipt of their application complete in all respect.

In case of initial approval of the establishment, the IDP shall assess the unit in two stages. In the first visit the IDP shall assess the infrastructure and equipment facilities of the establishment and also their compliance of regulatory requirements specified in the GOI Notification/ Executive Instructions and if satisfied recommend for the conditional approval of the establishment

In case the Competent Authority grants conditional approval, the establishments will be allowed to start processing of milk/manufacturing of milk products meant for export (however, export to the EU countries will be permitted only after the acceptance by EC). The processor shall intimate the Agency as soon as production has commenced. While the processing activities are in progress, an IDP shall visit the establishment again for on-site verification of compliance with the regulatory requirements specified in the GOI Notification/ Executive Instructions with respect to the GHP, GMP and HACCP based procedures Based on the satisfactory assessment report of the IDP, the full approval shall be granted to the establishment by the Competent Authority.

However, in cases where a non-EU approved establishment submits application for the approval to process milk products for export to the EU countries, the conditional approval is not required. In such cases, the IDP may conduct assessment of infrastructure facilities and HACCP implementation of the establishment in the first instance itself and if satisfied recommend for the full approval of the establishment. In such cases, the establishment should ensure that the processing activities are in progress in the establishment during the IDP visit and shall demonstrate the compliance with GHP, GMP and HACCP and other regulatory requirements.

2.3.2. The composition of IDP shall be as constituted by EIC from time to time.

2.3.2.1 Members of the Inter Departmental Panel will be decided by the In-charge of the Export Inspection Agency from the composition of IDP as constituted by EIC. The EIA representative of the IDP (convener) shall be an officer at the level of Deputy Director, having background (qualification/experience) of Food Schemes.

Note: 1. The present IDP comprises representatives from EIC, APEDA, MoFPI, EIA, NDDB, NDRI/*Dairy Science College, State level Veterinary College* and representative of industry and co - operatives.

2. In unavoidable circumstances, a senior Assistant Director having relevant qualification and enough experience in food scheme may be nominated as EIA representative by the In-charge of the Agency.

2.3.2.2 The quorum of IDP shall be three.

2.3.3 The IDP shall assess the infrastructure and equipment facilities of the unit and also 10% of the identified Dairy farms/chilling centres subject to a minimum of one farm during on-site visit. The prescribed Assessment Report Format placed at Annexure IIIA shall be used for reporting its observations. (The requirements for the approval of the establishment to process milk products meant for export is enclosed at Annexure IC and Annexure ID.

In case the IDP finds any deficiency during its assessment, the same shall be recorded in the non-conformity report which shall be counter signed by the representative of the establishment as a token of acceptance as per Annexure IV. The copy of the NCR may be handed over to the establishment along with any observation for improvement. Additional suggestions for improvement, if any, shall be given to the processor separately, the implementation of which shall not be a part of the approval procedures.

The IDP convener shall submit the assessment report and recommendations of the IDP to the In-charge of Export Inspection Agency within three working days of completion of the visit to the applicant's establishment. In case verification of rectifications of the deficiencies is needed, the same may be undertaken as per the time frame prescribed by the Panel (maximum three months from the date of intimation of deficiencies to the establishment). The verification report shall be submitted to the Agency In-charge within three working days of verification. The recommendations of the Panel shall clearly state whether the applicant's establishment is recommended for full approval/conditional approval or not.

Note: Enough flexibility shall be given while assessing. The aim shall be to avoid the cross contamination which can also be achieved by time and space separation.

2.3.4 The report of the IDP visit shall be examined by the In-charge of the Export Inspection agency concerned. The following three situations may arise:

2.3.4.1 In case, the IDP recommends full approval/conditional approval to the establishment and if agreed to, by the In-charge of EIA, the In-charge of food scheme, shall take following actions

Note: The conditional approval is given to the establishment on the initial stage of approval after satisfactory assessment of infrastructure and equipment facilities.

a. Allot an approval number to the establishment in the following manner

- EIA-Mumbai – 1/ Factory No / MP/ Year of Approval
  - EIA-Kolkata – 2 / Factory No / MP/ Year of Approval
  - EIA-Kochi - 3 / Factory No / MP/ Year of Approval
  - EIA-Delhi – 4 / Factory No / MP/ Year of Approval
  - EIA-Chennai- 5 / Factory No / MP/ Year of Approval
- (“Factory No” shall be allotted in serial order i.e,01, 02 etc.)

For example: for the first approved unit at EIA- Kochi in the year 2007, the unit shall be allotted approval No. “3/01/MP/07”.

- b. Open a file with 4 parts: Part A, Part B, Part C and Part D.

“Part A” shall bear the Approval Number followed by suffix “A” (e.g. “3/01/MP/07- A”). This file shall contain approval documents such as application for approval/renewal, IDP assessment reports, approval of additional facilities, veterinarian/ technologists, merchant exporter and other correspondence relating to the unit.

“Part B” file shall bear the approval number followed by suffix ‘B’. (e.g. “3/01/MP/07-B”) This file contains copies of monitoring reports, supervisory visit reports, NCR (Non Conformity Report), Suggestions for improvements and laboratory test reports.

“Part C” file shall bear approval number with suffix ‘C’ (e.g. “3/01/MP/07- C”) and shall have copies of Certificate for Export (CFE) issued by the unit and Health Certificates issued by EIA.

“Part D” file shall bear approval number with suffix ‘D’ (e.g. “3/01/MP/07- D”) and have details of foreign Complaints including all relevant papers and details of action taken regarding “On Alert” etc.

All records of file A and D shall be kept as permanent records. However records of File B and C shall be kept for at least three years.

- c. The conditional approval is granted by the In-charge of the Agency for a period of three months from the date of approval, which may be extended to a maximum period of six months. The conditional approval shall be intimated to the establishment as per the format given at Annexure VI.

2.3.4.2 In case, the IDP does not recommend approval and if agreed to, the In-charge of the EIA shall convey the same to the applicant, within seven working days of the receipt of the IDP report, along with the reasons for which applicant establishment has not been considered fit for full/conditional approval in the prescribed format Annexure V

2.3.4.3 In case of deficiencies in infrastructure and equipment facilities as reported by the IDP, which can be rectified within a reasonable time (maximum of three months from the date of intimation to the establishment), either the IDP or Convener of IDP as may be decided by Agency In-charge concerned (see clause 2.3.3) may carry out on-site verification of the corrective action/measures taken by the unit.. Further, procedure shall be followed as per clause 2.3.3 and 2.3.4 as applicable.

2.3.5 The establishment shall be allowed to process milk products in their establishment for all destinations including EU after grant of Full/Conditional approval. However, actual export to the countries of the EU shall commence only from the date of EIC approval, based on the EC notification, if applicable. EIA concerned shall start issuing health certificate to the establishment on behalf of EIC from the date of EIC letter.

In the meantime, the establishment shall be allowed to process and export their milk products to countries other than EU.

2.3.6 The conditionally approved establishment on starting production shall ensure compliance with the requirements of GHP, GMP and HACCP and inform the EIA concerned for arranging the second IDP visit for conducting HACCP auditing and also to assess the adequacy of the processing activities of the establishment. The establishment should have production of milk products in their unit at the time

of IDP Visit.

- 2.3.7 The IDP shall assess the unit for compliance with the requirements of GHP, GMP and HACCP by an on-site visit and submit its report to the In-charge of the Agency in the prescribed format placed at Annexure IIIB. The deficiencies observed, if any, in HACCP implementation, GMP etc. are recorded in the report as per Annexure IV and a copy of the same shall be given to the processor for corrective action which shall be carried out within a maximum period of one month, there after verified by the official(s) as decided by the Agency In-charge concerned. If required, the IDP shall recommend the extension of the conditional approval of the unit beyond three months. However, in any case the conditional approval will not be extended for more than six months from the initial date of conditional approval.
- 2.3.8 On satisfactory completion of assessment of GHP, GMP and HACCP, the IDP shall recommend grant of full approval and submit report to the In-charge of the Agency within three working days after the completion of the assessment.
- 2.3.9 If satisfied, the In-charge of the Agency shall grant the full approval of the establishment for a period of two years from the date of the conditional approval, which shall be intimated to the unit as per the format specified at Annexure VII with a copy marked to EIC. The certificate of approval shall be issued by EIC as per the format specified at Annexure VIII.
- 2.3.10 Once the In-Charge of Agency grants the full approval to the establishment, the existing list of the establishment(s) shall be updated by including the name of this establishment by EIC and a copy of the updated list along with specific recommendation for approval shall be submitted directly or through MoC&I, sent to the Mission of India in Brussels for submitting to EC, with copies to Customs and EIA concerned.

### 3. APPROVAL OF VETERINARIAN/TECHNOLOGIST

- 3.1 The Inter Departmental Panel (IDP) shall grant the approval of Veterinarian/technologist(s) only after satisfactory assessment. For this purpose, an individual intending to get approval as a Veterinarian/technologist shall submit an application in duplicate, as per the format given at Annexure IX along with prescribed fee given in clause 17, to the controlling office of EIA.
- 3.2 The Head office of EIA shall arrange assessment of the Veterinarian/technologist by the IDP, constituted as per clause 2.3.2, who shall submit the report as per the format given at Annexure IXA. On approval of Veterinarian/technologist, a certificate of approval shall be issued as per the prescribed format placed at Annexure IXB by the EIA concerned.
- 3.3 The approval granted to the Veterinarian/technologist is valid for two years from the date of approval and after two years the Veterinarian/technologist shall apply afresh to the controlling office of EIA along with the required assessment fee as prescribed in clause 17, for re-assessment of the veterinarian/ technologist by the IDP.
- 3.4 In case an approved Veterinarian/technologist of an establishment shifts to another processor, there shall be no need for fresh assessment. The processor shall inform the EIA of any change in veterinarian/ technologist.

### 4. PROCEDURE FOR APPROVAL OF ADDITIONAL FACILITIES/ ACTIVITIES OF APPROVED ESTABLISHMENT

- 4.1 The approved establishments seeking approval of additional facilities/activities shall submit their application in the prescribed format placed at Annexure X in duplicate along with relevant documents as mentioned in the application form to the controlling local office of the Export Inspection Agency and also with the application fee as prescribed in clause 17.
  - 4.1.1 Application(s) received shall be scrutinised and the discrepancies / shortcomings observed shall be immediately communicated to the applicant for rectification. In case of the approval of additional



processing activity, the revised HACCP plan addressing the new activity shall be submitted to the EIA concerned along with the process flow chart for verification. Adequacy audit of the HACCP manual with respect to the additional activities shall be done by EIA officer(s) authorized by the In-charge of the Agency.

- 4.1.2 Applications complete in all respect shall be forwarded to the Head office of EIA. The In-charge of the Agency shall decide whether the assessment of the establishment to be carried out by the IDP or by the In-charge of food scheme / EIA official, depending upon the nature of additional facility/activity requested for approval.
- 4.1.3 The Convener-IDP/In-charge of Food Scheme shall ensure that assessment of the additional facility/activity of applicant establishment is carried out within fifteen working days of receipt of their application complete in all respect.
- 4.1.4 The prescribed Assessment Report Format placed at Annexure XA shall be used for reporting the observations.
- 4.1.5 In case any major or serious deficiencies are observed during assessment, these shall be brought to the notice of the establishment through the NCR (Annexure IV) for taking corrective action within an agreed time period, maximum of one month. The rectifications conducted by the establishment are verified by either the IDP or by the Convenor of the IDP/ EIA official as may be decided by the In-charge of Agency concerned.

The report and recommendations shall be submitted to the In-charge of the EIA concerned within three working days of completion of the assessment of the applicant's establishment. The recommendations shall clearly state whether the additional facility/activity is recommended for approval or not.

- 4.1.6 The In-charge of the EIA concerned shall examine the assessment report of the IDP/In-charge of the Food Scheme.
- 4.1.7 In case the IDP/In-charge of the Food scheme/ EIA official recommends the additional facilities/activities for approval, the In-charge of EIA shall approve the additional facility/activity and inform the unit concerned within three working days of the receipt of the assessment report.
- 4.1.8 In case the IDP/In-charge of the Food Scheme/senior EIA official does not recommend approval, the In-charge of the EIA concerned shall convey to the applicant, within seven working days of the receipt of the IDP report, the reasons for which the additional facilities/activities of the establishment have not been approved.

Note: In case, the processor wants to incorporate the additional process activities in the certificate of approval, the original certificate of approval issued earlier shall be submitted to EIA for incorporation of the new process activities.

## 5. PROCEDURE FOR RENEWAL OF APPROVAL OF ESTABLISHMENT

- 5.1 The approved establishment seeking renewal of approval shall submit application(s), in duplicate, at least *Sixty days* in advance of the expiry of earlier approval to the controlling local office of the EIA in the form prescribed at Annexure XI along with relevant documents and application fee as prescribed in clause 17. EIA may remind the processor (As per Annexure XII) *Seventy five days* before the expiry of the approval.
  - 5.1.1 Application(s) received shall be scrutinised and any discrepancies / shortcomings observed shall be immediately communicated to the applicants for rectification.
  - 5.1.2 Applications, complete in all respect shall be forwarded to the In-charge of the Agency for arranging assessment of the establishment.

The Convener-IDP shall ensure that assessment of applicant establishment is carried out at the earliest.

Note: It shall be ensured by the In-charge of the Agency and the IDP Convenor that all formalities for the renewal of approval are completed before the expiry of approval. The IDP shall be arranged in consultation with the applicant. It should also be ensured that the establishment is in operation during the IDP visit.

In case the establishment does not apply for renewal in time and if the renewal of approval is not completed within the validity period due to the delay on the part of the processor and the approval granted to the unit lapses, the establishment will need to apply for fresh approval.

The IDP shall use the prescribed Assessment Report format placed at Annexure XIII

- 5.2 In case the IDP finds any deficiency during assessment, these shall be listed in the NCR, (Annexure IV) a copy of which shall be given to the establishment for taking corrective action within an agreed time period. The IDP shall submit its report and recommendations to the In-charge of the EIA concerned within three working days of completion of its assessment of the applicant's establishment. The recommendations of the IDP shall clearly state whether the applicant establishment is recommended for renewal of approval or not.

The assessment reports shall be examined by the EIA concerned.

- 5.2.1 If the IDP does not recommend for renewal of approval, the In-charge of the EIA concerned shall withdraw the approval granted to the establishment within three working days of the receipt of IDP report, with due intimation to EIC for informing the same to the EU, where applicable.
- 5.2.2 In case the IDP recommends renewal of approval and the in-charge of Sub-Office submits the satisfactory performance report as per the Annexure XIV the In-charge EIA shall grant the renewal of approval for a period of two years from the date of expiry of earlier approval and inform the establishment accordingly, with a copy marked to EIC.
- 5.2.3 Certificate of approval shall be issued by EIC as per the prescribed format placed at Annexure VIII and sent to the processing unit through the EIA concerned. The certificate under normal circumstances shall be valid for a period of two years from date of expiry of earlier approval.

## 6. PERMISSION TO PROCESS AND PACK MILK PRODUCTS FOR EXPORT BY MERCHANT EXPORTER

- 6.1 Approved establishments shall be permitted to process and pack milk products for export by one or more merchant exporter(s), depending upon their production capacity. However, only a maximum of three merchant exports are permitted at a given time.
- 6.2 Approved milk product establishments and the merchant exporter(s) shall also be permitted to export "on account" of Export Houses, Trading Houses, Star Trading Houses or Super Start Trading Houses only. However, it may be ensured while issuing Certificates for Export (CFE) for such "on account" export, the column no.1 of the certificate should contain the details of the exporter as well as the "on account" exporter.
- 6.3 Establishments intending to process and pack milk products on behalf of merchant exporter(s) should submit their application to the EIA concerned as per the format given at Annexure XV, along with a fee as prescribed in clause 17 and also the documents specified therein. Application complete in all respect shall be considered by EIA, based on the capacity fixed for daily production vis-a-vis the requirements of the merchant exporter(s)
- 6.4 Approval to process/handle milk products meant for export by the merchant exporter(s) is given by the EIA concerned as per the format given at Annexure XVA.
- 6.5 Certificate for Export (CFE) issued by the approved establishment meant for export for the merchant exporter/ Export House is to be got counter signed by the EIA concerned, for which a fee as prescribed in clause 17 has to be paid for each certificate by the processor to the EIA concerned. The EIA may collect the monitoring fee directly from the merchant exporter on request from the approved establishment.

- 6.6 When an approved processor requests EIA for cancellation of permission given to process and pack milk products for any merchant exporter, the permission shall be withdrawn using format given at Annexure XVB.

## 7. CHANGE IN THE NAME OF THE COMPANY

- 7.1. In case there is a change in the name of the company, the establishment shall furnish the following documents to the controlling local office of the EIA under whose jurisdiction the establishment is situated:

- (i) Attested/Certified legal documents relating to the change
- (ii) Any other relevant document (Ref: documents listed in clause 2.1.3 e, f, j, k and l)

- 7.2 In the case of request for transfer of approval under a Wet Lease Agreement (an agreement wherein the approved establishment is leased out to another party with all approved facilities including personnel without any change except that the party which has taken the approved establishment on wet lease will be the new processor), or in case of change in ownership without changing the approved facilities including personnel, the processing unit shall furnish the documents mentioned at 7.1 to the EIA.

In addition, the party taking the approved establishment on wet lease or purchase shall also request for transfer of the approval in its name without change of approval number and submit the undertaking and guarantee required to be given by all approved processors, along with other legal documents relating to taking over the establishment on wet lease/sale deed.

On receipt of the above documents EIA In-charge shall examine the validity of such documents and on being satisfied shall approve the change of name/transfer of approval and inform the establishment with intimation to EIC. In case of EU approved establishment, EIC shall inform the change of name to the EU

Note: (i) In the above case, there will not be any physical shifting or restructuring of infrastructure facilities of the factory and the managerial, supervisory personnel, workers and the HACCP programme will continue to be the same.

(ii) As certain time may be required for informing the EU/ importing country, arrangements are to be made for exporting the consignments to the EU/ other country in the name of old company during the interim period

- 7.3 In case there is change in the ownership with change in the premises, manpower or process etc., a fresh approval as per the prescribed norms will be required.

## 8. RESPONSIBILITIES OF THE APPROVED ESTABLISHMENT

### 8.1 General

- a. As the sole responsibility in maintaining the quality and safety of the products processed in the establishment lies with the approved establishment, it shall maintain GHP, GMP and HACCP based own check system. The establishment shall exercise proper controls at all stages of production starting from raw material procurement (including raw milk production control) to the final despatch of the cargo and maintain records thereof. The establishment shall comply with all the regulatory requirements of the GOI Order and Notification S.O 2719 and S.O. 2720 both dated 28<sup>th</sup> November 2000, as well as those specified by the importing country and by EIC from time to time.
- b. Establishments shall maintain all the approved infrastructure and equipment facilities of the unit in good repair. For major alterations/ changes in the infrastructure and equipment facilities, prior approval shall be taken from the Competent Authority.
- c. All the controls and sampling procedures shall be in compliance with GHP, GMP and HACCP.

Proper control of CCPs shall be ensured and any deviation in the process flow or, changes made in the HACCP Manual shall be brought to the notice of the EIA concerned immediately.

Implementation of HACCP shall be monitored at all stages so as to ensure the quality and safety of the product. Time/ temperature controls shall be exercised at all stages of processing, storage and transportation of the material. There should be a proper documented recall procedures incorporated in the HACCP Manual of the establishment.

- d. Traceability of raw milk, permitted chemicals, etc. shall be maintained right from the source of production. The processor shall maintain test reports pertaining to the quality and safety of the raw material and the additives/ preservatives used.
- e. Establishments shall validate the processing method used for pasteurisation, UHT treatment, sterilization etc and calibrate all the recording devices at a laid down frequency appropriate to ensure proper temperature control.
- f. A cleaning and disinfections programme should be implemented to ensure that all parts of the establishment are appropriately cleaned, including tables, utensils, equipments etc. The programme should be continuously and effectively monitored for its suitability and effectiveness and whenever necessary, documented.
- g. Personal hygiene and behaviour of the employees shall be strictly monitored to ensure the safety of products handled. Health cards shall be maintained for all workers handling food products.
- h. Proper control shall be exercised to avoid cross contamination of the product processed.
- i. Suitable pest control measures shall be adopted to eradicate pests inside the factory premises.
- j. Milk products of other establishments should not be permitted to be stored in the approved premises of the establishment without prior permission from the EIA concerned. Moreover, milk products processed in the approved establishment shall not be stored in other establishments without prior permission/approval from EIA
- k. Approved establishments shall ensure that CFE blanks supplied to them are not misplaced or misused. They shall also ensure that the monitoring fees and other fees are paid to the EIA concerned and shall submit copies of CFEs used, on fortnightly basis.
- l. Establishments shall test the raw material, additives, water, finished products, etc. as per the laid down norms or have test reports arranged by suppliers, where necessary.
- m. Establishments shall procure raw milk only from the identified milk production holdings, for which they shall have sufficient control over them to ensure the wholesomeness of the milks.
- n. Any change in the veterinarian/ technologist shall be informed to the EIA concerned immediately.
- o. Wherever, raw milk is used for processing, shall be fit for human consumption.
- p. All equipments must be cleaned and disinfected before processing/packing milk & milk products.
- q. Each particle of raw milk/ milk products shall undergo heat treatment (for example pasteurization, Ultra High Temperature or Sterilization) as quickly as possible so as to make it conform to recognized international standard. If processing is not carried out immediately, liquid milk must be kept at a temperature not more than 4°C. The storage period at 4°C must not exceed 48 hrs or 36 hours if milk is kept at a temperature not exceeding 6°C.
- r. Proper waste disposal system shall be developed to avoid possible cross contamination.
- s. Training shall be imparted to the employees on a laid down frequency.

## 8.2 Quality Control

Proper quality control measures/sampling plan shall be established by the processor, documented and implemented to ensure the wholesomeness of the products processed.

a) Primary Production:

The establishment shall exercise proper controls over the identified Milk Production holdings from which raw milk is being procured. The establishment shall conduct periodic audit for verification of requirements for GHP, Food safety, animal health, water, feed and feed additives, etc. as specified at Annexure IC. The verification may also include testing of samples drawn from the farms, wherever applicable.

*The processor shall initiate procedures to ensure that raw milk meets following criteria:*

<i>Plate count at 30 Deg C (per ML)</i>	<i>&lt; or equal to 100000(*) (For raw cow milk)</i>
	<i>&lt; or equal to 1500000 ( for milk from other species)</i>
<i>Somatic Cell Count (per ml)</i>	<i>&lt;or equal to 400000 (For cow milk )</i>

*\*Rolling geometric average over a two –month period, with at least two samples*

*() Rolling geometric average over a three-month period, with at least one sample per month, unless the Competent Authority specifies another methodology to take account of seasonal variations in production level*

b) Checks for residues of chemical contaminants

Approved establishments shall ensure that the identified milk production holdings, from where the raw milk is being procured, is tested for prohibited pharmacological substances, environmental contaminants, etc. given at Annexure IE. The samples shall be tested by EIC approved lab if the internal facilities are inadequate.

The frequency of testing different parameters is given below:

- Pesticide residues –once in three months
- Heavy Metals- Cadmium, arsenic and lead once in two months and all ~~all~~ once in three months
- Drugs (Total residues of antibiotics as beta lactum)- once in a month
- Aflatoxin (as aflatoxin M1)- Once in two months

The establishment shall have Self Residue Monitoring Plan in place and addressed in HACCP.

Moreover, the consignments meant for export may also be tested for residual parameters as per the requirements of the importing country, whenever required.

c) Organoleptic checks

Organoleptic checks of raw material, process and product samples may also be conducted by the approved veterinarian/ technologist / qualified personnel to ascertain the freshness and other organoleptic qualities of the product, wherever applicable.

d) Microbiological Checks

All batches of milk products after treatment must be tested for pathogens, to verify food safety and process hygiene criteria, the tolerance limit of which is given below.

### Milk Powder and Whey powder

- Enterobacteriaceae- –  $n = 5$ ,  $c = 0$ ,  $m = 10$  cfu/ gm ,  $M = 10$ cfu/gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ )(It is at the end of manufacturing process)
- Salmonella –  $n = 5$ ,  $c = 0$ ,  $m =$  Absent in 25 gm ,  $M =$  Absent in 25 gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ) (It applies when products are placed on the market during their shelf life)
- Coagulase positive staphylococci –  $n = 5$ ,  $c = 2$ ,  $m = 10$ cfu/ gm ,  $M = 100$  cfu/ gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ) (It is at the end of manufacturing process)

### Ice-cream

- Salmonella –  $n = 5$ ,  $c = 0$ ,  $m =$  Absent in 25 gm ,  $M =$  Absent in 25 gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ) (It applies when products are placed on the market during their shelf life)
- Enterobacteriaceae- –  $n = 5$ ,  $c = 2$ ,  $m = 10$  cfu/ gm ,  $M = 100$ cfu/gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ )(It applies at the end of manufacturing process)

### Cheese, Milk powder & whey powder

- Staphylococcal enterotoxins-  $n=5$ ,  $c=0$ ,  $m=$  not detected in 25 gm,  $M=$  not detected in 25 gm, where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ) (It applies when products are placed on the market during their shelf life)

### Dried Infant formula and dried dietary foods

- Enterobacter sakazaki-  $n=30$ , $c=0$ ,  $m=$ Absent in 10 gm,  $M=$  Absent in 10 gm gm where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ) (It applies when products are placed on the market during their shelf life)
- Enterobacteriaceae-  $n = 10$ ,  $c = 0$ ,  $m =$  Absent in 10 gm ,  $M =$  Absent in 10 gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ )(It applies at the end of the manufacturing process)

### Pasteurised milk and other pasteurised liquid Dairy products

- Enterobacteriaceae-  $n = 5$ ,  $c = 2$ ,  $m = <1$  cfu/ml,  $M = 5$ cfu/ml (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ )(it applies at the end of manufacturing process)

### Cheese made from milk or whey that has undergone heat treatment

- E. coli-  $n = 5$ ,  $c = 2$ ,  $m = <100$  cfu/gm,  $M = 1000$ cfu/gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ), (it applies at the time during manufacturing process when count is expected to be highest)

### Unripened soft cheese (fresh Cheese) made from milk or whey that has undergone pasteurisation or a stronger heat treatment

- Coagulase positive staphylococci-  $n = 5$ ,  $c = 2$ ,  $m = <10$  cfu/gm,  $M = 100$ cfu/gm (where  $n$  = number of units comprising the sample,  $c$  = number of sample units giving values between  $m$  and  $M$ ), (it applies at the end of manufacturing)

In addition the milk products to be tested for pathogens as mentioned in the notification.

### Sanitation and hygiene control samples

Sanitation and hygiene control samples from food contact surfaces and workers hand shall be tested for TPC, Coliforms and Staph. aureus at least once in fifteen days to ascertain the effectiveness of cleaning and sanitisation.

#### e) Water

Establishments shall exercise proper quality control on water used in their factory. They shall check the microbiological parameters such as TPC and Coliforms in their in-house lab at least once in a fortnight.

