

**EXECUTIVE INSTRUCTION
FOR
EXPORT OF MILK & MILK PRODUCTS**



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CONTENTS

Sl. No	Item	Page No
	Introduction	5
1.	Procedure for approval of establishment	5
2.	Procedure for approval of veterinarian/technologist	11
3.	Procedure for approval of additional facilities/ activities of approved establishment	12
4.	Procedure for renewal of approval of establishment	13
5.	Permission to process and pack milk and milk products for export by merchant exporter	15
6.	Change in the name of the company	15
7.	Responsibilities of the approved establishment	16
8.	Official Control by the Competent Authority	24
9.	Guidelines for dealing with unsatisfactory monitoring or other visit reports and /or test reports and violations	32
10.	Action to be taken in case of failure of samples drawn during RMP	33
11.	Procedure to be followed when an approved processing establishment temporarily suspends its production for export	33
12.	Information and Record	34
13.	Reporting to Head Office	34
14.	Time frames	35
15.	Export Certification	35
	Consignment wise inspection (CWI)	39
16.	Fee Structure	41
17.	Procedure to be followed for complaints received from Importing Countries	42
18.	Appeal	47
19.	Power to relax	47

ANNEXURES

Annexure No.	Page No.
Annexure I : Application for approval	48
Annexure IA : Undertaking	65
Annexure IB : Guarantee	66
Annexure IC: General hygiene provisions for primary production and associated operations	67
Annexure ID: Requirements for approval of establishment for processing milk products for export	70
Annexure IIA: Adequacy Audit: Scrutiny of application and HACCP based food safety management system	76
Annexure IIB: Audit observation sheet	77
Annexure IIIA: Assessment report for infrastructure and equipment facilities	78
Annexure IIIB: Assessment report for GMP, GHP, GVP, HACCP etc	90
Annexure IIIC: Assessment report for full approval for infrastructure, equipment facilities implementation of GMP, GHP, GVP and HACCP based Food Safety Management System	98
Annexure IV: Non-confirmatory report	116
Annexure V: Letter of Non-approval	117
Annexure VI: Letter of conditional approval	118
Annexure VII: Letter of full approval to process milk products for export to EU/Non-EU	120
Annexure VIIA: Letter of approval to process milk products for export to EU/Non-EU	122
Annexure VIII: Certificate of approval	185
Annexure IX: Application for approval of veterinarian/technologist	124
Annexure IXA: Assessment report of veterinarian/technologist	125
Annexure IXB: Certificate of approval of veterinarian/technologist	126
Annexure X: Application for approval of additional facilities/processing activities	127
Annexure XA: Assessment report for additional/processing activities of the establishment	130
Annexure XB: Letter for approval of additional facilities/processing activities	134
Annexure XI: Application for renewal of approval of establishment	135
Annexure-XII: Reminder letter to units for renewal of approval	137
Annexure-XIII: Assessment report for renewal of approval of establishment	138
Annexure-XIV: Statement of performance of Unit	145
Annexure-XV: Request for permission to process and pack milk products for export by merchant exporter	146
Annexure XVA: Letter of permission to process and pack Milk product by merchant exporter	147
Annexure XVB: Letter of withdrawal of permission to process and pack milk products for export by merchant exporter	148
Annexure-XVI: Monitoring parameters for water (98/93/EC)	149

Annexure-XVII: Monitoring report	150
Annexure XVIIA: Non-Confirmatory report	153
Annexure XVIIIB: Suggestions for improvement	154
Annexure XVIIIC: Farm visit report	155
Annexure XVIIID: Frequency of monitoring of milk products processing establishments	158
Annexure XVIII: Supervisory visit report	159
Annexure XIX: Corporate audit report	161
Annexure XXA: Health certificate to EU Countries	162
Annexure XXB: Health certificate to Non-EU Countries	169
Annexure XXC: Public health attestation to be submitted by the establishment	170
Annexure XXD: Animal health attestation to be issued by controlling veterinary authority	172
Annexure XXE: Request letter from establishment for health certificate	173
Annexure-XXI: Certificate for export	174
Annexure-XXIA: Monthly statement on certificate issued by exporter of milk products	175
Annexure XXII: Indemnity bond	176
Annexure XXIII: Monthly report of monitoring/supervisory visit to the EU/Non-EU approved milk product establishments	177
Annexure XXIV: Change in the list of approved units	178
Annexure-XXV: Details of sample failed during monitoring of EU approved milk unit	179
Annexure-XXVI: Status report on milk product establishment which had complaint from importing countries	180
Annexure-XXVII: Application for consignment wise inspection (CWI)	182
Annexure-XXVIII: Health/Veterinary certificate for export under CWI	183
Annexure-XXIX Letter of rejection	184

INTRODUCTION

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. 4031(E) and S.O 4032(E) both dated 09.11.2020, on the basis of which the establishments processing milk products meant for export are being approved by the Competent Authority (Export Inspection Agencies (EIAs) established under Section 7 of the Export (Quality Control and Inspection) Act, 1963) or consignment of milk products are certified under Consignment Wise Inspection(CWI).

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 (EIC)/EIAs is to exercise official control by approving the units and implementing an effective surveillance system or to certify the consignments to ensure the compliance to the requirements schedule under S.O.4031(E) of the order dated 09.11.2020.

1. PROCEDURE FOR APPROVAL OF ESTABLISHMENT

1.1 Application for approval

- 1.1.1 The establishment intending to process milk & milk products for export shall submit the application for approval in the prescribed format placed at **Annexure I** along with documents given at 1.1.3 to the nearest office of EIA under whose jurisdiction the establishment is situated.
- 1.1.2 Application fee as given in clause 16 shall be paid online by the applicant and submit to the Export Inspection Agency concerned along with the application form.
- 1.1.3 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 used in processing needs to be tested as per IS: 4251 or any other water standard which covers all the requirements of 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), 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, 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 OR name & address of the EIC approved establishments supplying milk & milk products as raw material for processing along with the supplying contract between both the establishments.
- h) Bio-data of the Veterinarian/technologist(s) with self-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) Certified copy of the order allotting Importer Exporter Code number (IEC).
- l) Copy of FSSAI license.

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

1.2 Processing applications for approval

1.2.1 Applications received shall be scrutinized 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 **five 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 authorized by In-charge of the Food Scheme. 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 **ten working days**. The deficiencies, if any, shall be communicated to the applicant for rectification.

- 1.2.2 When the application is complete in all respect, In-charge of the Agency shall depute a suitable officer as required by Clause 1.3.2 as Convener of Inter Departmental Panel (IDP) for assessment of the establishment.
- 1.2.3 Application pending for more than one year due to non-compliance by the establishment shall be rejected. However, the establishment may apply a fresh with all required documents and fees.

1.3 Assessment of the establishment

- 1.3.1 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 newly constructed 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 to 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 and exporting of milk/manufacturing of milk products (however, export to the EU countries will be permitted only after listed on EU Traces System). 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, GVP and HACCP based procedures. Based on the satisfactory assessment report of the IDP, the **full approval** shall be granted to the establishment by the Agency In charge.

However, in cases, where establishment is already in production & has implemented HACCP based FSMS or a non-EU approved establishment submits application for the approval to process milk products for export to EU countries, the conditional approval is not required. In such cases, the IDP may conduct assessment of infrastructure & equipment facilities and implementation of HACCP based FSMS at the establishment (as per **Annexure IIIC**) 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 visit of IDP

and shall demonstrate the compliance to implementation of GHP, GMP, GVP and HACCP based FSMS and other regulatory requirements.

- 1.3.2 The Competent Authority may take the assistance of representatives from the Council, Agricultural and Processed Food Products Export Development Authority (APEDA), Department of Animal Husbandry and Dairying under Ministry of Fisheries, Animal Husbandry and Dairying, Ministry of Food Processing Industries, Food Safety and Standards Authority of India, National Dairy Development Board, National Dairy Research Institute, Industry, Co-operatives in the matter of approval of establishment.
- 1.3.3 Members of the Inter Departmental Panel will be decided by the IDP convener in consultation with the In-charge of the Export Inspection Agency from the composition of IDP as defined in GOI notification S.O. 4032(E) dated 09.11.2020. The EIA representative of the IDP (convener) shall be an officer at the level of Deputy Director, having background (qualification/experience) of Food Schemes. In unavoidable circumstances, Assistant Director having relevant qualification and enough experience in food scheme may be nominated as EIA representative by the In-charge of the Agency.
- 1.3.4 The minimum quorum of IDP shall be **three**.
- 1.3.5 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 and milk products meant for export is available in **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 assessment of 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 recommended. Enough flexibility shall be given while assessing. The aim shall be to ensure the food safety and to avoid the cross contamination.

1.3.6 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:

1.3.6.1 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:

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

- EIA-Mumbai – 01/ Factory No / MP/Year of Approval
- EIA-Kolkata – 02 / Factory No / MP/Year of Approval
- EIA-Kochi - 03 / Factory No / MP/Year of Approval
- EIA-Delhi –04 / Factory No / MP/Year of Approval
- EIA-Chennai- 05 / 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 2022, the unit shall be allotted approval No. “03/01/MP/22”.

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. “03/01/MP/22-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. “03/01/MP/22-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. “03/01/MP/22-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. “03/01/MP/22-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 B shall be kept updated up to last approval/renewal of the establishment. However records of file C shall be kept for at least three years and file D records to be kept permanent.

- 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**.
- 1.3.6.2 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 **three 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**.
- 1.3.6.3 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 assessment of the establishment), either the IDP or Convener of IDP (either by onsite verification or based on the documentary evidences) as may be decided by Agency In-charge concerned. Further, procedure shall be followed as per 1.3.6 as applicable.
- 1.3.7 The establishment shall be allowed to process milk and milk products in their establishment for all destinations including EU after grant of Full/Conditional approval. However, export to the EU countries shall commence only from the date of EIC approval, based on listing the name of establishment on EU traces system. The actual export to the countries of the EU shall commence only from the date of listing on EU traces system, if applicable. However, the establishment shall be allowed to process and export their milk and milk products to countries other than EU.
- 1.3.8 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 and milk products in their unit at the time of IDP visit.
- 1.3.9 The IDP shall assess the unit for compliance with the requirements of GHP, GMP, GVP 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 (either by onsite verification or based on documentary evidence) as decided by the Agency In-charge concerned. If required, the convener of 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.

- 1.3.10 If establishment is already in production, the IDP shall assess the unit for compliance with the requirements of infrastructure and equipment facility and implementation of GHP, GMP, GVP and HACCP based food safety management system as per **Annexure- IIIC**.
- 1.3.11 On satisfactory completion of assessment of infrastructure, equipment facilities, implementation of GHP, GMP and HACCP based food safety management system, 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.
- 1.3.12 If satisfied, the In-charge of the Agency shall grant the full approval of the establishment for a period of **three years** from the date of the conditional approval, which shall be intimated to the unit as per the format specified at **Annexure VII / VIIA** as applicable with a copy marked to EIC. The EIA shall send a draft Certificate of Approval to EIC as per the format specified at **Annexure VIII** along with the letter of approval for the signature of the Director(I & Q/C), wherever applicable.
- 1.3.13 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 and updated list to be sent to EIC. Concerned EIA shall issue the letter of approval to the establishment with a copy to Customs under intimation to EIC.

2. APPROVAL OF VETERINARIAN/TECHNOLOGIST

- 2.1 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 as per the format given at **Annexure IX** along with prescribed fee given in clause 16, to the controlling office of EIA.
- 2.2 The Head office of EIA shall arrange assessment of the Veterinarian/Technologist by the IDP, constituted as per clause 1.3.2, 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 by concerned EIA as per the prescribed format placed at **Annexure IXB** by the EIA concerned.
- 2.3 The approval granted to the Veterinarian/Technologist is valid for **three years** from the date of approval and after three years the Veterinarian/Technologist shall apply afresh to the controlling office of EIA along with the required assessment fee as prescribed in clause 16, for re-assessment of the veterinarian/ technologist by the IDP.

- 2.4 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.
- 2.5 The Convener-IDP/In-charge of Food Scheme shall ensure that assessment of the Veterinarian/Technologist is carried out within fifteen working days of receipt of their application complete in all respect.
- 2.6 The number of approved veterinarian/technologist shall be adequate as per production capacity and product scope of establishment.
- 2.7 The minimum quorum of IDP shall be two for assessment of veterinarian/technologist.

3. PROCEDURE FOR APPROVAL OF ADDITIONAL FACILITIES/ACTIVITIES OF APPROVED ESTABLISHMENT

- 3.1 The approved establishments seeking approval of additional facilities/activities shall submit their application in the prescribed format placed at **Annexure X** 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 16.
- 3.2 Application(s) received shall be scrutinized 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 scheme.
- 3.3 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 or approval can be granted based on documents, depending upon the nature of additional facility/activity requested for approval.
- 3.4 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.

- 3.5** The prescribed Assessment Report Format placed at **Annexure XA** shall be used for reporting the observations.
- 3.6** 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 Convener of the IDP/ EIA official (either by onsite verification or based on documentary evidence) 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 recommended.
- 3.7** The In-charge of the EIA concerned shall examine the assessment report of the IDP/In-charge of the Food Scheme.
- 3.8** 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 as per the format specified at **Annexure XB** within three working days of the receipt of the assessment report.
- 3.9** In case the IDP/In-charge of the Food Scheme/ EIA official does not recommend approval, the In-charge of the EIA concerned shall convey to the applicant, within **three 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 and EIA shall send the recommendations to EIC for issuance of new Certificate of Approval.

4. PROCEDURE FOR RENEWAL OF APPROVAL OF ESTABLISHMENT

- 4.1** The approved establishment seeking renewal of approval shall submit application(s) 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 16. EIA may remind the processor (As per **Annexure XII**) Seventy five days before the expiry of the approval.
- 4.2** Application(s) received shall be scrutinized and any discrepancies / shortcomings observed shall be immediately communicated to the applicants for rectification.

- 4.3** 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 within **fifteen working days** of receipt of their application complete in all respect.

Note: It shall be ensured by the In-charge of the Agency and the IDP Convener 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**.

- 4.4** The minimum quorum of IDP for renewal of approval shall be **two**.
- 4.5** 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 recommended for approval.
- 4.6** The assessment reports shall be examined by the EIA concerned and following may happen:
- 4.6.1 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.
- 4.6.2 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 **three years** from the date of expiry of earlier approval and inform the establishment accordingly as per the format specified at **Annexure VIIA** with a copy marked to EIC.
- 4.6.3 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 three years from date of expiry of earlier approval.

