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EXECUTIVE INSTRUCTIONS FOR APPROVAL/ REGISTRATION AND MONITORING OF COLLECTION CENTRES, COLLECTION CENTRES CUM BONE MILLS, RENDERING PLANTS, INTEGRATED SLAUGHTER HOUSE, OSSEIN AND GELATINE FOR EXPORT

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CONTENTS

APPENDIX

ANNEXURE

1.	**INTRODUCTION**
1.1	The requirements for the approval/ registration of the facilities (independent collection centres, collection centres cum bone mills, rendering plants, integrated slaughter houses with establishments, establishments manufacturing crushed bones, ossein & gelatine) to process or to undertake processing of allied activities related to export have been published vide GOI Order S.O.725 (E) & Notification S.O. 726 (E) both dated 3rd April 2012 on the basis of which the above facilities processing crushed bones, ossein & gelatine meant for export are being approved by the Competent Authority (CA) i.e. CAPEXIL. The Central Competent Authority (CCA) (Export Inspection Council of India) , through it's field organisation, Export Inspection Agency, shall ensure that the Competent Authority carries out its responsibilities as per the instructions issued by it from time to time. The Primary responsibility for meeting the health requirements of importing countries and also those specified in the GOI Notifications lies with the above facilities, for which they are required to plan and implement detailed HACCP based process control (own check system), where needed, and to maintain necessary records. The role of Export Inspection Council (EIC), Export Inspection Agencies (EIAs) & CAPEXIL is to exercise Official Control by approving the facilities and implementing an effective surveillance system to ensure compliance to the requirements as per Rule 5 (1) and Rule 5 (6) of the Notification S.O. 726 dated 3rd April 2012.
2.	**PROCEDURE FOR APPROVAL/ REGISTRATION OF THE FACILITY**
	Facilities intending to supply hide cuttings/ crushed bones/gel bones to Ossein and Gelatine plants need to be approved/ registered by the Competent Authority. Minimum requirements for approval/ registration of the facilities are given at **Appendix - A, B, C, D & E (Page No. 25-65).**
2.1	**Application for approval/ registration**
2.1.1	The facilities intending to process and / or to carry out allied activities, for export of crushed bones, ossein & gelatine shall submit an application for approval/ registration in the prescribed format placed at **Annexure 1 (Page No. 86)** in duplicate along with documents specified in the prescribed format to the nearest office of CAPEXIL under whose jurisdiction the operational base of the applicant is situated. The complete address of the regional offices of CAPEXIL is placed at **Annexure 2. (Page No. 88)**
2.1.2	Application fee as per **Annexure 3 (Page No. 90)** shall be paid by the applicant by way of demand draft / pay order drawn in favour of the CAPEXIL concerned along with the application.
2.1.3	The application shall be accompanied by the following documents as applicable based on requirement. a) HACCP Manual (if the facility intends to process and / or carry out allied activities for export) b) Layout plan covering all sections including machineries as applicable (site plan and building plan preferably in A-4 size).

	c) Attested / Self Certified copies of documents proving legal identity of the applicant and scope of their operations. (for example Partnership deed for partnership firm, Certificate from applicant's bank for proprietary concern, Certificate of incorporation, Memorandum & Articles of Association for company) d) Attested / Self Certified copy of lease agreement for the premises and building where ever necessary. e) Attested / Self Certified copy of registration certificate / memorandum issued by State Govt authority as applicable (If not available at the time of applying for approval, this may be submitted before grant of full approval). f) Bio-data of the responsible person with attested copies of degree certificate(s), experience certificate(s), training certificate, appointment letter, in case of integrated slaughter house. g) Attested / self certified copy of consent to operate letter / letter submitted to PCB requesting for grant of consent to operate, where applicable(As regards Ossein and Gelatine plants) issued by State Pollution Control Board concerned. (In case the consent to operate letter is not available at the time of applying for approval, this shall be submitted before the grant of approval. However in such cases a copy of the application made to State Pollution Control Board shall be submitted at the time of filing application for approval to CAPEXIL). With regard to collection centers cum bone mills self certified copy of the application may be submitted to Capexil. h) Attested / Self Certified copy of the order allotting Importer Exporter Code number (IEC), if applicable.
2.2	**Processing applications for approval/ registration**
	Applications received shall be scrutinised within 7 working days by the CAPEXIL office where it has been received and the discrepancies / shortcomings observed shall be immediately communicated to the applicant for rectification.
2.3	**Assessment of the facility**
2.3.1	The Convener of panel shall ensure that assessment of applicant's facility is carried out within 30 days from the date of receipt of application complete in all respect During on-site visit, the panel shall assess the infrastructure and equipment facilities and also their compliance to regulatory requirements specified in the GOI Notification / Executive Instructions and if satisfied, recommends for the approval/ registration of the facility. Once approved by the Competent Authority, the facility shall be allowed to start production or carry out related activities.