Moreover, EU approved establishment shall test water used in the factory for all parameters as per EC Directive No.98/83/EC at least once in two years or whenever the source of water is changed. Water shall also be tested for parameters [Table-A (1) of EC Directive No.98/83/EC] as mentioned in Annexure XVI once in a year.

However, establishments approved for export to countries other than EU shall test water used in the factory as per IS 4251 on yearly basis except for radiological parameters.

#### f) Additives

If additives are being used in the factory it shall be of food grade quality, as acceptable to the importing country.

### 8.3 Records

Proper records shall be maintained by the processor at all stages of production, storage and transportation of milk products including primary production of raw milk(at milk production holdings) and should be made available to the EIA/EIC officials for verification. The processor shall maintain the following basic records.

- ❖ Traceability records pertaining to the raw milks, other food ingredients, additives, preservatives etc.
- ❖ Milk production monitoring records
- ❖ Raw material receiving and evaluation records.
- ❖ Temperature records of chill room (s)/ storage tanks (when in operation), pasteurizer, chillers, driers etc.
- ❖ Quality control records.
- ❖ Consolidated daily production records
- ❖ Packing records
- ❖ Microbiological / chemical test reports pertaining to milk/milk product, water, sanitary samples, other food ingredients, additives, etc.
- ❖ Packing/packaging material records
- ❖ CCP monitoring records
- ❖ Corrective action and verification records
- ❖ Cleaning and sanitation records
- ❖ Pest Control records
- ❖ Calibration records
- ❖ Infrastructure and equipment maintenance records
- ❖ Training records

#### 8.4 *Marking of approval number on export packages.*

Identification mark and details of the approved establishment shall be applied before the product leaves the establishment. However, a new mark need not be applied to a product unless its packing and /or wrapping is removed or it is further processed in another establishment in which case the new mark must indicate the approval number of the establishment where these operations takes place.

The mark may be applied to the wrapping or the packaging, or printed on a label affixed to the package

The approval number along with the specified 'Q' Mark as given below, shall be printed/labelled on all the export packages of milk products. The marks shall be legible and indelible, and the characters easily decipherable and must be clearly displayed for the competent authorities.



Approval No. \_\_\_\_\_

In addition to the general requirements for identification marking, consignments of milk products, destined not for retail but for use as an ingredient in the manufacture of another product, must have a label giving the temperature at which the milk products must be maintained and the period during which conservation may thus be assured.

However, export of milk products without printing "Q" mark on the master cartons will be allowed in case where there is a specific request to that effect from the foreign buyer. In such cases, the exporter shall have to get prior permission from the EIA concerned after submitting relevant document(s). Even in such cases, the approval number of the processing establishment shall legibly printed/labelled on the cartons.

**Note:** Export package means the final package produced before the Customs in India and which is received and checked by the Customs at the importing end.

#### 9. OFFICIAL CONTROL BY THE COMPETENT AUTHORITY

Strict confidentiality shall be maintained in all the official control visits and the establishments should not be given prior information about the visit. The visits shall be conducted unforeseen and unexpected. For proper official control, a three-tier surveillance system will be followed as per details given below:

##### 9.1 Monitoring by EIA officials

9.1.1 EIA officials shall carry out periodic monitoring of the milk product processing establishments to ensure that

- i. All the approved facilities are being maintained by the establishment as per requirements
- ii. All the regulatory requirements and those specified by the importing countries are being complied with and
- iii. The products processed in the establishment conform to specification.

9.1.2 An officer of the level of Assistant Director / Technical Officer, authorised by the controlling officer



shall carry out monitoring.

9.1.3 The monitoring officials shall verify the own checks system adopted by the unit at all stages of production starting from raw material reception to final despatch of the consignment, for which it is essential that unit shall have production at the time of visits. If there is no production in the unit at the time of visit, the processing activity of the unit shall be assessed during subsequent visit.

9.1.4 Frequency of monitoring of milk product establishments:

*On initial approval of units, monitoring visits shall be carried out once in a month. If the performance of the unit is satisfactory for a year and in the absence of any foreign rejection/complaint, the frequency of monitoring shall be reduced to once in two months*

*After satisfactory performance for further one year on the basis of surveillance visits and in the absence of foreign rejection/complaint, the frequency of monitoring shall be reduced to once in three months.*

*When the units have not exported for at least for at least 6 months, the frequency of monitoring visits and supervisory visits by EIA shall be once in 6 months and once in a year respectively.*

In case, at any stage, non-satisfactory performance on account of any major deficiency is observed during monitoring, the monitoring frequency shall be increased to once in a month. However, frequency of monitoring shall not be increased in case of contamination of products with chemical contaminants such as antibiotics, heavy metals or pesticides detected during surveillance visits or at the importing country. In such cases, the frequency of monitoring of milk production holdings shall be increased as decided by the In-charge of the Agency concerned. The performance of the unit, whose monitoring frequency has been increased to once in a month on account of non-satisfactory performance, shall be reviewed after one year. If the performance of the unit during one year is found satisfactory and if there is no foreign rejection/complaint during the period, the frequency of monitoring shall be reduced to once in two months. Further review of frequency of monitoring shall be done after a year as per the above procedure.

The responsibility for periodical review of performance of units and submission of recommendations to the in-charge of EIA shall be that of the controlling field office/ sub office of EIA. The proforma placed at Annexure XVIII shall be used for this purpose. The re-fixation of monitoring frequency shall be done by the in-charge of the Agency. Each EIA shall maintain office-wise records showing name, approval number and frequency of monitoring.

9.1.5 Areas of monitoring

The monitoring shall broadly focus on: -

- *Facility checks:* to ensure that all the approved facilities are being maintained by the unit. This also includes verification of sanitary and hygienic conditions prevalent at all sections of the unit.
- *Verification of traceability.* This include the verification of records maintained by the unit to ensure that raw milk is procured only from the identified milk production holdings, the list of which had already been submitted by the unit. The identified milk production holdings shall also be visited by the monitoring official to verify the hygienic conditions, health conditions of the animals, use of veterinary medicinal products , if any, good veterinary practices (GVP)/ good farming practices, controls exercised by the unit over milk production holding etc.
- *Verification of compliance to the GHP and HACCP* to ensure that the unit has complied with the HACCP in to as envisaged in their HACCP manual and also controls exercised by the unit are adequate and effective. This includes verification of CCP monitoring, GMP, GHP, SOP, SSOP, traceability, good storage practices, raw material / process/ product controls, time/temperature controls, controls on additives/ preservatives, quality management of water, calibration and validation, etc.

- *Verification of testing and lab practices:-* to ensure that the sampling procedures and test methods adopted by the establishment are adequate and reliable. This includes good lab practices followed in in-house lab of the unit, effectiveness of lab chemicals, reliability of testing etc.
- *Verification of records:-* to ensure that the records maintained by the unit are in order and cover all the controls exercised by the unit.
- *Fraud control:-* to ensure that the unit is not violating the laid down norms. This includes violations with respect to export of milk products processed in un-authorized places, storages of milk products from other establishments without prior permission, misuse of CFE, improper labelling, exceeding capacity limits etc.
- *Drawl of official samples:-* to ensure the wholesomeness of the products and effectiveness of cleaning and sanitation. This includes drawl of sanitary samples, samples for testing microbial parameters, organoleptic checks etc. and residual parameters, whenever required.

*Note.* Detailed HACCP auditing may be done at least once in a year. However, all the other areas shall be covered during each monitoring visit, including verification of HACCP records and the own check systems adopted by the unit.

### 9.1.6 Additional Checks

The monitoring officials shall also check and record the following:

- Chlorination levels of water used for disinfecting feet, hands, and washing utensils/ equipment, etc., wherever applicable. It should be thoroughly rinsed with potable plain water after disinfecting. A general guideline for chlorination in the establishment is given below:

Hand disinfection	20 ppm.
Food Contact surfaces	100 – 200 ppm.
Floor, walls, etc.	100 - 200 ppm.
Foot dip	100ppm

Any other acceptable disinfectant / sanitizer may be used for the purpose and should be addressed in the HACCP.

- Temperature of liquid milk products after cooling.
- Temperature of milk store/ silos
- Temperature of milk/ milk products in the silo/stores after pasteurization.
- Temperature of powder store.
- Temperature of frozen products, chilled products
- Pasteurization temperature and time/equivalent flow rate of the liquid.

### 9.1.7 Raw material checks

Monitoring officials shall conduct various quality checks on the available raw milk procured by the unit/establishment from identified milk production holdings for its freshness and wholesomeness. For this purpose, samples shall be selected from different sources of raw milk available at the time of the visit. Raw milk not meeting the standards shall not be allowed for further processing. The observations shall be recorded in the monitoring report and also in the milk procurement register maintained by the processor. It shall be ensured that only clean and fit for human consumption raw milk is accepted for further processing.

### 9.1.8 Microbiological/Chemical checks

The monitoring officials shall also draw samples for testing microbiological and chemical parameters,

as per the details given below:

S. No.	Parameters	Products/ Stage	Frequency
1	TPC, Enterobacteriaceae, Salmonella, coagulase positive staphylococci, other pathogens as per notification	Finished milk products	Every monitoring visit
2	TPC, Coliforms	Water	Every monitoring visit
3	TPC, Coliforms	Swabs from food contact surfaces	Every monitoring visit
4	TPC, Coliforms, S.aureus,	Swabs from worker's hand	Every monitoring visit

*Note: In case of difficulties in testing samples at EIA laboratories due to storage/transportation of samples, the same may be tested at any EIC approved laboratories.*

#### 9.1.9 Sampling scale and sampling procedures

##### (i) Microbiological analysis

One sample of 500 gm./ml of finished milk product shall be drawn for testing the microbial parameters mentioned at Sl. No. 1 of clause 9.1.8.

##### (ii) Sanitary samples

Monitoring officials shall draw samples for checking the sanitary conditions and hygienic practices of the establishment as shown below:

(a)	Water used in the factory	1 sample of 1 ltr.
(b)	Swabs (1) Food contact surface (2) Workers hand	1 sample 1 sample

The above swab samples shall be drawn either before start of the work or after normal cleaning if processing is in progress, adopting the following procedure:

##### Water

Water sample is collected from taps (Tap number to be mentioned in the sample covering notes) in sterile bottles /conical flasks of 1 litre capacity with ground flask stoppers having an overhanging rim. They are sterilised at 160°C for 1 hour after being covered by Kraft paper. The opening and closing of the sterile bottle must be done with meticulous care to avoid any contamination. When water sample is drawn from a tap, flame the tip of the tap using spirit and allow water to flow for 5 minutes before collection. In case the test is to be undertaken after 3 hours, the bottle must be kept in ice. If sample is to be taken from chlorinated water supply, it is important that any trace of chlorine should be neutralized immediately after collection. A crystal of sodium thiosulphate or 0.1 ml. of 2% solution of thiosulphate introduced into the sampling bottle prior to sterilisation serves neutralisation of chlorine. Immediately before testing, the water sample should be mixed by inverting the bottle several times. Thereafter some of the contents are poured off, the stopper is replaced and the bottle is shaken vigorously up and down.

##### Swab from worker's hand and food contact surfaces

##### Collection of Swabs:

25.cm<sup>2</sup>. area is swabbed using a square template of 5 cm x5 cms. The swab is moved through a distance 12.5 cms. during the swabbing operation .A steel template of correct size, which can be readily sterilized by alcohol flaming can be used to outline the area.

First wipe the swab slowly and firmly in an interior direction through a distance of 12.5 cms. Rotate the swab against the direction of the overall wiping movement. Then stroke the area in the same direction three times, turning the swab slightly between strokes. Finally roll the swab once over the wiped area, but in the opposite direction from that in which the original strokes were made. This will serve to pick up whatever may be adhering to the surface. Place the swab immediately into bottle containing 100ml. of the diluents, in a wide mouthed 4oz. sample bottle. Pull the stick free if the swab in the medium is to be transported, hold it under the same condition as water samples are being transported i.e. hold it below 5°C until analysed.

The sample collected shall be transported to the laboratory in the usual manner under sealed condition and accompanied by covering note containing details of tests to be carried out.

#### Maximum Permissible limits

S.No	Samples	TPC at 37°C	Coliforms	S. aureus
1.	Water	20 per ml**	Absent in 100 ml (MPN)	--
2.	Food contact surfaces	100 per cm <sup>2</sup>	Absent / cm <sup>2</sup>	--
3.	Worker's Hand	100 per cm <sup>2</sup>	Absent / cm <sup>2</sup>	Absent / cm <sup>2</sup>

*Note* \*\* For establishments approved only for non-EU, the limit of TPC in water is 50 per ml.

#### (vi) Proficiency testing of the in-house laboratory of the processing establishments.

In order to ascertain the proficiency of the in-house lab of the establishment, the monitoring officials shall draw aseptically 2 sets of samples (one sample divided into 2 sets) from the selected production batch during the monitoring at least once in a year. One set of sample is sent to EIA Lab and the other set is sent to the in-house lab of the establishment for testing all microbiological parameters specified at Cl. 9.1.8. No fee will be charged from the processor for this purpose.

The test results shall be compared by the EIA and if variation more than 10% is observed, same will be communicated to the unit for corrective action and subsequent verification and sampling by EIA

#### (vii) Analysis for chemical contaminants

Samples for analysing chemical contaminants shall be drawn as per Residue Monitoring Plan (RMP) of EIC, whenever applicable.

#### (viii) Sampling scale for finished products:

The number of packages selected for preparing composite laboratory sample shall be  $(\sqrt{n+1})/2$ ; where n= total number of packages in a batch / lot / consignment.

Note: If the fractional number is less than 0.5, it should be rounded off to the lower digit and if it is 0.5 and above, the same shall be rounded off to the higher digit

#### 9.1.10 Reporting system

After completing the monitoring, the report shall be prepared in the Monitoring Report Pro-forma (Annexure XVII). The reports shall be submitted to the controlling office of EIA within three working days of the visit along with Non Conformity Report (NCR) as per Annexure VIIA and Suggestions for Improvement (Annexure VIIA), if any.

Similarly, the report for farm monitoring shall be submitted in the Farm Monitoring Report Pro-forma (Annexure VIIC).

Sub Office shall send a copy of Monitoring Report, test report, NCR and Suggestion Report to HO on monthly basis for all the establishments. In case of failure of the samples, it shall be intimated to the processor. Test reports can also be given to the processor if specific requests have been made for the same.

Formats of Non Conformity Report (NCR) and Suggestion Report are placed at Annexure XVIIIA and Annexure XVIIIB respectively. This format shall be used during monitoring visits/supervisory visits as well as in other surveillance visits.

Non-conformities observed during the surveillance visits shall be recorded in the NCR and shall be provided to the establishment for taking corrective action/rectification of deficiencies within an agreed time period, which is determined, based on gravity of the deficiencies. The monitoring official shall also mention in the NCR, the earlier deficiencies which are not rectified by the unit. The monitoring report along with the copy of NCR shall be submitted to the controlling officer of the sub-office or to the Deputy Director (In-charge) of Food Division/Scheme within three working days for scrutiny, acceptance and follow up action.

In case of sub-office, copy of the Monitoring Visit Reports along with relevant laboratory analysis reports shall be sent to EIA-HO for records.

## 9.2 Supervisory visit

Supervisory visit shall be carried out by an officer of the level of Deputy Director and above from the Agency concerned having adequate experience in operation of Food Scheme. The frequency of supervisory visits shall be once in six months.

The Supervisory visit shall be conducted for

1. checking the documentation and compliance of the requirements of the EC Directives in case of EU approved units and GOI Notifications,
2. performance of the monitoring visits carried out by the monitoring officers.
3. performance of the tasks carried out by the approved veterinarian(s)

Samples if any, drawn during such visits shall be sent to the laboratories of Agency concerned. Test report shall be made available within one week. The report of supervisory visit shall be submitted within three working days to the In-charge of the Agency concerned.

In addition, the availability of water test reports from EIA laboratory or EIC approved laboratory for complete testing as applicable shall be checked

The pro-forma of Supervisory Visit Report is given at Annexure XVIII

A copy of each Supervisory Visit Report shall be maintained in the files of Export Inspection Agency HO as well as controlling sub-office.

## 9.3 Corporate Audit

Audit of each Agency will be carried out at the frequency of at least once in a year. The main objective of the corporate audit is to ensure uniform implementation of the rules and regulations issued by the Competent Authority and shall comprise:-

- Examination of records of processor maintained by the Agency like reports of visits, lab reports, approval/renewal of approval etc.
- Visit by the audit team to at least 10% of the approved establishments, subject to a minimum of one.
- The audit team shall comprise of at least two officers from the other Agency(ies) and/or EIC, of the level of Deputy Director having adequate experience in operation of Food Scheme or in

unavoidable circumstances, senior Assistant Director having adequate experience in operation of specific Food Scheme, as nominated by Director (I&QC). If required, experts from outside can also be included in the corporate audit team. The report of audit shall be submitted to Director (I&QC) as per format specified at Annexure XIX.

## 10 GUIDELINES FOR DEALING WITH UNSATISFACTORY MONITORING OR OTHER VISIT REPORTS AND / OR TEST REPORTS AND VIOLATIONS

### 10.1 Deficiencies.

- a) The deficiencies, which do not affect the wholesomeness (food safety) of the products shall be considered as minor deficiencies and those which affect the safety of the food product shall be considered as major deficiencies.
- b) A number of minor deficiencies or repeated minor deficiencies indicating a system failure would also be treated as major deficiency.

***Some of the other Major deficiencies are as follows:***

*\*Contamination with pathogens (Salmonella, enterobacteriaceae, etc.) or with hazardous substances like heavy metals, antibiotics, pesticide residues etc. above permissible limits shall be considered as major deficiency.*

*\*Failure of sanitary samples for TPC, Coliforms or S. aureus in three consecutive instances may be considered as major deficiency*

### 10.2 Actions to be taken in case of deficiencies observed

10.2.1 In case of minor deficiencies observed during the visit, the non-conformities shall be communicated to the processor through the NCR and EIA officer shall verify the corrective actions taken by the processor, during the subsequent visit. However, if the processor fails to rectify the defects within the agreed time period, then the action specified at 10.2.2 shall be followed.

10.2.2 In case of major deficiencies observed during the visits, the explanation of the processor may be called with time frame for rectification. Further, any one or more of the following actions may be taken depending on the nature of deficiencies, with approval of the Director, EIC.

- (i) The processor may be placed under consignment-wise inspection until the rectification is carried out and verified to EIAs satisfaction by an on-site visit by Deputy Director level officer.

In case of failure on account of chemical contaminants, the approved processor shall suspend procurement of raw milk from the specific source immediately until the appropriate corrective action has been taken by the milk production holding(s). Subsequently, the samples of raw milk drawn from the specific source shall be tested for the specific contaminant(s), the cost of which shall be borne by the processor as per clause No. 17.

- (ii) The processor may be advised to suspend production and export until rectification is carried out and verified by an on-site visit by Deputy Director level Officer. However, during the suspension period production may be permitted if requested by the processor, in un-avoidable circumstances with the approval of the Competent Authority under the supervision of an EIA Officer for which fee applicable for deputation of an officer has to be paid by the processor as per clause 17, to the EIA concerned.

- Revocation of suspension, if required as per (ii) above, shall be done with due approval of Director (I & QC).

### 10.3 Action against violations

In case of violations, such as (i) misuse of Certificates for Export (CFE) (ii) Storing of milk products at un-authorised premises (iii) Non-payment of monitoring fee (iv) processing of milk/manufacturing of

milk products in unauthorised establishments (v) major failure in meeting GMP/GHP/HACCP etc., have been detected, the following penalties shall be imposed on the defaulting unit by the Competent Authority with due approval of the Director (I&QC).

- (a) A show - cause notice shall be issued by the EIA to the unit, for which the unit has to submit a reply within one week along with a statement of stock declared as on date. Meanwhile, the Competent Authority would suspend the Export production of the milk products in the establishment from the date of the issuance of the letter. No production is allowed during that period. However, stock in hand may be allowed to be exported in special cases after due consideration with the written permission of the C.A.
- (b) If the same violation is observed for a second time in the same unit, the unit would be suspended from production and exports for a period of three months.
- (c) If the same violation is reported for a third time or more than two malpractices reported in a period of six months, Competent Authority may withdraw the approval granted to the unit.
- (d) When the show cause notice is issued by the EIA, processor may contact the competent authority, if he/she wishes so, to explain his/her side.

#### 11. ACTION TO BE TAKEN IN CASE FAILURE OF SAMPLES DRAWN DURING RMP

When the samples drawn for Residue Monitoring Plan (RMP) fails to meet the requirements, EIA shall take appropriate action as specified in the RMP.

#### 12. PROCEDURES TO BE FOLLOWED WHEN AN APPROVED PROCESSING ESTABLISHMENT TEMPORARILY SUSPENDS ITS PRODUCTION

When an approved establishment decides to suspend its processing activities temporarily for a period exceeding thirty days for reasons such as:

- (i) General repairs/routine maintenance
- (ii) Improving their hygienic and sanitary conditions
- (iii) Identifying the cause of contamination and taking corrective action to prevent recurrence
- (iv) Major alteration/construction work etc.
- (v) Any other activities, which may result in change in production flow or give scope for contamination of milk products etc.
  - The processor shall intimate the local office of the EIA, the date from which it intends to suspend its operation, the purpose and the probable date by which it intends to resume its production activity.
  - Upon receipt of intimation, EIA may discontinue monitoring visit/Supervisory Visit to the establishment. The processor shall not commence production without prior permission from EIA.
  - When the establishment is ready to resume production, the processor shall request EIA concerned for permission to commence production. Before granting permission to start production, the EIA concerned shall take following actions:
    - For (i), (ii) and (iii) the establishment shall be assessed by the monitoring officer to ensure satisfactory conditions after carrying out the changes.
    - For (iv) and (v) the establishment shall be assessed by a team of EIA officers or by an IDP as decided by In-charge of the EIA to ensure satisfactory conditions.

Note: During monitoring visits if it is observed that the unit is not having production for the past one month, the unit shall be allowed to start production only after the satisfactory on-site assessment by the monitoring official(s) deputed by the In-charge of the Agency

**13. INFORMATION AND RECORD**

Further, updated information shall be maintained by each Sub Office and HO of every EIA. The monthly statements of updated information shall be sent by each Sub Office to the Head Office of Agency concerned on every first working day of the following month, in the required formats, for compiling and updating information for the Agency, for further submission to EIC as and when required

**14. REPORTING TO EIC**

Each Sub Office shall send the monthly reports to the Head Office of Agency concerned by first working day of the following month and the Agency shall compile the following information in the required format for submission to EIC as per the time frame given at clause 15.

- Details of monitoring and supervisory visits planned and carried out as per Annexure XXIII.
- Change in the list of approved milk product establishments as per Annexure XXIV
- Details of monitoring samples failed as per Annexure XXV.
- Status of the establishment having foreign rejections as per Annexure XXVI.

**15. TIME FRAMES: Time frames prescribed for various activities shall be as under:**

* Submission of reports of monitoring and supervisory visits	Three working days	
* Testing of monitoring samples in EIA Laboratories	1 week	
* Submission of monthly reports to EIC	by 7 <sup>th</sup> of succeeding month	
* Closure of complaints	<i>From foreign buyers</i>	Maximum of 3 months or time taken to offer 10 consignments for inspection, whichever is earlier.
	In case of rejection consignments	After testing of returned consignments.

**16 EXPORT CERTIFICATION****16.1 Certificate for Export (CFE)****16.1.1 Procedure**

Since all the consignments of milk Products meant for export should undergo quality control and inspection prior to shipment and should be accompanied by a Certificate for Export (CFE) as per the format given at Annexure XXI, the approved processing units shall issue a Certificate for Export (validity for which shall be forty five days from the date of issue) for every export consignment.

Certificate blanks shall be obtained from the EIA concerned by payment of charges as per clause 17. Each set of certificate blank will consist of original (in white) intended for Indian Customs; duplicate (in pink) to be forwarded to the local office of EIA and the last two copies (in green and blue) for the use of the processing unit. EIAs shall maintain proper records of issuance of blank CFEs and their utilisation by the establishments.

The responsibility for the maintenance and proper utilisation of the CFEs issued to them lies with the approved establishment. They shall issue CFEs only for those milk products that are processed in their approved establishment and have undergone all the quality checks/ tests specified. The establishment is liable for penal action for the misuse of CFEs issued to them.



Only persons authorised by the establishment shall be allowed to sign the CFEs and the list of persons authorised to sign CFEs shall be made available to the EIA.

If the validity of CFE is expired, then the same can be revalidated upto another thirty days and the monitoring fee will not be charged again, if there is no upward revision in FOB value. However no refund will be given in case of downward revision in FOB value.

In case of cancellation or damage of CFE, the establishment has to submit the original of the cancelled CFE to EIA, with other three copies (full set) and original Health Certificate (HC) (if already issued) pertaining to the CFE.

#### 16.1.2 Issuance of Certificate for Export

- 16.1.2.1 Books of CFE blanks shall be issued on request from the approved processing establishment only after the approval of DD In-charge of the scheme/ officer in-charge and after the previous CFEs issued have been accounted for and paid for. However exporters may have up to 5 sets remaining so as not to cause any operational problems.
- 16.1.2.2 Every approved processing unit must have a Pass Book account system operating with the controlling office of EIA. The processor shall ensure that adequate balance is always maintained in their deposit account with EIA for the payment of monitoring fee and other certification fee. No CFE blanks shall be issued unless there is adequate balance in their account.
- 16.1.2.3 In case of lost certificates, exporter shall submit an indemnity bond to that effect to the EIA concerned as per the format given at Annexure-XXII. EIA, in turn, shall inform the Customs to check that those numbers have not been presented to them. Further, Customs shall be informed not to accept those specific certificates in future.

#### 16.1.3 Statement of Certificates for Export issued

- 16.1.3.1 Every approved establishment shall submit periodic statement of Certificate for Export issued, *enclosing the pink copy* of CFE on fortnightly basis for the export of milk products in the pro-forma given at Annexure XXIA. Nil statement shall be submitted in case of no exports during the period. Based on the statement submitted by the approved establishments, local EIA office shall debit monitoring fee from the deposit account of the establishment as per clause 17.
- 16.1.3.2 The pink copy of every CFE issued along with the related production batch details, product/variety wise packing list and invoice copy shall be attached to the statement. In case, the pink copy of the CFE has already been submitted to EIA for obtaining Health Certificate or any other purpose, this may be indicated in the remarks column.
- 16.1.3.3 if the approved establishments are not submitting the statements even after fifteen days, no further CFE blanks shall be issued to them. Moreover, a show-cause notice may be issued to the establishment as to why the production and export may not be suspended by the Competent Authority.

#### 16.2 Health Certificate Issuance

##### 16.2.1 General

All consignment of Indian milk products exported to the EU are required to be accompanied by a numbered original health certificate, in accordance with the model Annexure XXA duly completed, signed and dated. The model health certificate meant for the Non-EU approved establishments is placed at Annexure XXB. The original of the health certificate is required for customs clearance at the destination and shall be made available to the customs authorities at the destination before the arrival of the consignment. The consignments cannot be cleared on the basis of a copy of the original or on the basis of a fax copy of the original. Health Certificate should be issued before or on the day of shipment and cannot be issued retrospectively.