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

- 5.1** Approved establishments shall be permitted to process and pack milk and 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. The number of approved merchant exporters may be increased, with the approval of Agency In -charge based on the production capacity and volume of export.
- 5.2** Approved 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.
- 5.3** Establishments intending to process and pack milk or 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 16 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).
- 5.4** Approval to process/handle milk and milk products meant for export by the merchant exporter(s) is given by the EIA concerned as per the format given at **Annexure XVA**.
- 5.5** 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 16 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. 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**.

6. CHANGE IN THE NAME OF THE COMPANY

- 6.1** In case there is a change in the name of the company or 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 establishment shall furnish the relevant legal documents to the controlling local office of the EIA under whose jurisdiction the establishment is situated.

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 **within five working days** under 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.

6.2 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.

7. RESPONSIBILITIES OF THE APPROVED ESTABLISHMENT

7.1 General

7.1.1 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, GVP 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 dispatch of the cargo and maintain records thereof. The establishment shall comply with all the regulatory requirements of the GOI Order and Notification S.O 4031 and S.O. 4032 both dated 11th November 2020, as well as those specified by the importing country and by EIC from time to time.

7.1.2 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 which may affect food safety, prior approval shall be taken from the Competent Authority.

- 7.1.3 All the controls and sampling procedures shall be in compliance with GHP, GMP, GVP 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 concerned EIA 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.
- 7.1.4 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.
- 7.1.5 Establishments shall validate the processing method used for pasteurization, UHT treatment, sterilization etc and calibrate all the recording devices at a laid down frequency appropriate to ensure proper temperature control.
- 7.1.6 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.
- 7.1.7 Personal hygiene and behavior 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.
- 7.1.8 Proper control shall be exercised to avoid cross contamination of the product processed.
- 7.1.9 Suitable pest control measures shall be adopted to eradicate pests inside the factory premises.
- 7.1.10 Milk and 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.
- 7.1.11 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 monthly basis.

- 7.1.12 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.
- 7.1.13 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 milk.
- 7.1.14 Any change in the veterinarian/ technologist shall be informed to the EIA concerned immediately.
- 7.1.15 Wherever, raw milk is used for processing, shall be fit for human consumption.
- 7.1.16 All equipments must be cleaned and disinfected before processing/packing of milk & milk products.
- 7.1.17 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 cooled immediately to not more than 8°C in the case of daily collection, or not more than 6°C if collection is not daily. However if the processing of milk begins immediately after milking or within 4 hours of acceptance at the establishment FBO may keep milk at a higher temperature.
- 7.1.18 During transport the cold chain must be maintained and on arrival at the establishment the temperature of the milk must not be more than 10 °C.
- 7.1.19 Establishment shall ensure adequate separation of EU-eligible and non-EU-eligible food commodities during the whole production and storage chain in case the establishments is authorized for export to the EU & Non EU both and for supply to domestic market also, if any .
- 7.1.20 Proper waste disposal system shall be developed to avoid possible cross contamination.
- 7.1.21 Training shall be imparted to the employees on a laid down frequency.

7.2 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.

7.2.1 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 regular/periodic audit for verification of requirements for GHP, GVP, Food safety, animal health, animal welfare, 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:

For raw cow milk:

Plate count at 30 °C (per ML) < or equal to 100000 (*)

Somatic cell count (per ml) < or equal to 400000 (**)

For raw milk from other species

Plate count at 30 °C (per ML) < or equal to 1500000 (*)

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

**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.

Official veterinarian/approved veterinarian shall verify the below veterinary checks during periodic farm visits:

- the health status of the animals.
- the absence of use of prohibited or unauthorized pharmacologically active substances.
- Possible presence of residues of authorized pharmacologically active substances, pesticides or contaminants does not exceed the levels as per laid down requirement.

7.2.2 Checks for residues of chemical contaminants

Approved establishments shall ensure that the identified milk production holdings, from where the raw milk is being procured, are tested for prohibited pharmacological substances, environmental contaminants, etc. as per the RMP parameters mentioned in EIC RMP plan prepared annually for Milk products and same is available on EIC website www.eicindia.gov.in. The samples shall be tested by EIC approved lab if the internal facilities are inadequate. The establishment shall have Self Residue Monitoring Plan in place and shall be addressed in HACCP.

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 once in three months.
- Drugs (Total residues of antibiotics as beta lactam)- once in a month.
- Aflatoxin (as Aflatoxin M1)- Once in two months.

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

7.2.3 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.

7.2.4 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- $n = 5, c = 0, m = 10 \text{ cfu/ gm}, M = 10 \text{ cfu/gm}$ (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 – $n = 5, c = 0, m = \text{Absent in } 25 \text{ gm}, M = \text{Absent in } 25 \text{ gm}$ (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 – $n = 5, c = 2, m = 10 \text{ cfu/ gm}, M = 100 \text{ cfu/ gm}$ (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 – $n = 5, c = 0, m = \text{Absent in } 25 \text{ gm}, M = \text{Absent in } 25 \text{ gm}$ (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- $n = 5, c = 2, m = 10 \text{ cfu/ gm}, M = 100 \text{ cfu/gm}$ (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 value

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 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 21asteurizat liquid Dairy products

- Enterobacteriaceae- $n=5$, $c=2$, m = <1 cfu/ml, M = 5cfu/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 = 1000cfu/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 pasteurization or a stronger heat treatment

- Coagulase positive staphylococci- $n=5$, $c=2$, m = <10 cfu/gm, M = 100cfu/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).

In addition the milk products to be tested for pathogens as mentioned in the notification / importing country requirements.

7.2.5 Sanitation and hygiene control samples

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

7.2.6 Water

Establishments shall exercise proper quality control on water used in processing 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 or any other water standard which cover all the requirements of IS 4251 on yearly basis except for radiological parameters.

7.2.7 Additives

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

7.3 Records

Proper records shall be maintained by the processor at all stages of production, storage and transportation of milk & 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
- Animal health records
- Records of use of veterinary medicinal products
- Farm Visits records

7.4 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/labeled 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 Number:

In addition to the general requirements for identification marking, consignments of milk and 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 or milk products must be maintained and the period during which conservation may thus be assured.

However, export of milk or 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/labeled 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.

7.5 HANDLING OF IMPORTED RAW MATERIAL FOR EXPORT PRODUCTION

- a.** If the approved establishment wants to use any imported raw material for the production of milk products, it shall seek prior permission from concerned Agency-in-charge.
- b.** The approved establishment importing raw material for further processing and export shall address the processing of the imported raw material in their HACCP plan and maintain proper records including traceability.
- c.** The approved establishment shall inform the concerned EIA / Sub Office before the consignment of imported raw material reaches their premises. The establishment shall submit all details of imported raw material including quantity, types of product, type of pack, country of origin, Veterinary Certificate, Health Certificate, test report(s) if any, Certificate of Origin issued by the importing country, copy of BL and bill of entry.
- d.** After scrutiny of the details submitted by the approved establishment, EIA shall conduct physical verification of imported raw material and draw composite sample covering all production codes / batches for testing of microbiological parameters and residue parameters to meet the requirement of importing country, where it is intended to be exported, after processing, in EIA-lab / EIC approved lab. Testing charges shall be borne by the processor. Only after the satisfactory test results, the raw material shall be permitted for further processing.
- e.** However, in case the approved establishments submits test report(s) pertaining to the samples drawn from the imported raw material for testing above parameters at the country of origin and if the same is found satisfactory, only one in ten of the imported raw material from that exporter may be subjected for testing as per Cl. 7.5 (d) above.
- f.** If the approved establishment submits the test report(s) of samples drawn from the imported raw material by Port Health Organization (PJ-IO) for custom clearance in India and if the same is found to meet the requirements of importing country where it is intended to be exported, after processing, testing as specified at Cl. 7.5 (d) need not be done.

8. 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:

8.1 Monitoring by EIA officials

- 8.1.1 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.
- 8.1.2 An officer, authorized by the controlling officer shall carry out monitoring.
- 8.1.3 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 dispatch 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.
- 8.1.4 Frequency of monitoring of milk product establishments:
- a) Monitoring visits shall be carried out **once in four months** during 1st year of approval and **once in six months** from 2nd year onwards. When the units are not producing for export for at least Six months, the monitoring and supervisory visits by EIA shall be discontinued. The monitoring and supervisory may be resume once approved establishment start production for export.
 - b) 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 six months. If the performance of the unit during six months is found satisfactory and if there is no foreign rejection/complaint during the period, the frequency of monitoring shall be reduced to the original frequency as defined at (a) above.
 - c) 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 performa placed at **Annexure XVIIID** 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.

Note: In case of EU approved establishments monitoring frequency shall be once in three months.

8.1.5 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 and milk products processed in unauthorized places, storages of milk products from other establishments without prior permission, misuse of CFE, improper labeling, 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 when establishment informed about the change in HACCP manual 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.

8.1.6 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	200 ppm

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.

8.1.7 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.

8.1.8 Microbiological/Chemical checks:

The monitoring officials shall also draw samples for testing microbiological and chemical parameters, as per the details given below:

Sr. No.	Parameters	Products/ Stage	Frequency
1	TPC, Enterobacteriaceae, Salmonella, coagulase positive, Shigella &	Finished milk products	Every monitoring visit

	L.monocytogenes		
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.

8.1.9 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 no. 8.1.8.

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	1 sample
	(2) Workers hand	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 liter capacity with ground flask stoppers having an overhanging rim. They are sterilized 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 sterilization serves neutralization 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 cm² area is swabbed using a square template of 5 cm x 5 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 100 ml 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 analyzed.

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	--
2.	Food contact	100 per cm ²	Absent / cm ²	--
3.	Worker's Hand	100 per cm ²	Absent / cm ²	Absent / cm ²

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

(ii) 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. 8.1.8. 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

(iii) Analysis for chemical contaminants

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

(iv) 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.

8.1.10 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 XVIII** and Suggestions for Improvement (**Annexure XVIIB**), if any. The official veterinarian shall conduct regular / periodic audit of dairy farms for verification of requirements for GVP, animal health, animal welfare, water, feed and feed additives, etc and the report for farm monitoring shall be submitted in the Farm Monitoring Report Pro-forma (**Annexure XVIIC**).

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 XVIII** and **Annexure XVIIB** 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 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.

8.2 Supervisory visit

Supervisory visit shall be carried out by an officer, having adequate experience in operation of Food Scheme authorized by in-charge of the agency. Agency in-charge shall ensure that the officer deputed for supervisory visit shall be senior to the officer who has conducted the monitoring visit. The frequency of supervisory visits shall be once in a year.

Note: In case of EU approved establishments Supervisory frequency should 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.

8.3 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**.

9. GUIDELINES FOR DEALING WITH UNSATISFACTORY MONITORING OR OTHER VISIT REPORTS AND / OR TEST REPORTS AND VIOLATIONS

9.1 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

9.2 Actions to be taken in case of deficiencies observed

9.2.1 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 9.2.2 shall be followed.

9.2.2 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.
- (ii) 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.
- (iii) 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.

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

9.3 Action against violations

In case of violations, such as

- (i) misuse of Certificates for Export (CFE)
- (ii) Storing of milk products at un-authorized premises
- (iii) Non-payment of monitoring fee
- (iv) processing of milk/manufacturing of milk products in unauthorized establishments
- (v) major failure in meeting GMP/GHP/HACCP etc.,

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 Competent Authority.
- 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.

10. 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.

11. 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.

12. 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.

13. REPORTING TO HEAD OFFICE

Each Sub Office shall send the monthly reports to the Head Office of Agency concerned by first working day of the following month. The Agency shall compile the following information in the required format as per the time frame given at clause 14 and agency will submit the same to EIC as and when required. 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**.

14. TIME FRAMES:

Time frames prescribed for various activities shall be as under:

Submission of reports of monitoring	Three working days
Testing of monitoring samples	One week
Closure of complaints	
From foreign buyers	Maximum of three months or time taken to offer 10 consignments for inspection, whichever is earlier.
In case of rejection	After testing of returned consignment

15. EXPORT CERTIFICATION

15.1 Certificate for Export (CFE)

15.1.1 Since all the consignments of milk and milk products meant for export by an approved establishment 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.

15.1.2 Certificate blanks shall be obtained from the EIA concerned by payment of charges as per clause 16. 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 utilization by the establishments.

15.1.3 The responsibility for the maintenance and proper utilization of the CFEs issued to them lies with the approved establishment. They shall issue CFEs only for milk and 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.

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

15.1.5 If the validity of CFE is expired, then the same can be revalidated up to 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.

15.1.6 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.

15.2 Issuance of Certificate for Export

- a) Books of CFE blanks shall be issued on request from the approved processing establishment only after the approval of the 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 five sets remaining so as not to cause any operational problem.
- b) 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.

15.3 Statement of Certificates for Export issued

- a) Every approved establishment shall submit periodic statement of Certificate for Export issued, 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 enclosing the pink copy of CFE on monthly 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. If the approved establishments are not submitting the statements along with online fee receipt for requisite monitoring fee even after one month, 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.

15.4 Health Certificate Issuance

15.4.1 General

All consignment of Indian milk and milk products meant for export are required to be accompanied by a numbered original Health Certificate as per the formats specified by Importing Country. The format specified by EU is placed at **Annexure XXA**. In cases, no

specific format is desired by an importing country, the model health certificate for 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. Health Certificate should be issued before or on the day of shipment and cannot be issued retrospectively. An approved establishment can obtain one Health Certificate on retrospective basis in a financial year and shall be issued with the approval of concerned Agency-In charge subjected to acceptance of the same by the importing country (applicable for export to Non EU countries only).

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.16.
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 16.

15.4.2 Procedure:

- (i) The Health Certificate shall be issued only for milk and milk products processed in establishments, approved and monitored by the EIA or for the consignments inspected and found in compliance to the requirements of importing country in case of CWI. The processor/exporter shall request for health certificate from the controlling office of EIA with the following:
 - a) Copy of online application applied on the website of Export Inspection Council.
 - b) Requisite online fee receipt as per Clause No. 16.
 - 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. 16.
- (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 and 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.
- (iv) It shall be noted that the approved establishment shall test the milk and finished milk products periodically for chemical contaminants as per requirements.
- (v) Health certificate shall be issued online in duplicate, the original for the exporter for forwarding to the importer, other copy for record of local EIA.
- (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 color different from that of other endorsements. While issuing health certificate, the issuing officer must ensure that the color of the signature is different from the color of the printing of certificate. Since the certificate is usually printed in black, the signature must not be in black color. 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) Health certificates shall be printed only on secured stationary available at each EIA.
- (ix) If 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.