	Export of crushed bones, ossein & gelatine to Non EU countries shall be allowed after approval by the CAPEXIL. However, in case of the EU, the export of crushed bones, ossein & gelatine shall be permitted only after enlisting the name of the facility in the EC approved establishment list. The list can be seen on EC website.
2.3.2	The composition of panel shall be as constituted by EIC from time to time.
2.3.3	The specific members of the panel shall be decided by the CA from the composition of panel as constituted by EIC.
2.3.4	The panel may comprise representatives from CAPEXIL, regional Quarantine (DAHD&F), MoA, FSSAI, State Veterinary Officer, laboratory expert or Empanelled Experts based on the need for expertise to objectively carryout the assessment. If required, external experts having suitable qualification in crushed bones, ossein & gelatine and adequate experience in auditing the processing facility / laboratory may be included in the panel from the list of EIC empanelled experts.
2.3.5	The Convener of the panel shall be the representative from CAPEXIL
2.3.6	The quorum of panel shall be two. However, it must be ensured that the panel has appropriate experts to carryout an objective assessment of the facility.
2.3.7	The panel shall assess the infrastructure and equipment facilities of the facility and shall use the prescribed Assessment Report Format placed at **Annexure 4 (Page No.91)** for reporting its observations. Enough flexibility shall be given while assessing the infrastructure / equipment facilities and the aim shall be to avoid cross contamination.
2.3.8	In case the panel finds any deficiency during its assessment, the same shall be recorded in the Non- Conformity Report (NCR) which shall be counter-signed by the representative of the facility as a token of acceptance. A copy of the NCR shall be handed over to the facility. Suggestions for improvement, if any, shall be given to the facility separately, the implementation of which shall not be a part of the approval procedures.
2.3.9	The convenor of the panel shall submit the assessment report to regional in-charge of CAPEXIL with recommendations of the panel within 3 working days after completion of the visit to the applicant's facility. In case verification of the rectifications is needed, the same may be undertaken as per the time frame prescribed by the Panel (maximum 3 months).The said report shall be submitted within 3 working days of verification to regional in charge of CAPEXIL. The recommendations of the Panel shall clearly state whether the applicant's facility is recommended for approval or not.
2.3.10	The report of the panel visit shall be examined by the to regional in charge of the CAPEXIL concerned. The following three situations may arise:

2.3.11	In case the facility is recommended for approval/ registration by the panel, and if agreed to, the CAPEXIL, shall take following actions: a) Allot an certificate of approval/ registration to the collection center as per **Annexure 05 (Page No.93)** and to collection centres cum bone mills, rendering plants, integrated slaughter houses with establishments, establishments manufacturing crushed bones, ossein & gelatine as per **Annexure 6 and 6A (Page No.94-95)** Approval/ registration numbers *shall be allotted to facility in chronological order and it* should be used only once for a particular facility, except in the case of change of name where same number is requested by the facility. In case the approval is withdrawn, the approval number of the facility shall not be allotted to a new facility. The CAPEXIL shall maintain proper records for allotment of approval numbers. b) Open a file with 3 parts as applicable: Part A, Part B, and Part C. "**Part A**" shall bear the Approval/ registration Number followed by suffix "A" (e.g. "861 A"). This file shall contain approval/ registration documents such as application for approval / registration, panel assessment reports, approval/ registration of additional facilities, responsible person merchant exporter (if approved by CAPEXIL) and other correspondence relating to approval of the facility. "**Part B**" file shall bear the approval/ registration number followed by suffix 'B'. (e.g. "861 B") This file shall contain copies of monitoring reports, supervisory visit reports, HACCP audit reports, NCR (Non Conformity Report), suggestions for improvement and laboratory test reports. "**Part C**" file (if applicable) shall bear approval number with suffix 'C'(e.g. "861 C") and have details of Foreign Complaints including all relevant papers and details of all actions taken thereof including imposition and revocation of "Internal Alert" etc. All regional in-charge of CAPEXIL shall submit copies of all relevant records (Part A, B & C) of inspection and approval/ registration of the facility to coordinating office of CAPEXIL, New Delhi on regular basis. Concerned EIAs shall maintain the records (**Part D**) of Health Certificates issued to approved establishments by EIA. All records of File A shall be kept at least for a period of five years after withdrawal of approval. However records of File B, C and D shall be kept for, at least, three years.
2.3.12	In case the panel does not recommend approval/ registration and if agreed to, the In-charge of the CAPEXIL shall convey the same to the applicant, within seven days of the receipt of the panel report, along with the reasons