Note:

1. If Health Certificate is lost in transit or otherwise, the establishment may request for issuance of a duplicate health certificate by submitting an indemnity bond (Annexure XXII) in a non judicial stamp paper stating clearly that if found later, the same will not be reused for any further export but shall be surrendered to EIA for further action. Under such circumstances a duplicate health certificate may be issued in lieu of the lost health certificate and the establishment shall pay charges as per Clause No.17.
2. The EIA may issue corrigendum or addendum or clarification to the health certificate already issued after examination of the request from the approved establishment for the purpose of ascertaining its genuineness. In such cases, prescribed fee for issuance of corrigendum or addendum or clarification shall be charged as per clause 17.

#### 16.2.2 Procedure:

- (i) The Health Certificate shall be issued only for milk products processed in establishments, approved and monitored by the EIA.

The processor/exporter shall request for health certificate from the controlling office of EIA with the following:

- a. Application in the prescribed format as per Annexure XXE giving all necessary information
  - b. Authorisation to EIA to debit fee as per Clause No.17, as applicable, from its deposit account at EIA
  - c. The pink copy of the Certificate for Export issued by the approved establishment.
  - d. Invoice copy
  - e. Declaration pertaining to the details to be mentioned in the health certificate including the product is produced as per the requirement, meets specifications of the importing country and is fit for human consumption.
  - f. *Certificate of analysis.( for residues, drugs and heavy metals for the period of production of the consignment and the additional parameters to be indicated in the health certificate clearly indicating about compliance of the consignment as per the requirement of importing country. Certificate of analysis should be from EIC approved lab if in-house testing facilities are inadequate)*
- (ii) In case certificate is required in foreign language other than English additional charges will be levied as per Clause No. 17.
  - (iii) The controlling local office of the EIA responsible for monitoring the units shall issue health certificate to the processor/exporter after satisfying itself that the milk products are processed in approved establishments having valid approval number and after satisfying the relevant requirements such as testing of every control unit (Production batch) by the unit for organoleptic, chemical and bacteriological factors and maintenance of test records.  
It shall be noted that the approved establishment shall test the milks and finished milk products periodically for chemical contaminants as per requirements.
  - (iv) Health certificate shall be prepared in duplicate, the original for the exporter for forwarding to the importer, other copy for record of local EIA. Statement of health certificates issued shall be sent to Head Office on monthly basis.
  - (v) The certificate shall consist of single page printed on both sides and where additional pages are attached; all the pages should form the part of certificate and cannot be separated.
  - (vi) Where additional pages are attached to the certificate, the signature and stamp of the certifying official shall appear on each page and each page shall be numbered ' x- (page number) of y (total number of pages)' on the bottom and shall bear the Certificate reference

number of the certificate allotted by the Competent authority on the top.

- (vii) Each health certificate shall bear the name, designation and signature of the representative of EIA and the official stamp of EIC in a colour different from that of other endorsements. While issuing health certificate, the issuing officer must ensure that the colour of the signature is different from the colour of the printing of certificate. Since the certificate is usually printed in black, the signature must not be in black colour. The signature shall be in blue or red colour on the original of the certificate. The copies of the certificate shall have the carbon impression of the signature. The colour of the stamp shall also be different from that of the printing.

- (viii) Reference number of health certificate:

Since no two certificates issued from India should have the same number, the given below system shall be followed for giving the reference number:

Each Sub-office shall give serial number for each health certificate issued prefixed by Agency/Sub-Office codes.

For Example:

Sub-Office:

EIA-Chennai, SO:Hyderabad	MP/CH/HY
EIA-Kochi, SO:Bangalore	MP/CN/BL

As an example, the certificate issued by Sub-office: Bangalore will have a reference number: MP/CN/BL/1, MP/CN/BL/2...

- (ix) Annexes, if any, such as results of analysis shall have the same reference number as that of the health certificate.
- (x) In case, the importing country requires any additional health attestation pertaining to the health/ disease status of the milch animals, the approved establishment shall obtain the same from the State Veterinary Department as per Annexure XXD and submit to the EIA concerned for necessary attestation in the Health Certificate along with a declaration as per Annexure XXC and the application as per Annexure XXE. Based on the animal health attestation from the State Veterinary Department, the EIA concerned shall issue health certificate incorporating the required information.
- (xi) The health certificate shall be valid for 10 days from the date of issue, unless otherwise stated. However, the term of validity shall be extended by the time taken by the voyage for transport by ship, as declared by the processor/exporter.(can be changed)

## 17. FEE STRUCTURE

The prescribed fee shall be paid in the form of Demand draft / bankers cheque in favour of Export Inspection Agency concerned or through the deposit account held at the Export Inspection Agency concerned as applicable.

<u>Sl. No.</u>	<u>Activity</u>	<u>Fee (in Rs.)</u>
1.	Application for approval / renewal of approval of establishment	Rs 2000/- towards application fee and Rs.3000/- towards other charges including adequacy audit.
2.	Application for approval of additional activity / facility	Rs.5000/-
3.	Application for approval / renewal of approval of veterinarian/ technologist	Rs.2000/-
4.	Monitoring fee	@ 0.2% of FOB value of exports

5.	Countersigning of Certificate for Export (CFE) for Merchant Exporter	Rs.100/- as Service Charge
6.	Consignment-wise Inspection on account of official control (as per clause 10.2.2 (ii) <i>and in other cases</i> )	@ 0.3% of the FOB value of exports (including monitoring fee) + Testing charges
8.	Issue of Health Certificate	Rs.100/-
9.	Issuance of corrigendum or addendum or clarification to Health Certificate	Rs.100/-
10.	Issuance of Health Certificate in Foreign Language other than English	Rs.100/- + other actual expenses
11.	Verification of corrective actions/measures taken by the establishment on account of complaints or major deficiencies	Rs.2000/- per man-day
12	Deputation of an officer to verify reprocessing /rectification of deficiencies on account of complaints or major deficiencies	Rs.2000/- per man-day
13	Visit for additional monitoring / drawing samples for testing on account of complaint for importing countries	Rs.2000/- per man-day + Testing charges
14	Drawing samples at the request of the processor	Rs.2000/- per man-day
15	Certificate for Export (CFE) blanks	Rs.20/- per set

## 18. PROCEDURE TO BE FOLLOWED FOR COMPLAINTS RECEIVED FROM IMPORTING COUNTRIES

### 18.1 General

When a complaint is received from the importing country or a consignment of milk product is detained or specific control measures are imposed by the importing countries on food safety grounds such as product contamination with pathogenic micro organisms or with residues (antibiotic, pesticides, etc.) or any complaint due to failure in quality parameters, the following procedure shall be adopted in order to prevent recurrence and deal with the rejected consignment.

- 18.2 In case of receipt of information directly by the exporter regarding rejection of the cargo by overseas health authorities in any importing country, the exporter shall inform the EIA concerned immediately with a copy to Export Inspection Council of India (in case of Merchant exporter, a copy of the communication will also be sent to the manufacturer/ processor).

In case of receipt of complaint at EIC it shall immediately be referred to the EIA concerned. EIC may simultaneously seek complete details from the complainant.

- 18.3 The processing unit shall immediately be placed 'on alert' by the EIA concerned, which will mean

- frequency of monitoring visit shall be increased to two visits/month.
- In case the situation is due to in-process contamination such as pathogens, permitted pharmacological substances, other permitted substances (such as Phosphates, antioxidants, etc.), etc. above the permissible level, or the situation is due to environmental contamination such as, PCB, dioxin, pesticides, etc. or use of prohibited pharmacological substances (Chloramphenicol, Nitrofurans, etc.), etc. ten consecutive consignments shall be subjected to consignment-wise testing for the specific contaminant. For this purpose samples are drawn from all the batches of the consignment to make a composite sample. In case of rejection due to failure in quality parameters, next ten consignments are inspected for organoleptic factors, microbiological factors. The inspected consignments shall be allowed for export to EU or Non-EU, only after satisfactory test results of the EIA-laboratory or EIC approved laboratory for the specific parameter(s). However, if the consignment fails for any of the parameters tested, the consignment may be re-tested batch wise on request from the exporter/ manufacturer and only those batches, conforming to the specification for specific parameter(s) shall be allowed for export.

- The increased monitoring frequency shall be discontinued at a stage where the four consecutive monitoring visit reports and test reports are satisfactory.

Note : Charges as per clause No. 17 shall be paid by the processor for the every additional visit for monitoring/sampling for re-testing, if any. Cost of testing and retesting, if any, of ten consecutive consignments, shall also be borne by the processor.

18.4 EIA shall seek complete information in detail about the consignment in question from the processor as given below:

- a) Full particulars of the consignment such as product name, quantity, batch no./grade list along with attested copies of related documents such as purchase order/ letter of credit, certificate for export, health certificate, bill of lading, test reports etc. and also source of raw materials used for processing and export details. (Details regarding prices need not be furnished by the exporter/processor).
- b) Details of whereabouts of the consignment.
- c) The particulars of milk products held in stock.
- d) If the processor has got the consignment in question, analysed independently or surveyed by an independent surveyor, in the country where it was detained, the copies of such test/survey reports shall be made available to the competent authority for examination.
- e) Corrective action(s) proposed/taken by the processor to prevent recurrence of the problem.

18.5 EIA shall immediately arrange a visit by a panel of experts (within a week) to the processing unit for

- Collection of information as required in 18.4 above, if the same has not been furnished in time.
- Assessment of the processing establishment to determine the cause of specific contamination.

Assessment of the processing establishment shall be carried out by a team of two senior officers from EIA. During the assessment the following shall be checked:

- a) The implementation of HACCP with respect to the specific contaminant/ contamination.
- b) The Controls to prevent specific contamination in the product and appropriate laboratory analysis for the verification of the same.
- c) The Corrective action(s) proposed/taken.

In addition, appropriate samples of swabs for sanitation and Hygiene control; raw material, water, feed, in-process product, finished product, etc., as applicable for cause of contamination may be drawn and tested in EIA laboratory /EIC approved laboratory.

Note: *During assessment, it may be necessary to assess GMP and personal hygiene with specific reference to the cause of rejection. It may not be necessary to have a fresh assessment related to infrastructure facilities and other aspects of HACCP. Sanitation and hygiene control samples, additives etc. need only to be tested in relation to the specific cause of rejection.*

18.6 Based on the assessment, the team shall prepare a detailed report and submit to the Head Office of the EIA. This report shall contain the following information as appropriate and applicable to the specific contamination:

- a) Details of checks/controls for the specific pathogen/contaminant on raw materials from different sources and subsequent follow-up action planned and carried out by the processor.
- b) Disinfection methods, which are normally carried out in the unit to sanitise equipment/tools used in processing and in handling raw material following GMP.
- c) Systems established in the unit to *ensure* hygienic conditions in various phases of processing milk products.

- d) Periodic checks and other controls effected by the unit after the knowledge of product contamination with scope to guarantee the hygienic condition.
- e) Adequacy or otherwise of the checks, laboratory testing and other controls on raw materials, in-process products and finished products. Whether disinfectant level of water for various activities are properly maintained, checked at regular intervals and records are maintained. Whether the unit has conducted testing of water at the laid down frequency and records are maintained.
- f) Whether or not the processing establishment is capable of producing safe milk products.
- g) Whether HACCP plan is adequate and HACCP-based procedures are in place as per plan
- h) Findings on the possible reasons for complaint.

The Head office of EIA shall communicate the deficiencies, if any, observed during the assessment, to the processor in writing for remedial action.

## 18.7 Dealing with returned consignments

18.7.1 If the consignment has been brought back to India, it shall be stored in an approved storage. The processor shall inform the details of the storage of the consignment to the EIA concerned, which in turn shall be informed to EIC.

18.7.2 On receiving the above intimation the following actions shall be taken:

- (a) The local office of EIA shall arrange to get the consignment inspected/tested for organoleptic factors, microbiological factors and chemical factors, as applicable. One composite sample each from every production batch shall be tested for the specific contaminant at two different laboratories. For this purpose, testing shall be done at EIA Laboratory or EIC approved laboratory. The results shall be communicated to the Agency Head Office. The charges for visit and testing shall be payable by the processor as per clause 17.
- (b) If all the samples tested from the brought back consignment show negative results for the specific contaminant(s), the In-charge of EIA concerned may take decision to release the consignment for export to the country other than the country/ union of countries where the consignment had been rejected.

**Note:** Export Inspection Council where considered necessary may inform results to MoCI as well as EC/importing country.

- (c) If any of the samples tested from the consignment brought back on account of food safety complaint shows positive results, the processor shall dispose of (reprocess or destroy) the consignment in a manner acceptable to In-charge of EIA concerned.
- (d) The schedule of reprocessing shall be furnished to the local Office of EIA by the processor for arranging supervision of reprocessing.
- (e) The processor shall offer the reprocessed consignment for inspection by EIA.
- (f) EIA shall inspect the reprocessed products batch-wise for all parameters as per the sampling plan as given at clause No. 9.1.9 (x).
- (g) The fee for EIA supervision with regard to reprocessing shall be as per clause 17, in addition to the charges towards consignment-wise inspection Testing fee shall be borne by the processor.

**Note:** *Reprocessing is not applicable in case of rejection due to residues of prohibited substances, environmental contamination, etc.*

- (h) If the reprocessed products are found export worthy on inspection, the lots/batches shall be allowed for export to countries other than the country or union of countries where it had been detained prior to its reprocessing.

*Note: In the case of a sample from the returned consignment testing positive for residues, the batches testing positive will not be permitted for exports.*

18.8 If the following points are satisfactory:

- a) The consignment if brought back, on account of the complaint and tested for the contaminant is found free of the contamination/ defects as evidenced by the test reports/ organoleptic reports.
- b) The assessment report indicates that the processing establishment has been maintaining proper hygienic conditions and implementing HACCP.
- c) The periodical monitoring conducted by EIA during the past three months indicates satisfactory hygienic conditions in the unit.
- d) Samples drawn during the assessment visit conforms to the requirements.

EIA shall put up the case with relevant papers/reports to the Director (I&QC) with a recommendation for taking up the matter with the foreign health authority for revoking their specific control measures/rapid alert, as the case may be. EIC may make the necessary recommendation to the foreign health authority through half yearly dossiers.

The EIA concerned shall reduce the number of monitoring visits to once in a month, provided at least four fortnightly monitoring visits have been carried out since 'On alert' was imposed. It may be noted that the unit shall continue to be 'On alert' even if recommendation to foreign health authority as above is made, if any, and revocation of 'On alert' would be considered only after ten consecutive consignments have passed and monitoring/supervisory visits during the period are satisfactory. The 'On alert' imposed on the unit shall be revoked only after the approval of the Director (I&QC).

18.9 However, if any of the above points are unsatisfactory,

- i.e. (i) The consignment, if brought back, is on testing found to be contaminated /defective
  - (ii) The assessment report indicates unsatisfactory hygienic conditions in the unit;
  - (iii) Samples drawn during assessment visit fail;
- (a) Production and export to all countries shall be stopped till causes of contamination are properly identified and appropriate corrective actions are taken to prevent recurrence.
  - (b) Processor to show cause within ten days why the approval granted to the establishment may not be withdrawn in the light of the complaint and the findings.

18.9.1 Once the processor informs the EIA that corrective actions have been carried out, verification, of the corrective actions, shall be carried out by the EIA. The processor may be allowed to resume production for export only after satisfactory on-site verification of the rectifications of the deficiencies and approval of the Director (I&QC).

18.9.2 If the Competent Authority is not satisfied with the reply of the processor as above, or with the corrective action taken and verified as above, the approval granted to the establishment may be withdrawn.

18.9.3 After resumption of production, an officer, not below the rank of Technical Officer shall be deputed to such units for a minimum period of ten days extendable up to thirty days for continuous monitoring of the enforcement of various standards relating to the quality control, food hygiene and food safety. The cost of such deputation of EIA officers shall be charged to the units as per clause No. 17 (if working is more than one shift, all shifts should be covered at random).

*Note: Superintendence as described above will be waived off in case of rejections due to residues, if the unit can prove that the rejection is not due to a cause identified in the processing unit.*

18.9.4 After resumption of production, the next ten consecutive consignments shall be inspected by the EIA concerned. The consignment wise inspection shall be carried out till such time the ten consecutive consignments are cleared satisfactorily. The Cost of testing shall be borne by the processor. Based on the satisfactory test results, EIA shall allow the consignment produced by the establishment for export. The samples shall be drawn as per the sampling scale as per clause No. 9.1.9(x).

18.9.5 The unit shall be taken off from the “ON ALERT” list only after monitoring as per 18.9.3 and testing of consignments are found satisfactory.

Note: In specific cases, if decided by the Competent Authority, there may be deviation in the above procedure.

## 19. Appeal

19.1 Any person aggrieved by:

- a) Decision of the competent authority not to accord approval to the establishments as per rule 4.15 Notification No. S.O. 2720 dated 28.11.2000;
- b) Refusal of Competent authority to issue Veterinary Health Certificate as per rule 5 of the said notification
- c) Decision of the competent authority to denotify processor exporter as per rule 7 of the said notification.

may prefer an appeal within ten days of receipt of such communication to an appellate authority appointed from time to time by the Central Government.

19.2 The appeal may be sent to EIC for forwarding the same to the Chairman, Appellate Authority ‘

- a) At least two-thirds of the total membership of the Appellate Authority shall consist of non-officials.
- b) The quorum for any meeting of the Appellate Authority shall be three.
- c) The appeal shall be disposed off within thirty days of its receipt.
- d) The non-official members would be eligible for TA/DA as admissible to them from time to time for attending the meetings of the Appellate Authority. The expenditure on this account will be borne by the Export Inspection Council.

Appellate Authority consists of the following five members appointed for the purpose by the Central Government Additional Secretary, MOC&I, New Delhi (Chairman)

- Joint Secretary, MOC&I, New Delhi
- Chairman APEDA, New Delhi
- Director, NDRI, Karnal
- President, IDA, New Delhi

## 20. POWER TO RELAX

In case any situation arises, which is not covered by the executive instructions, EIAs may make a suitable recommendation to EIC for decision by Director (I&QC).

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**APPLICATION FOR APPROVAL**  
**(Milk Products Processing Establishments)**

From

To

Export Inspection Agency-\_\_\_\_\_

Sir,

Please carry out the assessment of our establishment as required under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 for approval to process milk products for export to all countries including European Union/Non-EU countries.

We furnish below the information regarding the facilities existing in our establishment, and primary production holdings.

We undertake that our establishment meets the requirements stipulated in Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 and also the other requirements specified by EIC from time to time.

Please find enclosed herewith a Demand Draft bearing No. \_\_ dated \_\_\_\_\_ for Rs. \_\_\_\_\_ drawn in favour of \_\_\_\_\_ payable at \_\_\_\_\_ towards the application fee.

Section-I: Information		
A	General	
1	Name and address of the establishment seeking approval (Give Contact Numbers and E-mail, if any)	
2	Name and Addressed of the Registered office of the establishment (Give Contact Numbers and E-mail, if any)	
3	Name of the Chief Executive (MD/Mg. Partner/Proprietor) (Give Contact Numbers and E-mail, if any)	
4	Is the processing plant owned or leased by the applicant	Owned/leased
5	If leased, name of the plant owner, plant name and address.	
6	Month and Year of Construction	
7	Month and Year of last major alterations	
8	Month and Year of Commercial Production	
9	Approval requested for export to (Countries)	All countries including European Union /Countries other than EU.
10	Scope of approval. Give Name(s) of the product(s).	
11	Additional activities, if any, in the same premise and other than the products mentioned at 1.10	

12	Annual production during the previous year (a) Milk Products (Within the scope of approval) (b) Others (specify)			
13	Total exports during the last two years Financial Year Destinations (Countries) Quantity in Metric Tons FOB Value in Rupees in Lakhs.			
14	Whether all year production or seasonal production			
15	Give number of working hours and shifts per day			
16	Give number of working days per week. Specify weekly holiday			
<b>B.</b>	<b>Information on Structure of the Establishment</b>			
17	Is there any chill room / chill storage for storage of food products? Give numbers and storage temperatures			
18	Are there storage facilities for in-process liquid milk/food products? Give type of storage facility and temperature of storage			
19	Whether the unit have chilling facility to reduce the temperature of the liquid milk products below 6 °C? If yes, specify method and capacity of chilling.			
20	Is there facility for pasteurization of liquid milk products? Give number of pasteurises and their capacities			
21	Whether the unit have spray drying facility?-I f yes, give details like type and capacity.			
22	Whether there is packing room for every milk product separate from processing activities and storage?			
23	Is there adequate integrated storage facility for dried/frozen finished milk products? Give details like type of storage, purpose, number of storages and capacity of storage.			
24	Give details like Numbers, type, capacities and registration numbers of vehicles of the establishment of its own for transportation of raw material and finished products	<u>Numbers</u>	<u>Capacity</u>	<u>Regn. Nos.</u>
	(a) Refrigerated Vehicle			
	(b) Insulated Vehicles			
	(c) Non-insulated Vehicles			
25	Does the establishment hire outside vehicles? If yes, Give details as above.			
<b>C.</b>	<b>Information about personnel</b>			
26	Give number of veterinarian/ technologists and veterinarians available in the establishment			
27	Give name, designation, qualifications and experience of the personnel qualified and responsible for developing, implementing and maintaining HACCP-based procedures.			

28	Give name, designation, qualifications and experience of the veterinarian(s) and technologist(s) supervising the processing and other related operations	
29	Give name, designation, qualifications and experience of the qualified personnel, conducting microbiological and chemical analysis	
30	Give number of supervisors apart from the above, responsible for processing and handling of food products and maintenance of sanitation and hygiene in the establishment and milk products production separately.	
31	Give number of male workers in the processing establishment in each shift and at milk washing facilities, if separate.	
32	Give number of female workers in the processing establishment in each shift	

Section-II: PRIMARY PRODUCTION AND RAW MATERIAL		
A	Hygiene Provisions and record keeping in raw Milk Production and handling(collection and transport)	
1	Whether the establishment has identified milk production holdings?	
2	Are milk production holdings owned or contracted by the establishment?	
3	Whether the details of all milk production holdings supplying raw milk provided?	
4	Whether the establishment ensures that raw milk comes from animals that do not show any symptoms of infectious diseases communicable to humans through milk such as brucellosis, tuberculosis?	
5	Are infected milch animals or suspected of being infected, (brucellosis, tuberculosis) isolated to avoid other animal's milk?	
6	Are animals undergoing medical treatment and likely to transfer residues to the milk identified & not used for human consumption?	
7	Is there any infrastructure for educating farmers for clean milk production?	
8	Are there any incentive given to the farmers for clean milk production?	
9	Give the details of the identified layer farms like name, address, capacity, and distance from the processing establishment, etc. (separate list may be attached) along with location map showing route and distance from the processing establishment, on an A4 paper.	
10	Are these under supervision/controls of the unit to ensure the wholesomeness of the raw milk procured? Specify.	
11	Are there controls to ensure good farming practices and good veterinary practices?	

12	Are there adequate measures to protect raw milk production against any contamination	
13	Are there adequate measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary medicinal products and biocides and the storage, handling and disposal of waste in raw milk production and associated operations	
14	Are there controls to prevent use of prohibited antibiotics/pharmacological substances and Chemicals?	
15	Are there adequate measures relating to animal health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents in raw milk production and associated operations?	
16	Is there cleaning and where necessary, disinfecting of facilities used in connection with milk production and associated operations, including facilities used to store and handle feed?	
17	Is there cleaning and where necessary, disinfecting of equipment, containers, crates, vehicles and vessels?	
18	Is the water used potable or clean, where necessary, to prevent contamination?	
19	Are the personnel trained on health risks and the personnel, handling foodstuff in good health?	
20	Is there prevention of animals and pests from causing contamination?	
21	Is the waste and hazardous material handled and stored properly to prevent contamination?	
22	Is there prevention of the introduction and spreading of contagious diseases transmissible to humans through food, including taking precautionary measures when introducing new milch animals and reporting suspected outbreaks of such diseases to the competent authority	
23	Are the samples (feed, water, milk, etc.) drawn for relevant analyses that have importance to human health and records maintained?	
24	Are there appropriate actions on account of the results of any relevant analysis carried out on samples taken from the milch animals or other samples that have importance to human health	
25	Is there correct use of feed additives and veterinary medicinal products?	
26	Is there appropriate remedial action when informed of problems identified during official controls	
27	Specify the mode of transport of raw milk from the milk production holding	
28	Are there records relating to measures put in place to control hazards in an appropriate manner?	
29	Are there records of nature and origin of feed fed to the milch animals?	

30	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
31	Are there records of the occurrence of diseases that may affect the safety of milk products	
32	Are there records of other relevant reports on checks carried out on milch animals or raw milk	
33	Are there records of the details of employees such as veterinarians and farm technicians, assisting in raw milk production	
<b>B</b>	<b>Requirement for Premises &amp; Equipment</b>	
34	Are there adequate measures to protect milk production against any contamination?	
35	Is the premise for storage of milk protected against vermin and have adequate separation from premises where animal are housed?	
36.	Are the surfaces of equipment that are intended to come into contact with milk (utensils, containers etc.) washable and non toxic?	
37	Are the milk production holdings under supervision/controls of the unit to ensure the wholesomeness of the raw milk procured?	
38	Is cold chain maintained during transportation to ensure the arrival temperature of raw milk below 10 Deg. C?	
<b>C</b>	<b>Staff Hygiene</b>	
39	Does person performing milking/or handling of raw milk wear suitable clean clothes and maintain high degree of personal hygiene and is medically fit for the purpose?	
40.	Are there suitable facilities near place of milking for washing hands and arms?	