The health certificate shall be valid for 45 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) with the approval of Agency In Charge.

15.4.3 **CONSIGNMENT WISE INSPECTION FOR EXPORT OF MILK AND MILK PRODUCTS TO THE COUNTRIES OTHER THAN EUROPIAN UNION**

15.4.3.1 **Scope**

An exporter intending to export milk and milk products to Non –EU countries may apply under consignment wise inspection (CWI) subject to the requirements of the importing countries from time to time.

15.4.3.2 **Application for inspection**

15.4.3.2.1 The exporter seeking health certificate for a consignment of milk and milk products shall submit their application for inspection in the prescribed format given at **Annexure- XXVII** to the concerned EIA in their region.

15.4.3.2.2 Application shall be accompanied with a copy of the technical specification of export contract, invoice, packing list and other details if applicable.

15.4.3.2.3 The application shall be accompanied with receipt of online inspection fee as applicable as per clause 16.

15.4.3.2.4 The application shall be given not less than the three days before the inspection is to be carried out if the premises are situated at the same station as office of EIA; and not less than five days before the inspection is to be carried out if the premises are situated at other location.

15.4.3.2.5 The CWI procedure is applicable for consignments meant for export to Non–EU Countries only.

15.4.3.3 **Inspection**

The inspection shall be carried out by the concerned EIA either at the port of shipment or at the premises of the packer or manufacture premises or any other premises, where the consignment is offered by the exporter subjected to adequate

facilities for the inspection including drawing, preparation and sealing of the samples, being provided by the exporter.

In addition to this, the agency shall have the right to reassess the quality of the consignment at any place of storage, in transit or at the port before the actual shipment.

15.4.3.4 **Sampling**

For the purpose of testing of consignment with reference to the standard specifications of importing country, sample in triplicate (laboratory sample, reference sample and exporter sample) shall be drawn from each lot offered for inspection by the designated EIA officer. The samples drawn shall be sealed in presence of exporter.

The samples drawn shall be sealed in presence of exporter in such a way that unauthorized opening is detectable. All the samples shall be properly identified at least with following information:

- Date of sampling
- Intimation number/application number
- Invoice number and country of export
- Lot size with batch number
- Sample weight
- Name and designation of the sampling officer

One sample shall be given to the exporter, while the second sample shall be sent to EIA laboratory for testing as per the specifications of importing country.

15.4.3.5 **Testing**

The lab sample shall be sent to EIA laboratory/ EIC approved lab or sent by courier with due acknowledgement in case the inspection is done by EIA sub-office but shall in no case be left with the exporter. The exporter's sample will be analyzed only in case of dispute and for which testing charges shall be borne by exporter.

Lab samples shall be tested for all parameters as requested and provided by exporter and prescribed in the schedule of executive instruction/contractual/international specification as per the method of analysis referred in Codex Alimentarius Commission/AOAC or any other internationally recognized method. Testing charges shall be borne by processor/exporter on actual basis.

In case the sample conforms to the prescribed specifications, the EIA shall issue health certificate as per the requirement of importing country or the format prescribed in **Annexure-XXVIII**. The health certificate shall be valid for a period of 45 days.

If the sample drawn is found not conforming to the prescribed specification, the consignment will be rejected for export and the rejection letter will be issued as per the prescribed format given in the **Annexure-XXIX**.

16. FEE STRUCTURE

The prescribed fee shall be paid in the form of online payment via link available on website www.eicindia.gov.in to Export Inspection Agency concerned as applicable.

Activity	Fees(Applicable taxes extra)
Application for approval / renewal of approval of establishment	Rs 5000/-
Application for approval of additional activity / facility	Rs.5000/-
Application for approval / renewal of approval of veterinarian/ technologist	Rs.2000/-
Monitoring fee for approved establishments	0.2% of FOB value subjected to a maximum of Rs.25 lakhs per annum per exporter or processor.
Countersigning of Certificate for Export (CFE) for Merchant Exporter	Rs.500/-
Consignment-wise Inspection (CWI)	0.4% of the FOB value of exports
Issue of Health Certificate	Rs. 500/-
Issuance of corrigendum or addendum or clarification to Health Certificate	Rs. 500/-
Issuance of Health Certificate in Foreign Language other than English	Rs. 500/-
Consignment-wise Inspection on account of official control (as per clause 10.2.2 (ii) and in other cases)	@ 0.3% of the FOB value (including monitoring fee) +Testing Charges
Verification of corrective actions/measures taken by the establishment on account of complaints or major deficiencies	Rs.2000/-
Deputation of an officer to verify reprocessing /rectification of deficiencies on account of complaints or major deficiencies	Rs.2000/-
Visit for additional monitoring / drawing samples for testing on account of complaint for importing countries	Rs.2000 and testing charges as applicable
Drawing samples at the request of the processor	Rs.2000/-
Certificate for Export (CFE) blanks	Rs.20/- per set
Approval of merchant exporter	Rs. 5000/-
Minimum monitoring fee applicable to be paid by approved establishment per year (w.e.f. date of approval)	25000/-

17. PROCEDURE TO BE FOLLOWED FOR COMPLAINTS RECEIVED FROM IMPORTING COUNTRIES

17.1 General

When a complaint is received from the importing country or a consignment of milk or 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.

- 17.2** 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 (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.

- 17.3** The processing unit shall immediately be placed 'On Alert' by the EIA concerned and the frequency of monitoring visit shall be increased to twice per 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. 16 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.

17.4 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 and the particulars of milk products held in stock.
- c) 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.
- d) Corrective action(s) proposed/taken by the processor to prevent recurrence of the problem.
- e) 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 17.4 above, if the same has not been furnished in time.

17.5 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.

17.6 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 sanitize 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 affected 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.

17.7 Dealing with returned consignments

17.7.1 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.

17.7.2 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 16.

- 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.
- 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. 8.1.9.
- g. The fee for EIA supervision with regard to reprocessing shall be as per clause 16, 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

17.8 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 conform 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).

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

The consignment, if brought back, is on testing found to be contaminated /defective the assessment report indicates unsatisfactory hygienic conditions in the unit;

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.

17.9.1 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).

17.9.2 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.

17.9.3 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. 16 (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.

17.9.4 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. 8.1.9.

17.9.5 The unit shall be taken off from the "ON ALERT" list only after monitoring as per 17.9.3 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.

18. Appeal

18.1 Any person aggrieved by the,-

- (i) decision of the Competent Authority not to accord approval;
- (ii) decision of the Competent Authority to withdraw approval;
- (iii) refusal of Competent Authority to issue Health or Veterinary Certificate,

may prefer an appeal within forty -five days from the date on which the decision or order is served on such person to an Appellate Authority appointed by the Central Government.

18.2 At least two-thirds of the total membership of the Appellate Authority shall consist of non-officials.

18.3 The quorum for any meeting at the Appellate Authority shall be three.

18.4 The appeal shall be disposed of within thirty days of its receipt

19. POWER TO RELAX

In case any situation arises, which is not covered by the Executive Instructions, Agency In charge may make a suitable recommendation to EIC for decision by Director (I&Q/C).

Annexure I**APPLICATION FOR APPROVAL****(Milk & 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 & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020 for approval to process milk & 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 & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020 and also the other requirements specified by EIC from time to time. Please find enclosed herewith an online fee receipt 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 point10 above			
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	Information on Structure of the Establishment			
1	Is there any chill room / chill storage for storage of food products? Give numbers and storage temperatures?			
2	Are there storage facilities for in-process liquid milk/food products? Give type of storage facility and temperature of storage?			
3	Whether the unit has chilling facility to reduce the temperature of the liquid milk products below 6 °C? If yes, specify method and capacity of chilling?			
4	Is there facility for pasteurization of liquid milk products? Give number of pasteurizes and their capacities?			
5	Whether the unit have spray drying facility? If yes, give details like type and capacity.			
6	Whether there is packing room for every milk product separate from processing activities and storage?			
7	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.			
8	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	Numbers	Capacity	Regn. Nos.
	(a) Refrigerated Vehicle			
	(b) Insulated Vehicles			
	I Non-insulated Vehicles			

9	Does the establishment hire outside vehicles? If yes, Give details as above.	
C	Information about personnel	
1	Give number of veterinarian/ technologists and veterinarians available in the establishment	
2	Give name, designation, qualifications and experience of the personnel qualified and responsible for developing, implementing and maintaining HACCP-based procedures.	
3	Give name, designation, qualifications and experience of the veterinarian(s) and technologist(s) supervising the processing and other related operations	
4	Give name, designation, qualifications and experience of the qualified personnel, conducting microbiological and chemical analysis	
5	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.	
6	Give number of male workers in the processing establishment in each shift and at milk washing facilities, if separate.	
7	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.	
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 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 zoonosis 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?	
26	Is there correct use of feed additives and veterinary medicinal products?	
27	Is there appropriate remedial action when informed of problems identified during official controls	
28	Specify the mode of transport of raw milk from the milk production holding	
29	Are there records relating to measures put in place to control hazards in an appropriate manner?	
30	Are there records of nature and origin of feed fed to the milch animals?	
31	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
32	Are there records of the occurrence of diseases that may affect the safety of milk products?	
33	Are there records of other relevant reports on checks carried out on milch animals or raw milk?	
34	Are there records of the details of employees such as veterinarians and farm technicians, assisting in raw milk production?	
B	Requirement for Premises & Equipment	
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 °C?	
6	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?	
C	Staff Hygiene	

1	Are there suitable facilities near place of milking for washing hands and arms?	
Section-III: GENERAL FACILITY AND HYGIENE REQUIREMENTS OF THE PROCESSING ESTABLISHMENTS		
A.	General requirements for premises and infrastructure	
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 odors, dust, etc?	
2.	Layout, design, construction, location and size of food premises:	
(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	Lavatories	
(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	Washing facilities:	
(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	Ventilation:	
(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	Drainage facilities	
(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	Change room facilities	
(a)	Are adequate separate changing facilities (change room and facilities therein), where necessary, provided for personnel handling raw material, unprocessed products and processed	
(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?	
(g)	Is there storage for cleaning agents and disinfectants in	

	areas where food is not handled?	
B.	Specific requirements in rooms where foodstuff are prepared, treated or processed	
1	Design and layout to permit good food hygiene practices, including protection against contamination between and during operations	
(a)	Floor	
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)	Walls	
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)	Ceiling: 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)	Windows and other openings	
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 doors easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	
(f)	Surfaces (including surfaces of equipment)	
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	
(g)	Cleaning facilities	
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?	
C	Transport	
1	Are the conveyances and/or containers used for transporting raw milk/food kept clean, 56 asteuriz 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?	
2	Are the receptacles in vehicles and/or containers used for transporting anything other than food where it may result in contamination?	
3	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	Equipment requirements	
1	Are all the articles, fittings and equipment with which food comes into contact?	
2	Effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination?	
3	Constructed, of such materials and kept in such good order, repair and condition as to minimize any risk of contamination?	
4	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?	
5	Installed in such a manner that does allow adequate cleaning of the equipment and the surrounding area?	
6	Is equipment, where necessary, fitted with an appropriate control device such as time, temperature, pressure, flow rate, etc. ?	
7	Are the process control equipment and devices calibrated at regular intervals?	
8	Are the chemical additives, where have to be used to prevent corrosion of equipment and containers, used in accordance with good practice?	

E	Food waste	
1	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?	
2	Are the non-edible by-products and other refuse deposited in closable containers or any other appropriate foot operable container to prevent contamination?	
3	Are the containers made of an appropriate construction, kept in sound condition, easy to clean and, where necessary, to disinfect?	
4	Is there adequate provision made for the storage and disposal of food waste, non-edible by-products and other refuse?	
5	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?	
6	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?	
F	Water supply	
1	Is there documented water management system? Are the outlets identified and serially numbered in the plumbing layout diagram?	
2	Is the water tested as per 98/83/EC or IS:4251 for potability, as applicable?	
3	Is there adequate supply of potable water, which is used whenever necessary to ensure that foodstuffs are not contaminated (clean water may also be used for external washing)? What is the method of treatment?	
4	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?	
5	Is the non-potable water connects with, or allows reflux into, potable water systems?	
6	Is the recycled water used, if any, in processing or as an ingredient presents a risk of contamination?	
7	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?	
8	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?	
9	Is there appropriate measure to prevent contamination through back suction?	

10	Is water storage tank easily cleanable and protected from outside contamination? State frequency of cleaning water tanks.	
G	Personal hygiene	
1	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?	
2	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 58asteuri, 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?	
3	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?	
H	Provisions applicable to foodstuffs	
1	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?	
2	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?	
3	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?	
I	Pest control	
1	Are adequate documented procedures in place to control pests?	
2	Whether bait map showing serially numbered bait stations provided?	
3	Are adequate procedures in place to prevent domestic animals from having access to places where food is prepared, handled or stored?	

J	Storage conditions	
1	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?	
2	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?	
3	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?	
4	Are hazardous and/or inedible substances adequately 59asteur and stored in separate and secure containers?	
K	Wrapping and packaging of foodstuffs	
1	Is the material used for wrapping and packaging a source of contamination?	
2	Are the wrappings and packing materials stored in such a manner that they are exposed to a risk of contamination?	
3	Are wrapping and packaging operations carried out so as to avoid contamination of the products? (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.)	
4	Is the wrapping and packaging material re-used for foodstuffs easy to clean and, where necessary, to disinfect?	
L	Heat treatment	
1	Does the heat treatment process used to process an unprocessed product or to process further a processed product:	
2	Raise every particle of the product treated to a given temperature for a given period of time?	
3	Prevent the product from becoming contaminated during the process?	
4	Does the process employed achieve the desired objectives?	
5	Are the main relevant parameters (particularly temperature, pressure, sealing and microbiology), checked regularly including by the use of automatic devices?	