	for which applicant facility has not been considered fit for approval/ registration as per format given in **Annexure 7(Page No. 96)**
2.3.13	In case the deficiencies observed and recorded by the panel can be rectified within a reasonable time (maximum of three months), a copy of Non-Conformity Report (NCR) shall be given to the facility for rectification of the deficiencies within an agreed period of time not exceeding three months. The verification of the rectifications carried out by the applicant facility shall be done either by panel or Convener of panel or any other officer authorised by the CAPEXIL. Once verified and found satisfactory, the actions as per clause 2.3.11 shall be followed. In case of facility meant for export the CAPEXIL shall issue 'Certificate of Approval' to them as per the format specified at **Annexure 5 & 6 (Page No. 93& 94)** for a period of two years from the date of the approval. Simultaneously CA shall send the recommendations to EIC requesting to send the name to EC.
2.3.14	**Action to be taken by the Export Inspection Council (EIC)** a) On receipt of the recommendations of CAPEXIL, the technical division in EIC shall examine the documents and if these are in order, submit the same to the Director (I&QC) within 7 working days. b) Once the Director (I&QC), grants the concurrence, the existing list of the facilities shall be updated by including the name of the facility and a copy of the updated list along with specific recommendation shall be sent to EC for including the name in the third country establishment list with copies to CAPEXIL, EIAs, DoC, and MoA.
2.3.15	On receipt of approval from EC, the EIC shall inform the same to EIAs & CAPEXIL.
3.	**Procedure for approval of additional facilities / activities of approved / registered facilities.**
3.1	The approved/ registered units seeking approval/ registration of additional facilities / activities such as additional product, new process activities etc. shall submit their application, in duplicate, in the prescribed format placed at **Annexure-1 (Page No. 86)** along with relevant documents as mentioned in the application form to the controlling local office of the CAPEXIL and also with the application fee as per Annexure-3 (Page No.xxx) - which shall be paid by way of demand draft / pay order drawn in favour of the CAPEXIL concerned.
3.2	Application(s) received shall be scrutinised and the discrepancies / shortcomings observed shall immediately be 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 concerned CAPEXIL office along with the process flow chart and SOP for verification. Adequacy audit of the HACCP manual with respect to the additional activities shall be done by CAPEXIL officer(s) authorized by the CA.

3.3	The CA shall decide whether the assessment of the unit to be carried out by the panel or by the CAPEXIL officer (convener of panel) depending upon the nature of additional facility / activity to be assessed for approval/ registration.
3.4	The Convener of the panel shall ensure that assessment of the additional facility / activity of applicant unit is carried out within 15 working days of receipt of their application complete in all respect.
3.5	The prescribed Assessment Report Format placed at **Annexure- 4 (Page No. 91)** 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 unit through the NCR for taking corrective action within an agreed time period, maximum of one month. The rectifications carried out by the unit shall be verified by either the panel or the Convenor of the panel, or any other officer authorised by CA. The report and recommendations shall be submitted to the CA within 3 working days of completion of the assessment of the applicant's unit. The recommendations shall clearly state whether the additional facility / activity is recommended for approval/ registration or not.
3.7	The CA shall examine the assessment report of the panel / convener of the panel.
3.8	On approval of the facility intended for export to EU, CAPEXEL shall communicate the same to EIC for informing to EC.
3.9	The new Certificate of Approval / Registration shall be issued to the unit by CA (upon receipt of the old CoA) after incorporating the additional process activities in the certificate of approval / registration.
3.10	In case the panel / convener of the panel does not recommend approval/ registration, the CA shall convey to the applicant, within seven working days of the receipt of the panel report, the reasons for which, the additional facilities / activities of the unit have not been approved/ registered.
4.	**Action to be taken by EIC**
4.1	On receipt of the satisfactory report of the panel / convener of the panel along with the recommendations of CA, the technical division of EIC shall process and submit a note to the Director (I&Q/C) for his concurrence.
4.2	If need be, the change in the scope shall be communicated by EIC to EC. Till the new scope is not updated on EC website, health certificate with new scope shall not be issued by EIAs. CAPEXIL shall endorse new scope in the health certificate once the new scope is updated on the EC website.
5.	**Procedure for renewal of approval / registration of the facility**
5.1	CA shall remind the facility about renewal 90 days before the expiry of current approval / registration. The letter shall be addressed to the highest authority of the facility. The approved / registered facilities, seeking renewal of approval /