<b>Section-III: GENERAL FACILITY AND HYGIENE REQUIREMENTS OF THE PROCESSING ESTABLISHMENTS</b>		
<b>A.</b>	<b>General requirements for premises and infrastructure</b>	
1.	<u>Premise</u>	
(a)	Whether it has defined curtilage and roads around the building concreted or tarred or turfed?	
(b)	Is it kept clean and maintained in good repair and free from swamps, stagnated water, dumps, rodent harbourage, other animals, environmental contaminations like smoke, objectionable odours, dust, etc., etc.?	
2.	<u>Layout, design, construction, location and size of food premises:</u>	
(a)	Does it permit adequate maintenance, cleaning and/or disinfecting, avoid or minimize air-borne contamination and provide adequate working space to allow for the hygienic performance of all operations?	
(b)	Does it protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces	

(c)	Does it permit good food hygiene practices, including protection against contamination and, in particular, pest control	
(d)	Where necessary, does it provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining food at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.	
(e)	Is it kept clean and maintained in good repair and condition?	
3	<u>Lavatories</u>	
(a)	Are there an adequate number of flush lavatories available and connected to an effective drainage system?	
(b)	Are the lavatories opened directly into rooms in which food is handled?	
4	<u>Washing facilities:</u>	
(a)	Are there an adequate number of washbasins available, suitably located and designated for cleaning hands at all entry points and in food handling areas?	
(b)	Are the washbasins for cleaning hands provided with hot and cold running water, materials for cleaning hands like detergent, disinfectant, etc. and for hygienic drying e.g. single use towels?	
(c)	Are there feet disinfection facilities like foot dip provide, wherever applicable?	
5	<u>Ventilation:</u>	
(a)	Is there suitable and sufficient means of natural or mechanical ventilation?	
(b)	Is the mechanical airflow from a clean area to a contaminated area?	
(c)	Are the ventilation systems constructed as to enable filters and other parts requiring cleaning or replacement, readily accessible?	
6	Do the sanitary conveniences have adequate natural or mechanical ventilation?	
7	Do the premises have adequate natural and/or artificial lighting?	
8	<u>Drainage facilities</u>	
(a)	Are they adequate for the purpose intended?	
(b)	Are they designed and constructed to avoid the risk of contamination.	
(c)	Where drainage channels are fully or partially open, are they designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled?	
9	<u>Change room facilities</u>	
(a)	Are adequate separate changing facilities (change room and facilities therein), where necessary, provided for personnel handling raw material, unprocessed products and processed products?	
(b)	Is there separate facility for male and female workers?	
(c)	Whether changing room facility is integrated into the plant layout properly?	
(d)	Does the changing room have smooth walls, floors and washbasins with soaps, disposable towels, nail brushes and non-hand operable taps?	
(e)	Whether there is arrangement for	
i)	Change of footwear	
ii)	Keeping street clothes separately	

iii)	Lockable cupboards	
iv)	Collection of soiled working clothes	
v)	Gumboots	
vi)	Headgear and wherever necessary gloves/ mouth cover	
(f)	Is there suitable in-house arrangement to launder the working clothes of the workers?	
10	Is there storage for cleaning agents and disinfectants in areas where food is not handled?	
B.	Specific requirements in rooms where foodstuffs are prepared, treated or processed	
11	Design and layout to permit good food hygiene practices, including protection against contamination between and during operations	
(a)	<u>Floor</u>	
i)	Are the surfaces maintained in a sound condition and easy to clean and, where necessary, to disinfect?	
ii)	Is it impervious, non-absorbent, washable and non-toxic materials or appropriate to prevent contamination?	
iii)	Do they allow adequate surface drainage?	
(b)	<u>Walls</u>	
i)	Are the surfaces maintained in a sound condition and are easy to clean and, where necessary, to disinfect?	
ii)	Is it impervious, non-absorbent, washable and non-toxic materials or appropriate to prevent contamination and does have a smooth surface up to a height appropriate for the operations?	
(c)	<u>Ceiling</u> : Are the ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles?	
(d)	<u>Windows and other openings</u>	
i)	Are they constructed to prevent the accumulation of dirt?	
ii)	Are those, which can be opened to the outside environment, where necessary, fitted with insect-proof screens, which can be easily removed for cleaning?	
iii)	Are, where open windows would result in contamination, kept closed and fixed during production?	
(e)	Are the <u>doors</u> easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	
(f)	<u>Surfaces (including surfaces of equipment)</u>	
i)	Are, in areas where food is handled and in particular those in contact with food maintained in a sound condition and are easy to clean and, where necessary, to disinfect?	
ii)	Are these smooth, washable corrosion-resistant and non-toxic materials or appropriate to prevent contamination	
12	<u>Cleaning facilities</u>	
i)	Are adequate facilities provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment?	
ii)	Are these facilities constructed of corrosion-resistant materials, easy to clean and do they have an adequate supply of hot and cold water?	

iii)	Do the every sink or other such facility provided for the washing of food have an adequate supply of hot and/or cold potable water and kept clean and, where necessary, disinfected?	
iv)	Are the cleaning agents and disinfectants are stored separately under lock and key?	
<b>C</b>	<b><u>Transport</u></b>	
13	Are the conveyances and/or containers used for transporting raw milk/food kept clean, sanitised and maintained in good repair and condition to protect food from contamination and are, where necessary, designed and constructed to permit adequate cleaning and/or disinfection?	
14	Are the receptacles in vehicles and/or containers used for transporting anything other than food where it may result in contamination?	
15	Are the conveyances and/or containers, where used for transporting anything in addition to food or for transporting different foodstuffs at the same time, has effective product separation?	
<b>D</b>	<b>Equipment requirements</b>	
16	Are all the articles, fittings and equipment with which food comes into contact	
(i)	Effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination?	
(ii)	Constructed, of such materials and kept in such good order, repair and condition as to minimize any risk of contamination?	
(iii)	with the exception of non-returnable containers and packaging, constructed, of such materials and kept in such good order, repair and condition as to enable them to keep clean and, where necessary, disinfected?	
(iv)	Installed in such a manner that does allow adequate cleaning of the equipment and the surrounding area?	
17 (i)	Is equipment, where necessary, fitted with an appropriate control device such as time, temperature, pressure, flow rate, etc. ?	
(ii)	Are the process control equipment and devices calibrated at regular intervals?	
18	Are the chemical additives, where have to be used to prevent corrosion of equipment and containers, used in accordance with good practice?	
<b>E</b>	<b>Food waste</b>	
19	Are the non-edible by-products and other refuse removed as quickly as possible from rooms where food is present so as to avoid their accumulation?	
20	Are the non-edible by-products and other refuse deposited in closable containers or any other appropriate foot operable container to prevent contamination?	
21	Are the containers made of an appropriate construction, kept in sound condition, easy to clean and, where necessary, to disinfect?	
22 (i)	Is there adequate provision made for the storage and disposal of food waste, non-edible by-products and other refuse?	
(ii)	Are the refuse stores are designed and managed in such a way as to enable them to keep clean and, where necessary, free of animals and pests?	
23	Is all waste eliminated in a hygienic and environmentally friendly way in accordance with state pollution control board's consent and does not constitute a direct or indirect source of contamination?	



<b>F</b>	<b>Water supply</b>	
24 (i)	Is there documented water management system? Are the outlets identified and serially numbered in the plumbing layout diagram?	
(ii)	Is the water tested as per 98/83/EC or IS:4251 for potability, as applicable?	
25	Is there adequate supply of potable water, which is used whenever necessary to ensure that foodstuffs are not contaminated ( <i>clean water may also be used for external washing</i> )? What is the method of treatment?	
26 (i)	Is the non-potable water circulated in a separate duly identified system, where it is used for fire control, steam production, refrigeration and other similar purposes?	
(ii)	Is the non-potable water connects with, or allows reflux into, potable water systems?	
27 (i)	Is the recycled water used, if any, in processing or as an ingredient presents a risk of contamination?	
(ii)	Is it of the same standard as potable water, acceptable to the competent authority and will not affect wholesomeness of the foodstuff in its finished form?	
28	Is the steam used directly in contact with food likely to contain substance that presents a hazard to health or likely to contaminate the food?	
29 (i)	Is there appropriate measure to prevent contamination through back suction?	
(ii)	Is water storage tank easily cleanable and protected from outside contamination? State frequency of cleaning water tanks.	
<b>G</b>	<b>Personal hygiene</b>	
30	Is every person working in a food-handling area maintaining a high degree of personal cleanliness and wearing suitable, clean and, where necessary, protective clothing?	
31	Is person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea, permitted to handle food or enter any food-handling area in any capacity, if there is any likelihood of direct or indirect contamination? Are the health cards maintained for all employees?	
32	Does any person so affected and employed in the establishment and who is likely to come into contact with food report immediately the illness or symptoms, and if possible their causes, to the processing establishment?	
<b>H</b>	<b>Provisions applicable to foodstuffs</b>	
33	Does the establishment accept raw materials or ingredients, other than food, or any other material used in processing products, even though they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the establishment applies normal hygienic sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption?	
34	Are the raw materials and all ingredients stored in the premises kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination?	

35	At all stages of production, processing and distribution, is the food protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state?	
36	<u>Pest control</u>	
(i)	Are adequate documented procedures in place to control pests?	
(ii)	Whether bait map showing serially numbered bait stations provided?	
(iii)	Are adequate procedures in place to prevent domestic animals from having access to places where food is prepared, handled or stored?	
37	<u>Storage conditions</u>	
	Are the raw materials, food ingredients, intermediate products and finished products likely to support the reproduction of pathogenic microorganisms or the formation of toxins, kept at temperatures that might result in a risk to health?	
38	Does the establishment have suitable rooms for manufacturing, handling and wrapping processed foodstuffs, large enough for separate storage of raw materials from processed material and sufficient separate refrigerated storage?	
39	Are the foodstuffs, where held or served at chilled temperatures, cooled as quickly as possible following the heat-processing stage or final preparation stage when no heat process is applied, to a temperature, which does not result in a risk to health?	
40	Are hazardous and/or inedible substances adequately labelled and stored in separate and secure containers?	
I	<u>Wrapping and packaging of foodstuffs</u>	
41	Is the material used for wrapping and packaging a source of contamination?	
42	Are the wrappings and packing materials stored in such a manner that they are exposed to a risk of contamination?	
43	Are wrapping and packaging operations carried out so as to avoid contamination of the products? ( <i>Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness must be assured.</i> )	
44	Is the wrapping and packaging material re-used for foodstuffs easy to clean and, where necessary, to disinfect?	
J	<u>Heat treatment</u>	
45	Does the heat treatment process used to process an unprocessed product or to process further a processed product:	
(i)	raise every particle of the product treated to a given temperature for a given period of time?	
(ii)	prevent the product from becoming contaminated during the process?	
46 (i)	Does the process employed achieve the desired objectives?	
(ii)	Are the main relevant parameters (particularly temperature, pressure, sealing and microbiology), checked regularly including by the use of automatic devices?	
47	Does the process used conform to an internationally recognized standard (for example, pasteurization, UHT, heat treatment, etc.)?	
K	<u>Maintenance</u>	
48	Is there appropriate maintenance schedule for maintaining infrastructure and equipment facilities and records thereof?	
49	Whether all equipment labelled and marked?	

<b>L</b>	<b>Training</b>	
50	Are the food handlers supervised and instructed and/or trained in food hygiene matters commensurate with their work activity?	
51	Have the persons those responsible for the development and maintenance of the procedure for the operation of relevant guides received adequate training in the application of the HACCP principles?	
52	Are the persons those responsible for compliance with the requirements of national law trained?	
<b>M</b>	<b>Testing facility</b>	
53	Is there in-house testing facility for analysis of raw materials, in-process samples, finished products, hygiene and sanitation control samples, etc.?	

<b>Section-IV: REQUIREMENTS CONCERNING PRODUCTS</b>		
<b>A</b>	<b>Application of the Identification Mark</b>	
1	Is the Identification mark and details of the approved establishment applied before the product leaves the establishment?	
a)	Are the consignments of milk products, destined not for retail but for use as an ingredient in the manufacture of another product, have label giving the temperature at which the milk products must be maintained and the period during which conservation may thus be assured?	
2	Is new mark applied to a product after further processing in another approved establishment with the approval number of the establishment where these operations take place?	
<b>B</b>	<b>Form of the Identification Mark</b>	
3	Are marks legible and indelible and the characters easily decipherable? Is It clearly displayed for the competent authorities?	
4	Does the mark indicate the name of the country in which the establishment is located?	
<b>C</b>	<b>Method of Marking</b>	
5	Is the mark applied directly to the product, the wrapping or the packaging, or printed on a label affixed to the product, the wrapping or the packaging depending on the presentation of different products of animal origin?	
6	Is the mark an irremovable tag of resistant material?	
<b>D</b>	<b>HACCP-based Procedures (Hazard analysis and critical control points)</b>	
7	Are the HACCP principles in place, implemented and maintained?	
8	The HACCP principles	
a)	Are the hazards, if any, need to be prevented, eliminated or reduced to acceptable levels identified appropriately?	
b)	Are the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels identified appropriately?	
c)	Are the critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards established appropriately?	
d)	Are the monitoring procedures at critical control points established and implemented effectively?	
e)	Are the corrective actions when monitoring indicates that a critical control point is not under control established?	

f)	Are the procedures, which need to be carried out regularly, to verify that the measures outlined in (a) to (e) above are working effectively, established?	
g)	Are the documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in (a) to (f) above established?	
9	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	
10	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
11	Are the documents up-to-date at all times?	
12	Are the documents and records retained for an appropriate period?	
13	<u>Traceability of raw milk procurement:</u> Do the procedures guarantee that each lot of raw milk accepted onto premises:	
(a)	Is properly identified?	
(b)	Is accompanied by the relevant information from the holding of provenance controlled / supervised by the processing establishment?	
(c)	Come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits?	
(d)	Is clean?	
(e)	Is fit for consumption, as far as the food business operator can judge?	
(f)	Is in a satisfactory state?	
14	In the event of failure to comply with any of the requirements listed under point 13 (a to f) above, is it notified to the approved veterinarian/ technologist and took appropriate measures?	
E)	<b>Food Chain Information</b>	
15	Does the processing establishment is accepting milk without request and relevant food safety information, contained in the records kept at the holding of provenance, such as;	
(i)	The status of the holding of provenance or the regional animal health status?	
(ii)	The health status of milk supplied to the establishment?	
(iii)	Veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods?	
(iv)	The occurrence of diseases that may affect the safety of milk products?	
(v)	The results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the milch animals or other samples taken to diagnose diseases that may affect the safety of milk products, including samples taken in the framework of the monitoring and control of zoonoses and residues?	
(vi)	Relevant reports about previous <i>ante</i> -and <i>post-mortem</i> inspections of milch animals from the same holding of provenance including, in particular, reports from the veterinarian?	
(vii)	Production data, when this might indicate the presence of disease?	
(viii)	The name and address of the veterinarian attending the holding of provenance?	

16	If any lot of raw milk arrives at the processing establishment without food chain information, is it notified to the approved veterinarian/ technologist immediately?	
17	Are the raw milk processed with the permission of the approved veterinarian/ technologist?	

Section-V: SPECIFIC REQUIREMENTS		
<b>A</b>	<b>Raw milk criteria &amp; Handling</b>	
1	Is the raw milk stored and transported at a temperature preferably constant, which is best suited to assure optimal conservation of their hygiene properties?	
2	Does raw milk meet the criteria for SPC and Somatic Cell Count as specified in the Executive instructions?	
3	Is raw milk cooled to 6 Deg C or below and kept at that temperature until processed?	
<b>B</b>	<b>Milk Products Processing</b>	
4	<u>Requirements for Establishments</u>	
(i)	Does each particle of the liquid milk undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level	
(ii)	Does a batch that has been insufficiently processed, undergo processing again immediately in the same establishment, rendering the reprocessing fit for human consumption?	
5	<u>Analytical Specifications</u>	
(i)	Is the unit having in-house facilities for inspection and testing?	
(ii)	Is the unit having separate qualified and competent personnel for conducting physical, chemical and microbiological tests?	
<b>C</b>	<b>Other Food Ingredients/additives/preservatives</b>	
6	Specify the additives/ preservatives used by the unit (separate list to be enclosed)	
7	Whether the additives/preservatives are of food grade quality, acceptable to importing country?	

Section-VI: Any other relevant information:

Yours faithfully,

Signature  
Name  
Designation

Place :  
Date :

Company Seal

Check list of enclosures:

- (1) Prescribed fee in the form of Demand Draft
- (2) HACCP Manual (including Organisational Chart of the establishment, Sanitary Standard Operating Procedures, process flow chart (s) with product description, manufacturing details in each step, Self-Residue Monitoring Plan.)
- (3) Attested copy of Potability certificate for water (Directive 98/83/EC or IS:4251, as applicable)
- (4) Location and Layout plan of the establishment (site plan and building plan in A-4 size), showing all infrastructure and equipment facilities

- (5) *Layout showing the process/product flow, personnel flow, water flow (Indicating serially numbered water taps) and effluent flow, on A4 size paper separately, in evidence of meeting food safety requirements*
- (6) *Certified Copy of the legal identify of establishment*
- (7) *Certified copy of Lease Deed, if applicable*
- (8) *List of identified farms meeting the minimum requirements specified at I C from which the establishment intend to procure milks for processing along with details like address, and distance from the processing establishment*
- (9) *Bio-data of veterinarian/ technologist(s)*
- (10) *Guarantee and undertaking*
- (11) *Attested copy of the consent letter issued by the State Pollution Control Board.*
- (12) *Attested copy of the order allotting Importer-Exporter Code (IEC) Number.*
- (13) *List of additives/ preservatives used in the processing.*

Note:

- a) *The application must be in duplicate,*
- b) *In case where a non-EU approved establishment submits application for the approval to process milk products for exports to the EU countries, the documents, which were submitted earlier, need not be submitted again, if there is no change.*

UNDERTAKING

(To be submitted in duplicate on company's letterhead along with application for approval of processing establishment.)

Ref. No. :

Date:

To

The Export Inspection Agency- -----,  
(Address)

Sub: Application for approval processing establishment.

Sir,

With reference to our application ref. No. ----- dated -----, we hereby undertake the following in respect of the processing of milk/manufacturing of milk products in our establishment.

We handle, process, store and transport milk products under proper hygienic conditions so as to meet the health requirements laid down by the Government of India/Importing Countries.

HACCP system has been established and implemented by us.

We use only approved disinfectants for water at acceptable level, and carry out checks on water in line with EC recommendations (98/83/EC) / or as per IS 4251 (in case of non EU)

Level of additives, where applicable, is monitored in accordance with the requirements of the importing country.

Yours faithfully,

Signature of Authorised Signatory

Name:

Designation:

Date:

Place:

*Strike whichever is not applicable.*

**GUARANTEE**

(To be submitted in duplicate on company's letterhead along with application for approval of processing establishments to the concerned EIA)

Ref. No. :

Date:

To

The Export Inspection Agency- -----,  
(Address)

**Sub: Guarantee for approval of processing establishment by EIA**

Sir,

In case, grant of approval to our establishment, we hereby guarantee the following:

HACCP that has been established and implemented by us shall be monitored and maintained continuously through out the food chain.

We will not obtain Health Certificates for our export consignments from authorities other than the Export Inspection Agency- \_\_\_\_\_.

We will not use semi-processed or processed milk products coming from an unapproved establishment.

Level of additives, where applicable, is monitored in accordance with the requirements of the importing country.

We shall provide to the Competent Authority and its representatives free access, at all times, to all parts of the establishment and to the records pertaining to production/quality of products being processed by us.

If the results of checks carried out by us or any information at the disposal of our personnel reveal the risk of health or suggest that such a risk might exist, we shall inform you immediately and take corrective actions under your official supervision.

We shall not export any milk product other than what is included in scope of approval.

We will not store the milk products of the other approved establishments in our premises without prior permission from the EIA concerned. We will not store any product of an unapproved establishment.

We will not misuse the CFEs issued to us and will maintain proper records of the same.

You may withdraw the approval granted to our establishment for processing of milk/manufacturing of milk products in case of violation of any of the above guarantees by us.

Signature of the  
Head of Production (Name and designation)

Place:  
Date :

Counter signature of Chief Executive Officer of the approved establishment (Name and designation)

Place:  
Date :



## GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

## Animal health requirements

## I. Raw milk must originate as follows:

- a) From cows, buffaloes, sheep and goats which are tuberculosis –free.
- b) From Cows and buffaloes which are brucellosis free.
- c) Cows and buffaloes should not show any symptoms of infectious diseases communicable to human beings through milk
- d) From the milch animals whose general state of health is not impaired by any visible disorder and which are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever or a recognizable inflammation of udder.
- e) The milch animals should not show any udder wound likely to affect the milk.
- f) The milch animals which have not been treated with substances dangerous or likely to be dangerous to human health that are transmissible to milk, unless the milk has complied with withdrawal period laid down.

## II. Hygiene provisions

- 1) As far as possible, food business operators are to ensure that Raw milk is protected against contamination, having regard to any processing that Raw milk will subsequently undergo.
- 2) Notwithstanding the general duty laid down above, food business operators are to comply with appropriate importing countries and national legislative provisions relating to the control of hazards in primary production and associated operations, including:
  - (a) measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary medicinal products, and biocides and the storage, handling and disposal of waste; and
  - (b) measures relating to animal health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents.
- 3) Milk production holdings producing raw milk are to take adequate measures, as appropriate:
  - a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
  - b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;
  - c) as far as possible to ensure the cleanliness of milch animals;
  - d) to use potable water, or clean water, whenever necessary to prevent contamination;
  - e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
  - f) as far as possible to prevent animals and pests from causing contamination;
  - g) to store and handle waste and hazardous substances so as to prevent contamination;
  - h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;
  - i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health; and
  - j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.
- 4) Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

### III. Record-keeping

- 5) Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.
- 6) Food business operators producing raw milk are, in particular, to keep records on:
  - (a) the nature and origin of feed fed to the milch animals;
  - (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
  - (c) the occurrence of diseases that may affect the safety of products of animal origin;
  - (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; and
  - (e) any relevant reports on checks carried out on animals or products of animal origin.
- 7) The food business operators may be assisted by other persons, such as veterinarians and farm technicians, with the keeping of records.

### IV Recommendations for guides to milk production holdings for good hygiene practice

- 8) The guides should contain guidance on good hygiene practice for the control of hazards in milk production and associated operations.
- 9) Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in importing countries and national legislation. Examples of such hazards and measures may include:
  - a. the control of contamination such as mycotoxins, heavy metals and radioactive material;
  - b. the use of water, organic waste and fertilizers;
  - c. the correct and appropriate use of plant protection products and biocides and their traceability;
  - d. the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
  - e. the preparation, storage, use and traceability of feed;
  - f. the proper disposal of dead animals, waste and litter;
  - g. protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
  - h. procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;
  - i. measures relating to the cleanliness of milch animals;
  - j. measures relating to record keeping.

## REQUIRMENTS FOR APPROVAL OF ESTABLISHMENT FOR PROCESSING MILK PRODUCTS FOR EXPORT

### 1. Surroundings

- 1.1 The premises shall be kept clean and shall have defined curtilage. All the roads in the premises shall be concreted / tarred or turfed to prevent wind blown dust.
- 1.2 There shall not be any swamps, stagnant water or signs of any rodent harbourage inside the premises.
- 1.3 The surroundings shall be reasonably free from objectionable odours, smokes, dust and other contaminants.

### 2. Constructions and Layout.

- 2.1 The immediate surrounding of the building shall be tarred/ concreted to prevent contamination from the surroundings.
- 2.2 The establishment shall be housed in a building of permanent nature affording sufficient protection from the environment and shall be of sufficient size for the work to be carried out under hygienic conditions. The design and layout shall be such as to preclude contamination.
- 2.3 The lay out of different sections shall be such as to facilitate smooth and orderly flow of work and to prevent possible cross contamination and backtracking. All the milk products handling areas shall be separate from areas used for residential purpose.
- 2.4 There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering.
- 2.5 The layout shall ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion.
- 2.6 The building shall provide sufficient protection against the entry and harbourage of rodent, insects, milch animals, other animals etc.
- 2.7 All the entry points shall have suitable air curtains or other suitable arrangements to prevent the entry of flies.
- 2.8 Wood shall not be used in the factory, except inside the cold storage.
- 2.9 Non –operative areas inside the establishment shall be properly cordoned off to avoid possible cross-contamination.

### 3. Milk receiving section.

- 3.1 There shall be a raised platform for receiving the material and the sides and roof of the platform shall be sufficiently protected from extraneous contamination.
- 3.2 The raw milk receiving section shall be sufficiently separated from processing area to prevent contamination
- 3.3 Signboards directing the employees to wash and sanitise hands before entering and after each absence shall be installed
- 3.4 Air curtains/fly killers shall be installed to prevent the entry of flies when the door is opened.

### 4 Workers entry points.

- 4.1 Suitable washing and sanitizing facilities for feet and hands shall be provided at the entry points.
- 4.2 The washbasins shall be provided with foot operable taps or non-hand operable taps.
- 4.3 Liquid soaps, disinfectants, nailbrushes, single use towels / hand dryers etc. shall be provided in sufficient quantities at all entry points.
- 4.4 Waste bins provided for collecting used towels shall be of foot-operated type.

## 5. Ceiling walls and floors.

- 5.1 The floor of the processing areas shall be smooth, impermeable and easy to clean and disinfect. There shall be no water stagnation on the floor. The floor shall have sufficient slope opposite to the flow of work or side ways.
- 5.2 The wall to floor and wall-to-wall junctions shall be rounded off to facilitate easy cleaning.
- 5.3 The walls should be durable, smooth, light coloured and easy to clean and disinfect.
- 5.4 The walls should not have projections and the entire fitting on the wall shall be made in such a way so as to clean and disinfect them easily. If possible, the electric switches or other fittings shall be fixed in other areas where no handling of milk product is carried out.
- 5.5 The ceiling shall be free from cracks and open joints and shall be smooth and easy to clean.
- 5.6 If structural elements or fittings are suspended below the ceiling, suitable protection shall be given to prevent falling of debris, dust or droppings.

## 6. Doors, windows and ventilators.

- 6.1 All the doors shall be tight fitting and the windows and ventilators shall have fly proofing nets to prevent the entry of flies.
- 6.2 All doors and windows shall be durable and made of corrosion resistant material and windowsills, if any, shall slope inwards. The windows/ ventilators shall be constructed at least one meter above the floor.
- 6.3 The doors shall be of self-closing type .
- 6.4 Mechanical ventilation/ exhaust fans shall be provided in areas where stagnation of air, condensation of fluid etc. are present
- 6.5 The opening of ventilation/ exhaust fan shall be provided with suitable fly proofing system.

## 7. Drainage

- 7.1 There shall be adequate drainage facility and slope of the drainage shall be opposite to the flow of work/ material.
- 7.2 The open end of the drainage shall be protected against the entry of rodents.
- 7.3 The drains shall be of adequate size having sufficient slope for easy cleaning.

## 8. Tables, utensils, equipments and machineries

- 8.1 All the utensils and equipments shall be made of non-corrodible material and shall be smooth with out cracks and crevices and easy to clean and disinfect.
- 8.2 All food contact surfaces shall be free from rust and paints.
- 8.3 Suitable arrangements shall be made to drain the water from the tables directly into the drainage with out falling on the floor.
- 8.4 Freezing equipments shall be suitable to freeze milk products and shall achieve the required core temperature within the stipulated time. The equipments shall be fitted with necessary gauges to indicate the temperature, pressure etc. The recording devices shall be calibrated at specified intervals.
- 8.5 Pasteurisers of suitable capacity having capability to maintain required temperatures and time shall be provided with automatic calibrated temperature devices
- 8.6 Milk products store rooms shall be clean having smooth floor, walls and roof and shall have suitable mechanism to control the temperature, if required.
- 8.7 Spray drying facility shall be equipped with approved air filters and the food contact surfaces shall be smooth, easy to clean and made up of no-corrosive material

## 9. Chill rooms , cold storages .

- 9.1 Chill rooms/storage tanks having adequate size with mechanical refrigeration system to maintain temperature at the required level (0°C to 4°C) shall be provided in the processing section.
- 9.2 The cold storage shall have suitable refrigeration system to maintain the required product temperature.
- 9.3 The floor, ceiling and walls of the cold storage and other storage rooms shall be smooth and easy to clean and disinfect.
- 9.4 Proper steps shall be taken to avoid contamination of the materials stored.
- 9.5 There shall be adequate lighting with protective covers.