6	Does the process used conform to an internationally recognized standard (for example, pasteurization, UHT, heat treatment, etc.)?	
M	Maintenance	
1	Is there appropriate maintenance schedule for maintaining infrastructure and equipment facilities and records thereof?	
2	Whether all equipment pasteur and marked?	
N	Training	
1	Are the food handlers supervised and instructed and/or trained in food hygiene matters commensurate with their work activity?	
2	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?	
3	Are the persons those responsible for compliance with the requirements of national law trained?	
O	Testing facility	
1	Is there in-house testing facility for analysis of raw materials, in- process samples, finished products, hygiene and sanitation control samples, etc.?	
Section-IV: REQUIREMENTS CONCERNING PRODUCTS		
A	Application of the Identification Mark	
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	Form of the Identification Mark	
1	Are marks legible and indelible and the characters easily decipherable? Is It clearly displayed for the competent authorities?	
2	Does the mark indicate the name of the country in which the establishment is located?	
C	Method of Marking	
1	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?	

2	Is the mark an irremovable tag of resistant material?	
D	HACCP-based Procedures (Hazard analysis and critical control points)	
1	Are the HACCP principles in place, implemented and maintained?	
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 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 I 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?	
3	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	
4	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
5	Are the documents up-to-date at all times?	
6	Are the documents and records retained for an appropriate period?	
7	Traceability of raw milks procurement: 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?	
8	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?	
(a)	Is clean?	

9	Is fit for consumption, as far as the food business operator can judge?	
10	Is in a satisfactory state?	
11	In the event of failure to comply with any of the requirements listed under points above, is it notified to the approved veterinarian/ technologist and took appropriate measures?	
E	Food Chain Information	
1	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 veterinary examination 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?	
2	If any lot of raw milk arrives at the processing establishment without food chain information, is it notified to the approved veterinarian/ technologist immediately?	
3	Are the raw milk processed with the permission of the approved veterinarian/ technologist?	
Section-V: SPECIFIC REQUIREMENTS		
A	Raw milk criteria & Handling	
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 °C or below and kept at that temperature until processed?	
B	Milk Products Processing	
1	Requirements for Establishments	
(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?	
2	Analytical Specifications	
(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?	
C	Other Food Ingredients/additives/preservatives	
1	Specify the additives/ preservatives used by the unit (separate list to be enclosed)	
2	Whether the additives/preservatives are of food grade quality, acceptable to importing country?	

Section-VI: Any other relevant information:

Place

Date
faithfully

Yours

Signature

Name &
Designation

Check list of enclosures:

- (1) Prescribed online fee receipt.
- (2) HACCP Manual (including Organizational 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 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, 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 IC 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.
- (14) Copy of FSSAI license

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.

Annexure IA

UNDERTAKING

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

Ref. No. :

Date:

To

The Export Inspection Agency ----

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 & 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) or.....

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

Yours faithfully,

Name

Signature

Date

Strike out whichever is not applicable.

Annexure IB

GUARANTEE

(To be submitted on establishment'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 throughout 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 & milk products other than what is included in scope of approval.

We will not store the milk & 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)

Annexure IC

GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS

1. Animal health requirements

Raw milk must originate from animals as follows:

- a) Milch animals, which are tuberculosis free.
- b) From milch animals which are brucellosis free.
- c) Milch animals should not show any symptoms of infectious diseases communicable to human beings through milk
- d) Milch animals should be in a good general state of health. There should not be any sign of disease to milch animals that might result in the contamination of milk, in particular, they are not suffering from any infection of the genital tract with discharge, enteritis with diarrhea 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.

2. 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 zoonosis 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.
 - k) Identification of milch animals undergoing medical treatment likely to transfer residues to the milk and to ensure prescribed withdrawal period of these animals before collection of milk for human consumption.
- 4) Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

3. Record-keeping

1. 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.

2. 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.
3. The food business operators may be assisted by other persons, such as veterinarians and farm technicians, with the keeping of records.

4. Recommendations for guides to milk production holdings for good hygiene practice

1. The guides should contain guidance on good hygiene practice for the control of hazards in milk production and associated operations.
2. 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. Proper disposal of dead animals, waste and litter;
 - f) Protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;
 - g) 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;
 - h) Measures relating to the cleanliness of milch animals;
 - i) Measures relating to record keeping.

Annexure-ID

REQUIRMENTS FOR APPROVAL OF ESTABLISHMENT FOR PROCESSING MILK PRODUCTS FOR EXPORT

1. Surroundings

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.

There shall not be any swamps, stagnant water or signs of any rodent harbourage inside the premises.

The surroundings shall be reasonably free from objectionable odours, smokes, dust and other contaminants.

2. Constructions and Layout

The immediate surroundings of the building shall be tarred/ concreted to prevent contamination from the surroundings.

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.

The layout 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.

There shall be adequate lighting and ventilation and light fixtures shall be protected with proper covering.

The layout shall ensure sufficient space in different sections for machinery, equipment, personnel etc. without congestion.

The building shall provide sufficient protection against the entry and harbourage of rodent, insects, milch animals, other animals etc.

All the entry points shall have suitable air curtains or other suitable arrangements to prevent the entry of flies.

Wood shall not be used in the factory, except inside the cold storage.

Non –operative areas inside the establishment shall be properly cordoned off to avoid possible cross- contamination.

3. Milk receiving section.

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.

The raw milk receiving section shall be sufficiently separated from processing area to prevent contamination

Signboards directing the employees to wash and sanitise hands before entering and after each absence shall be installed

Air curtains/fly killers shall be installed to prevent the entry of flies when the door is opened.

4. Workers entry points.

Suitable washing and sanitizing facilities for feet and hands shall be provided at the entry points.

The washbasins shall be provided with foot operable taps or non-hand operable taps.

Liquid soaps, disinfectants, nailbrushes, single use towels / hand dryers etc. shall be provided in sufficient quantities at all entry points.

Waste bins provided for collecting used towels shall be of foot-operated type.

5. Ceiling walls and floors.

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 sideways.

The wall to floor and wall-to-wall junctions shall be rounded off to facilitate easy cleaning.

The walls should be durable, smooth, light coloured and easy to clean and disinfect.

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.

The ceiling shall be free from cracks and open joints and shall be smooth and easy to clean.

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.

All the doors shall be tight fitting and the windows and ventilators shall have fly proofing nets to prevent the entry of flies.

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.

The doors shall be of self-closing type.

Mechanical ventilation/ exhaust fans shall be provided in areas where stagnation of air, condensation of fluid etc. are present

The opening of ventilation/ exhaust fan shall be provided with suitable fly proofing system.

7. Drainage

There shall be adequate drainage facility and slope of the drainage shall be opposite to the flow of work/ material.

The open end of the drainage shall be protected against the entry of rodents.

The drains shall be of adequate size having sufficient slope for easy cleaning.

8. Tables, utensils, equipments and machineries

All the utensils and equipments shall be made of non-corrodible material and shall be smooth without cracks and crevices and easy to clean and disinfect.

All food contact surfaces shall be free from rust and paints.

Suitable arrangements shall be made to drain the water from the tables directly into the drainage without falling on the floor.

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.

Pasteurisers of suitable capacity having capability to maintain required temperatures and time shall be provided with automatic calibrated temperature devices

Milk products store rooms shall be clean having smooth floor, walls and roof and shall have suitable mechanism to control the temperature, if required.

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.

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.

The cold storage shall have suitable refrigeration system to maintain the required product temperature.

The floor, ceiling and walls of the cold storage and other storage rooms shall be smooth and easy to clean and disinfect.

Proper steps shall be taken to avoid contamination of the materials stored.

There shall be adequate lighting with protective covers.

10. Change rooms and toilets

- Adequate number of change rooms for workers shall be provided for high risk and low risk areas.
- The change rooms shall be of adequate size having smooth washable walls and floors.
- There shall be flush lavatory and the lavatories shall not open directly to the working area.
- The toilets shall have self-closing doors and proper fly proofing system.
- 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.
- There shall be lockable cupboards and facility for keeping gumboots, shoes and chapels inside the change room.
- Suitable arrangements shall be made by the establishment to launder the working clothes of the workers.

11. Store rooms.

- There shall be separate stores for wet and dry items and the chemicals/ disinfectants should be properly labelled.

- Packing material store shall be of adequate size with proper fly and dust proofing system
- 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.
- Pest and rodent control measures shall also extend to the storerooms.

12. Water.

Water used in the factory for processing of milk products 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.

Potable water shall be used also for cleaning utensils, machinery, tables etc.

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.

Water store tank, both ground level and overhead, should be protected and clean regularly

The taps having hose connections shall be fitted with non- return valves

The water tanks shall be cleaned regularly as per SOP as per pre-decided frequency.

If water is brought from external source i.e. mobile water tankers, it should be cleaned and disinfected periodically.

13. Personal Hygiene

The employees engaged in processing activities shall be free from communicable diseases, open sores and wounds.

They shall be medically examined periodically (at least once in a year) 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.

Prophylactic injections shall be administered to the employees and record maintained thereof.

Communicable diseases in their homes to be notified and the employees shall

be medically examined after each absence due to illness.

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

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

14. In-house laboratory

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

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

The record of laboratory testing shall be maintained properly for verification by CA.

15. Transportation.

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

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.

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

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

Annexure IIA
EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA /
DELHI (MINISTRY OF COMMERCE & INDUSTRY)

GOVERNMENT OF INDIA

ADEQUACY AUDIT

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

1.	Name of the processing establishment:	
2.	Address of the processing establishment:	
	District:	
	State:	
	Country:	India
	Ph.	
	Fax:	
	Email	
3.	Address of the Regd. Office:	
	District:	
	State:	
	Country:	
	Ph.	
	Fax:	
	Email	
4.	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 & milk products and HACCP based food safety management system.

**EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA / DELHI
(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 & milk products			
Date(s) of assessment				
Opening Meeting Location and date				
Closing Meeting Location and date				
Name & qualification 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)

Section-I: Information		
A	General	
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.	Information on Structure of the Establishment	
1	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.
2	Does the establishment hire outside vehicles?	

3	Is there any chill room / chill storage for storage of food products? Specify numbers and storage temperatures.	
4	Are there storage facilities for in-process liquid milk/milk products? Specify type of storage facility and temperature of storage	
5	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.	
6	Is there facility for 80asteurization of liquid milk/milk product? Specify number of 80 asteurizat and their capacities.	
7	Whether the unit have spray-drying facility? If yes, give details like type and capacity.	
8	Whether there is packing room for every milk product separate from processing activities and storage?	
9	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. Information about personnel		
1	Number of veterinarian/ available in technologists and the establishment	
2	Name, designation, qualifications and experience of the personnel qualified and responsible for developing, implementing and maintaining HACCP-based procedures.	
3	Name, designation, qualifications and experience of the veterinarian(s) and technologist(s) supervising the processing and other related operations	
4	Name, designation, qualifications and experience of the qualified personnel, conducting microbiological and chemical analysis	
5	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.	
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

A	Hygiene Provisions and record keeping in Milk Production and handling
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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?	
(viii)	Is there any infrastructure for educating farmers for clean milk production?	
(ix)	Are there any incentive given to the farmers for clean milk production?	
B	Requirement for Premises & Equipment	
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?	
C.	Hygiene During milking, collection and transport	
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 zoonosis 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?	
9	Is the waste and hazardous material handled and stored properly to prevent contamination?	
10	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	
11	Are the samples (feed, water, milk, etc.) drawn for relevant analyses that have importance to human health and records maintained?	
12	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?	
13	Is there correct use of feed additives and veterinary medicinal products?	
14	Is there appropriate remedial action when informed of problems identified during official controls?	
15	Are there records relating to measures put in place to control hazards in an appropriate manner?	
16	Are there records of nature and origin of feed fed to the milch animals?	

17	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
18	Are there records of the occurrence of diseases that may affect the safety of milk products?	
19	Are there records of other relevant reports on checks carried out on raw milk?	
20	Is milk from animals showing clinical signs of udder disease used for human consumption?	
D	Staff Hygiene	
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?	
Section-III: GENERAL HYGIENE REQUIREMENTS		
A.	General requirements for premises and infrastructure	
1.	Premise	
(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.	Layout, design, construction, location and size of food premises:	
(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	Lavatories	
(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	Washing facilities:	
(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	Ventilation:	
(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	Drainage facilities	
(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	Change room facilities	
(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	
1	Design and layout to permit good food hygiene practices, including protection against contamination between and during operations	
(a)	Floor	
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)	Walls	
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)	Ceiling: 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)	Windows and other openings	
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 doors easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	
(f)	Surfaces (including surfaces of equipment)	
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	
2	Cleaning facilities	
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	Transport	
1	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?	
2	Are the receptacles in vehicles and/or containers used for transporting anything other than food where it may result in contamination?	
3	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	Equipment requirements	

1	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?	
2 (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?	
3	Are the chemical additives, where have to be used to prevent corrosion of equipment and containers, used in accordance with good practice?	
E	Food waste	
1	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?	
2	Are the non-edible by-products and other refuse deposited in closable containers or any other appropriate foot operable container to prevent contamination?	
3	Are the containers made of an appropriate construction, kept in sound condition, easy to clean and, where necessary, to disinfect?	
4 (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?	
5	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?	
F	Water supply	
1 (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 or any other water standard which covers all the requirements of IS: 4251 for potability, as applicable?	
2	Is there adequate supply of potable water, which is used whenever necessary to ensure that foodstuffs are not contaminated (clean water may also be used for external washing)? What is the method of treatment?	
3 (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?	
4 (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?	
5	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?	
6 (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.	
G	Pest control	
(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?	
H	Maintenance	
1	Is there appropriate maintenance schedule for maintaining infrastructure and equipment facilities and records thereof?	
2	Whether all equipment labelled and marked?	
I	Training	
1	Are the food handlers supervised and instructed and/or trained in food hygiene matters commensurate with their work activity?	

2	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?	
3	Are the persons those responsible for compliance with the requirements of national law trained?	
J	Testing facility	
1	Is there in-house testing facility for analysis of raw materials, in- process samples, finished products, hygiene and sanitation control samples, etc.?	

Section-IV: Any other relevant information

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

The processing establishment may be granted conditional approval to process milk & milk product for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020;

- a) For all countries including the European Union (EU) / Countries other than EU
- b) For processing (Scope of Approval –Milk & 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 conditional approval to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020, subject to rectification of the deficiencies given in the enclosed observation sheet within one/ two/ three months from the date of this assessment and subsequent, verification of the rectifications either by on-site verification or based on documentary evidence, by IDP-Convener/ IDP.