	registration shall submit application, in duplicate, at least 60 days in advance of the expiry of earlier approval to the controlling local office of the CA. The facility shall apply in the form prescribed at **Annexure-01 (Page No. 86)** along with the relevant documents, application and assessment fee as per **Annexure-03 (Page No. 90),** which shall be paid by way of demand draft / pay order drawn in favour of CA.
5.2	Application(s) received shall be scrutinised and any discrepancies / shortcomings observed shall be immediately communicated to the applicant for rectification.
5.3	The Convener of the panel shall ensure that assessment of applicant facility is carried out at the earliest.
5.4	It shall be ensured by the CA and the Convenor of the CA that all formalities for the renewal of approval / registration are completed well before the expiry of approval / registration. Assessment of the facility shall be arranged in consultation with the applicant.
5.5	In case the facility 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 / registration granted to the unit lapses, the unit will need to apply for fresh approval / registration. In case of facilities approved for export to EU, the letter for non-renewal of approval shall be issued by CA to the facility under intimation to EIC, and in-turn EIC shall send the recommendation to for delisting the unit from EC list.
5.6	Panel shall assess the infrastructure and equipment facilities, hygiene & sanitation, own-check system exercised by the facilities at all stages of production, implementation of statutory requirements, maintenance of records etc. **Annexure 4 (Page No.91)** to ensure that the approved facilities are maintained properly and control measures are adequate.
5.7	In case the panel finds any deficiency during assessment, these shall be recorded in the Non conformity report (NCR), **Annexure 11 (Page No.102)** a copy of which shall be given to the facility for taking corrective action within an agreed time period but well within the validity period of approval / registration The panel shall submit its report and recommendations to CA within 3 working days of completion of its assessment of the applicant's facility. The recommendations of the panel shall clearly state whether the applicant facility is recommended for renewal of approval / registration or not.
5.8	In the case, if the panel does not recommend for renewal of approval, the CA shall, within 3 days of the receipt of panel report, forward a copy of the panel report to EIC with recommendation to the Director (I&Q/C) to arrange delisting of the facility from the EC .list. (for EU approved facilities only).
5.9	In case the panel recommends renewal of approval / registration the CA shall grant the renewed Certificate of Approval / registration for a period of

	two years from the date of expiry of earlier approval and inform the facility accordingly.
6.	**Permission to process & pack crushed bones, ossein, & gelatine for merchant exporter**
	I. Approved facility shall be permitted to process and pack crushed bones, ossein & gelatine for export by one or more merchant exporter(s), depending upon their production capacity. II. Facility intending to process and pack crushed bones, ossein & gelatine on behalf of merchant exporters shall submit its application to CA as per the format given at **Annexure 8 (Page No. 97)**, along with the fee as per **Annexure 3 (Page No.90).** III. Permission to process / handle crushed bones, ossein & gelatine meant for export by the merchant exporter(s) is given at **Annexure 9 (Page No.99)** IV. When an approved processor requests CA for cancellation of permission given to process and pack crushed bones, ossein & gelatine for any merchant exporter for cancellation, the permission shall be withdrawn using format given at **Annexure 10 (Page No. 101)** . **V.** The validity of the permission granted by CAPEXIL for processing and packing crushed bones, ossein & gelatine in favour of merchant exporter shall be co-terminus with the validity of the approval of the facility / validity of the agreement entered between the processor and the merchant exporter, whichever is earlier However, if there is a break in approval of the facility or the agreement with the merchant exporter lapses, the permission given to the processor by CAPEXIL to pack crushed bones, ossein & gelatine for the merchant exporter gets automatically terminated and if the processor desires to cater to the same merchant exporter, it shall seek CAPEXIL permission afresh.
7.	**Change in the name of the facility**
7.1	In case there is a change in the name of the company, the facility concerned shall request CAPEXIL for change of name. An application shall be submitted along with the following documents, as applicable; i. Attested / Self certified legal documents relating to the change. ii. Attested / Self certified copy of legal identity of the new facility. iii. Attested / Self certified copy of the consent letter of PCB in the new name. iv. Attested / Self certified copy of the IE code in the new name. v. Original Certificate of approval / registration issued to the facility. vi. NOC (No objection Certificate) from existing facility stating that they have no objection in using the same approval / registration number by the new facility. vii. Undertaking from the new facility that they shall take all the responsibility of the quality and safety of the products processed / exported by the existing facility.
7.2	In the case of request for transfer of approval / registration under a Wet Lease Agreement (an agreement wherein the approved unit is leased out to