## 10. Change rooms and toilets

- 10.1 Adequate number of change rooms for workers shall be provided for high risk and low risk areas.
- 10.2 The change rooms shall be of adequate size having smooth washable walls and floors.
- 10.3 There shall be flush lavatory and the lavatories shall not open directly to the working area.
- 10.4 The toilets shall have self-closing doors and proper fly proofing system.
- 10.5 The change rooms shall have foot-operated washbasin provided with adequate soap, nail brushes and single used towels. There shall be a foot operated waste bin to collect the used towels.
- 10.6 There shall be lockable cupboards and facility for keeping gumboots, shoes and chapels inside the change room.
- 10.7 Suitable arrangements shall be made by the establishment to launder the working clothes of the workers.

## 11. Store rooms.

- 11.1 There shall be separate stores for wet and dry items and the chemicals/ disinfectants should be properly labelled.
- 11.2 Packing material store shall be of adequate size with proper fly and dust proofing system
- 11.3 Cartons shall be kept on cleanable pallets other than wood, away *from* the walls and covered properly. There shall be enough space for a person to walk around.
- 11.4 Pest and rodent control measures shall also extend to the storerooms.

## 12. Water.

- 12.1 Water used in the factory shall be of potable nature and shall meet the requirements of EC Directives No. 98/83/EC or IS : 4251 as the case may be.
- 12.2 Potable water shall be used also for cleaning utensils, machinery, tables etc.
- 12.3 A suitable water management system shall be followed and this shall include use of plumbing diagrams showing the entire reticulation of the water, identifying each tap with consecutive numbers.
- 12.4 Water store tank, both ground level and overhead, should be protected and cleaned regularly.
- 12.5 The taps having hose connections shall be fitted with non- return valves
- 12.5 The water tanks shall be cleaned regularly as per SOP as per pre-decided frequency.
- 12.5 If water is brought from external source i.e. mobile water tankers, it should be cleaned and disinfected periodically.

## 13. Personal Hygiene

- 13.1 The employees engaged in processing activities shall be free from communicable diseases, open sores and wounds.
- 13.2 They shall be medically examined periodically and shall maintain individual health cards issued by an approved medical officer showing that they are fit to handle food products and suitable to work in milk processing plant.
- 13.3 Prophylactic injections shall be administered to the employees and record maintained thereof.
- 13.4 Communicable diseases in their homes to be notified and the employees shall be medically examined after each absence due to illness.

13.5 All workers shall be provided with sufficient sets of clean work dress and headgears.

13.6 A person shall be made responsible for maintenance of personal hygiene of the workers.

#### 14. In-house laboratory

14.1 The establishment shall have a well-equipped in house laboratory for testing microbiological and other chemical parameters.

14.2 The testing shall be done by qualified veterinarian/ technologist (s) approved by the Competent Authority

#### 15. Transportation.

15.1 The establishment shall have suitable and adequate facilities for the transportation of raw material, finished products etc.

15.2 The food contact surfaces of the vehicles shall be smooth made of non-corrosive material and easy to clean and disinfect. They shall be cleaned properly before loading and after unloading and the records maintained thereof.

#### 16. Maintenance.

16.1 There shall be a documented procedure for maintenance of all sections, equipments, machineries etc.

16.2 The machineries/ equipments shall be marked with suitable identification numbers.

## LIST OF PESTICIDES AND DRUGS FOR MONITORING RESIUES

Sl. No.	Compounds	MRLs	Group
1.	Drugs (Antibiotics and growth promoters) banned for use		
1.1	Chloramphenicol*	ND	A <sub>6</sub>
1.2	Nitrofurans(including furazolidone)	ND	
1.3	Metronidazole	ND	
	Ronidazole	ND	
2	Total Residual antibiotics(as beta lactum)	ND	B <sub>1</sub>
	Penicillin-G		
	Ampicillin		
	Amoxicillin		
	Cefacetril		
	Cefalexin		
	Cefalonium		
	Cefaperazon		
	Cefapirin		
	Ceftiofur		
	Cloxaicillin		
	Dioloxacillin		
	Oxacillin		
	Nafcillin		
3.	Anthelmintics		B <sub>2a</sub>
	Albendazole	100 ppb	
	Fenbendazole	10 ppb	
4.	Non Steroidal anti-inflammatory drugs		B <sub>2(e)</sub>
	Phenyl Butazone	Not Established	
5.	Pesticide residues (Organochlorine compounds)	0.01 ppm	B <sub>3a</sub>
	Aldrin		
	Heptachlor		
	Lindane		
	Endosulfan		
	Chlordane		
	Diendrin		
	Methoxychlor		
6.	Organophosphorus pesticide (Group test)	0.01 ppm	B <sub>3b</sub>
	Dichlorovos		
	Ethion		
	Diazion		
	Malathion		
	Methyl parathion		
	Phosalone		
7.	Chemical elements(Heavy metals)		B <sub>3c</sub>
	Lead	0.02 ppm	
	Arsenic	5ppb	
	Tin	250ppm	
	Cadmium	0.1ppm	
	Zinc	1ppm	
	Mercury	0.1ppm	
8.	Mycotoxins(Aflatoxin M1)	0.5 ppb	B <sub>3d</sub>

\*Chloramphenicol : MRPL 0.3 µg/kg

\*\*Nitrofurans : MRPL 1.0 µg/kg

EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA  
(MINISTRY OF COMMERCE & INDUSTRY)  
GOVERNMENT OF INDIA

ADEQUACY AUDIT  
for scrutiny of application and HACCP based food safety management system document

Name of the processing establishment : M/s.

Address of the processing establishment :

District:  
State:  
Country: India.  
Ph.  
Fax:  
E.mail:

Address of the Regd. Office :

District:  
State:  
Country: India.  
Ph.  
Fax:  
E.mail:

Scope of assessment : Adequacy audit of document to adjudge suitability of the infrastructure and equipment facilities of the establishment for processing, handling and storage of milk products and HACCP based food safety management system.

Details of Adequacy audit (*HACCP document must be audited by an official having adequate knowledge of HACCP*)

Type of document for audit	Name and Designation of the Auditor	Authorised by	Date of audit	Remarks (satisfactory / unsatisfactory)
Scrutiny of application				
HACCP document				

Please find enclosed audit observations on desk audit of application and/or HACCP based FSM system, submitted for kind perusal and further necessary action.

Signature of Auditor  
Name  
Designation  
Organization  
Date





**EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA  
(MINISTRY OF COMMERCE & INDUSTRY)  
GOVERNMENT OF INDIA**

**ASSESSMENT REPORT  
FOR INFRASTRUCTURE AND EQUIPMENT FACILITIES**

Name of the processing establishment	: M/s.			
Address of the processing establishment	Address: District: State: Country: India. Ph. Fax: E.mail:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: E.mail:			
Scope of assessment	: On-site verification to adjudge suitability of the infrastructure and equipment facilities of the establishment for processing, handling and storage of milk products			
Date(s) of assessment	:			
Opening Meeting Location and date				
Closing Meeting Location and date				
Name of IDP members	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)
Name of Representative(s) of the establishment	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)

<b>Section-I: Information</b>	
<b>A</b>	<b>General</b>
1	Name of the Chief Executive (MD/Mg. Partner/Proprietor) (Give

	Contact Numbers and E-mail, if any)	
2	Is the processing plant owned or leased by the applicant	Owned/leased
3	If leased, name of the plant owner, plant name and address.	
4	Month and Year of Construction	
5	Month and Year of last major alterations	
6	Month and Year of Commercial Production	
7	Approval requested for export to (Countries)	All countries including European Union / Countries other than EU.
8	Scope of approval. Name(s) of the product(s).	
9	Additional activities, if any, in the same premise and other than the products mentioned above.	
10	Annual production during the previous year (a) Milk Products (Within the scope of approval) (b) Others (specify)	
11	Total exports during the last two years Financial Year Destinations (Countries) Quantity in Metric Tons FOB Value in Rupees in Lakhs.	
12	Whether all year production or seasonal production	
13	Number of working hours and shifts per day	
14	Number of working days per week. Specify weekly holiday	
<b>B.</b>	<b>Information on Structure of the Establishment</b>	
15	No. of vehicles the establishment has for transportation of raw materials, finished products, water(if applicable) 1) Refrigerated vehicle 2) Insulated Vehicle 3) Non-insulated vehicle 4) Three wheelers 5) Water tanker	No.      Capacity      Regd. No.
16	Does the establishment hire outside vehicles?	
17	Is there any chill room / chill storage for storage of food products? Specify numbers and storage temperatures.	
18	Are there storage facilities for in-process liquid milk/milk products? Specify type of storage facility and temperature of storage	
19	Whether the unit have chilling facility to reduce the temperature of the liquid milk products below 6°C? If yes, specify method and capacity of Chilling.	
20	Is there facility for pasteurisation of liquid milk/milk product ?	

	Specify number of pasteurisers and their capacities.	
21	Whether the unit have spray-drying facility? If yes, give details like type and capacity.	
22	Whether there is packing room for every milk product separate from processing activities and storage?	
23	Is there adequate integrated storage facility for dried/frozen finished milk products? Specify type of storage, purpose, number of storages and capacity of storage.	
C.	<b>Information about personnel</b>	
33	Number of veterinarian/ technologists and available in the establishment	
34	Name, designation, qualifications and experience of the personnel qualified and responsible for developing, implementing and maintaining HACCP-based procedures.	
35	Name, designation, qualifications and experience of the veterinarian(s) and technologist(s) supervising the processing and other related operations	
36	Name, designation, qualifications and experience of the qualified personnel, conducting microbiological and chemical analysis	
37	Number of supervisors apart from the above, responsible for processing and handling of food products and maintenance of sanitation and hygiene in the establishment and milks production separately.	
38	Number of male workers in the processing establishment in each shift.	
39	Number of female workers in the processing establishment in each shift.	

<b>Section-II: PRIMARY PRODUCTION AND RAW MATERIAL</b>		
<b>A</b>	<b>Hygiene Provisions and record keeping in Milk Production and handling</b>	
1(i)	Whether the establishment has identified milk production holdings?	
(ii)	Are milk production holdings owned or contracted by the establishment?	
(iii)	Whether the details of all milk production holdings supplying raw milk provided?	
(iv)	Specify name and other details of the milk production holding visited by the IDP.	
(V)	Whether the establishment ensures that raw milk comes from animals that do not show any symptoms of infectious diseases communicable to humans through milk such as brucellosis, tuberculosis?	
(Vi)	Are infected milch animals or suspected of being infected, (brucellosis, tuberculosis) isolated to avoid other animal's milk?	

(Vii)	Are animals undergoing medical treatment and likely to transfer residues to the milk identified & not used for human consumption?	
Vii)	Is there any infrastructure for educating farmers for clean milk production?	
Viii)	Are there any incentive given to the farmers for clean milk production?	
<b>B</b>	<b>Requirement for Premises &amp; Equipment</b>	
1	Are there adequate measures to protect milk production against any contamination?	
2	Is the premise for storage of milk protected against vermin and have adequate separation from premises where animal are housed?	
3.	Are the surfaces of equipment that are intended to come into contact with milk (utensils, containers etc.) washable and non toxic?	
4	Are the milk production holdings under supervision/controls of the unit to ensure the wholesomeness of the raw milk procured?	
5	Is cold chain maintained during transportation to ensure the arrival temperature of raw milk below 10 Deg. C?	
<b>C.</b>	<b>Hygiene During milking, collection and transport</b>	
1	Are there adequate measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary medicinal products and biocides and the storage, handling and disposal of waste in milks production and associated operations?	
2	Are there controls to prevent use of prohibited antibiotics/pharmacological substances and Chemicals?	
3	Are there adequate measures relating to animal health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents in milk production and associated operations?	
4	Is there cleaning and where necessary, disinfecting of facilities used in connection with raw milk production and associated operations, including facilities used to store and handle feed?	
5	Is there cleaning and where necessary, disinfecting of container, utensils, tanks etc. intended for transporting raw milk ,	
6	Is the water used potable or clean, where necessary, to prevent contamination?	
7	Are the personnel trained on health risks and the personnel, handling raw milk in good health?	
8	Is there prevention of animals and pests from causing contamination?	
8	Is the waste and hazardous material handled and stored properly to prevent contamination?	

9	Is there prevention of the introduction and spreading of contagious diseases transmissible to humans through food, including taking precautionary measures when introducing new milch animals and reporting suspected outbreaks of such diseases to the competent authority	
10	Are the samples (feed, water, milk, etc.) drawn for relevant analyses that have importance to human health and records maintained?	
11	Are there appropriate actions on account of the results of any relevant analysis carried out on samples taken from the milch animals or other samples that have importance to human health?	
12	Is there correct use of feed additives and veterinary medicinal products?	
13	Is there appropriate remedial action when informed of problems identified during official controls?	
14	Are there records relating to measures put in place to control hazards in an appropriate manner?	
15	Are there records of nature and origin of feed fed to the milch animals?	
16	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
17	Are there records of the occurrence of diseases that may affect the safety of milk products?	
18	Are there records of other relevant reports on checks carried out on raw milk?	
19	Is milk from animals showing clinical signs of udder disease used for human consumption?	
D	<b>Staff Hygiene</b>	
1	Does person performing milking/or handling of raw milk wear suitable clean clothes and maintain high degree of personal hygiene and is medically fit for the purpose?	
2.	Are there suitable facilities near place of milking for washing hands and arms?	

<b>Section-III: GENERAL HYGIENE REQUIREMENTS</b>		
A.	<b>General requirements for premises and infrastructure</b>	
1.	<u>Premise</u>	
(a)	Whether it has defined curtilage and roads around the building concreted or tarred or turfed?	
(b)	Is it kept clean and maintained in good repair and free from swamps, stagnated water, dumps, rodent harbourage, other animals, environmental contaminations like smoke, objectionable odours, dust, etc., etc.?	
2.	<u>Layout, design, construction, location and size of food premises:</u>	

(a)	Does it permit adequate maintenance, cleaning and/or disinfecting, avoid or minimize air-borne contamination and provide adequate working space to allow for the hygienic performance of all operations?	
(b)	Does it protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces	
(c)	Does it permit good food hygiene practices, including protection against contamination and, in particular, pest control	
(d)	Where necessary, does it provide suitable temperature-controlled handling and storage conditions of sufficient capacity for maintaining food at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.	
(e)	Is it kept clean and maintained in good repair and condition?	
3	<u>Lavatories</u>	
(a)	Are there an adequate number of flush lavatories available and connected to an effective drainage system?	
(b)	Are the lavatories opened directly into rooms in which food is handled?	
4	<u>Washing facilities:</u>	
(a)	Are there an adequate number of washbasins available, suitably located and designated for cleaning hands at all entry points and in food handling areas?	
(b)	Are the washbasins for cleaning hands provided with hot and cold running water, materials for cleaning hands like detergent, disinfectant, etc. and for hygienic drying e.g. single use towels?	
(c)	Are the facilities for washing food separate from the hand-washing facility?	
(d)	Are there feet disinfections facilities like foot dip provide, wherever applicable?	
5	<u>Ventilation:</u>	
(a)	Is there suitable and sufficient means of natural or mechanical ventilation?	
(b)	Is the mechanical airflow from a clean area to a contaminated area?	
(c)	Are the ventilation systems constructed as to enable filters and other parts requiring cleaning or replacement, readily accessible?	
6	Do the sanitary conveniences have adequate natural or mechanical ventilation?	
7	Do the premises have adequate natural and/or artificial lighting?	
8	<u>Drainage facilities</u>	
(a)	Are they adequate for the purpose intended?	
(b)	Are they designed and constructed to avoid the risk of contamination.	
(c)	Where drainage channels are fully or partially open, are they designed as to ensure that waste does not flow from a contaminated area towards or into a clean area, in particular an area where foods likely to present a high risk to the final consumer are handled?	
9	<u>Change room facilities</u>	
(a)	Are adequate separate changing facilities (change room and facilities therein), where necessary, provided for personnel handling raw material, unprocessed products and processed products?	
(b)	Is there separate facility for male and female workers?	

(c)	Whether changing room facility is integrated into the plant layout properly?	
(d)	Does the changing room have smooth walls, floors and washbasins with soaps, disposable towels, nail brushes and non-hand operable taps?	
(e)	Whether there is arrangement for	
i)	Change of footwear	
ii)	Keeping street clothes separately	
iii)	Lockable cupboards	
iv)	Collection of soiled working clothes	
v)	Gumboots	
vi)	Headgear and wherever necessary gloves/ mouth cover	
(f)	Is there suitable in-house arrangement to launder the working clothes of the workers?	
10	Is there storage for cleaning agents and disinfectants in areas where food is not handled?	
B.	Specific requirements in rooms where foodstuffs are prepared, treated or processed	
11	Design and layout to permit good food hygiene practices, including protection against contamination between and during operations	
(a)	<u>Floor</u>	
i)	Are the surfaces maintained in a sound condition and easy to clean and, where necessary, to disinfect?	
ii)	Is it impervious, non-absorbent, washable and non-toxic materials or appropriate to prevent contamination?	
iii)	Do they allow adequate surface drainage?	
(b)	<u>Walls</u>	
i)	Are the surfaces maintained in a sound condition and are easy to clean and, where necessary, to disinfect?	
ii)	Is it impervious, non-absorbent, washable and non-toxic materials or appropriate to prevent contamination and does have a smooth surface up to a height appropriate for the operations?	
(c)	<u>Ceiling</u> : Are the ceilings (or, where there are no ceilings, the interior surface of the roof) and overhead fixtures constructed and finished so as to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable mould and the shedding of particles?	
(d)	<u>Windows and other openings</u>	
i)	Are they constructed to prevent the accumulation of dirt?	
ii)	Are those, which can be opened to the outside environment, where necessary, fitted with insect-proof screens, which can be easily removed for cleaning?	
iii)	Are, where open windows would result in contamination, kept closed and fixed during production?	
(e)	Are the <u>doors</u> easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	
(f)	<u>Surfaces (including surfaces of equipment)</u>	
i)	Are, in areas where food is handled and in particular those in contact with food maintained in a sound condition and are easy to clean and, where necessary, to disinfect?	
ii)	Are these smooth, washable corrosion-resistant and non-toxic materials or appropriate to prevent contamination	



12	<u>Cleaning facilities</u>	
i)	Are adequate facilities provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment?	
ii)	Are these facilities constructed of corrosion-resistant materials, easy to clean and do they have an adequate supply of hot and cold water?	
iii)	Do the every sink or other such facility provided for the washing have an adequate supply of hot and/or cold potable water and kept clean and, where necessary, disinfected?	
iv)	Are the cleaning agents and disinfectants are stored separately under lock and key?	
C	<u>Transport</u>	
13	Are the conveyances and/or containers used for transporting milk/milk product kept clean and maintained in good repair and condition to protect food from contamination and are, where necessary, designed and constructed to permit adequate cleaning and/or disinfection?	
14	Are the receptacles in vehicles and/or containers used for transporting anything other than food where it may result in contamination?	
15	Are the conveyances and/or containers, where used for transporting anything in addition to food or for transporting different foodstuffs at the same time, has effective product separation?	
D	<u>Equipment requirements</u>	
16	Are all the articles, fittings and equipment with which food comes into contact	
(i)	effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination?	
(ii)	constructed, of such materials and kept in such good order, repair and condition as to minimize any risk of contamination?	
(iii)	with the exception of non-returnable containers and packaging, constructed, of such materials and kept in such good order, repair and condition as to enable them to keep clean and, where necessary, disinfected?	
(iv)	installed in such a manner that does allow adequate cleaning of the equipment and the surrounding area?	
17 (i)	Is equipment, where necessary, fitted with an appropriate control device such as time, temperature, pressure, flow rate, etc. ?	
(ii)	Are the process control equipment and devices calibrated at regular intervals?	
18	Are the chemical additives, where have to be used to prevent corrosion of equipment and containers, used in accordance with good practice?	
E	<u>Food waste</u>	
19	Are the non-edible by-products and other refuse removed as quickly as possible from rooms where food is present so as to avoid their accumulation?	
20	Are the non-edible by-products and other refuse deposited in closable containers or any other appropriate foot operable container to prevent contamination?	
21	Are the containers made of an appropriate construction, kept in sound condition, easy to clean and, where necessary, to disinfect?	
22 (i)	Is there adequate provision made for the storage and disposal of food waste, non-edible by-products and other refuse?	

(ii)	Are the refuse stores are designed and managed in such a way as to enable them to keep clean and, where necessary, free of animals and pests?	
23	Is all waste eliminated in a hygienic and environmentally friendly way in accordance with state pollution control board's consent and does not constitute a direct or indirect source of contamination?	
<b>F</b>	<b>Water supply</b>	
24 (i)	Is there documented water management system? Are the outlets identified and serially numbered in the plumbing layout diagram?	
(ii)	Is the water tested as per 98/83/EC or IS:4251 for potability, as applicable?	
25	Is there adequate supply of potable water, which is used whenever necessary to ensure that foodstuffs are not contaminated ( <i>clean water may also be used for external washing</i> )? What is the method of treatment?	
26 (i)	Is the non-potable water circulated in a separate duly identified system, where it is used for fire control, steam production, refrigeration and other similar purposes?	
(ii)	Is the non-potable water connects with, or allows reflux into, potable water systems?	
27 (i)	Is the recycled water used, if any, in processing or as an ingredient presents a risk of contamination?	
(ii)	Is it of the same standard as potable water, acceptable to the competent authority and will not affect wholesomeness of the foodstuff in its finished form?	
28	Is the steam used directly in contact with food likely to contain substance that presents a hazard to health or likely to contaminate the food?	
29 (i)	Is there appropriate measure to prevent contamination through back suction?	
(ii)	Is water storage tank easily cleanable and protected from outside contamination? State frequency of cleaning water tanks.	
36	<u>Pest control</u>	
(i)	Are adequate documented procedures in place to control pests?	
(ii)	Whether bait map showing serially numbered bait stations provided?	
(iii)	Are adequate procedures in place to prevent domestic animals from having access to places where food is prepared, handled or stored?	
<b>G</b>	<b>Maintenance</b>	
37	Is there appropriate maintenance schedule for maintaining infrastructure and equipment facilities and records thereof?	
38	Whether all equipment labelled and marked?	
<b>H</b>	<b>Training</b>	
39	Are the food handlers supervised and instructed and/or trained in food hygiene matters commensurate with their work activity?	
40	Have the persons those responsible for the development and maintenance of the procedure for the operation of relevant guides received adequate training in the application of the HACCP principles?	
41	Are the persons those responsible for compliance with the requirements of national law trained?	
<b>I</b>	<b>Testing facility</b>	

42	Is there in-house testing facility for analysis of raw materials, in-process samples, finished products, hygiene and sanitation control samples, etc.?	
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Section-IV: Any other relevant information:

Section-V: Recommendations of the Inter Departmental Panel (IDP)

The processing establishment may be granted full/conditional approval to process milk product for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000;

a) for all countries including the European Union (EU) / Countries other than EU  
 b) for processing (Scope of Approval -Milk Products which may be allowed to be processed in the establishment)

and  
 c) with annual installed production capacity of \_\_\_MT

Or

The processing establishment may be granted full/conditional approval to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000, subject to rectification of the minor deficiencies given in the enclosed observation sheet within one/ two/ three months from the date of this assessment and subsequent an on-site verification of the rectifications, by IDP-Convener/ IDP.

Or

The processing establishment may not be approved to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000. The deficiencies observed are given in the enclosed observations sheet. The establishment may apply a fresh after rectification of the deficiencies.

Section VI: Suggestions for improvement, if any:

Signature			
Name			
Place:			
Date			

**EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA  
(MINISTRY OF COMMERCE & INDUSTRY)  
GOVERNMENT OF INDIA**

**ASSESSMENT REPORT  
FOR GMP, GHP, GVP, HACCP, etc.**

Name of the processing establishment	: M/s.			
Address of the processing establishment	Address: District: State: Country: India. Ph. Fax: E.mail:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: E.mail:			
Scope of assessment	: On-site verification to assess implementation of HACCP based food safety management system for processing, handling and storage of milk products			
Date(s) of assessment	:			
Opening Meeting Location and date				
Closing Meeting Location and date				
Name of IDP members	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)
Name of Representative(s) of establishment	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)

Section-I: Information about personnel		
1.	Number of technologists and veterinarians available in the establishment	
2.	Are there appropriate personnel qualified, experienced and responsible for developing, implementing and maintaining HACCP-based procedures?	

3.	Are there appropriate qualified and experienced technologist(s) for supervising the processing and other related operations?	
4.	Are there appropriate qualified and experienced personnel for conducting microbiological and chemical analysis?	
5.	Are there appropriate qualified and experienced personnel responsible for processing and handling of food products and maintenance of sanitation and hygiene in the establishment and milk production separately?	
6.	Number of male workers in the processing establishment in each shift .	
7.	Number of female workers in the processing establishment in each shift .	

Section-II: PRIMARY PRODUCTION AND RAW MATERIAL		
<b>A</b>	<b>Hygiene Provisions and record keeping in Raw Milk Production and handling</b>	
1.	Are there appropriate actions on account of the results of any relevant analysis carried out on samples taken from the milch animals or other samples that have importance to human health?	
2	Is there appropriate remedial action when informed of problems identified during official controls?	
3	Are there records of other relevant reports on checks carried out on milch animals or raw milk?	
<b>B.</b>	<b>Other Food Ingredients/additives/preservatives</b>	
5	Are there controls on procurement of other Food Ingredients, additives, preservatives, etc.?	
6	Is list of the additives/ preservatives furnished?	
7	Whether the additives/preservatives are of food grade quality, acceptable to importing country?	

Section-III: GENERAL HYGIENE REQUIREMENTS		
<b>A</b>	<b><u>Transport</u></b>	
1	Are the conveyances and/or containers, where used for transporting anything in addition to food or for transporting different foodstuffs at the same time, has effective product separation?	
<b>B</b>	<b>Personal hygiene</b>	
2	Is every person working in a food-handling area maintaining a high degree of personal cleanliness and wearing suitable, clean and, where necessary, protective clothing?	
3	Is person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea, permitted to handle food or enter any food-handling area in any capacity, if there is any likelihood of direct or indirect contamination? Are the health cards maintained for all employees?	