Or

The processing establishment may not be approved to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. 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 & Qualification			
Designation			
Organisation			
Place/Date			

**EXPORT INSPECTION AGENCY – KOCHI / MUMBAI / CHENNAI/KOLKATA / DELHI
(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 & milk products			
Date(s) of assessment				
Opening Meeting Location and date				
Closing Meeting Location and date				
Name & Qualification 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		
A	Hygiene Provisions and record keeping in Raw Milk Production and handling	
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.	Other Food Ingredients/additives/preservatives	
1.	Are there controls on procurement of other Food Ingredients, additives, preservatives, etc.?	
2.	Is list of the additives/ preservatives furnished?	
3.	Whether the additives/preservatives are of food grade quality, acceptable to importing country?	
Section-III: GENERAL HYGIENE REQUIREMENTS		
A	Transport	
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	Personal hygiene	
1.	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?	
2.	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 92 asteuri, 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?	
3.	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?	
C	Provisions applicable to foodstuffs	
1.	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?	
2.	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?	
3.	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?	
4.	Storage conditions	
	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?	
5.	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?	
6.	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?	
7.	Are hazardous and/or inedible substances adequately labeled and stored in separate and secure containers?	
D	Wrapping and packaging of foodstuffs	
1.	Is the material used for wrapping and packaging a source of contamination?	
2.	Are the wrappings and packing materials stored in such a manner that they are exposed to a risk of contamination?	
3.	Are wrapping and packaging operations carried out so as to avoid contamination of the products? (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.)	
4.	Is the wrapping and packaging material re-used for foodstuffs easy to clean and, where necessary, to disinfect?	
E	Heat treatment	
1.	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?	
2.(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?	
3.	Does the process used conform to an internationally recognized standard (for example, pasteurization, heat treatment, UHT etc.)?	
Section-IV: REQUIREMENTS CONCERNING PRODUCTS		
A	Application of the Identification Mark	
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	Form of the Identification Mark	
1.	Are marks legible and indelible and the characters easily decipherable? Is It clearly displayed for the competent authorities?	
2.	Does the mark indicate the name of the country in which the establishment is located?	

C	Method of Marking	
1.	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?	
2.	Is the mark an irremovable tag of resistant material?	
D	HACCP-based Procedures (Hazard analysis and critical control points)	
1.	Are the HACCP principles in place, implemented and maintained?	
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 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 I 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?	
2.	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	
3.	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
4.	Are the documents up-to-date at all times?	
5.	Are the documents and records retained for an appropriate period?	
6.	Traceability of raw milk procurement: 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?	
7.	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	Food Chain Information	
1.	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 ante –and post-mortem 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?	
2.	If any lot of raw milk arrives at the processing establishment without food chain information, is it notified to the approved technologist immediately?	
3.	Is the raw milk processed without permission of the approved technologist?	
Section-V: SPECIFIC REQUIREMENTS		
A	Raw Milk Criteria & Handling	
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	Milk Products Processing	
1	Requirements for Establishments	
(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?	
(iv)	Does the storage period at 4 °C before processing exceed 48 hours?	
2.	Analytical Specifications	
(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 & milk product for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020, in continuation to the conditional approval granted earlier. However, Non – EU approved units if applies for approval to EU, conditional approval is

Or

The processing establishment may be granted full approval to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020, 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 verification of the rectifications either by on-site verification or based on documentary evidence, by IDP-Convener/ IDP.

Or

The processing establishment may not be approved to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. 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 & Qualification			
Designation			
Organization			
Place:			
Date			

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

ASSESSMENT REPORT

**FOR INFRASTRUCTURE, EQUIPMENT FACILITIES IMPLEMENTATION OF GMP,
GHP, GVP AND HACCP BASED FOOD SAFETY MANAGEMENT SYSTEM,**

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 and implementation of GMP, GHP, GVP, HACCP based food safety management system at the establishment for processing, handling and storage of milk & milk products			
Date(s) of assessment				
Opening Meeting Location and date				
Closing Meeting Location and date				
Name & qualification 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)

Section-I: Infrastructure and equipments		
A	General	
1	Name of the Chief Executive (MD/Mg. Partner/Proprietor) (Give	
2	Contact Numbers and E-mail, if any)	
3	Is the processing plant owned or leased by the applicant	Owned/leased
4	If leased, name of the plant owner, plant name and address.	
5	Month and Year of Construction and Commercial Production	
6	Approval requested for export to (Countries)	All countries including European Union /Countries other than EU.
7	Scope of approval. Name(s) of the product(s).	
8	Additional activities, if any, in the same premise and other than the products mentioned above.	
9	Annual production during the previous year (a) Milk Products (Within the scope of approval) (b) Others (specify)	
B	Requirement for Premises & Equipment	
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?	
C	General requirements for premises and infrastructure	
1	Premise	
(a)	Whether it has defined cartilage 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	Layout, design, construction, location and size of food premises:	

3	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?	
4	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	
5	Does it permit good food hygiene practices, including protection against contamination and, in particular, pest control	
6	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.	
7	Is it kept clean and maintained in good repair and condition?	
8	Lavatories	
(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?	
9	Washing facilities:	
(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?	
10	Ventilation:	
(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?	

(d)	Do the sanitary conveniences have adequate natural or mechanical ventilation?	
(e)	Do the premises have adequate natural and/or artificial lighting?	
11	Drainage facilities	
(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?	
12	Change room facilities	
(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 Gumboots	
(v)	Headgear and wherever necessary gloves/ mouth cover	
(vi)	Is there suitable in-house arrangement to launder the working clothes of the workers	
(f)	Is there storage for cleaning agents and disinfectants in areas where food is not handled?	
D	Specific requirements in rooms where foodstuffs are prepared, treated or processed	
1	Design and layout to permit good food hygiene practices, including protection against contamination between and during operations	
(a)	Floor	

(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)	Walls	
(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?	
(iii)	Ceiling: 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?	
(c)	Windows and other openings	
(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?	
(iv)	Are the doors easy to clean and, where necessary, to disinfect and have smooth and non-absorbent surfaces or appropriate to prevent contamination?	
(f)	Surfaces (including surfaces of equipment)	
(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?	
(d)	Cleaning facilities	
(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? 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?	
(iii)	Are the cleaning agents and disinfectants are stored separately under lock and key?	
(E)	Transport facilities	
1	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.
2	Does the establishment hire outside vehicles?	
3	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?	
4	Are the receptacles in vehicles and/or containers used for transporting anything other than food where it may result in contamination?	
5	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?	
(F)	Equipment requirements	
1	Are all the articles, fittings and equipment with which food comes into contact	
2	Effectively cleaned and, where necessary, disinfected at a frequency sufficient to avoid any risk of contamination?	
3	Constructed, of such materials and kept in such good order, repair and condition as to minimize any risk of contamination?	
4	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?	
5	Installed in such a manner that does allow adequate cleaning of the equipment and the surrounding area?	

6	Is equipment, where necessary, fitted with an appropriate control device such as time, temperature, pressure, flow rate, etc?	
7	Are the process control equipment and devices calibrated at regular intervals?	
8	Are the chemical additives, where have to be used to prevent corrosion of equipment and containers, used in accordance with good practice?	
(G)	Special storage facility	
1	Are there any chill room / chill storage for storage of food products? Specify numbers and storage temperatures.	
2	Are there storage facilities for in-process liquid milk/milk products? Specify type of storage facility and temperature of storage	
3	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.	
4	Is there facility for pasteurization of liquid milk/milk product? Specify number of pasteurizer and their capacities.	
5	Whether the unit have spray-drying facility? If yes, give details like type and capacity.	
6	Whether there is packing room for every milk product separate from processing activities and storage?	
7	Is there adequate integrated storage facility for dried/frozen finished milk products? Specify type of storage, purpose, number of storages and capacity of storage.	
(H)	Food waste	
1	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?	
2	Are the non-edible by-products and other refuse deposited in closable containers or any other appropriate foot operable container to prevent contamination?	
3	Are the containers made of an appropriate construction, kept in sound condition, easy to clean and, where necessary, to disinfect?	
4	Is there adequate provision made for the storage and disposal of food waste, non-edible by-products and other refuse?	
5	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?	
6	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?	

(I)	Water supply	
1	Is there documented water management system? Are the outlets identified and serially numbered in the plumbing layout diagram?	
2	Is the water tested as per 98/83/EC or IS:4251 for potability, as applicable?	
3	Is there adequate supply of potable water, which is used	
	whenever necessary to ensure that foodstuffs are not contaminated (clean water may also be used for external washing)? What is the method of treatment?	
4	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?	
5	Is the non-potable water connects with, or allows reflux into, potable water systems?	
6	Is the recycled water used, if any, in processing or as an ingredient presents a risk of contamination?	
7	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?	
8	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?	
9	Is there appropriate measure to prevent contamination through back suction?	
10	Is water storage tank easily cleanable and protected from outside contamination? State frequency of cleaning water tanks.	
(J)	Pest control	
1	Are adequate documented procedures in place to control pests?	
2	Whether bait map showing serially numbered bait stations provided?	
3	Are adequate procedures in place to prevent domestic animals from having access to places where food is prepared, handled or stored?	
(K)	Maintenance	
1	Is there appropriate maintenance schedule for maintaining infrastructure and equipment facilities and records thereof?	
2	Whether all equipment 105asteur and marked?	
3	Are the food handlers supervised and instructed and/or trained in food hygiene matters commensurate with their work activity?	

4	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?	
5	Are the persons those responsible for compliance with the requirements of national law trained?	
6	Is there in-house testing facility for analysis of raw materials, in-process samples, finished products, hygiene and sanitation control samples, etc.?	
(L)	Testing facility	
1	Is establishment has sufficient infrastructure facility for testing of milk product?	
2	Is establishment has sufficient equipment facility for testing of milk products?	
3	Is establishment standardized laboratory methods for testing of milk products?	
4	Is establishment has sufficient trained staff for testing of milk products?	
Section-II: Implementation of GMP, GHP, GVP, HACCP based food safety system		
A	Information about personnel	
1	Number of veterinarian/ technologists and available in the establishment	
2	Are appropriate qualified and experience personnel responsible for developing, implementing and maintaining HACCP-based procedures.	
3	Are appropriate qualified and experience veterinarian(s)/ technologist(s) supervising the processing and other related operations	
4	Are appropriate qualified and experience personnel, conducting microbiological and chemical analysis.	
5	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.	
6	Number of male workers in the processing establishment in each shift.	
7	Number of female workers in the processing establishment in each shift.	
8	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?	
9	Number of male workers in the processing establishment in each shift.	

10	Number of female workers in the processing establishment in each shift.	
B	Hygiene Provisions and record keeping in Raw Milk Production and handling	
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	Whether the establishment has identified milk production holdings?	
3	Are milk production holdings owned or contracted by the establishment?	
4	Whether the details of all milk production holdings supplying raw milk provided?	
5	Specify name and other details of the milk production holding visited by the IDP.	
6	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?	
7	Are infected milch animals or suspected of being infected, (brucellosis, tuberculosis) isolated to avoid other animal's milk?	
8	Are animals undergoing medical treatment and likely to transfer residues to the milk identified & not used for human consumption?	
9	Is there any infrastructure for educating farmers for clean milk production?	
10	Are there any incentive given to the farmers for clean milk production?	
C	Hygiene During milking, collection and transport	
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 zoonosis 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?	
9	Is the waste and hazardous material handled and stored properly to prevent contamination?	
10	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	
11	Are the samples (feed, water, milk, etc.) drawn for relevant analyses that have importance to human health and records maintained?	
12	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?	
13	Is there correct use of feed additives and veterinary medicinal products?	
14	Is there appropriate remedial action when informed of problems identified during official controls?	
15	Are there records relating to measures put in place to control hazards in an appropriate manner?	
16	Are there records of nature and origin of feed fed to the milch animals?	
17	Are there records of veterinary medicinal products or other treatments administered to the milch animals, dates of administration and withdrawal periods?	
18	Are there records of the occurrence of diseases that may affect the safety of milk products?	
19	Are there records of other relevant reports on checks carried out on raw milk?	
20	Is milk from animals showing clinical signs of udder disease used for human consumption?	
D	Personnel Hygiene	
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?	
3	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?	
4	Is detail medical examination record of employees available and certified fit to work in food industries?	
5	Does the establishment have provision to check the workers for illness or symptoms?	
E	Other Food Ingredients/additives/preservatives	
1	Are there controls on procurement of other Food Ingredients, additives, preservatives, etc.?	
2	Is list of the additives/ preservatives furnished?	
3	Whether the additives/preservatives are of food grade quality, acceptable to importing country?	
F	Provisions applicable to foodstuffs	
1	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?	
2	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?	
3	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?	
G	Storage conditions	
1	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?	
2	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?	
3	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?	
4	Are hazardous and/or inedible substances adequately pasteurized and stored in separate and secure containers?	
H	Wrapping and packaging of foodstuffs	
1	Is the material used for wrapping and packaging a source of contamination?	
2	Are the wrappings and packing materials stored in such a manner that they are exposed to a risk of contamination?	
3	Are wrapping and packaging operations carried out so as to avoid contamination of the products? (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.)	
4	Is the wrapping and packaging material re-used for foodstuffs easy to clean and, where necessary, to disinfect?	
I	Heat treatment	
1	Is the heat treatment process used to process raw milk adequate to show a negative reaction to the phosphatase test?	
2	Are temperature raise every particle of the product treated to a given temperature for a given period of time?	
3	Are product prevented from becoming contaminate during the process?	
4	Does the process employed achieve the desired objectives?	
5	Are the main relevant parameters (particularly temperature, pressure, sealing and microbiology), checked regularly including by the use of automatic devices?	
6	Does the process used conform to an internationally recognized standard (for example, pasteurization, heat treatment, UHT etc.)?	
J	Application of the Identification Mark	
1	Is the Identification mark and details of the approved establishment applied before the product leaves the establishment?	
2	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?	
3	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?	
K	Form of the Identification Mark	
1	Are marks legible and indelible and the characters easily decipherable? Is It clearly displayed for the competent authorities?	
2	Does the mark indicate the name of the country in which the establishment is located?	
L	Method of Marking	
1	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?	
2	Is the mark an irremovable tag of resistant material?	
M	HACCP-based Procedures (Hazard analysis and critical control points)	
1	Are the HACCP principles in place, implemented and maintained?	
2	The HACCP principles	
3	Are the hazards, if any, need to be prevented, eliminated or reduced to acceptable levels identified appropriately?	
4	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?	
5	Are the critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards established appropriately?	
6	Are the monitoring procedures at critical control points established and implemented effectively?	
7	Are the corrective actions when monitoring indicates that a critical control point is not under control established?	
8	Are the procedures, which need to be carried out regularly, to verify that the measures outlined in (a) to I above are working effectively, established?	