	another party with all the approved / registered facilities including personnel without any change except that the party which has taken the approved unit on wet lease will be the new processor), or in case of change in ownership without changing the approved facilities including personnel, the processing unit shall furnish the documents mentioned at 7.1 to the CA. In addition, the party taking the approved / registered unit on wet lease or purchase shall also request for transfer of the approval in its name without change of approval / registration number and submit an undertaking and a guarantee required to be given by all approved / registered processors, along with other legal documents relating to taking over the unit on wet lease / purchase. On receipt of the above documents the CA shall examine the validity of such documents and on being satisfied, recommend to the CCA (in case of EU facilities only) the change of name / transfer of approval / registration. EIC, will inform EC about the change of name of the approved facility. 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. As certain time may be required for the listing the name of the company by EU, permission may be given to export the consignments to the EU in the new name with old company name in bracket during the interim period, if requested by the exporter. However this recommendation has to come from CA.
7.3	In cases of change in the ownership with change in the premises, manpower or process etc., a fresh approval / registration as per the prescribed norms shall be required.
8.	**Responsibilities of the approved / Registered facilities**
8.1	**General**
	a) As the sole responsibility in maintaining the quality and safety of the products processed / handled in the units, lies with the approved facilities, they shall develop and implement HACCP based own check system. The facility shall exercise proper controls at all stages of production / handling starting from raw material procurement to the final despatch of the cargo and maintain records thereof. The facility shall comply with all the regulatory requirements of the GOI Notifications as well as those specified by the importing country and by CA & CCA time to time. b) Units shall maintain all the approved facilities in good repair. For major alterations / changes in the infrastructure, prior approval shall be taken from the CA. c) All the control measures and sampling procedures adopted by the approved facility shall be addressed in the HACCP manual. Proper

	identification and monitoring of CCPs shall be ensured by the Approved facility. d) HACCP system has to be reviewed by the approved facility at least once in a year or in case of any change in the product / process / source of raw material or in case of customer complaint. The review records shall be maintained for verification. e) Implementation of HACCP (own check system) shall be monitored at all stages so as to ensure the quality and safety of the product. There should be a proper documented recall procedures incorporated in the HACCP Manual of the approved facility f) Traceability of the raw material, ingredients, etc. shall be maintained right from the source of production. Test reports pertaining to the quality and safety of the raw material, ingredients shall be maintained by the processor. g) A cleaning and disinfection programme should be implemented to ensure that all parts of the unit are appropriately cleaned, including tables, utensils, equipment etc. The programme should be continuously and effectively monitored for its suitability and effectiveness and whenever necessary, documented. h) Personal hygiene and behaviour of the employees shall be strictly monitored to ensure the safety of products handled. Health cards shall be maintained for all employees coming in contact with food products / ingredients / food contact surfaces etc. with the attestation "Fit to handle food products and suitable to work in the approved facility duly authenticated by a registered medical practitioner. i) Proper control shall be exercised to avoid cross contamination of the product processed / handled. j) Suitable pest control measures shall be adopted to eradicate pests inside the factory premises. k) Crushed bones, ossein & gelatine products of other facilities shall not be allowed to be stored in the approved premises of the unit without prior permission from the CA. Moreover, crushed bones, ossein & gelatine processed in the approved facility shall not be stored in other approved unit(s) without prior permission from CA. However, in case of emergency, an approved processor may store the material in another approved unit, which shall be intimated to the CA concerned in the subsequent working day with reasons and full details of the material. Similarly, the approved unit which has accepted the crushed bones, ossein & gelatine products from another approved unit for storing shall maintain proper stock register for such crushed bones, ossein & gelatine products for verification by CA. Under no circumstances, crushed bones, ossein & gelatine products meant for export shall be shifted to un-approved facility.

	l) Any change of the responsible person(s) / veterinarians shall be informed to the CA concerned immediately by the approved facility. m) Approved facility shall conduct internal audits at least once in a year covering all areas of SSOP, GMP, SOP, HACCP etc. and maintain records. Validation of critical limits / HACCP Plan shall also be conducted on a laid down frequency.
8.2	**Identification and packing of the product**
	a. The processor shall ensure that Gelatine intended for human consumption is kept separately and is identifiable during production, storage and transportation. During storage and transportation, a label shall be affixed / attached to the container, carton or other packaging material, clearly indicating whether it is 'intended for human consumption' or 'intended for technical use'. Packages containing Gelatine fit for human consumption shall also indicate the date of minimum durability. b. Gelatine whether intended for human consumption or not intended for human consumption can be produced and stored in the same establishment provided that the raw materials and production process comply with requirements applying to gelatine intended for human consumption. c. Each export package shall be legibly and indelibly marked with the following: (i) Name and address of establishment with approval number; (ii) Name and address of exporter, if different from the establishment; (iii) Batch or lot number; (iv) Year, month of processing or manufacturing; (v) Date of minimum durability; (vi) Gross weight and net weight; (vii) "GELATINE INTENDED FOR HUMAN CONSUMPTION" or "GELATINE SUITABLE FOR ANIMAL CONSUMPTION / TECHNICAL PURPOSES", depending upon the end use; and (viii) Product of India.
8.3	**Quality Control**
	Proper quality control measures / sampling plan shall be established by the approved facility documented and implemented to ensure the wholesomeness of the products processed.
8.4	**Requirements for finished products:** Each production batch of gelatine shall meet the requirements as mentioned in **Appendix- E (Page No. 65)**
8.5	**Records**
	Proper records as per **as given in the check lists (Appendix A to E)** shall be maintained by the approved / registered facility