4	Does any person so affected and employed in the establishment and who is likely to come into contact with food report immediately the illness or symptoms, and if possible their causes, to the processing establishment?	
<b>C</b>	<b>Provisions applicable to foodstuffs</b>	
5	Does the establishment accept raw materials or ingredients, other than food, or any other material used in processing products, even though they are known to be, or might reasonably be expected to be, contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances to such an extent that, even after the establishment applies normal hygienic sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption?	
6	Are the raw materials and all ingredients stored in the premises kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination?	
7	At all stages of production, processing and distribution, is the food protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state?	
8	<u>Storage conditions</u>	
	Are the raw materials, food ingredients, intermediate products and finished products likely to support the reproduction of pathogenic micro-organisms or the formation of toxins, kept at temperatures that might result in a risk to health?	
9	Does the establishment have suitable rooms for manufacturing, handling and wrapping processed foodstuffs, large enough for separate storage of raw materials from processed material and sufficient separate refrigerated storage?	
10	Are the foodstuffs, where held or served at chilled temperatures, cooled as quickly as possible following the heat-processing stage or final preparation stage when no heat process is applied, to a temperature, which does not result in a risk to health?	
11	Are hazardous and/or inedible substances adequately labelled and stored in separate and secure containers?	
<b>D</b>	<b>Wrapping and packaging of foodstuffs</b>	
12	Is the material used for wrapping and packaging a source of contamination?	
13	Are the wrappings and packing materials stored in such a manner that they are exposed to a risk of contamination?	
14	Are wrapping and packaging operations carried out so as to avoid contamination of the products? ( <i>Where appropriate and in particular in the case of cans and glass jars, the integrity of the container's construction and its cleanliness must be assured.</i> )	
15	Is the wrapping and packaging material re-used for foodstuffs easy to clean and, where necessary, to disinfect?	
<b>E</b>	<b>Heat treatment</b>	
16	Is the heat treatment process used to process raw milk adequate to show a negative reaction to the phosphatase test?	
(i)	raise every particle of the product treated to a given temperature for a given period of time?	
(ii)	prevent the product from becoming contaminated during the process?	

17 (i)	Does the process employed achieve the desired objectives?	
(ii)	Are the main relevant parameters (particularly temperature, pressure, sealing and microbiology), checked regularly including by the use of automatic devices?	
18	Does the process used conform to an internationally recognized standard (for example, pasteurization, heat treatment, UHTetc.)?	

<b>Section-IV: REQUIREMENTS CONCERNING PRODUCTS</b>		
<b>A</b>	<b>Application of the Identification Mark</b>	
1	Is the Identification mark and details of the approved establishment applied before the product leaves the establishment?	
a)	Are the consignments of milk products, destined not for retail but for use as an ingredient in the manufacture of another product, have label giving the temperature at which the milk products must be maintained and the period during which conservation may thus be assured?	
2	Is new mark applied to a product after further processing in another approved establishment with the approval number of the establishment where these operations take place?	
<b>B</b>	<b>Form of the Identification Mark</b>	
3	Are marks legible and indelible, and the characters easily decipherable? Is It clearly displayed for the competent authorities?	
4	Does the mark indicate the name of the country in which the establishment is located?	
<b>C</b>	<b>Method of Marking</b>	
5	Is the mark applied directly to the product, the wrapping or the packaging, or printed on a label affixed to the product, the wrapping or the packaging depending on the presentation of different products of animal origin?	
6	Is the mark an irremovable tag of resistant material?	
<b>D</b>	<b>HACCP-based Procedures (Hazard analysis and critical control points)</b>	
7	Are the HACCP principles in place, implemented and maintained?	
8	The HACCP principles	
a)	Are the hazards, if any, need to be prevented, eliminated or reduced to acceptable levels identified appropriately?	
b)	Are the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels identified appropriately?	
c)	Are the critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards established appropriately?	
d)	Are the monitoring procedures at critical control points established and implemented effectively?	
e)	Are the corrective actions when monitoring indicates that a critical control point is not under control established?	
f)	Are the procedures, which need to be carried out regularly, to verify that the measures outlined in (a) to (e) above are working effectively, established?	
g)	Are the documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in (a) to (f) above established?	
9	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	

10	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
11	Are the documents up-to-date at all times?	
12	Are the documents and records retained for an appropriate period?	
13	<u>Traceability of raw milk procurement:</u> Do the procedures guarantee that each supply of raw milk accepted onto premises:	
(a)	Is properly identified?	
(b)	Is accompanied by the relevant information from the holding of provenance controlled / supervised by the processing establishment?	
(c)	Come from a holding or an area subject to a movement prohibition or other restriction for reasons of animal or public health, except when the competent authority so permits?	
(d)	Is clean?	
(e)	Is fit for consumption, as far as the food business operator can judge?	
(f)	is in a satisfactory state?	
14	In the event of failure to comply with any of the requirements listed under point 13 (a to f) above, is it notified to the approved veterinarian/ technologist and took appropriate measures?	
E)	<b>Food Chain Information</b>	
15	Does the processing establishment accept raw milk without request and relevant food safety information, contained in the records kept at the holding of provenance, such as;	
(i)	The status of the holding of provenance or the regional animal health status?	
(ii)	the health status of raw milk supplied to the establishment?	
(iii)	Veterinary medicinal products or other treatments administered to the animals within a relevant period and with a withdrawal period greater than zero, together with their dates of administration and withdrawal periods?	
(iv)	The occurrence of diseases that may affect the safety of milk products?	
(v)	The results, if they are relevant to the protection of public health, of any analysis carried out on samples taken from the milch animals or other samples taken to diagnose diseases that may affect the safety of milk products, including samples taken in the framework of the monitoring and control of zoonoses and residues?	
(vi)	Relevant reports about previous <i>ante</i> -and <i>post-mortem</i> inspections of milch animals from the same holding of provenance including, in particular, reports from the official veterinarian?	
(vii)	Production data, when this might indicate the presence of disease?	
(viii)	the name and address of the veterinarian attending the holding of provenance?	
16	If any lot of raw milk arrives at the processing establishment without food chain information, is it notified to the approved technologist immediately?	
17	Is the raw milk processed without permission of the approved technologist?	

<b>Section-V: SPECIFIC REQUIREMENTS</b>	
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A	Raw Milk Criteria & Handling	
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1	Is the raw milk stored and transported at a temperature, preferably constant, which is best suited to assure optimal conservation of their hygiene properties?	
2	Does the raw milk meet the criteria for SPC & Somatic Cell Count as laid down in the Executive instructions?	
3.	Is raw milk cooled to 6 Dec C or below and kept at that temperature until processed?	
<b>B</b>	<b>Milk Products Processing</b>	
<b>3</b>	<b>Requirements for Establishments</b>	
b)(i)	does each particle of the liquid milk undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level?	
(ii)	Does a batch that has been insufficiently processed undergo processing again immediately in the same establishment, rendering the reprocessing fit for human consumption?	
(iii)	Where a batch is found unfit for human consumption, is it destroyed to ensure that it is not used for human consumption?	
h)	Does the storage period at 4 °C before processing exceed 48 hours?	
<b>7</b>	<b>Analytical Specifications</b>	
(i)	Is the unit having in-house facilities for inspection and testing?	
(ii)	Is the unit having separate qualified and competent personnel for conducting physical ,chemical and microbiological tests?	

**Section-VI: Any other relevant information:**

**Section-VII: Recommendations of the Inter Departmental Panel (IDP)**

The processing establishment may be granted full approval to process milk product for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000, in continuation to the conditional approval granted earlier. However, Non – EU approved units if applies for approval to EU, conditional approval is not required.

Or

The processing establishment may be granted full approval to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000, subject to rectification of the minor deficiencies given in the enclosed observation sheet within a maximum period of one month from the date of this assessment and subsequent an on-site verification of the rectifications, by IDP-Convener/ IDP. The conditional approval may be further extended, if required.

Or

The processing establishment may not be approved to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000. The conditional approval granted to the establishment may be withdrawn. The deficiencies observed are given in the enclosed observations sheet. The establishment may apply a fresh after rectification of the deficiencies.

Section VIII: Suggestions for improvement, if any:

Signature			
Name			
Place:			
Date			

EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA  
(MINISTRY OF COMMERCE & INDUSTRY)  
GOVERNMENT OF INDIA

NON -CONFORMITY REPORT

Name of the Unit :

Scope of visit:

DEFICIENCIES

Signature

.....

Name

.....

Designation

.....

Organization

.....

Date

.....

Fully agree with the observations /recommendations

Signature (representative of the unit)

Name

Designation

Date

Seal of the firm

(Letter of Non approval to process milk products for export to EU/Non-EU)  
(format of non-approval letter)

EXPORT INSPECTION AGENCY – \_\_\_\_\_

No. EIA/

Date : \_\_\_\_\_

To

--

Dear Sirs,

Sub: Non approval to process milk products for export to EU/Non-EU.

Ref: Your application dated \_\_\_\_\_.

The Inter Departmental Panel (IDP) of experts visited your processing establishment, particulars of which are given below, for adjudging its suitability for approval under the Export of Milk Products (QC, I & M) Rules, 2000 for processing of milk/manufacturing of milk products for export to all countries including European Union/Non-EU countries:

Name and Location of the Establishment	Date of IDP Visit

The IDP has observed certain defects/deficiencies in your processing establishment, which are given in the annexure. In view of the nature of defects/deficiencies, it is regretted that your processing establishment cannot be now approved to process milk products for export to all countries including EU/ Non-EU countries.

You may, however, rectify all the defects/deficiencies, ensure that your processing establishment meets the above mentioned requirements and apply for approval afresh.

Please acknowledge receipt.

Yours faithfully,

Joint Director I/C

Encl: Annexure

Copy to:

- (1) The Officer In-charge  
EIA-\_\_\_\_\_, Sub Office: \_\_\_\_\_
- (2) The Director (I&Q/C), EIC, New Delhi –110 001

(Letter of Conditional approval to process milk products for export to EU/Non-EU

**EXPORT INSPECTION AGENCY – \_\_\_\_\_**  
**(MINISTRY OF COMMERCE AND INDUSTRY)**  
**GOVERNMENT OF INDIA**

No. EIA/

Date:

To

M/S. ....  
 .....  
 .....

Dear Sirs,

Sub: Conditional Approval of Milk Processing establishment under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000

Ref: Your application No. \_\_\_\_\_ dated \_\_\_\_\_

Please refer to your application cited above for approval of your establishment, for processing and packing of milk products for export as required under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000

In exercise of the powers conferred by Rule 4.15 of the said Rules, the Panel of Experts visited your establishment on \_\_\_\_\_ to assess the suitability of the infrastructure and equipment facilities for processing Milk Products for export.

After due consideration of the report of the Panel of Experts, your processing establishment has been granted conditional approval under Rule 4.15 of the Export of Milk Products (QC, I & M) Rules, 2000 to process milk products for export. The conditional approval granted to your establishment is valid for a period of three months from \_\_\_\_\_ up to and including \_\_\_\_\_ as per following details: ,.

1.	Name of the establishment	
a)	Address of the establishment	
b)	Address of the Regd. Office	
2.	Approval No.	
3.	Scope of approval (Items covered)	
4.	Approval granted to export	All countries including EU Non-EU countries only

During the conditional approval you are permitted to process milk products meant for export in your approved establishment. However, the export of milk products to the EU will be permitted only after full approval by EIC. You are requested to apply for full approval as soon as your establishment comply with HACCP based food safety requirements and all the activities are operational, so as to arrange a second IDP

visit to assess the processing activities and HACCP implementation of your establishment. It shall be ensured that your establishment have production of milk products at the time of the IDP visit.

The approval number allotted to your establishment shall be legibly marked on all export packages of milk products. The details of identification mark shall comply with the requirements given in the executive instructions. “Q” Mark along with approval number shall be legibly printed / labelled on all export packages (master cartons) of milk products as required by the Executive Instructions.

Your establishment shall henceforth come under the purview of monitoring by Export Inspection Agency-\_\_\_\_\_, as under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 It shall issue “Certificate for Export” for every consignment of milk products meant for Non-EU countries. The validity of the “Certificate for Export” issued by the establishment shall be forty five days from the date of issuance. A fee @ 0.2% of FOB value shall be paid to EIA for every consignment of milk products exported by the unit or through its merchant exporter(s), if any. Certificate for Export meant for Merchant exporter, should be got countersigned by the Export Inspection Agency-\_\_\_\_\_, on payment of fee @ 0.2% of FOB value and service charges of Rs.100/- for each certificate. Certificate blanks are to be obtained from the controlling EIA office at a cost of Rs.20/- per set.

You should open a deposit account and ensure that adequate balance is always maintained in your deposit account with Export Inspection Agency-\_\_\_\_\_ for payment of monitoring fee and other applicable fee/charges. You should submit the two copies of the “Certificate for Export” to Export Inspection Agency-\_\_\_\_\_ along with fortnightly statement on the consignments exported and certificates issued, on a regular basis for debiting of the required monitoring fee. The statement should reach EIA office on or before 20th and 5<sup>th</sup> of every month.

You are also advised to develop and implement HACCP based “Own Checks” system and ensure proper maintenance of records. Should you need any health certificate, you should request this office with complete details along with the pink copy of the “Certificate for Export” and all relevant analytical test reports for the consignment.

Please acknowledge receipt.

Yours faithfully,

Agency In-Charge

Copy to :

1. The Director (I & Q/C) EIC, New Delhi – 110 001.
2. The Commissioner of Customs
3. The Officer In-charge, (Sub office concerned)
4. The Additional Director, EIC, New Delhi with a request for updating website
5. Party File ( )

(Letter of Full approval to process milk products for export to EU/Non-EU)

**EXPORT INSPECTION AGENCY – \_\_\_\_\_**  
**(MINISTRY OF COMMERCE AND INDUSTRY)**  
**GOVERNMENT OF INDIA**

No. EIA/

Date:

To

M/S. ....  
 .....  
 .....

Dear Sirs,

Sub: Full Approval of Milk Processing establishment under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000

Please refer to your application for approval of your establishment dated \_\_, for processing and packing of milk products for export as required under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000.

In exercise of the powers conferred by Rule 4.15 of the said Rules, the Panel of Experts visited your establishment on \_\_\_\_\_ to assess the adequacy of the implementation of HACCP based food safety management system for processing milk products for export.

After due consideration of the report of the Panel of Experts, your processing establishment has been granted full approval under Rule 4.15 of the Export of Milk Products (QC, I & M) Rules, 2000 to process milk products for export. The full approval granted to your establishment is valid for a period of two years from \_\_\_\_\_ up to and including \_\_\_\_\_ as per following details:

1.	Name of the establishment	
a)	Address of the establishment	
b)	Address of the Regd. Office	
2.	Approval No.	
3.	Scope of approval (Items covered)	
4.	Approval granted to export	All countries including EU Non-EU countries only

You may export milk products to countries other than EU. However, the export of milk products to the EU will be permitted only after permission of EIC in this regard.

The approval number allotted to your establishment shall be legibly marked on all export packages of milk products. The details of identification mark shall comply with the requirements given in the executive instructions. “Q” Mark along with approval number shall be legibly printed / labelled on all export packages (master cartons) of milk products as required by the Executive Instructions.

Your establishment continue to be under the purview of monitoring by Export Inspection Agency-\_\_\_\_\_, as under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 It shall issue “Certificate for Export” for every consignment of milk products. The validity of the “Certificate for Export” issued by the establishment shall be forty five days from the date of issuance. A fee @ 0.2% of FOB value shall be paid to EIA for every consignment of milk products exported by the unit or through its merchant exporter(s), if any. Certificate for Export meant for Merchant exporter, should be got countersigned by the Export Inspection Agency-\_\_\_\_\_, on payment of fee @ 0.2% of FOB value and service charges of Rs.100/- for each certificate. Certificate blanks are to be obtained from the controlling EIA office at a cost of Rs.20/- per set.

You should ensure that adequate balance is always maintained in your deposit account with Export Inspection Agency-\_\_\_\_\_ for payment of monitoring fee and other applicable fee/charges. You should submit the two copies of the “Certificate for Export” to Export Inspection Agency-\_\_\_\_\_ along with fortnightly statement on the consignments exported and certificates issued, on a regular basis for debiting of the required monitoring fee. The statement should reach EIA office on or before 20th and 5<sup>th</sup> of every month.

You are also advised to maintain and review regularly the HACCP based “Own Checks” system and ensure maintenance proper records. Should you need any health certificate, you should request this office with complete details along with the pink copy of the “Certificate for Export” and all relevant analytical test reports for the consignment.

You should apply to EIA concerned within 60 days from the date of expiry of approval.

Please acknowledge receipt.

faithfully,

Yours

Charge

Agency In-

Copy to :

1. The Director (I & Q/C) EIC, New Delhi – 110 001.
2. The Commissioner of Customs
3. The Officer In-charge, (Sub office concerned)
4. The Additional Director, EIC, New Delhi with a request for updating website
5. Party File ( )



EXPORT INSPECTION COUNCIL OF INDIA  
Ministry of Commerce & Industry  
Govt. of India  
*Certificate of Approval*

In exercise of the powers conferred by the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 vide Notification No.S.O.2720 dated 28<sup>th</sup> November 2000, published in the Gazette of India, Extra Ordinary, Part II, Section 3, Sub Section (ii), dated 16.12.2000.

.....  
(Name of the establishment)

having their registered office at .....

.....  
(Address of the registered office)

is hereby granted approval/renewal of approval for a period of two years

valid upto and including.....under approval No.....

for .....

.....  
(Nature of activity of the establishment)

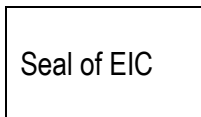
in its establishment situated at .....

.....  
(Location of the establishment)

for export to.....

(Name of the importing Country)

subject to the conditions that the establishment should continue to meet the requirements of GOI Notifications No.S.O 2720 dated 28.11.2000 effective from date 16 December 2000 as amended.



Place : New Delhi

Signature :

Date:

Name : Ms. Shashi Sareen

Designation: Director (I&Q/C)

3<sup>rd</sup> Floor, NDYMCA Cultural Centre Building, 1 Jai Singh Road, New Delhi:110001

Tel:+ 91-11-23365540, 23748189 Fax: +91-11-23748024

E.mail :eic@eicindia.org

Web: www:eicindia.org

To

The Joint Director/Deputy Director In-charge  
Export Inspection Agency -

Sub: Application for approval of Veterinarian/Technologist.

Sir,

I am a qualified \_\_\_\_\_(professional qualification) seeking approval of EIA as an approved veterinarian/technologist for inspection/testing, handling, processing, storage and transportation of milk products meant for export. Kindly, find the following details for your perusal. Please also find enclosed copies of qualification certificate, experience certificates, \_\_\_\_\_ .

1.	Name and Address with contact number	:	Mr./Ms.
2.	Educational / Professional qualifications indicating main subject of study (Only degree level and postgraduate qualifications need be shown.) (Attach attested copies of the certificates)	:	
3.	Date of Birth	:	
4.	Present place of posting with approval No. of the processing establishment where presently posted and designation.	:	
5.	Particulars of training undergone in the field of milk processing and/or quality control.	:	
6.	Experience (in number of years) in the field of milk processing/quality control (attach experience certificate)	:	
7.	(a) Whether previously approved by EIA	:	Yes / No
	(b) If yes, reference number and date of approval letter (Attach a copy of approval letter)	:	

Herewith, I declare that the above information is true and correct to the best of my knowledge.

In case, I am approved by EIA, I shall abide to the rules, regulations and executive instructions issued by EIC/EIA and shall carry out all the tasks of the approved veterinarian/ technologist specified, in order to ensure the quality and safety of the milk products, meant for export.

I am enclosing a Demand Draft No. \_\_\_\_\_ dated \_\_\_\_\_ for Rs. \_\_\_\_\_ drawn on. \_\_\_\_\_ Bank in favour of Export Inspection Agency-\_\_\_\_\_ towards assessment fee for approval of the veterinarian/ technologist.

Signature  
Name  
Designation  
Place  
Date

**EXPORT INSPECTION AGENCY – \_\_\_\_\_**  
**REPORT OF ASSESSMENT OF VETERINARIAN/TECHNOLOGIST**

1.	Name and Address of the establishment to which the candidate is attached	}	
2.	Approval No. of the establishment	}	
3.	Name of the veterinarian/technologist	}	Mr./Ms.
4.	Educational/professional qualifications	}	
5.	Experience in milk processing / QC	}	
6.	Date of Assessment	}	
7.	Whether the qualifications and experience are verified	}	Yes / No.
8.	Is this the first approval of veterinarian/ technologist or renewal of the approval?	}	
	<b><u>Factors of assessment</u></b>		<b><u>Panel observations</u></b>
8.	Ability to supervise milk processing operations	}	
9.	Knowledge of sampling techniques	}	
10.	Knowledge of organoleptic inspection of milk products	}	
11.	Knowledge of microbiological testing of milk products	}	
12.	Knowledge of chemical testing of milk products	}	
13.	Knowledge of sanitation and hygiene control	}	
14.	Knowledge of HACCP based own checks system	}	
15.	Knowledge of record keeping	}	
16.	Knowledge of milk product Notifications and Executive Instructions/ EC directives	}	
17.	Quality Consciousness	}	
18.	Knowledge of regulatory Requirements of importing countries	}	
19.	Any other in formations	}	

**REMARKS/ RECOMMENDATIONS OF THE PANEL OF EXPERTS:**

Signature			
N a m e			
Institution			
Date			

EXPORT INSPECTION AGENCY – \_\_\_\_\_  
(MINISTRY OF COMMERCE AND INDUSTRY)  
GOVERNMENT OF INDIA

Certificate of Approval of Veterinarian/Technologist

(In exercise of the powers conferred by Document No. EIC/Milk –Ex. Instructions./ June 2007 / Issue 4)

Sh./Smt. ....  
(Name of the veterinarian/ technologist)

holding.....  
(Qualification)

and residing at .....  
(Residential address)

is hereby approved as a veterinarian/ technologist to handle Milk Products meant for export for a period of two years

valid up to and including .....

subject to the conditions that the performance of the veterinarian/ technologist if found not satisfactory, the Export Inspection Agency-\_\_\_\_\_reserves the right to withdraw the approval granted to him/her to function as the approved veterinarian/ technologist. Moreover, after the expiry of the validity of the approval, the veterinarian/ technologist shall be reassessed by the IDP for granting fresh approval.

Place:

Signature:

Date: (Seal)

Name:

Designation:

|

*(APPLICATION FOR APPROVAL OF ADDITIONAL FACILITIES/PROCESSING ACTIVITIES)*

From

To

Sir,

Please carry out the assessment of our establishment for additional facilities/ activities as required under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules 2000 and also the requirements communicated by EIC from time to time for processing milk products for export.

We furnish below the information regarding the additional facilities/processing activities added in our establishment.

We undertake that our establishment meets the requirements stipulated in Export of Milk products (quality Control Inspection and Monitoring) Rules 2000 and also the other requirements specified by the importing countries.

You may please charge fee applicable from our deposit account maintained at EIA.

**1.General Information**

1.1	Name and address of establishment seeking approval for additional facilities/activities.	
1.2	Processor Code number, allotted by EIA	
1.3	Name of the Chief Executive (MD/MG. Partner/Proprietor) with telephone, fax, E-mail address, if changed.	
1.4	Details of additional facility/activity requested for approval	

**2.Construction and layout**

2.1	Whether any alteration made in the building and layout? (give details)	
2.2	If so, whether it satisfies the requirements of GoI notification and EU/importing country regulations?	
2.3	Whether walls, floor and roof are smooth and easily cleanable	
2.4	Whether windows, ventilators and doors are made as per norms?	
2.5	Are the lighting and ventilation adequate?	
2.6	Whether adequate washing and sanitizing facilities provided?	
2.7	Is pest control adequate?	

**3. Raw material**

3.1	Is there any change in the source of raw material procurement?(give detail)	
3.2	If so, whether proper traceability has been established and documented?	
3.3	Whether the quality and safety of the raw material ensured?	

#### 4. Additional facilities

4.1	Specify the additional facilities created with details	
4.2	Whether the additional facilities created are in line with the requirements of GOI notification and EC/importing country regulations?	
4.3	Whether the sanitary and hygienic conditions of the facilities are satisfactory?	
4.4	Is the location of the additional facility suitable for smooth flow of work?	
4.5	Whether adequate precautions have been taken to avoid cross contamination?	
4.6	Whether provisions have been made for cleaning and sanitation?	
4.7	Calibrated temperature recording devices installed where applicable?	
4.8	Whether the installation of the new facility increases the production capacity of the unit ?	
4.9	If so what is the expected new production capacity ?	
4.10	Whether the new facility has been incorporated in the HACCP manual suitably.	

#### 5. Additional activities

5.1	Specify the additional activities requested for approval with details	
5.2	Whether the additional activities have been properly addressed in the HACCP manual and submitted to the EIA for verification?	
5.3	Whether HACCP is in place?	
5.4	Whether CCPs have been identified and monitored properly?	
5.5	Whether proper raw material, process and product controls are laid down to ensure the safety and quality of the product?	
5.6	Are the employees maintaining good hygienic practices?	
5.7	Whether Freezing /Spray drying /pasteurisation etc. activities involved for the new facility?	
5.8	If so, are the time/temperature controls properly validated by an approved agency?	
5.9	Whether additional man power is required for the new process activity ?	
5.10	If so, give details of number of employees / supervisors/ veterinarian/ technologist recruited	
5.11	Whether additional equipments, machineries required for the new process activity ?	
5.12	If so, give details of equipments, machineries erected/ acquired	
5.13	Are the new gauges and thermometers calibrated?	
5.14	Whether calibrated automatic temperature recording devices have been installed where applicable?	
5.15	If additional water are required for processing new product, whether the same are tested as per 98/83/EC/IS:4251?	

6. Any other information.

Yours faithfully,

Signature :

Name :

Designation :

Company seal:

Place:

Dates

*Check List of enclosures*

1. Authorisation to charge fee applicable from our deposit account maintained at EIA.
2. Up-to-date layout plan of establishment showing alterations made if any.
3. Flow chart of processing operation where applicable.
4. Plumbing diagram (where applicable)
5. Attested copy of potability certificate of water  
(as per the Directive 98/83/EC or, IS 4251) where applicable
6. HACCP manual, where applicable

EXPORT INSPECTION AGENCY- \_\_\_\_\_  
 MINISTRY OF COMMERCE  
 GOVERNMENT OF INDIA

**ASSESSMENT REPORT FOR ADDITIONAL FACILITIES/ PROCESSING ACTIVITIES OF THE ESTABLISHMENT**

Name of the processing establishment	: M/s.			
Approval number of the establishment				
Current scope of approval (Name of the products and countries for export)				
Additional scope of approval requested for				
Address of the processing establishment	Address: District: State: Country: India. Ph. Fax: E.mail:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: E.mail:			
Scope of assessment	: Verification to adjudge suitability of the infrastructure and equipment facilities of the establishment and implementation of HACCP based food safety management system for processing, handling and storage of milk products pertaining to additional facilities/ activities.			
Date(s) of assessment	:			
Opening Meeting Location and date				
Closing Meeting Location and date				
Name of IDP members	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)
Name of Representative(s) of the establishment	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)



**1.General Information**

1.1	Name and address of establishment seeking approval for additional facilities/activities.	
1.2	Processor Code number, allotted by EIA	
1.3	Name of the Chief Executive (MD/MG. Partner/Proprietor) with telephone, fax, E-mail address, if changed.	
1.4	Details of additional facility/activity requested for approval	

**2.Construction and layout**

2.1	Whether any alteration made in the building and layout? (give details)	
2.2	If so, whether it satisfies the requirements of GoI notification and EU/importing country regulations?	
2.3	Whether walls, floor and roof are smooth and easily cleanable	
2.4	Whether windows, ventilators and doors are made as per norms ?	
2.5	Are the lighting and ventilation adequate?	
2.6	Whether adequate washing and sanitizing facilities provided?	
2.7	Is pest control adequate?	