9	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?	
10	Are the procedure reviewed when any modification is made in the product, process, or any step to make the necessary changes to it?	
11	Is the evidence of compliance with HACCP principles furnished to the competent authority?	
12	Are the documents up-to-date at all times?	
13	Are the documents and records retained for an appropriate period?	
14	Traceability of raw milk procurement: Do the procedures guarantee that each supply of raw milk accepted into premises:	
15	Is properly identified?	
16	Is accompanied by the relevant information from the holding of provenance controlled / supervised by the processing establishment?	
17	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?	
(a)	Is clean?	
(b)	Is fit for consumption, as far as the food business operator can judge?	
(c)	is in a satisfactory state?	
18	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?	
N	Food Chain Information	
1	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;	
2	The status of the holding of provenance or the regional animal health status?	
3	The health status of raw milk supplied to the establishment?	
4	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?	

5	The occurrence of diseases that may affect the safety of milk products?	
6	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?	
7	Relevant reports about previous ante –and post-mortem inspections of milch animals from the same holding of provenance including, in particular, reports from the official veterinarian?	
8	Production data, when this might indicate the presence of disease?	
9	the name and address of the veterinarian attending the holding of provenance?	
10	If any lot of raw milk arrives at the processing establishment without food chain information, is it notified to the approved technologist immediately?	
11	Is the raw milk processed without permission of the approved technologist?	
0	Raw Milk Criteria & Handling	
1	Is 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?	
2	Is the raw milk stored and transported at a temperature, preferably constant, which is best suited to assure optimal conservation of their hygiene properties?	
3	Does the raw milk meet the criteria for SPC & Somatic Cell Count as laid down in the Executive instructions?	
4	Is raw milk cooled to 6 °C or below and kept at that temperature until processed?	
P	Requirements for Establishments	
1	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?	
2	Does a batch that has been insufficiently processed undergo processing again immediately in the same establishment, rendering the reprocessing fit for human consumption?	
3	Where a batch is found unfit for human consumption, is it destroyed to ensure that it is not used for human consumption?	
4	Does the storage period at 4 °C before processing exceed	

	48 hours?	
Q	Laboratory testing	
	Are the establishment standardized testing methods for microbial as well as chemical examination?	
	Are the establishment has written sampling methods for various sampling and sampling plan?	
	Are establishment testing sample as per frequency described in HACCP/SOP?	
	Are the establishment maintaining record of testing properly?	

Section-VI: Any other relevant information:

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

The processing establishment may be granted approval to process milk & milk product for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020,

Or

The processing establishment may be granted approval to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020, subject to rectification of the deficiencies given in the enclosed observation sheet within a maximum period of one/two/three month from the date of this assessment and subsequent verification of the rectifications either by on-site verification or based on documentary evidence, by IDP-Convener/ IDP.

Or

The processing establishment may not be approved to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. The deficiencies observed are given in the enclosed observations sheet. The establishment may apply a fresh after rectification of the

Section VIII: Suggestions for improvement, if any:

Signature			
Name & Qualification			

Designation			
Organization			
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 & Qualification			
Designation			
Organisation			
Place			
Date			

Fully agree with the observations/recommendations

Signature (representative of the unit)

Name
Designation Date
Seal of the firm

Annexure V

(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 & milk products for export to EU/Non-EU. Ref:
Your application dated ____.

Name and Location of the Establishment	Date of IDP Visit

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 & Milk Products (QC, I & M) Rules, 2020 for processing of milk/manufacturing of milk products for export to all countries including European Union/Non-EU countries:

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 & 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,

Agency In-Charge

Encl: Annexure

Copy to:

- (1) The Officer In-charge
EIA-_____, Sub Office: _____
- (2) The Director (I&Q/C), EIC, New Delhi –110 023

Annexure VI(Letter of Conditional approval to process milk & 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 & Milk Products Processing establishment under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020.**

Ref: Your application No. ____ dated

Please refer to your application cited above for approval of your establishment, for processing and packing of milk & milk products for export as required under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020

In exercise of the powers conferred by Rule 4(2)(c) of the said Rules, the Panel of Experts visited your establishment on ____ to assess the suitability of the infrastructure and equipment facilities for processing of Milk & 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(2)(c) of the Export of Milk & Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020 to process milk & 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 & milk products meant for export in your approved establishment. However, the export of milk & 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 has production of milk & 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 & 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 & 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 & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. It shall issue “Certificate for Export” for every consignment of milk & milk products meant for export to 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 & 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.500/- 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 payment of requisite monitoring fee and other applicable fee/charges through online link available on website www.eicindia.gov.in. You should submit the two copies of the “Certificate for Export” to Export Inspection Agency- along with monthly statement on the consignments exported and certificates issued, on a regular basis along with requisite online fee receipt. The statement should reach EIA office on or before 5th 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 – 110 023.
2. The Commissioner of Customs
3. The Officer In-charge, (Sub office concerned)
4. Computer cell, EIC, New Delhi with a request for updating website
5. Establishment File ()

Annexure VII(Letter of Full approval to process milk & 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 & Milk Products Processing establishment under the Export of Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020

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 & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020.

In exercise of the powers conferred by Rule 4(2)(c) 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 of milk & 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(2)(c) of the Export of Milk & Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020 to process milk & milk products for export. The full approval granted to your establishment is valid for a period of three 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 & milk products to countries other than EU. However, the export of milk & 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 & 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 / labeled on all export packages (master cartons) of milk & milk products as required by the Executive Instructions.

Your establishment continues to be under the purview of monitoring by Export Inspection Agency- , as under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. It shall issue “Certificate for Export” for every consignment of milk & 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.500/-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 payment of requisite monitoring fee and other applicable fee/charges through online link available on website www.eicindia.gov.in. You should submit the two copies of the “Certificate for Export” to Export Inspection Agency- along with monthly statement on the consignments exported and certificates issued, on a regular basis along with requisite online fee receipt. The statement should reach EIA office on or before 5th 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.

Yours faithfully,

Agency Charge

Copy to:

1. The Director (I & Q/C) EIC, New Delhi – 110 023.
2. The Commissioner of Customs
3. The Officer In-charge, (Sub office concerned)
4. Computer Cell, EIC, New Delhi with a request for updating website
5. Establishment File ()

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

EXPORT INSPECTION AGENCY - ____

**(MINISTRY OF COMMERCE AND INDUSTRY)
GOVERNMENT OF INDIA**

Date:

To

M/S.
.....
Dear Sirs,

Sub: Approval of Milk & Milk Products Processing establishment under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020

Please refer to your application for approval of your establishment dated, for processing and packing of milk & milk products for export as required under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020.

In exercise of the powers conferred by Rule 4(2)(c) of the said Rules, the Panel of Experts visited your establishment on _____ to assess the adequacy of infrastructure & equipment facilities and implementation of GMP, GHP, GVP and HACCP based food safety management system for processing milk & milk products for export.

After due consideration of the report of the Panel of Experts, your processing establishment has been granted approval under Rule 4(2)(c) of the Export of Milk & Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020 to process milk & milk products for export. The approval granted to your establishment is valid for a period of three 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 & 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 & 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 & milk products as required by the Executive Instructions.

Your establishment continues to be under the purview of monitoring by Export Inspection Agency- , as under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. 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.500/-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 payment of requisite monitoring fee and other applicable fee/charges through online link available on website www.eicindia.gov.in. You should submit the two copies of the “Certificate for Export” to Export Inspection Agency- along with monthly statement on the consignments exported and certificates issued, on a regular basis along with requisite online fee receipt. The statement should reach EIA office on or before 5th 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.

Yours faithfully,

Agency Charge

Copy to:

1. The Director (I & Q/C) EIC, New Delhi – 110 023.
2. The Commissioner of Customs
3. The Officer In-charge, (Sub office concerned)
4. Computer Cell, EIC, New Delhi with a request for updating website
5. Establishment File ()

Annexure IX

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 & 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	
(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 & milk products, meant for export.

I am enclosing a online fee receipt towards assessment fee for approval of the veterinarian/ technologist.

Signature
Name
Designation
Place
Date

Annexure IXA

EXPORT INSPECTION AGENCY-

REPORT OF ASSESMENT 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		M r. / M s.
4.	Educational/professional qualifications		
5.	Experience in milk processing / QC		
6.	Date of Assessment		
7.	Whether the qualifications and experience are verified		Ye s / No.
	Is this the first approval of veterinarian/ technologist or renewal of the approval?		
	Factors of assessment		Panel observations
8.	Ability to supervise milk processing operations		
9.	Knowledge of sampling techniques		
10.	Knowledge of organoleptic inspection of milk & milk products		
11.	Knowledge of microbiological testing of milk & milk products		
12.	Knowledge of chemical testing of milk & 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 & 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 & Qualification			
Institution			
Date			

EXPORT INSPECTION AGENCY- _____

(MINISTRY OF COMMERCE AND INDUSTRY)
GOVERNMENT OF INDIA

Certificate of Approval of Veterinarian/Technologist

Sh./Smt.(Name of the veterinarian / technologist)
Holding (Qualification) and residing at..... (Residential address) is hereby
approved as a veterinarian/ technologist to handle Milk & Milk Products meant for export for a
period of three 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:

Name:

Designation:
(Seal)

Annexure X(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 & Milk Products (Quality Control, Inspection and Monitoring) Rules 2020 and also the requirements communicated by EIC from time to time for processing milk & 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 & Milk products (quality Control Inspection and Monitoring) Rules 2020 and also the other requirements specified by the importing countries.

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 /pasteurization 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 is required for processing new product, whether the same are tested as per 98/83/EC/IS: 4251?	

8 Any other information.

Yours faithfully,

Signature :

Name :

Designation :

Company seal:

Place:
Dates

Check List of enclosures

1. Online fee receipt
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
7. List of additional equipment/machinery,where applicable

Annexure XA

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: Email:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: Email:			
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 & milk products pertaining to additional facilities/ activities.			
Date(s) of assessment				
Opening Meeting Location and date				
Closing Meeting Location and date				
Name & Qualification 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	Whether the installation of the new facility increases the production capacity of the unit	
4.8	If so what is the expected new production capacity?	

4.9	Calibrated temperature recording devices installed where applicable?	
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 /pasteurization 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?	

9 **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 & 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 be approved under the Export of Milk & Milk Products (Quality control, Inspection and Monitoring) rules 2020.

Or

The above additional facilities/processing activities of the establishment may be approved under the Export of Milk & Milk Products (Quality control, Inspection and Monitoring) rules 2020., subject to rectification of the deficiencies given in the enclosed observation sheet within a maximum period of one/two/three month from the date of this assessment and subsequent verification of the rectifications either by on-site verification or based on documentary evidence, by IDP-Convener/ IDP.

Or

The above additional facilities/processing activities of the establishment may not be approved under the Export of Milk & Milk products (Quality Control, Inspection and Monitoring) rules 2020. The deficiencies observed are given in the attached sheet.

Reasons:

Suggestions for improvement, if any:

Signature			
Name & Qualification			
Designation			
Organisation			
Place			
Date			

**(Letter of Approval of Additional Facilities / Activities)
EXPORT INSPECTION AGENCY.....
(MINISTRY OF COMMERCE AND INDUSTRY)
GOVERNMENT OF INDIA**

To,

M/s.

Sub: Approval of Additional facilities/activities of Milk & Milk Products processing establishment under the export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020

Ref:

Sir,

Please be informed that the following Additional facilities/Processing activities have been approved in your establishment (Name of establishment.....EIC Approval no.:.....) for export to all countries including EU/ countries other than EU.

Additional Processing Facilities/Activities:

1. ...
2. ...
3. ...

Revised Scope of approval is:

1. ...
2. ...

Please acknowledge the receipt of this letter.

Yours faithfully,

Joint Director

Copy to: -

1. The Director (I & QC), EIC, New Delhi-110023
2. The Computer Centre, EIC, New Delhi: - for website updating
3. Establishment File

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 & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020 may kindly be renewed from the date of expiry of the earlier approval.

Requisite online fee receipt is enclosed

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 not approved)	
17.	Layout changes, if any, during the last two years	
18.	Additional facilities/equipment provided, if any, during the last two	
19.	Source of raw material used.(Attach the list of identified farms)	
20.	Name and Address of the merchant exporter(s) presently catering to	
21.	Name and Address of merchant exporter(s) catered for last two years	
22.	Any other relevant information	

It is hereby testified that the above information is true to the best of my knowledge.

Place:

Date:

Signature

Name:

Designation:

Company Seal:

Annexure XII

(Reminder letter to units for renewal of approval)

EXPORT INSPECTION AGENCY –

No. EIA/

Date:

To

(Name and Address of establishment)

Dear Sir,

Sub: Renewal of Approval of establishment to process milk & 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 & 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 & 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 online fee receipt 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

Annexure XIII

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	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.ma:			
Address of the Regd. Office	Address: District: State: Country: India. Ph. Fax: E.ma:			
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 & milk products for renewal of approval of the establishment.			
Date(s) of assessment				
Opening Meeting Location and date				
Closing Meeting Location and date				
Name & Qualification 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 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 & 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	
2.0	Information on Structure of the Establishment	
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	<u>Registration. No.</u> <u>Capacity</u>

	Water tanker	
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:	
3.0	Information about personnel	
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.	Qualification
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	
4.0	Raw Material	
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?	
5.0	Surroundings	
5.1	Whether the conditions of approval are still maintained satisfactorily?	Yes / No
5.2	If not, what are the deficiencies?	
6.0	Construction and Layout	
6.1	Whether the conditions of approval are still maintained satisfactorily?	
6.2	If not, what are the deficiencies?	
7.0	Plant facilities: Are there adequate facilities for the following?	
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	
8.0	Raw material receiving section	
8.1	Whether the conditions of approval are still maintained satisfactorily?	
8.2	If not, what are the deficiencies?	
9.0	Chill Room/ Storage tanks	
9.1	Is chill room/ Storage tanks provided for storing Liquid milks?	