9	**Official Control by the Competent Authority**
	Strict confidentiality shall be maintained in all the official control visits and the facilities 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 shall be followed as per details given below:
9.1	**Monitoring by CAPEXIL officials (CA)**
	CA officials shall carry out periodic monitoring of the approved / registered facility to ensure that: a) all the approved/ registered facilities are being maintained by the unit are as per requirements; b) all the regulatory requirements and those specified by the EU / importing countries are being complied with; and c) the products processed/handled in the facility conform to specification.
	Monitoring shall normally be done by CA officer and each officer shall be assigned to units as per the discretion of the controlling officer.
	The monitoring officials shall verify the own checks system adopted by the unit at all stages of production starting from raw material reception to final despatch of the cargo, for which it is essential that unit shall have production at the time of visit. If there is no production in the unit at the time of monitoring visit, the processing activity of the unit shall be re-assessed during the subsequent visit.
9.1.1	**Frequency of monitoring the approved / registered facility:**
	a) On initial approval of the facility monitoring visits shall be carried out **once in once in a year** b) In case, at any stage, non-satisfactory performance on account of any major deficiency is observed during monitoring / supervisory visit / inspection and testing at importing country resulting in foreign complaint, the monitoring frequency shall be **once in six months** and the same shall be reviewed after one year.
9.1.2	**Areas of monitoring**
	The monitoring shall broadly focus on If applicable on the following
	a) **Facility checks**: to ensure that all the approved/ registered facilities are being maintained by the unit. This also includes verification of sanitary and hygienic conditions prevalent at all sections of the unit. b) **Verification of HACCP Implementation**:- to ensure that the unit has implemented the HACCP in to as envisaged in its HACCP manual and also controls exercised by the unit are adequate and effective. This includes verification of CCP, GMP, GHP, SOP, SSOP, traceability, good storage practices, raw material / process/ product controls and calibration etc. c) **Verification of testing and lab practices**: -The objective is to

	ensure that the sampling procedures and test methods adopted by the approved facility are adequate and reliable. This includes good laboratory practices (GLP) followed by the in-house lab of the unit, effectiveness of lab chemicals, reliability of testing etc. d) **Verification of records**: - The objective is to ensure that the records maintained by the unit are in order and are addressing all the controls exercised by the unit.
9.1.3	**Reporting system**
	After completing the monitoring, a report shall be prepared in the Monitoring Report Pro-forma given at **Annexure 4 (Page No. 91)** along with the Non Conformity Report (NCR) if any and Suggestions for Improvement Report shall be submitted to the controlling office of CA within 3 working days of the visit. Test reports may be given to the processor if requested by him. Formats of Non Conformity Report (NCR) and Suggestion for Improvement Report are placed at **Annexure-11 & Annexure-12 (Page No 102&103)** These formats shall be used during monitoring visits / supervisory visits as well as by other surveillance visits. Non-conformities observed during the surveillance visits shall be recorded in the monitoring report and one copy shall be provided to the approved facility 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 monitoring report the earlier deficiencies which are not rectified by the unit. The monitoring report along with the monitoring report shall be submitted to CAPEXIL within 3 days for scrutiny, acceptance and follow up action. However, in case any major discrepancies affecting the food safety are observed, the same shall be brought to the notice CAPEXIL immediately for timely action.
9.2	**Supervisory visit (CA)**
	a) Supervisory visit shall be carried out by an officer of the level of Deputy Director and above by CAPEXIL having adequate experience in operation of Scheme / other Food Scheme. The frequency of supervisory visits shall be once in **18 months.** **b)** The Supervisory visit shall be conducted for I. Checking the documentation and compliance of the requirements of the importing country such as EC Directives / Regulations in case of EU approved units, and GOI Notifications, as applicable. II. Quality of monitoring carried out by the monitoring officers. **c)** Samples, if any, drawn during such visits shall be sent to the laboratories of the EIAs. Test report shall be made available within one week. The report of supervisory visit shall be submitted within 3 working days to CA. **d)** The pro-forma of Supervisory visit Report is given in **Annexure-4 (Page No.91)**