**3.Raw material**

3.1	Is there any change in the source of raw material procurement?(give detail)	
3.2	If so, whether proper traceability has been established and documented?	
3.3	Whether the quality and safety of the raw material ensured?	

**4. Additional facilities**

4.1	Specify the additional facilities created with details	
4.2	Whether the additional facilities created are in line with the requirements of GOI notification and EC/importing country regulations?	
4.3	Whether the sanitary and hygienic conditions of the facilities are satisfactory?	
4.4	Is the location of the additional facility suitable for smooth flow of work?	
4.5	Whether adequate precautions have been taken to avoid cross contamination?	
4.6	Whether provisions have been made for cleaning and sanitation ?	
4.7	Calibrated temperature recording devices installed where applicable?	
4.8	Whether the installation of the new facility increases the production capacity of the unit	
4.9	If so what is the expected new production capacity ?	
4.10	Whether the new facility has been incorporated in the HACCP manual suitably.	

**5. Additional activities**

5.1	Specify the additional activities requested for approval with details	
-----	---	--

5.2	Whether the additional activities have been properly addressed in the HACCP manual and submitted to the EIA for verification?	
5.3	Whether HACCP is in place?	
5.4	Whether CCPs have been identified and monitored properly?	
5.5	Whether proper raw material, process and product controls are laid down to ensure the safety and quality of the product?	
5.6	Are the employees maintaining good hygienic practices?	
5.7	Whether Freezing /Spray drying /pasteurisation etc. activities involved for the new facility?	
5.8	If so, are the time/temperature controls properly validated by an approved agency?	
5.9	Whether additional man power is required for the new process activity ?	
5.10	If so, give details of number of employees / supervisors/ veterinarian/ technologist recruited	
5.11	Whether additional equipments, machineries required for the new process activity ?	
5.12	If so, give details of equipments, machineries erected/ acquired	
5.13	Are the new gauges and thermometers calibrated?	
5.14	Whether calibrated automatic temperature recording devices have been installed where applicable?	
5.15	If additional water are required for processing new product, whether the same are tested as per 98/83/EC/IS:4251?	

## 6. Any other information.

### Recommendations of the Inter-Departmental Panel (IDP)

Name of establishment and Address	
Approval Number allotted by EIA	
Nature of activities already approved	
Countries to which the above unit is eligible to process	All countries including the European Union (EU) Countries other than EU
Milk products, which may be allowed to be processed in the above unit.	
Additional facilities/ activities requested for approval	

The above additional facilities/processing activities of the establishment may not be approved under the Export of Milk products (Quality Control, Inspection and Monitoring) rules 2000. The deficiencies observed are given in the attached sheet.

Or

The above additional facilities/processing activities of the establishment may be approved under the Export of Milk Products (Quality control, Inspection and Monitoring) rules 2000.

Reasons:

Suggestions for improvement, if any:

Signature :			
Name :			
Designation :			
Organisation :			
Date :			

**APPLICATION FOR RENEWAL OF APPROVAL OF ESTABLISHMENT**  
( To be submitted in duplicate two months before the expiry of current approval )

From

.....  
.....  
.....

To

The Joint Director  
Export Inspection Agency – \_\_\_\_\_

Sir,

The approval granted to our establishment, particulars of which are given below, to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000 may kindly be renewed from the date of expiry of the earlier approval.

You may please charge fee applicable from our deposit account maintained at EIA.

1.	Name and address of the establishment	
2.	Approval Number allotted by EIA	
3.	Date of expiry of current approval	
4.	Address of the registered office of the establishment (If different from the one at Sl. No.1 above)	
5.	Nature of activities for which the establishment is approved and renewal sought	
6.	Approval sought to process milk products for export to:	All countries including EU/non-EU countries only
7.	Export during last two years (with details of volume, value, destination etc.)	
8.	Annual Production during the last two years	
9.	No. of complaints received from foreign buyers/importing countries during the last two years (give year wise details)	
10.	Nature of complaints and action taken with details	
11.	Details of changes in the name and in management, of the company if any	
12.	Name of the Chief Executive Officer (CEO)(with Telephone no., Fax, etc.)	
13.	Pollution Control Board consent letter Number and its validity.	
14.	Test Report Number, date and name of approved laboratory in respect of water used in the factory.	
15.	Date of review/revision of HACCP manual	
16.	No. of veterinarian/ technologists (approved and non approved)	
17.	Layout changes, if any, during the last two years	
18.	Additional facilities/equipment provided, if any, during the last two years	
19.	Source of raw material used.(Attach the list of identified farms)	



(Reminder letter to units for renewal of approval)

EXPORT INSPECTION AGENCY –

No. EIA/

Date:

To

(Name and Address of establishment)

Dear Sirs,

Sub: Renewal of Approval of establishment to process milk products for export to EU/non-EU countries

Ref: Approval No. \_\_\_\_\_; Validity of current approval: Up to \_\_\_\_\_

The approval accorded to your establishment to process milk products for export to EU/non-EU countries will be expiring on the date shown above. If you wish to continue export of milk products beyond the date of expiry of the current approval, you will have to seek renewal of approval at least 60 days before the date of expiry of current approval. A format of the application for renewal of approval is enclosed for your convenience.

Your application along with relevant documents along with the prescribed fee may please be sent to this office in duplicate at least 60 days before the date of expiry of the current approval.

On receipt of your application, arrangements will be made to get your establishment assessed by the Inter Departmental Panel of experts for considering renewal of approval.

Yours faithfully,

Joint/Deputy Director In-charge

Encl: Format of application for renewal of approval

**EXPORT INSPECTION AGENCY - \_\_\_\_\_**  
(Ministry of Commerce, Govt. of India)

**ASSESSMENT REPORT FOR RENEWAL OF APPROVAL OF ESTABLISHMENT**  
(For Infrastructure and Equipment Facilities and HACCP based Food Management System)

Name of the processing establishment	: M/s.			
Approval number of the establishment				
Scope of approval (Name of the products and countries for export)				
Address of the processing establishment	Address: District: State: Country: India. Ph. Fax: E.mail:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: E.mail:			
Scope of assessment	: On-site verification to adjudge suitability of the infrastructure and equipment facilities of the establishment and implementation of HACCP based food safety management system for processing, handling and storage of milk products for renewal of approval of the establishment.			
Date(s) of assessment	:			
Opening Meeting Location and date				
Closing Meeting Location and date				
Name of IDP members	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)
Name of Representative(s) of the establishment	Designation	Organization	Opening Meeting (Sign)	Closing Meeting (Sign)

1.	<b>General Information</b>	
1.1	Name and address of the establishment seeking renewal of approval and official address.	
1.2.	Approval Number	
1.3.	Name of the Chief Executive(MD/Mg. Partner/Proprietor)	
1.4.	Is the processing plant owned or leased by the applicant	Owned / Leased
1.5.	If leased, name of the plant owner, plant name and address:	
1.6.	Expiry date of validity of approval	
1.7.	Nature of activities for which the establishment is approved	
1.8.	Approval sought to process milk Products for export to (countries)	All Countries including the EU Countries other than EU
1.9.	Additional activities, if any	
1.10	No. of working hours per day	
1.11	No. of working days per week	
2.	<b>Information on Structure of the Establishment</b>	
2.1.	Details of Identified farms	
2.2.	Details of milk Chilling Centres/Collection centres	
2.3.	If not integrated, give address(es) and distance from the establishment	
2.4.	Whether the unit has acquired any additional milk Chilling facility/collection centres during last two years.	
2.5.	Whether the milk Chilling/collection facility is under the control of the establishment?	
2.6 a)	Number and capacity of the chill room/ storage tanks(s)	
b)	Number and capacity of the Frozen Storage(s)	
c)	Number and capacity of rooms for storing dried products	
2.7	Is frozen/other storage integrated to the unit?	
2.8	Number of vehicles the establishment has for transportation of raw material, finished product and water. Refrigerated Vehicle Insulated Vehicle Non – Insulated Vehicle Water tanker	<u>Number</u> <u>Capacity</u> <u>Regn. No.</u>
2.9.	Does the establishment hire outside vehicle?	
2.10.	Whether any structural additions have been made since last approval /renewal of approval ? If so, give details: 1. 2. 3.	
3.	<b>Information about personnel</b>	
3.1.	No. of approved veterinarian/ technologists	
3.2.	Whether the No. of veterinarian/ technologists adequate?	
3.3	Sl. No. Name of approved Veterinarian/ technologists 1. 2.	Qualifications
3.4.	No. of Supervisors	Pre-processing Processing
3.5.	Total No. of Male Workers	
3.6.	Total No. of Female Workers	
3.7.	No. of work shifts per day	
4.	<b>Raw Material</b>	



4.1.	Source of raw material	
4.2.	Mode of transport of raw material from the milk production holdings	
4.3.	Is there any arrangement for traceability of raw materials?	
4.4.	Whether the establishment is controlling the milk production holdings properly?	
5.	<b>Surroundings</b>	
5.1.	Whether the conditions of approval are still maintained satisfactorily ?	Yes / No
5.2.	If not, what are the deficiencies?	
6.	<b>Construction and Layout</b>	
6.1.	Whether the conditions of approval are still maintained satisfactorily?*	
6.2.	If not, what are the deficiencies?	
7.	<b>Plant facilities: Are there adequate facilities for the following?</b>	
7.1.	Storing inedible material, disinfectants and insecticides	
7.2.	Separate storage for wet and dry items	
7.3.	Storing packaging material	
7.4.	Rest room for workers	
7.5.	Changing room for workers	
7.6.	Vehicle Washing	
7.7.	Water treatment plant	
7.8.	Alarm system to give warning when power fails	
7.9.	Generator	
7.10.	Toilets	
8.	<b>Raw material receiving section</b>	
8.1.	Whether the conditions of approval are still maintained satisfactorily? *	
8.2.	If not, what are the deficiencies?	
9.	<b>Chill Room/ Storage tanks</b>	
9.1.	Is chill room/ Storage tanks provided for storing Liquid milks?	
9.2.	Is it maintained as required?	
10	<b>Milk Reception and inspection section</b>	
10.1.	Whether the conditions of approval are still maintained satisfactorily? *	
10.2.	If not, what are the deficiencies?	
10.3	Whether the unit have separate milk reception section?	
10.4	If so, whether the same meets the requirement?	
11.	<b>Processing Section</b>	
11.1.	Whether the conditions of approval are still maintained satisfactorily? *	
11.2.	If not, what are the deficiencies?	
12	<b>Water</b>	
12.1.	Whether the source of water and water management system are same as at the time of approval	Yes / No
12.2.	If not, what are the changes and whether these meet the requirements?	
12.3.	Whether water used for processing is tested regularly?	
13.	<b>Chemicals/Additives</b>	
13.1.	Whether chemicals and additives, if used, tested/approved and records maintained as required?	
13.2.	If not, what are the deficiencies?	
14	<b>Freezing</b>	
14.1.	Whether the number and type of freezers are the same as at the time of approval?	
14.2.	If not, what are the changes?	

15	<b>Pasteurisers, Spry driers, hot chambers,UHT Sterliser</b>	
15.1	Are the numbers and conditions of pasteurisers are the same as per the previous approval?	
15.2	If not, specify the changes observed	
15.3	Are the numbers and conditions of pasteurisers, hot chambers,UHT steriliser, spray driers are the same as per the previous approval?	
15.4	If not, specify the changes observed	
16.	<b>Packaging and Frozen Storage</b>	
16.1.	Whether the conditions of approval are still maintained satisfactorily?*	Yes / No
16.2.	If not, what are the deficiencies?	
17	<b>Toilet Facilities</b>	
17.1.	Whether the conditions of approval are still maintained satisfactorily?*	Yes / No
17.2.	If not, what are the deficiencies?	
18.	<b>Personnel Hygiene</b>	
18.1.	Whether the conditions of approval are still maintained satisfactorily? *	Yes / No
18.2.	If not, what are the deficiencies?	
19.	<b>Cleaning and Disinfection of Plant, Equipment and Utensils</b>	
19.1.	Whether the conditions of approval are still maintained satisfactorily?*	Yes/No
19.2	If not, what are the deficiencies?	
20	<b>Changing Room</b>	
20.1	Whether the conditions of approval are still maintained satisfactorily?*	Yes/No
20.2	If not, what are the deficiencies?	
21	<b>Effluent Treatment</b>	
21.1.	Does the unit have an efficient effluent treatment system?	
21.2.	Does it comply with the statutory requirements ? Specify validity of PCB Consent letter	
22.	<b>Maintenance Schedule</b>	
22.1.	Whether the documented maintenance procedure is adequate and records of maintenance kept?	
22.2.	If not, what are the deficiencies?	
23	<b>HACCP-based Procedures (Hazard analysis and critical control points)</b>	
23.1	Are the HACCP principles in place, implemented and maintained?	
23.2	The HACCP principles	
a)	Are the hazards, if any, need to be prevented, eliminated or reduced to acceptable levels identified appropriately?	
b)	Are the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels identified appropriately?	
c)	Are the critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards established appropriately?	
d)	Are the monitoring procedures at critical control points established and implemented and maintained effectively?	
e)	Are appropriate corrective actions taken when monitoring indicates that a critical control point is not under control?	
f)	Are the measures outlined in (a) to (e) above verified regularly to ensure that the system is working effectively?	
g)	Are the documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in (a) to (f) above maintained?	
23.3	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	

23.4	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
23.5	Are the documents up-to-date at all times?	
23.6	Are the documents and records retained for an appropriate period?	
23.7	Is the traceability of raw milk accepted onto premise and the milk products processed maintained?	
23.8	Whether verification of effective working of HACCP system conducted as per the laid down frequency?	
23.9	Number of internal audits conducted during last two years	
24.	<b>Rodent / Vermin Control</b>	
24.1.	Whether the documented rodent/vermin control system is adequate and records maintained?	
24.2.	If not, what are the deficiencies?	
25.	<b>Transportation</b>	
25.1.	Are the facilities for transport of raw materials and finished products, and for cleaning and sanitisation of transport vehicles satisfactory?	Yes / No
25.2.	If not, what are the deficiencies?	
26.	<b>Inspection and Testing</b>	
26.1.	Are the inspection and testing facilities adequate?	Yes / No
26.2	If not, what are the deficiencies?	
26.3	Is the unit testing all the specified parameters as per the laid down frequency?	
27.	<b>Training</b>	
27.1	Whether the food handlers are supervised and instructed and/or trained in food hygiene matters which commensurate with their work activity?	
27.2	Whether those responsible for the development and maintenance of the HACCP have received adequate training in the application of the HACCP principle?	

## 27. Recommendations of the IDP

The processing establishment may be granted renewal of approval to process milk product for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000, for further period of two years from the date of expiry of earlier approval:

- d) for all countries including the European Union (EU) / Countries other than EU
- e) for processing (Scope of Approval -Milk Products which may be allowed to be processed in the establishment)

and

- f) with annual installed production capacity of \_\_\_MT

Or

The processing establishment may not be granted renewal of approval to process milk products for export under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2000. The deficiencies observed are given in the enclosed observations sheet. The establishment may apply a fresh after rectification of the deficiencies.

28 Suggestions for improvement, if any:

Signature			
Name			
Place:			
Date			

EXPORT INSPECTION AGENCY - \_\_\_\_\_

**Statement of Performance of Unit**  
(for the past two years)

Name and address of the establishment :  
 Approval No. :  
 Period of report : From ..... till date.

SI No.	Particulars	Monitoring Visits(MV)	Supervisory Visits (SV)	Lab. Test Reports (LR)
(a)	Numbers			
(b)	Overall Performance of the Unit			
(c)	If performance is unsatisfactory, main reasons for it			

*Details of complaints from importing country or importer*

Number of complaints	Nature of complaints	Countries from where complaints received	On Alert status

Signature of Officer In charge:

Date :

Name :

Place :

Designation :

(To be typed on company letterhead)

To

The Joint Director-  
Export Inspection Agency- \_\_\_\_\_

Sir,

Sub : Request for permission to process and pack milk products for export by merchant exporter.

Ref. : Approval Number of the establishment \_\_\_\_\_

We request that permission may kindly be granted to us to process and pack milk products in our approved processing establishment for export by the following merchant exporter(s).

- 1) Name and Address of the merchant exporter(s) :
- 2) Countries to which exports are proposed to be made :
- 3) Production capacity of the unit as fixed by EIC/EIA :

We hereby state that we, as approved processor, shall be responsible for the quality and safety of the milk products processed and packed by us for export by the merchant exporter(s). We also undertake to comply with the directions that may be given in this regard by EIC/EIA *and assure that the production capacity fixed by EIA for our establishment will not be exceeded at any time.*

We also assure you that milk products meant for export by the merchant exporter(s), for which Certificate for Exports are to be issued by us, will only be processed in our approved unit under our control and the products will not be taken out of our control or stored in unauthorised/un-approved places by the merchant exporter(s).

We also undertake that we shall be responsible and liable for any act of omission or commission by the merchant exporter(s) in respect of any quality issue or in respect of any trade related issues including cheating.

Yours faithfully,

Signature :  
 Name :  
 Designation :  
 Company Seal :

Place :

Date :

Encls.

- 1. Certified true copy of the agreement entered into between the processor and the merchant exporter(s)
- 2. Declaration from merchant exporter(s) stating that he will abide by the rules and regulations laid down by EIC/EIA .

(Letter of permission to process and pack Milk Products for merchant exporter)

EXPORT INSPECTION AGENCY  
( MINISTRY OF COMMERCE AND INDUSTRY )  
GOVERNMENT OF INDIA

No. EIA/

Date :

--

Dear Sirs,

Sub: Permission to process and pack Milk Products for merchant exporter: M/s. (Name and address of merchant exporter)

Ref: Your letter dated \_\_\_\_\_

With reference to your letter cited above, you are informed that you are permitted to process and pack Milk Products for export by merchant exporter: M/s. \_\_\_\_\_ (Name and address of merchant exporter), to any country including EU/Non EU countries, subject to the following conditions:

1. The export packages must bear the name, address and approval number of the approved processing establishment and also the name and address of the merchant exporter;
2. The approved processor (M/s. (Name and address of approved processor)), with processor Code No. ( ) shall be responsible for the quality and safety of the milk products processed by it for export by the merchant exporter;
3. The approved processor shall ensure that the consignments of milk products processed by it for export by the merchant exporter are not taken out of its control or stored in unauthorised/unapproved premises by the merchant exporter before the actual shipment for export; and
4. The approved processor shall maintain proper records showing the details of milk products processed by it for the merchant exporter and such records shall be made available to the monitoring officials of the EIC/EIA for verification.
5. The validity of the permission granted by EIA for processing and packing milk products in favour of merchant exporter shall be co-terminus with the validity of the approval of the establishment / validity of the agreement entered between the processor and the merchant exporter, WHICHEVER IS EARLIER.

Please acknowledge receipt.

Yours faithfully,

[ \_\_\_\_\_ ]  
Agency In-Charge

Copy to

- (1) The Joint Director, EIC, New Delhi-110001.
- (2) The Officer In-charge, EIA-\_\_\_\_\_, SO: \_\_\_\_\_.

( Letter of Withdrawal of permission to process and pack Milk Products for export by merchant exporter)

EXPORT INSPECTION AGENCY – \_\_\_\_\_  
( MINISTRY OF COMMERCE AND INDUSTRY )  
GOVERNMENT OF INDIA

No. EIA/

Date:

To,

Dear Sirs,

Sub: Withdrawal of permission to process and pack Milk Products for export by merchant exporter.

Ref: (1) Your letter No. dated \_\_\_\_\_.  
(2) Our letter No. EIA/ \_\_\_\_\_ dated: \_\_\_\_\_.

In pursuance of your request cited above, the permission given to you to process and pack milk products for the following merchant exporter(s) is hereby withdrawn:

Name and Address of Merchant Exporter }  
} }  
} }  
} }  
} }

Yours faithfully,

[ \_\_\_\_\_ ]  
Agency In-Charge

Copy to

- (3) The Joint Director, EIC, New Delhi-110001.
- (4) The Officer In-charge, EIA-\_\_\_\_\_, SO: \_\_\_\_\_.



MONITORING PARAMETERS FOR WATER (98/83/EC)

S.No.	Parameters
1	Aluminium (Note No.1)
2.	Ammonium
3.	Colour
4.	Conductivity
5.	Clostridium perfringens (including spores) (Note-2)
6.	Escherichia, Coli (E.Coli)
7.	Hydrogen Ion concentration
8.	Iron (Note-1)
9.	Nitrite(Note-3)
10.	Odour
11.	Pseudomonas aeruginosa (Note-4)
12.	Taste
13.	Colony count 22°C and 37°C (Note-4)
14.	Coliform bacteria
15.	Turbidity

Note No.1 Necessary only when used as flocculent

Note No.2 Necessary only if the water originate from or is influenced by surface water

Note No.3 Necessary only when chloramination is used as a disinfectant

Note No.4 Necessary only in the case of water offered for sale in bottles or containers

## EXPORT INSPECTION AGENCY – \_\_\_\_\_

## MONITORING REPORT

Date of Visit

Name of the Processing Establishment

Approval No.

Product being processed at the time of visit

Sl. No.		Observations/suggestions
(1)	(2)	(3)
<b>General</b>		
1.	Name and Designation of Monitoring officer(s) last visited	
2.	Whether defects pointed out earlier have been rectified by the unit	
3.	Mention deficiencies that are not rectified	
4.	Whether any time frame given for rectification	
5.	Results of samples tested in the previous visit	
6.	Action taken in case of failure of test results	
<b>Facility Checks</b> ( <i>Record observations on the maintenance of infrastructure facilities and sanitary / hygienic conditions at each section mentioned below</i> )		
1.	Premises	
2.	Raw material receiving area.	
3.	Workers entry points	
4.	Change rooms and toilets	
5.	Milk products storage room(s)	
6.	Processing section	
7.	Spray drying, pasteurisation section ,UHT	
8.	Packing section	
9.	Chill rooms/storage tanks	
10.	Cold storages, other stores	
11.	Machineries/equipments	
12.	Tables and utensils	
13.	Lights and ventilations /AC	
14.	Floor, walls and roof	
15.	Drainage	
16.	Packing material store	
17.	Chemical store	
18.	Water purification system	
19.	Pasteurization facility, hot room facility	
20.	Effluent treatment plant	
<b>HACCP Implementation of the Unit</b>		
1	Whether the identified CCPs monitored properly and recorded?	
2	Whether all control measures are in place?	
3	Whether appropriate corrective actions as stipulated in the HACCP plan taken in case of deviation from Critical limits?	
4	Whether the monitoring and corrective actions, if any, recorded and verified at laid down frequency by the responsible person(s)?	
5	Whether validation is being done regularly?	
6	Whether the instruments used for measurement are calibration periodically?	
7	Whether the HACCP reviewed and amended suitably, if required?	

Own Check system (give details on the following controls exercised by unit)		
1.	Raw Material control	
2.	Process control	
3.	Product control	
4.	Time/Temp control	
5.	Control on additives / preservatives	
6.	Quality management of water	
7.	Calibrations	
8.	Pest control	
9.	Personal hygiene	
10.	Raw milk testing for residues as per EIC prescribed frequency	
11.	Maintenance	
Testing and lab practices in the in house laboratory		
1.	Good laboratory practices	
2.	Reliability of testing	
3.	Lab chemicals	
4.	Equipments and utensils of lab	
5.	Calibrations of lab equipments	
6.	Proficiency testing	
Verification of records		
1.	Traceability records	
2.	Raw Material records	
3.	Production records	
4.	Pasteurization, Spray drying, UHT Freezing records	
5.	Packing records	
6.	Storage and transportation records	
7.	Quality control and Inspection records	
8.	Test reports	
9.	Calibrations records	
10.	Sanitary and hygiene records	
11.	Personal hygiene records	
12.	Time/temperature records	
13.	Water test reports	
14.	Disinfections and sanitation records	
Additional Checks ( Verify and record the observations)		
1	<u>Temperature of the Products</u>	Product                      Temp
a.	Product temperature at different processing stages like pasteurization, chilling, freezing, heat treatment etc.	
b.	Temperature of the Frozen product during storage	
c.	Temperature of the product after pasteurization and stabilisation.	
2.	<u>Temperature of the facilities</u>	
a.	Raw milk storage	
b.	Chill rooms/ Storage tanks	
c.	Cold storages	
d.	Powder store	
3.	Time taken or flow rate of liquid for pasteurization	
4.	Time taken for freezing	

5.	Moisture content of spray dried products	
<b>Fraud control (Specify if violations are noticed in the following area)</b>		
1.	Misuse of CFEs	
2.	Exceeding capacity limits	
3.	Improper labelling	
4.	Manipulation of records	
5.	Storing of cargo of other establishments without permission	
6.	Processing in unauthorised places	
<b>Details of samples drawn during monitoring</b>		
1.	Finished product for microbiology analysis	
2.	Sanitation and hygiene control samples including water samples	
3.	Raw Milk Samples for RMP	
3.	Proficiency testing of in-house laboratory	
<b>Any other relevant information</b>		
<b>Recommendations</b>		

- Overall Rating – Satisfactory/unsatisfactory

- Deficiency reported to the establishment  
(As per Non Conformity report)

Signature

Name  
Designation  
Date

Place

Remarks of the Controlling Officer

Signature

Name  
Designation  
Date  
Place

EXPORT INSPECTION AGENCY – \_\_\_\_\_

**NON-CONFORMITY REPORT (NCR)**

Name of the establishment :  
Approval No. :  
Nature of inspection :  
Date of Visit :  
Name and Designation of EIA officer(s)  
Name and Designation of the representative of the establishment

1. Earlier *NCR* pending for rectification

2. Details of deficiency/non-conformity observed along with the details of the major NCR

3. Comments / Agreed action:

- 
- i. Acknowledgement of report copy
  - ii. Deficiencies/non-conformities have been fully explained and understood by the establishment
  - iii. Confirmation of agreed or proposed corrective actions to be made to EIA within .....(7/15/30 etc.) days

Signature : .....  
Name : .....  
Designation : .....  
(EIC / EIA officer)

Signature :  
Name :  
Designation :  
Representative of the establishment

Note: *It is advised that a copy of this report be pasted by the establishment in the establishment inspection register for necessary follow up action and future reference.*

EXPORT INSPECTION AGENCY – \_\_\_\_\_

SUGGESTIONS FOR IMPROVEMENT

Name of the establishment :  
Address :  
Approval No. :  
Nature of inspection :  
Date of Visit :  
Name and Designation of EIA officer(s)  
Name and Designation of the representative of the  
establishment

- 1.
- 2.
- 3.
- 4.
- 5.