9.2	Is it maintained as required?	
10	Milk Reception and inspection section	
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?	
11.0	Processing Section	
11.1	Whether the conditions of approval are still maintained satisfactorily?	
11.2	If not, what are the deficiencies?	
12.0	Water	
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?	
13.0	Chemicals/Additives	
13.1	Whether chemicals and additives, if used, tested/approved and records maintained as required?	
13.2	If not, what are the deficiencies?	
14.0	Freezing	
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	Pasteurisers, Spry driers, hot chambers, UHT Steriliser	
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	
16.0	Packaging and Frozen Storage	
16.1	Whether the conditions of approval are still maintained satisfactorily?	Yes / No
16.2	If not, what are the deficiencies?	
17.0	Toilet Facilities	
17.1	Whether the conditions of approval are still maintained satisfactorily?	Yes / No
17.2	If not, what are the deficiencies?	
18.0	Personnel Hygiene	
18.1	Whether the conditions of approval are still maintained satisfactorily?	Yes / No
18.2	If not, what are the deficiencies?	
19.0	Cleaning and Disinfection of Plant, Equipment and Utensils	
19.1	Whether the conditions of approval are still maintained satisfactorily?	Yes/No
19.2	If not, what are the deficiencies?	
20.0	Changing Room	
20.1	Whether the conditions of approval are still maintained	Yes/No

	satisfactorily?	
20.2	If not, what are the deficiencies?	
21.0	Effluent Treatment	
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	
22.0	Maintenance Schedule	
22.1	Whether the documented maintenance procedure is adequate and records of maintenance kept?	
22.2	If not, what are the deficiencies?	
23.0	HACCP-based Procedures (Hazard analysis and critical control points)	
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 I 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	
24.0	Rodent / Vermin Control	
24.1	Whether the documented rodent/vermin control system is adequate and records maintained?	
24.2	If not, what are the deficiencies?	
25.0	Transportation	

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?	
26.0	Inspection and Testing	
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?	
27.0	Training	
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 & milk product for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020, for further period of three years from the date of expiry of earlier approval:

- 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

Or

The processing establishment may not be granted renewal of approval to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020 subject to rectification of the minor deficiencies given in the enclosed observation sheet.

Or

The processing establishment may not be granted renewal of approval to process milk & milk products for export under the Export of Milk & Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020. 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 & Qualification			
Organization			
Place:			
Date			

EXPORT INSPECTION AGENCY - _____

Statement of Performance of Unit

(for the past three 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			
	If performance is unsatisfactory main reasons for it			

Details of complaints from importing country or importer

Number & Nature of complaints received	Countries from where complaints

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 & 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 & 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 & 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 & 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:

Encl:

- 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.

Annexure – XVA

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

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

No. EIA/

Date:

--

Dear Sir,

Sub:Permission to process and pack Milk & 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 & 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 approval number shall be responsible for the quality and safety of the milk & milk products processed by it for export by the merchant exporter;
3. The approved processor shall ensure that the consignments of milk & 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 & 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 Director, EIC, New Delhi-110023.
- (2) The Officer In-charge, EIA-____, SO: _____.

Annexure – XVB

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

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

No. EIA/

Date:

To,

Dear Sir,

Sub: Withdrawal of permission to process and pack Milk & 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 & 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 Director, EIC, New Delhi-110023.
(4) The Officer In-charge, EIA-...., SO:.....

Annexure – XVI**MONITORING PARAMETERS FOR WATER (98/83/EC)**

<u>S.No.</u>	<u>Parameters</u>
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 originates from or is influenced by surface

Note No.3 Water Necessary only when chlorination 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 processing establishment:

Approval Number:

Products processed at the time of Visit:

Sl. No.		Observations/suggestions
(1)	(2)	(3)
General		
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	
<i>Facility Checks (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	
HACCP Implementation of the Unit		
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	

4	Whether the monitoring and corrective actions, if any, recorded and verified at laid down frequency by the responsible	
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	
12.	Separation of EU & Non EU food commodities	
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	Temperature of the Products	Product Temp

a.	Product temperature at different processing stages like pasteurization, chilling, freezing, heat treatment	
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	
Fraud control (Specify if violations are noticed in the following area)		
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	
Details of samples drawn during monitoring		
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	
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 – _____

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.

Annexure XVIIB

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.

Action agreed by the processor:

Signature:
Name:
Designation
(EIC/EIA Officer)

Signature:
Name:
Designation
(Representative of the establishment)

Annexure –XVIIC

**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/ suggestion
(1)	(2)	(3)
General		
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	
Hygiene Provisions and record keeping in Raw Milk Production and handling		
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 shell 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 shell milks production and associated operations?	
8	Is there cleaning and where necessary, disinfecting of facilities used in connection with shell 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	
15	Are the samples (feed, water, raw milk, etc.) drawn for relevant analyses that have importance to human health and records	
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

Annexure –XVIID**EXPORT INSPECTION AGENCY –.....****SUB OFFICE:****FREQUENCY OF MONITORING OF MILK & MILK PRODUCTS PROCESSING ESTABLISHMENTS****REVIEW 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	For use of Head Office 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

Annexure - XVIII

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 ⇒ N

Remarks of the Agency In-charge Signature :

Name :

Designation :

Date : Place:

Signature :

Name :

Designation :

Date :

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

Annexure XIX

**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.	

Team Leader

Auditor

Proposed Corrective actions Probable
Date of Completion

Auditee

Auditor
Team LeaderNC cleared/downgraded/statuesque
Date

Annexure XXA

CHAPTER 36

**MODEL ANIMAL HEALTH/OFFICIAL CERTIFICATE FOR THE ENTRY INTO THE UNION
OF DAIRY PRODUCTS INTENDED FOR HUMAN CONSUMPTION THAT ARE REQUIRED
TO UNDERGO A SPECIFIC RISK-MITIGATING TREATMENT OTHER THAN
PASTEURIZATION (MODEL DAIRY-PRODUCTS-ST)**

COUNTRY		Animal health/Official certificate to the EU	
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference
		I.3 Central Competent Authority	QR CODE
		I.4 Local Competent Authority	
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code	
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code	
	I.8 Region of origin Code	I.10 Region of destination Code	
	I.11 Place of dispatch Name Registration/ Approval No Address Country ISO country code	I.12 Place of destination Name Registration/ Approval No Address Country ISO country code	
	I.13 Place of loading	I.14 Date and time of departure	
	I.15 Means of transport <input type="checkbox"/> Aircraft <input type="checkbox"/> Vessel <input type="checkbox"/> Railway <input type="checkbox"/> Road vehicle Identification	I.16 Entry Border Control Post	
		I.17 Accompanying documents Type Code Country ISO country code Commercial document reference	

I.18	Transport conditions	<input type="checkbox"/> Ambient	<input type="checkbox"/> Chilled	<input type="checkbox"/> Frozen
I.19	Container number/Seal number	Container No		
		Seal No		
I.20	Certified as or for	<input type="checkbox"/> Products for human consumption		
I.21	<input type="checkbox"/> For transit	Third country	ISO country code	I.22 <input type="checkbox"/> For internal market
				I.23 <input type="checkbox"/> For re-entry
I.24	Total number of packages	I.25	Total quantity	I.26 Total net weight/gross weight (kg)
I.27	Description of consignment			
	CN code	Species		
		Cold store	Identification mark	Type of packaging
		Treatment type	Nature of commodity	Number of packages
				Net weight
				Batch No
<input type="checkbox"/> Final consumer	Date of collection/production	Manufacturing plant	Approval or registration number of plant/establishment/centre	

COUNTRY

Certificate model DAIRY-PRODUCTS-ST

Part II: Certification	II. Health information	
	II.a Certificate reference	II.b IMSOC reference
	<p>II.1. Public health attestation [to delete when the Union is not the final destination of the dairy products]</p> <p>I, the undersigned, declare that I am aware of the relevant requirements of Regulation (EC) No 178/2002 of the European Parliament and of the Council^A, Regulation (EC) No 852/2004 of the European Parliament and of the Council^B, Regulation (EC) No 853/2004 of the European Parliament and of the Council and Regulation (EU) 2017/625 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/627^C and hereby certify that the dairy product described in Part I was produced in accordance with these requirements, in particular that:</p> <p>(a) it was produced from raw milk:</p> <p>(i) which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Articles 49 and 50 of Implementing Regulation (EU) 2019/627;</p> <p>(ii) which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;</p> <p>(iii) which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004;</p> <p>(iv) which has not been obtained from animals showing a positive reaction to the test for tuberculosis or brucellosis;</p> <p>(v) which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection of residues or substances submitted in accordance with Article 29 of Council Directive 96/23/EC^D, and milk is listed in Commission Decision 2011/163/EU^E for the concerned country of origin;</p> <p>(vi) which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of Regulation (EC) No 853/2004, complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Commission Regulation (EU) No 37/2010^F;</p>	

^A Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

^B Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

^C Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

^D Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

^E Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

^F Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

COUNTRY

Certificate model DAIRY-PRODUCTS-ST

	<p>(vii) which has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council^c, and the maximum levels for contaminants laid down in Commission Regulation (EC) No 1881/2006^h.</p> <p>(b) it comes from (an) establishment(s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 of Regulation (EC) No 852/2004, regularly audited by the competent authorities, and being listed as an EU approved establishment;</p> <p>(c) it has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004;</p> <p>(d) it meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria laid down in Commission Regulation (EC) No 2073/2005ⁱ;</p> <p>(e) it has undergone or been produced from raw milk which has been submitted to a heat treatment referred to in II.2.2, and sufficient to ensure, where applicable, a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment;</p> <p>(f) the dairy product described in Part I has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and the maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.</p> <p>II.2. Animal health attestation [to delete when the dairy products are derived from solipeds, leporidae or other wild land mammals others than ungulates]</p> <p>The dairy products described in Part I:</p> <p>II.2.1. originate from the zone/s with code/s:⁽²⁾ which, at the date of issue of this certificate is/are authorised for entry into the Union of dairy products that are required to undergo a specific risk-mitigating treatment and listed in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429; and</p> <p>either II.2.2. have been processed from raw milk obtained from only one species of animals, in particular from the species [<i>Bos Taurus</i>]⁽¹⁾ [<i>Ovis aries</i>]⁽¹⁾ [<i>Capra hircus</i>]⁽¹⁾ [<i>Bubalus bubalis</i>]⁽¹⁾ [<i>Camelus dromedarius</i>]⁽¹⁾ and the raw milk used for the processing of the dairy product has undergone:</p> <p style="padding-left: 40px;">(1) either [a sterilisation process, to achieve an Fo value equal to or greater than 3.]⁽¹⁾</p> <p style="padding-left: 40px;">(1) or [a ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.]⁽¹⁾</p>
--	--

^c Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

^h Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

ⁱ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

COUNTRY	Certificate model DAIRY-PRODUCTS-ST
	<p>(1) or [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment.](1)</p> <p>(1) or [a HTST treatment of milk with a pH below 7,0.](1)</p> <p>(1) or [a HTST treatment combined with another physical treatment by:</p> <p style="padding-left: 40px;">either [(i) lowering the pH below 6 for one hour.](1)</p> <p style="padding-left: 40px;">or [(ii)additional heating equal to or greater than 72 °C, combined with desiccation.](1)</p> <p>or II.2.2. have been processed mixing raw milk obtained from animals of the following species: [<i>Bos Taurus.</i>](1) [<i>Ovis aries.</i>](1) [<i>Capra hircus.</i>](1) [<i>Bubalus bubalis</i>](1) and [before](1) [after](1) mixing all the raw milk used for the processing of the dairy product has undergone:</p> <p style="padding-left: 40px;">(1) either [a sterilisation process, to achieve an Fo value equal to or greater than 3.](1)</p> <p style="padding-left: 40px;">(1) or [an ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.](1)</p> <p style="padding-left: 40px;">(1) or [a high temperature short time pasteurisation treatment (HTST) at 72 °C for 15 seconds applied twice to milk with a pH equal to or greater than 7,0 achieving, where applicable, a negative reaction to an alkaline phosphatase test, applied immediately after the heat treatment.](1)</p> <p style="padding-left: 40px;">(1) or [a HTST treatment of milk with a pH below 7,0.](1)</p> <p style="padding-left: 40px;">(1) or [a HTST treatment combined with another physical treatment by:</p> <p style="padding-left: 80px;">either [(i) lowering the pH below 6 for one hour.](1)</p> <p style="padding-left: 80px;">or [(ii) additional heating equal to or greater than 72 °C, combined with desiccation.](1)</p> <p>or II.2.2. have been processed from raw milk obtained from only one species of animals of species other than <i>Bos Taurus</i>, <i>Ovis aries</i>, <i>Capra hircus</i>, <i>Bubalus bubalis</i> or <i>Camelus dromedarius</i> and the raw milk used for the processing of the dairy product has undergone:</p> <p style="padding-left: 40px;">(1) either [a sterilisation process, to achieve an Fo value equal to or greater than 3.](1)</p> <p style="padding-left: 40px;">(1) or [an ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.](1)</p> <p>or II.2.2. have been processed mixing raw milk of different species, and at least one of the species of origin is other than <i>Bos Taurus</i>, <i>Ovis aries</i>, <i>Capra hircus</i>, <i>Bubalus bubalis</i> or <i>Camelus dromedarius</i> and all the raw milk used for the processing of the dairy product has undergone:</p> <p style="padding-left: 40px;">(1) either [a sterilisation process, to achieve an Fo value equal to or greater than 3.](1)</p>

COUNTRY

Certificate model DAIRY-PRODUCTS-ST

	<p>⁽¹⁾ or [an ultra-high temperature (UHT) treatment at not less than 135 °C in combination with a suitable holding time.]⁽¹⁾</p> <p>II.2.3. after the completion of the treatment referred to in point II.2.2, have been handled until packaged in a way to prevent any cross-contamination that could introduce an animal health risk.</p> <p>Notes</p> <p>In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this certificate include the United Kingdom in respect of Northern Ireland.</p> <p>This certificate is intended for entry into the Union of dairy products (as defined in Regulation (EC) No 853/2004) coming from zones listed in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429 and therefore authorized for entry into the Union of dairy products only if they have undergone a specific risk-mitigating treatment against foot and mouth disease, including when the Union is not the final destination of such dairy products.</p> <p>This animal health/official certificate shall be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.</p> <p>Part I:</p> <p>Box reference I.8: Provide the code of the zone as appearing in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429 .</p> <p>Box reference I.11: Name, address and approval number of the establishment of dispatch.</p> <p>Box reference I.15: Registration number (railway wagons or container and road vehicles), flight number (aircraft) or name (vessel) is to be provided. In the case of transport in containers their registration number and where there is a serial number of the seal it must be indicated in box I.19. In the case of unloading and reloading, the consignor must inform the border control post of entry into the Union.</p> <p>Box reference I.19: For containers or boxes, the container number and the seal number (if applicable) should be included.</p> <p>Box reference I.27: Use the appropriate Harmonised System (HS) code under the following headings: 04.01; 04.02; 04.03; 04.04; 04.05; 04.06; 15.17; 17.02; 19.01; 21.05; 21.06; 22.02; 28.35; 35.01; 35.02 or 35.04.</p> <p>Box reference I.27: Description of consignment:</p>
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COUNTRY

"*Manufacturing plant*": Introduce the approval number of the treatment and/or processing establishment(s) approved for export to the European Union.