	A copy of each Supervisory Visit Report shall be maintained in the relevant files of CAPEXIL e) NCs raised during the supervisory audit shall be followed up during the monitoring visits.
9.3	**Corporate Audit:** Audit of CAPEXIL under the corporate audit mechanism will be carried out by CCA at a frequency of at least **once every two year.**
	The main objective of the corporate audit is to ensure uniform implementation of the statutory rules and regulations, and executive instructions issued by the Central Competent Authority, and shall comprise:- ➢ Examination of records of approved / registered facility maintained by the CA in Part A, B and C as applicable. ➢ Visit to EIA to examine Part D of the file. ➢ Visit by the audit team to at least 5% of the approved facilities on rotational basis. The corporate audit team shall comprise at least 3 members nominated by the Director (I & Q/C).The lead auditor and auditors may be drawn from EIC and one more auditor shall be deputed by CAPEXIL. The report of audit shall be submitted to Director (I&QC) in format specified **at Annexure 13 (Page No. 104).**
10	**Guidelines for dealing with unsatisfactory monitoring or other visit reports and / or test reports and violations**
10.1	**Deficiencies** a) The deficiencies which do not affect the wholesomeness (food safety) of the products shall be considered as minor deficiencies and those which affect the safety of the food product shall be considered as major deficiencies. b) A number of minor deficiencies or repeated minor deficiencies indicating a system failure would also be treated as major deficiency.
10.2	**Some of the Major deficiencies are:** Contamination with pathogens (Salmonella) or with hazardous substances like heavy metals, residues etc. above permissible limits shall be considered as major deficiencies.
10.3	**Actions to be taken when deficiencies are observed**
10.3.1	In the case of **minor deficiencies** observed during the visit, it shall be communicated to the processor through the monitoring report and the

	corrective action shall be verified by the officer conducting the subsequent visit. However, if the processor fails to rectify the deficiencies within the agreed time period, then the action specified at 10.3.2 shall be followed.
10.3.2	In the 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 action(s) may be taken by CAPEXIL depending on nature of deficiencies, with intimation to the CCA . I. The processor may be placed under consignment-wise inspection until the rectification is done satisfactorily and verified by a DD – level officer. The cost of testing and deputation charge shall be borne by the processor as per actual. If any of the consignments are found violative of the prescribed standard, testing of consignments shall be continued till two consecutive consignments are found in conformity with the requirements. II. The processor may be advised to suspend production and export until rectification is done and verified by a visit of CA. Revocation of suspension, when required, shall be done by the CA III. In the case of failure in critical parameters such as microbiological factors., the next 2 consecutive consignments shall be tested, batch wise (code wise) and got cleared for the specific parameter(s). The defective batches (codes) will not be permitted for export. The cost of the testing and deputation shall be borne by the processor as per actuals. If any of the consignments / batches (codes) are found violative of the prescribed standard, testing of consignment(s) / batches (codes) shall be continued till three consecutive consignments / batches (codes) are found in conformity with the requirements.
11	**Action against violations**
	In the case of violations, such as (i) Storing of product at un-authorised / un-approved premises/ stores; (ii) Major failure in complying with GMP/GHP/HACCP; (iii) Processing and storing of products which are not covered under the scope of approval; (iv) Repeated quality complaints from importing countries; the penalties as decided by CA shall be imposed.
11.1	**Reporting system by CA to CCA**
	Reporting system shall be put in place requiring CAPEXIL to report the following to the CCA for the purpose of Management Control every quarter (March, June, Sept & Dec) by the 7th of the succeeding month. **i.** Details of monitoring and supervisory visits planned and carried out as per **Annexure 14 (Page No. 106)** **ii.** List of the approved facilities (to be sent through electronic

	communication only) as per **Annexure 15 (Page No. 107)** **iii.** Details of action taken in case of violation by the approved facility **iv.** Status of the establishment having foreign rejections as per **Annexure 16 (Page No.108)** **v.** Present frequency of the monitoring / supervisory visits to the facility
12	**Health Certificate**
12.1.1	**General**
	1. All consignments of crushed bones, ossein & gelatine products exported from India to the EU are required to be accompanied by a numbered original health certificate, in accordance with the relevant model given at **Annexure 17and 18 (Page No.111&113)** duly completed, signed and dated. The original of the health certificate is required for customs clearance at the destination and shall be made available to the customs authorities at the destination before the arrival of the consignment. The consignments cannot be cleared on the basis of a copy of the original or on the basis of a fax copy of the original. Health Certificate meant for EU should be issued before or on the day of shipment and cannot be issued retrospectively. 2. All EU approved facilities are required to obtain Health Certificate from Export Inspection Agencies only. 3. Only the officials of the Export Inspection Agency are authorized to issue and sign the health certificates for export of crushed bones ossein and gelatine products to EU. EIA shall issue health certificate as per the requirement of the Commission Regulation (EC) 2074/2005 of 5th December 2005(as amended from time to time) for export of crushed bones, ossein and gelatine intended for human consumption and as per chapter 11 of Commission Regulation (EC)142/2011 of 25th Feb 2011 for gelatin not intended for human consumption / gelatin outside feed chain. 4. If Health / Veterinary Certificate is lost in transit the facility may request for issuance of a duplicate health certificate by submitting an indemnity bond 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 certificate, stating the reason for the issue. The fee to be charged for duplicate health certificate is given at **Annexure-3 (Page No-90).**
12.1.2	**Procedure for issuance of Health Certificate/ Veterinary Certificate for EU countries**
	1. At the first instance approved facility shall get the declaration as stated in the health / veterinary certificate attested by local state government veterinarian and CAPEXIL on one set of health / veterinary certificate.