Agreed action by the processor :

Signature : .....

Name : .....

Designation : .....

(EIC / EIA officer)

Signature :

Name :

Designation :

Representative of the establishment

## EXPORT INSPECTION AGENCY – \_\_\_\_\_

## FARM VISIT REPORT

Date of Visit

Name of the Farm and location

Name and Approval No. of the establishment to which raw milk supplied:

Sl. No.	Requirements	Observations/suggestions
(1)	(2)	(3)
<b>General</b>		
1.	Name and Designation of Monitoring officer(s) last visited	
2.	Whether defects pointed out earlier have been rectified by the unit	
3.	Mention deficiencies that are not rectified	
4.	Whether any time frame given for rectification	
5.	Action taken in case of failure of test results	
<b>Hygiene Provisions and record keeping in Raw Milk Production and handling</b>		
1	Is the milk production holding owned or contracted by the establishment?	
2	Is the milk production holding under supervision/controls of the unit to ensure the wholesomeness of the raw milk procured?	
3	Are there controls to ensure good farming practices and good veterinary practices?	
4	Are there adequate measures to protect raw milk production against any contamination?	
5	Are there adequate measures to control contamination arising from the air, soil, water, feed, fertilizers, veterinary medicinal products and biocides and the storage, handling and disposal of waste in <del>shell</del> milks production and associated operations?	
6	Are there controls to prevent use of prohibited antibiotics/ pharmacological substances and Chemicals?	
7	Are there adequate measures relating to animal health and welfare that have implications for human health, including programmes for the monitoring and control of zoonoses and zoonotic agents in <del>shell</del> milks production and associated operations?	
8	Is there cleaning and where necessary, disinfecting of facilities used in connection with <del>shell</del> milks production and associated operations, including facilities used to store and handle feed?	
9	Is there cleaning and where necessary, disinfecting of equipment, containers, crates, vehicles and vessels?	
10	Is the water used potable or clean, where necessary, to prevent contamination?	
11	Are the personnel trained on health risks and the personnel, handling foodstuff in good health?	
12	Is there prevention of animals and pests from causing contamination?	
13	Is the waste and hazardous material handled and stored properly to prevent contamination?	

14	Is there prevention of the introduction and spreading of contagious diseases transmissible to humans through food, including taking precautionary measures when introducing new milch animals and reporting suspected outbreaks of such diseases to the competent authority	
15	Are the samples (feed, water, raw milk, etc.) drawn for relevant analyses that have importance to human health and records maintained?	
16	Are there appropriate actions on account of the results of any relevant analysis carried out on samples taken from the milch animals or other samples that have importance to human health?	
17	Is there correct use of feed additives and veterinary medicinal products?	
18	Is there appropriate remedial action when informed of problems identified during official controls?	
19	Specify the mode of transport of raw milk from milk production holding..	
20	Are there records relating to measures put in place to control hazards in an appropriate manner?	
21	Are there records of nature and origin of feed fed to the milch animals?	
22	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
23	Are there records of the occurrence of diseases that may affect the safety of milk products?	
24	Are there records of other relevant reports on checks carried out on milch animals or raw milk?	
25	Are there records of the details of employees such as veterinarians and farm technicians, assisting in raw milk production?	

Any other relevant information
Recommendations

- Overall Rating – Satisfactory/unsatisfactory
- Deficiency reported to the establishment  
(As per Non Conformity report)

Signature

Name  
Designation  
Date

Place

Remarks of the Controlling Officer  
Signature  
Name  
Designation  
Date  
Place



EXPORT INSPECTION AGENCY – .....SUB OFFICE: .....FREQUENCY OF MONITORING OF MILK PRODUCTS PROCESSING ESTABLISHMENTSREVIEW NO.

1	Name of the Establishment	
2	Address of the Establishment	
3	Approval Number	
4	Date of Approval	
5	Current frequency of monitoring and Date of fixation	
6	Period under report	From                      To
7	Performance of the unit during the period under report based on Monitoring Reports and Lab Test Reports	Satisfactory / Non Satisfactory
8	Details of complaints/rejections, if any, during the period under report from EU/other importing countries	
9	Frequency of monitoring proposed for the unit	
10	Date Signature of the Officer –In charge Name of OIC: Designation: Date:	
11	<u>For use of Head Office</u> Review and approval of frequency of monitoring by In-charge of EIA at Head Office  Signature of EIA In- charge Name: Designation: Date:	

Copy to:  
The Director (I&QC)  
EIC, New Delhi

**EXPORT INSPECTION AGENCY – \_\_\_\_\_**  
**SUPERVISORY VISIT REPORT**

1. Date of visit :
2. Approval No. :
3. Name of the Processing Establishment :
4. Product being processed at the time of visit :
5. Assessment of Unit

Sl. No.	Area	Satisfactory	Details of deficiencies, if observed/ Remarks
1.	Surroundings		
2.	Raw milk Unloading/Receiving area		
3.	Processing Section		
4.	Personal Hygiene		
5.	Change Room		
6.	Steam, if used		
7.	Chill Room/storage tanks		
8.	Freezing/ Pasteurization		
9.	Water/Chemical/Additives		
10.	Cold Storage/ dry storage		
11.	Rodent/Vermin Control		
12.	Effluent Treatment		
13.	Own Checks/HACCP system		
14.	Maintenance of records		
15.	Packaging/Storage/Transportation		
16.	Inspection and Testing Facilities		
17.	Any other relevant information i) Quality of the monitoring ii)Area of focus in which detailed assessment was done		

6. MVs since last SV :

Sl. No.	Date	MvO	Satisfactory / Unsatisfactory	Lab. Results	Deficiencies observed	Action by Processor

7. Results of Water :

8. Recommendations :

⇒ Overall Rating – Satisfactory / Unsatisfactory

⇒ *NCR*

Signature :

N a m e :

Designation :

Date :

Place:

Remarks of the Agency In-charge

Signature :

N a m e :

Designation :

Date :

Place:

Note: Monitoring Visit (MV) – supervisory Visit (SV) – Monitoring Officer (MvO) - Non-Conformance Report (NCR)

**EXPORT INSPECTION COUNCIL  
(MINISTRY OF COMMERCE)  
GOVERNMENT OF INDIA**

**CORPORATE AUDIT REPORT**

1.	Auditee	
2.	Dates of Audit	
3.	Activity under Audit	
4.	Scope of Audit	
5.	Audit Team	
6.	Audit Schedule	
(i)	Opening Meeting	
(ii)	Closing Meeting	
7.	Observations	
8.	Non Conformities	
9.	Any other Remarks	

**7. OBSERVATION FORM**

S.No.	Element	Observation	Reference
1.			
2.			
3.			
4.			

**8. NON-CONFORMITY REPORT (NCR)**

S.No.	Non-Conformity observed	Doc.Ref	Type of NC Major/Minor
1.			
2.			
3.			
4.			

**9. General Observations**

1.	
2.	
3.	
4.	
5.	
6.	

Team Leader

Auditor

Proposed Corrective actions

Probable Date of Completion

Auditee

NC cleared/down graded/statuesque

Auditor

Date

Team Leader

Model Milk -HTC

<p>1 Consignor (Name and address in full)</p>	<p style="text-align: center;"><b>Health Certificate</b></p> <p>for heat treated milk, milk based products made from heat-treated milk or heat treated milk based products for human consumption from third countries or parts of third countries authorised in column C of Annex I to Commission Decision 2004/438/EC intended for consignment to the European Community.</p> <p>No (1) <span style="float: right;">Original</span></p>
<p>2. Consignee (name and address in full)</p>	<p>3. Origin of the [ heat treated milk]/[milk based product] from [heat treated milk]/[heat treated milk based product (2)](3)</p> <p>3.1 ISO code and the name of Country (and region, where applicable) (4)_____</p> <p>3.2 Code of territory_____</p>
<p>5. Intended destination of the [heat treated milk]/[milk-based product] from [heat-treated milk]/[heat treated milk-based product](3):</p> <p>5.1 EU member state:</p> <p>5.2 Place of Destination</p>	<p>3.3 Name(s) and official approval number(s) of treatment and/or processing establishment(s) approved for export to the Community.</p> <hr/> <p>4. <b>Competent Authority</b></p> <p>4.1 Ministry:.....</p> <p>4.2 Service:.....</p> <p>4.3 Local/Regional level.....</p> <hr/> <p>6. Place of loading for exportation.....</p>
<p>7. Means of trans-nd consignment identification (5)</p> <p>7.1 [lorry ]/[Rail-Wagon]/[Ship]/[Aircraft](3)</p> <p>7.2 Registration number(s), ship name or flight number</p> <p>.....</p>	<p>7.3 Consignment identification details(6)</p>
<p>8. Identification of the [heat –treated milk]/milk based product] from [heat-treated milk]/[heat treated milk-based product](3)</p> <p>8.1 Milk from:.....(animal species)</p> <p>8.2 Description of [heat –treated milk]/milk based product] from [heat-treated milk]/[heat treated milk-based product](3):</p> <p>8.3 Code number (as appropriate):.....</p> <p>8.4Packaging:.....</p> <p>8.5 Number of packaging units:.....</p> <p>8.6Net Weight:.....</p>	

**9. Animal Health attestation:**

I, the undersigned, official veterinarian hereby certify :

9.1 That the (heat treated milk)/(milk based product) made from (heat treated milk)/heat treated milk based product) described above has been obtained from animals:

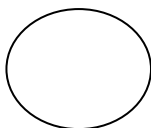
- a) under the control of the official veterinary service
- b) belonging to holdings which were not under restrictions due to foot-and –mouth disease or rinderpest, and
- c) subject to regular veterinary inspectors inspections to ensure that they satisfy the animal health conditions laid down in annex A , Chapter I of Directive 92/46/EEC

9.2 that I am familiar with the animal health requirements of Directive 92/46/EEC

**10. Official stamp and signature**

Done at.....

on.....



Stamp(7)

.....  
(Signature of official veterinarian)(7)

.....  
(name in capital letters, qualifications and title)

**Public Health attestation:**

I, the undersigned official inspector , hereby certify :

that the (heat treated milk)/milk based product) made from (heat treated milk)/(heat –treated milk based product) described above :

a) was manufactured from raw milk

- 1. not according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC containing residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to Regulation (EEC) no. 2377/90, as amended.,
- 2. not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing pesticide residues in excess of the maximum levels laid down in Annex-II to Directive 86/363/EEC, as amended,
- 3. not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing contaminants in excess of the maximum tolerances laid down in the Community list provided for in Article 2 (3) of Regulation (EEC) No. 315/93
- 4. Which comes from registered and checked holdings meeting the hygiene conditions laid down in Chapter II of Annex A to to directive 92/46/EEC
- 5. Which was obtained , collected , cooled , stored and transported in accordance with the specific hygienic conditions laid down in Chapter III of Annex A to Directive 92/46/EEC,.
- 6. Which meets the plate and somatic cell count standards laid down in Chapter IV of Annex-A to Directive 92/46/EEC, and
- 7. Which was collected and standardized , where necessary , in accordance with the hygiene conditions laid down in chapters I,III and IV of Annex B to Directive 92/46/EEC

b) comes from a treatment establishment and/or processing establishment offering equivalent guarantees to those laid down in chapter II of Directive 92/46/EEC shown on the list of establishments authorized to export to the European Community and which is subjected to supervision by the competent authority in accordance with the provisions of Chapter VI of Annex C to the directive 92/46/EEC;

c) has undergone, prior to import into the territory of the community:

either [I) a sterilization process, to achieve a F0 value equal to or greater than three  
 or [ii) an ultra high temperature (UHT) treatment at 132 Deg C for at least one second.  
 or [iii) a high temperature short time pasteurization treatment at 72 Deg C for at least 15 seconds or equivalent pasteurization effect achieving a negative reaction to a phosphatase test (HTST) applied twice to milk with a pH equal to or above 7.0]  
 or [IV) a HTST treatment of milk with a pH below 7.0  
 or [V) a HTST treatment combined with another physical treatment by :  
 either [ V) 1) either lowering the pH below 6 for one hour],  
 or [ V) 2) additional heating to 72 Deg C or more , combined with desiccation

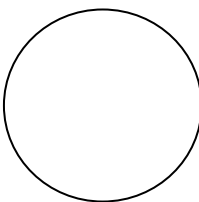
d) meets the relevant microbiological criteria laid down in Chapter II of Annex C to Directive 92/46/EEC;  
 e) has been wrapped and packaged in accordance with Chapter III of annex C to Directive 92/46/EEC;  
 f) was stored and transported in accordance with the requirements of Chapter V of Annex C to Directive 92/46/EEC  
 g) was transported , where appropriate , in tanks as described in Article 16(2) of Directive 92/46/EEC

11.2 that I am aware of the provisions contained in Directive 92/46/EEC, Annexes I & III to Regulation (EEC) No. 2377/90, Annex II to Directive 86/363/EEC and Regulation (EEC) No. 315/93

Official stamp and Signature  
 Done at ..... on .....

.....  
 (Signature of official inspector)(7)

.....  
 (name in capital letters, qualifications and title)

  
 (Stamp) (7)

**Notes**

- (1) Issued by the competent authority
- (2) Country and ISO code of the territory as appearing in Annex I to Decision 2004/438/EC (as last amended)
- (3) Keep as appropriate
- (4) To be specified if the authorisation to import into the Community is restricted to certain regions of the third country concerned.
- (5) The Registration number(s) or rail wagon or lorry and the name of the ship should be given as appropriate. If known the , flight number of the aircraft.  
 In case of transport in containers or boxes, the total number , their registration and seal numbers, if present, should be indicated under point 7.3
- (6) Complete if appropriate
- (7) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those embossed or watermark

Book No. Health Certificate (to Non-EU Countries) Sl. No.

For Milk products intended for export

Country of Despatch: India

Competent Authority: Export Inspection Agency-Mumbai/Calcutta/Kochi/Delhi/Chennai

Reference No. of export certificate (issued by processing plant) \_\_\_\_\_

1. Details identifying the milk products

- Description
- Quantity
- Type of packaging
- No. of packages
- Temperature required during storage and transport
- Manufacturing Date
- Expiry Date

2. Provenance of Milk Products

Address (es) and number(s) of preparation or processing plant(s) authorised for export by the competent authority

Approval number of t the plant(s)

3. Destination of the milk products

The milk products are to be despatched

From.....

(Place of Despatch)

To.....

(Country and place of destination)

By the following means of transport

.....

Name of address of consignor

Name of consignee and address at place of destination

4. Health Attestation

It is hereby certified that the milk products described above have been handled, processed, stored and transported under hygienic conditions as laid down in the Export of Milk Products (Quality Control, Inspection & Monitoring) Rules, 2000 as amended and found conforming to laid down standards and fit for human consumption and the plant, where the milk products have been processed , is approved and regularly monitored by the Export Inspection Agency(Competent Authority)

Place of issue:

Signature of authorised officer

Date of issue:

Name:

Designation

Seal

(Public Health attestation to be submitted by the establishment)

(To be typed on the letterhead of the approved establishment)

To Whom It May Concern

I, the *approved veterinarian/ technologist* of Ms/ \_\_\_\_\_ (name of the organization with address), hereby certify following for the export of milk products detailed in the Certificate for Export no. \_\_\_\_\_ dated \_\_\_\_\_ that

**Public Health attestation:**

the (heat treated milk)/milk based product) made from (heat treated milk)/(heat –treated milk based product) described above

a) was manufactured from raw milk

1. not according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC containing residues of anti-microbial substances in excess of the limits laid down in Annexes I and III to Regulation (EEC) no. 2377/90, as amended.,
2. not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing pesticide residues in excess of the maximum levels laid down in Annex-II to Directive 86/363/EEC, as amended,
3. not, according to the findings of monitoring plans at least equivalent to those provided for in Directive 92/46/EEC, containing contaminants in excess of the maximum tolerances laid down in the Community list provided for in Article 2 (3) of Regulation (EEC) No. 315/93
4. Which comes from registered and checked holdings meeting the hygiene conditions laid down in Chapter II of Annex A to to directive 92/46/EEC
5. Which was obtained , collected , cooled , stored and transported in accordance with the specific hygienic conditions laid down in Chapter III of Annex A to Directive 92/46/EEC.,
6. Which meets the plate and somatic cell count standards laid down in Chapter IV of Annex-A to Directive 92/46/EEC, and
7. Which was collected and standardized, where necessary, in accordance with the hygiene conditions laid down in chapters I, III and IV of Annex B to Directive 92/46/EEC

h) comes from a treatment establishment and/or processing establishment offering equivalent guarantees to those laid down in chapter II of Directive 92/46/EEC shown on the list of establishments authorized to export to the European Community and which is subjected to supervision by the competent authority in accordance with the provisions of Chapter VI of Annex C to the directive 92/46/EEC;

i) has undergone, prior to import into the territory of the community:

- either [I ) a sterilization process, to achieve a F0 value equal to or greater than three  
 or [II ) an ultra high temperature (UHT) treatment at 132 Deg C for at least one second  
 or [III) a high temperature short time pasteurization treatment at 72 Deg C for at least 15 seconds

or equivalent pasteurization effect achieving a negative reaction to a phosphatase test (HTST) applied twice to milk with a pH equal to or above 7.0]

or [IV) a HTST treatment of milk with a pH below 7.0

or [V) a HTST treatment combined with another physical treatment by :

either [V) either lowering the pH below 6 for one hour],

or [ V) additional heating to 72 Deg C or more , combined with desiccation

j) meets the relevant microbiological criteria laid down in Chapter II of Annex C to Directive 92/46/EEC;

k) has been wrapped and packaged in accordance with Chapter III of annex C to Directive 92/46/EEC;

l) was stored and transported in accordance with the requirements of Chapter V of Annex C to Directive 92/46/EEC

m) was transported , where appropriate , in tanks as described in Article 16(2) of Directive 92/46/EEC



that I am aware of the provisions contained in Directive 92/46/EEC, Annexes I & III to Regulation (EEC) No. 2377/90, Annex II to Directive 86/363/EEC and Regulation (EEC) No. 315/93

(Signature)

(Name and designation Seal)

Place:

Date:

(Animal Health attestation to be issued by controlling veterinary authority)

(To be typed on the letter head of the State Animal Husbandry Department)

To Whom It May Concern

**Animal Health attestation:**

I, the undersigned, official veterinarian hereby certify following for the export of milk products described in the Certificate for Export No. \_\_\_\_\_ dated \_\_\_\_\_, issued by M/s \_\_\_\_\_  
\_\_\_\_\_ (Name and the address of the unit)

That the (heat treated milk)/(milk based product) made from (heat treated milk)/heat treated milk based product) described above has been obtained from animals:

- a) under the control of the official veterinary service
- b) belonging to holdings which were not under restrictions due to foot-and –mouth disease or rinderpest, and
- c) subject to regular veterinary inspectors inspections to ensure that they satisfy the animal health conditions laid down in annex A , Chapter I of Directive 92/46/EEC
- d) I am familiar with the animal health requirements of Directive 92/46/EEC

(Signature)  
Designation

(Seal)

Place:

Date:

(Request letter from the establishment for health certificate)

(To be typed on the letterhead of the approved establishment/processor)

Date:

To,

The Joint Director  
Export Inspection Agency \_\_\_\_\_

Sir,

Sub: Request for issuance of Health Certificate for Export of milk products to EU / Non-EU as per requirement of the importing country

Ref: 1) Our approval number \_\_\_\_\_  
2) Certificate for Export No. \_\_\_\_\_ dated \_\_\_\_\_ for Export to \_\_\_\_\_ (Country)

In connection with the above subject, we hereby submit a the details of the information required by the importing country in the health certificate for the purpose of issuance of Health Certificate for Export of milk product(s)

Further, we require to furnish animal health attestation to the importing country, for which we hereby furnish the relevant declaration from our establishment and the health attestation dated \_\_\_\_\_ from \_\_\_\_\_ State \_\_\_\_\_ Animal Husbandry Department, \_\_\_\_\_. The public health attestation is also enclosed herewith.

Herewith, I submit that the information furnished is true and correct to the best of my knowledge and the milk product meant for export as detailed in the Certificate for Export cited under reference, is free from any hazardous substances and fit for human consumption.

Please debit the prescribed fee from our deposit account maintained at EIA and issue the Health Certificate for the consignment.



Yours faithfully,

(Authorized signatory)

Encl:

1. The information in the prescribed veterinary health certificate as required by the importing country
2. Certificate for export (pink copy) No. \_\_\_\_\_ dated \_\_\_\_\_
3. Invoice copy No
4. Certificate of analysis

**CERTIFICATE FOR EXPORT**

1. Name and Address of the Exporter		4. Buyer's Order No. & Date	5. VALID FOR CUSTOMS	
2. Name and Address of the Approved Processing Plant		6. Invoice No. & Date	7. Country of destination	
3. Details of Stamp on export packages		8. Certificate No.		
Approval No. 		Valid Upto and including.....		
9. Specification Reference				
10. Shipping marks	11. No. and kind of Pkgs.	12. Description of Goods	13. Quantity	14. FOB value
15. DECLARATION				
<p>The undersigned hereby declares:</p> <p>(i) that the above consignment has been processed in our processing plant which has valid approval and is under continuous monitoring by Export Inspection Agency - as per the Export of Milk Products (Quality Control, Inspection &amp; Monitoring) Rules, 2000.</p> <p>and</p> <p>(ii) that the consignment is exportworthy.</p>				
Place..... Date.....				_____ (Signature) _____ (Name) _____ (Designation)

**FORTNIGHTLY STATEMENT ON CERTIFICATES ISSUED FOR EXPORT OF MILK PRODUCTS**  
**FOR THE PERIOD FROM \_\_\_\_\_ to \_\_\_\_\_**

Name of the processor :

Approval Number :

**A. Details of certificates issued for direct exports and on account exports**

Certificate for Export No.	Date of issue	Commodity	F.O.B. Value (Rs.)	Invoice No. and Date (Enclose copy)	If on account Exports, the name and Address of the export house	Remarks

**B. Details of certificates issued for exports through Merchant Exporters**

Certificate for Export No.	Date of issue	Commodity	F.O.B. Value (Rs.)	Invoice No. and Date (Enclose copy)	Name and Address of Merchant Exporter	Remarks

**C. Details of certificates cancelled, if any**

Certificate for Export No.	Reasons for Cancellation	Remarks
		Full set of cancelled certificates enclosed

N.B. Pink copy of the certificates numbering \_\_\_\_\_ is enclosed.

Place : \_\_\_\_\_  
Date : \_\_\_\_\_

Signature : \_\_\_\_\_  
Name : \_\_\_\_\_  
Designation : \_\_\_\_\_  
(Company seal) : \_\_\_\_\_

To

The Officer in-charge  
Export Inspection Agency - \_\_\_\_\_  
Sub Office; \_\_\_\_\_

(On the letter head)

**INDEMNITY BOND**

We solemnly declare that the Certificate for Export (blank) with Serial No: ..... Book No : .....issued to us by Export Inspection Agency ..... has been lost/ misplaced without having been utilised for export of goods and the said certificate ,if traced latter, will not be utilised for export of any consignment, but will be surrendered to the Export Inspection Agency..... for cancellation.

We further declare that we are fully liable for any action in the event of the misuse of such certificate either by us or on account of us and we agree to keep the Export Inspection Agency indemnified in case of misuse or illegal use of such certificate

Witnesses

- 1.
- 2.

Place:  
Date:

Signature:  
Name and Designation  
Seal of the Company:

EXPORT INSPECTION AGENCY – .....

Monthly report of supervisory / monitoring visits to the EU/ Non EU approved Milk Product establishments for the month of.....

Sl.no	Action taken	EU		Non- EU	
		Supervisory	Monitoring	Supervisory	Monitoring
1	Number of visits planned				
2	Number of visits actually conducted				
3	Number of units which are satisfactory based on the visits				
4	Number of units which are unsatisfactory based on the visits				
5	Reasons for short fall, if any in supervisory /monitoring visits				
6	Action taken in case of each unsatisfactory unit				
7	Details of verification of corrective action taken by the processing units reported unsatisfactory in the earlier statements.				
8	Any other information				

Place :

Signature :

Date :

Name :

Designation:

EXPORT INSPECTION AGENCY – .....

(CHANGES IN THE LIST OF APPROVED UNITS (EU AND NON- EU) AS ON.....)

SL.N O	AP.NO	NAME AND ADDRESS OF ESTABLISH MNET	ADDRESS OF REGISTERED OFFICE	EU OR NON -EU	DATE OF INTIAL APPROVAL	VALID.OF APPROL.UP TO AND INCLUDING
(1)	(2)	(3)	(4)	(5)	(6)	(7)





## EXPORT INSPECTION AGENCY-----

Status Report on Milk Product Establishment, which had complaint from importing country.

As on \_\_\_\_\_(date)

1.	Name and Address of the Milk Product establishment	:
2.	Approval No.	:
3.	Details of Complaints: (a) Nature of complaint (b) RASFF Notification (c) Product (d) Health Certificate No. (e) Complaint Country	
4.	Date of placing the unit ' On Alert'	:
5.	Current Status and Location of the consignment in question a) Whether the consignment has been brought back to India b) If brought back, details of tests ➤ Test results by EIA ➤ Test results by other lab ➤ Action taken, if any c) If not brought back, status of the consignment	
6.	Assessment of the establishment a) Date of assessment b) Composition of assessment team c) Outcome of the Assessment <ul style="list-style-type: none"> <li>• Whether the unit meets the conditions specified in GOI Notification/other requirements</li> <li>• Implementation of HACCP</li> <li>• Routine testing by the unit</li> <li>• Traceability and the source of raw material used for the consignment in question.</li> <li>• Corrective action suggested/implemented, if any.</li> <li>• Whether the consignment has been tested prior to shipment for the contaminant(s)_ in question (if so, give details)</li> <li>• Test results of samples drawn during assessment (with details like number of samples, test methods, name of the Lab etc.</li> </ul>	
7.	Current status of Sanitation/Hygiene of the unit(after placing the unit ' on alert') <ul style="list-style-type: none"> <li>• No. of Monitoring Visits (MV) conducted</li> <li>• No. of Satisfactory MVRs including Lab reports</li> <li>• No. of unsatisfactory reports with details of non-compliance</li> </ul>	
8.	Details of consignment inspection tested (with details of testing method, Lab etc.) <ul style="list-style-type: none"> <li>▪ No. of consignments tested</li> <li>▪ No. of consignments passed</li> <li>▪ No. of consignments failed</li> <li>▪ Reason for failure/other remarks</li> </ul>	
9	Present status: <ul style="list-style-type: none"> <li>▪ Date of recommendations to EIC to send recommendation to the foreign health authority</li> <li>▪ Change in Frequency of Monitoring (F.M.), if any</li> <li>▪ Date of recommendation to EIC to lift 'on alert'</li> <li>▪ Date of Revocation of 'on alert' and EIC reference</li> </ul>	
10	Action pending	

Signature  
(Name and designation)