Part II:

(1) Keep as appropriate.

(2) Code of the zone in accordance with a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429.

(3) to be signed by:

— an official veterinarian when part II.2 Animal health attestation is not deleted

— a certifying officer or an official veterinarian when part II.2 Animal health attestation is deleted

[Official veterinarian]⁽¹⁾⁽³⁾/[Certifying officer]⁽¹⁾⁽³⁾

Name (in capital letters)

Date

Qualification and title

Stamp

Signature

HEALTH CERTIFICATE(to Non-EU Countries)
For Milk products intended for export

No:

Country of despatch: INDIA

Competent Authority: Export Inspection Council (Ministry of Commerce & Industry, Govt. of India) 2nd Floor, B-Plate, Block-1 Commercial Complex, East Kidwai Nagar New Delhi-110023, INDIA; Phone : +91-11- 20815386/87/88, E-mail:eic@eicindia.gov.in, Website: www.eicindia.gov.in

Reference No.: Certificate for Inspection:

(Issued by Processing Plant/EIA)

1. Details identifying the products

Description:

Quantity: NET WT:

Gross WT:

Type of Packaging:

Invoice No.:

No. of packages:

Temperature required during storage and transport:

Manufacturing date:

Expiry Date:

2. Provenance of products

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

Approval No. of the plant(s)

3. Destination of the products

The products are to be dispatched

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 products described above have been handled, processed, stored and transported under hygienic conditions as laid down in the Export of Milk and Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020 and found confirming to laid down standards and fit for human consumption & the establishment where the products have been processed is approved and regularly monitored by Export Inspection Agency - (Competent Authority)

Validity of the Certificate:

Place of Issue: Export Inspection Agency -

Signature of authorized officer

Date of issue:

Name:

Seal

Designation:

Annexure XXC

(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 dairy products described above was produced in accordance with requirements, in particular that

- (a) it was manufactured from raw milk:
 - i. Which comes from holdings registered in accordance with Regulation (EC) No 852/2004 and checked in accordance with Articles 49 and 50 of implementing Regulation (EU) 2019/627;
 - ii. Which was produced, collected, cooled, stored and transported in accordance with the hygiene conditions laid down in Chapter I of Section IX of Annex III to regulation (EC) No 853/2004;
 - iii. Which meets the plate and somatic cell count criteria laid down in Chapter I of Section IX of Annex III to regulation (EC) No 853/2004;
 - iv. Which has not been obtained from animals showing a positive reaction to the test for tuberculosis or brucellosis;
 - v. Which complies with the guarantees on the residues status of raw milk provided by the monitoring plans for the detection residues or substances submitted in accordance with Article 29 of Council Directive 96/23/EC, and milk is listed in Commission Decision 2011/163/EU for the concerned country of origin;
 - vi. Which, pursuant to testing for residues of antibacterial drugs carried out by the food business operator in accordance with the requirements of Annex III, Section IX, Chapter I, Part III, point 4 of regulation (EC) No 853/2004, complies with the maximum residue limits for residues of antibacterial veterinary medicinal products laid down in the Annex to Commission Regulation (EU) No 37/2010;
 - vii. Which, has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005 of the European Parliament and of the Council, and the maximum levels for contaminants laid down in Commission Regulation (EC) No 181/2006?
- (b) It comes from (an) establishment (s) applying general hygiene requirements and implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Article 5 OF Regulation (EC) No 852/2004, regularly audited by the competent authorities, and being listed as an approved EU approved establishment;

- (c) It has been processed, stored, wrapped, packaged and transported in accordance with the relevant hygiene conditions laid down in Annex II to Regulation (EC) No 852/2004 and Chapter II of section IX of Annex III to Regulation (EC) No 853/2004;
- (d) It meets the relevant criteria laid down in Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 and the relevant microbiological criteria laid down in Commission Regulation (EC) No 2073/2005;
- (e) It has undergone or been produced from raw milk which has been submitted to a heat treatment referred to in II.2.2 and sufficient to ensure, where applicable, a negative reaction to an alkaline phosphatase test applied immediately after the heat treatment;
- (f) The dairy product described in part I has been produced under conditions guaranteeing compliance with the maximum residue levels for pesticides laid down in Regulation (EC) No 396/2005, and the maximum levels for contaminants laid down in Regulation (EC) No 1881/2006.
- (g) The dairy products described above originate from the zone that at the date of issue of this certificate is /are authorized for entry in to the union of dairy products that are required to undergo a specific risk- mitigating treatment and listed in a list of third countries and territories adopted by the Commission in accordance with Article 230(1) of Regulation (EU) 2016/429; and
- (h) Dairy products have been processed from raw milk obtained from only one species of animals in particular from the species [Bos Taurus][Ovis aries] [Capra hircus] [Bubalus bubalis][Camelus dromedaries] and the raw milk used for the processing of the dairy product has undergone:

either [a sterilization process, to achieve an Fo value equal to or greater than 3]

or [a ultra-high temperature (UHT) treatment at not less than 135 Deg C in combination with a suitable holding time]

or [a high temperature short time pasteurization treatment (HTST) at 72 Deg C for 15 seconds applied twice to milk with a Ph equal to or greater than 7.0 achieving, where applicable, a negative reaction to a alkaline phosphatase test, applied immediately after the heat treatment]

or [a HTST treatment of milk with a pH below 7.0]

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

either [(i) lowering the pH below 6 for one hour]

or [(ii) additional heating equal to or greater than 72 Deg C, combined with desiccation]

Signature

(Name and designation)

Seal

Place:

Date:

Annexure XXD

(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 and I am familiar with the animal health requirements as laid down in Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004.

(Signature)

Designation

(Seal)

Place:

Date:

Annexure XXE

(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 & 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 & 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 find enclosed requisite amount online fee receipt to issue the Health Certificate for the consignment.


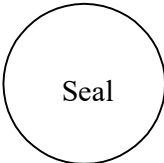
Yours faithfully,

(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**Annexure XXI**

1. Name and address of the exporter		4. Buyer's order no. & date		5. Valid for Custom	
2. Name and address of the approved processing unit		6. Invoice no. & date		7. Country of destination	
3. Details of stamp on export packages		8. Certificate no.:			
		Valid up to and including			
Approval no.....					
9. Specification reference					
10. Shipping marks	11. No. and Kind of Pkgs	12. Description of goods	13. Quantity (MT)	14. FOB value (Rs.)	
15. DECLARATION					
<p>The undersigned hereby declares:</p> <p>(i) That the above consignment has been processed in our establishment which has valid approval and is under continuous monitoring by Export Inspection Agency – as per the Export of Milk & Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020;</p> <p>(ii) That the consignment is export worthy.</p>					
				(Signature)	
				(Name)	
				(Designation)	
					
Place..... Date.....					

Annexure XXIA

MONTHLY STATEMENT ON CERTIFICATES ISSUED FOR EXPORT OF MILK & 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.

Signature:

Name:

Designation:

(Company seal):

Place:

Date:

Annexure XXII

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 utilized for export of goods and the said certificate, if traced latter, will not be utilized 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

Witness

- 1.
- 2.

Place:
Date:

Signature:
Name and Designation
Seal of the Company:

Annexure XXIII

EXPORT INSPECTION AGENCY –.....

**Monthly report of supervisory / monitoring visits to the EU/ Non EU approved
Milk & 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:

Annexure XXIV

EXPORT INSPECTION AGENCY –

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

SL.NO	AP.NO	NAME AND ADDRESS OF ESTABLISHMENT	ADDRESS OF REGISTERED OFFICE	EU OR NON - EU	DATE OF INITIAL APPROVAL	VALID.OF APPROVAL UP TO AND INCLUDING
(1)	(2)	(3)	(4)	(5)	(6)	(7)

Annexure XXVI**EXPORT INSPECTION AGENCY-----****Status Report on Milk & Milk Product Establishment, which had complaint from importing country.**

Ason _____(date)

1.	Name and Address of the Milk & Milk Product establishment	:
2.	Approval No.	:
3.	Details of Complaints: (a) Nature of complaint (b) RASFF Notification (c) Product (d) Health Certificate No.	
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.	<p>Assessment of the establishment</p> <p>a) Date of assessment</p> <p>b) Composition of assessment team</p> <p>c) Outcome of the Assessment</p> <p>d) Whether the unit meets the conditions specified in GOI Notification/other requirements</p> <ul style="list-style-type: none"> ▪ implementation of HACCP ▪ Routine testing by the unit ▪ Traceability and the source of raw material used for the consignment in question. ▪ Corrective action suggested/implemented, if any. ▪ Whether the consignment has been tested prior to shipment for the contaminant(s)_ in question (if so, give details) ▪ Test results of samples drawn during assessment (with details like number of samples, test methods, name of the Lab etc. 	
7.	<p>Current status of Sanitation/Hygiene of the unit(after placing the unit ‘ on alert’)</p> <p>No. of Monitoring Visits (MV) conducted</p> <p>No. of Satisfactory MVRs including Lab reports</p> <p>No. of unsatisfactory reports with details of non-compliance</p>	
8.	<p>Details of consignment inspection tested (with details of testing method, Lab etc.)</p> <p>No. of consignments tested</p> <p>No. of consignments passed</p> <p>No. of consignments failed</p>	
9	<p>Present status:</p> <p>Date of recommendations to EIC to send recommendation to the foreign health authority</p> <p>Change in Frequency of Monitoring (F.M.), if any Date of recommendation to EIC to lift ‘on alert’ Date of Revocation of ‘on alert’ and EIC reference</p>	
10	Action pending	

Signature

(Name and designation)

Annexure XXVII

APPLICATION FOR CONSIGNMENT WISE INSPECTION (CWI)

Exporter's Name Address		1	Invoice No. Date	10	Exporter's Ref.	11	
			Buyer's Order No. & Date		12		
			To		13		
			The Export Inspection Agency –				
Manufacturer's Name & Address		2	Please inspect the consignment and issue a health certificate. An online fee receipt of requisite amount is enclosed as inspection fee				
Any other relevant information		3	Date		Signature of Exporter		
Inspection required on	4	Weekly Holiday	5	Address where consignment is to be inspected			
Vessel / Flight No.	6	Part of Loading	7				
Probable date of Loading	8	Date of Sealing Flight	9				
Marks & Nos. 15	No. & kind of Pkgs	16	Description of Goods	17	Quantity as Declared	18	FOB Value (in Rs.) 19
Technical requirements including specifications / approved samples with its characteristics as stipulated in the export contact.							
20							
21							
<p>Declaration: Certified that the goods mentioned above have been manufactured / produced for export and consignment conforms to the relevant specification mentioned in GoI Order & Notification for Export of Milk & Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020.</p> <p>Certified that no additional technical or quality requirement other than mentioned above have been stipulated by the overseas buyer.</p>							
Signature & Date							

Annexure XXVIII

Health Certificate (CWI)
For Milk products intended for export to Non EU

No:

Country of despatch: INDIA

Competent Authority: Export Inspection Council (Ministry of Commerce & Industry, Govt. of India) 2nd Floor, B-Plate, Block-1 Commercial Complex, East Kidwai Nagar New Delhi-110023, INDIA; Phone : +91-11- 20815386/87/88, E-mail:eic@eicindia.gov.in, Website: www.eicindia.gov.in

Reference No.:

Details identifying the products

Description:

Quantity: NET WT:

Gross WT:

Type of Packaging:

Invoice No.:

No. of packages:

Temperature required during storage and transport:

Manufacturing date:

Expiry Date:

1. Provenance of products

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

Approval No. of the plant(s)

2. Destination of the products

The products are to be dispatched

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

3. Health Attestation

It is hereby certified that the products described above have been handled, processed, stored and transported under hygienic conditions as laid down in the Export of Milk and Milk Products (Quality Control, Inspection & Monitoring) Rules, 2020 and found confirming to laid down standards and fit for human consumption.

Validity of the Certificate:

Place of Issue: Export Inspection Agency -

Signature of authorized officer

Date of issue:

Name:

Seal

Designation:

Annexure XXIX

LETTER OF REJECTION

EXPORT INSPECTION AGENCY

To
M/S _____

Sub : Pre shipment Inspection of _____

Ref : Your Intimation No. _____ dated _____

Dear Sir,

With reference to your above mentioned intimation for inspection, this is to inform you that the consignment of _____ was inspected and it was not found conforming to the specification. It is, therefore, regretted that the certificate of export worthiness cannot be issued due to the following reasons.

Reason (s) for rejection 1)

2)

3)

4)

Yours faithfully,

Agency In charge

Export Inspection Agency-

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

In exercise of the powers conferred by the Export of Milk and Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020 vide Order & Notification No. S.O.4031 (E) and S.O. 4032 (E) both dated 09th November, 2020 published in the Gazette of India: Part – II, Section 3, Sub Section (ii), dated 09th November, 2020.

.....
(Name of the establishment)

having their registered office

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

is hereby granted approval /renewal of approval for a period of three years,

valid up to and including.....under Approval No.....

for processing of

.....

(Scope of approval)

for export to

.....

in its establishment situated at

.....

(Location of the establishment)

subject to the conditions that the plant shall continue to meet the requirements of GOI Order & Notification No. S.O.4031 (E) and S.O. 4032 (E) both dated 09th November, 2020

Place: New Delhi

Signature:

Name:

Designation:

Date:

2nd Floor, B-Plate, Block-1, Commercial Complex, East Kidwai Nagar, New Delhi-110023

Tel: +91- 011-20815386/87/88

Email: eic@eicindia.gov.in, Web: eicindia.gov.in