2. If offices of state government veterinary officer and regional office of CAPEXIL are located in different places, the final Health / Veterinary certificate shall be issued by the EIA offices on the strength of fax copy of declaration / information attested by local state government veterinary officer and CAPEXIL. The original copy of one set of Health / Veterinary certificate shall be submitted by the facility to the concerned EIA office within 15 days. On receipt of the said attested health certificate the processor shall request CCA for the issuance of final health certificate furnishing all necessary information along with

    a) A original copy of the health certificate attested by CAPEXIL and local state government veterinarian.
    For export to non EU countries the requirements of attestation on the health / veterinary certificate by the local state government veterinarian is not necessary if not required by the importing country.

    b) Test report related to analysis, if applicable

    c) Invoice, packing list pertaining to the consignment etc

    d) A copy of the label used on the cartons if applicable.

3. Controlling local office of CCA shall issue final health/veterinary certificate to the processor after satisfying itself that the products are processed in approved facility having valid approval number and after satisfying the relevant requirements. Each health certificate shall bear the name, designation and signature of the official veterinarian and the official stamp of EIC in a colour different from that of other endorsements. While issuing health certificate, the issuing officer must ensure that the colour of the signature is different from the colour of the ink used for printing the certificate. If the certificate is printed in black, the signature must not be in black colour.

4. Since addendum / corrigendum / authenticating the corrections are not permitted by many of the importing countries, utmost care shall be taken while issuing the health certificates. However, in unavoidable circumstances clarification letter may be issued to authenticate the corrections in the Health Certificates, provided the importing country accepts the same as informed by the processor / exporter in writing and the responsibility in getting the consignment cleared at the destination lies with the processor / exporter. A fee as stated at Annexure- 03 (Page No.xx) has to be paid by the processor for issuance of clarification letter.

5. The Health Certificate in the prescribed pro-forma shall be issued to the approved facility. While applying for health certificates the unit shall mention in their application form the language required in the health certificate. Health certificates may also be issued in bilingual language if requested by the processor.

6. Officer issuing the health certificate shall have the sound knowledge of

<table>
<tr><td></td><td>
veterinary legislation as regards the animal or products to be certified.

7. .Even though the language used for printing the health certificate is other than English, the entries in the health certificate can be made in English. Entries in the Health Certificate may also be made in the language of the destination port/country if the language is known to the certifying official or and authenticated by an authorized person meant for the purpose.

8. Health certificate shall be drawn up at least in the language understood by the certifying officer and at least one of the official languages of the country of destination as provided for in the Community legislation.

9. Certificate reference number of health certificate:
Since no two certificates issued from India should have the same number, the following system shall be adopted for giving the reference number:
Each Sub-office shall give a serial number for each health certificate issued prefixed by Agency/Sub-Office codes. Starting from No 1, the serial number will be continued for the whole financial year from 1st April to 31st March.
Following Agency codes shall be used.

<table>
<tr><td>EIA-Mumbai</td><td>EIA-Kochi</td><td>EIA-Chennai</td><td>EIA-Kolkata</td><td>EIA-Delhi</td></tr>
<tr><td>MUM</td><td>KOC</td><td>CHE</td><td>KOL</td><td>DEL</td></tr>
</table>
The Sub Office codes shall be decided by the in-charge of the respective Agency under intimation to EIC and shall consist of maximum three alphabets in capitals.
Ex. EIA/DEL/2012-13/00001

Note: Annexes to the health certificate, if any, shall have the same reference number as that of the health certificate. (For example:- results of analysis , details of variety/ types of products which could not be typed in description of commodity column for want of space, etc)
</td></tr>
<tr><td></td><td>Issue of health certificate shall be limited to only the actual quantities produced / processed by the approved facility. In no case should the certified quantity significantly exceed the production capacity, as assessed by the panel.
In case, the approved facilities store products meant for export to the EU in the approved storage prior to shipment, EIA shall also mention the approval no. of the storage in the health certificate issued for the export of the particular consignment, after obtaining necessary declaration from the processor / export in this regard.</td></tr>
<tr><td>12.1.3</td><td>Procedure for issuance of Health Certificate/ Veterinary Certificate for Non-EU countries</td></tr>
</table>

	The Health Certificate for consignments of products meant for export to Non-EU countries may be issued by the concerned EIA in the required format of importing country. If the importing country has specified any testing requirements, these shall be complied with before issuance of health certificate. Health certificates for export to Non-EU countries can also be issued in EU format on request by the processor, if the unit is approved for export to EU.
13.	**EXPORT CERTIFICATION**
	1. The export of crushed bones, ossein and gelatine shall be accompanied by a Certificate for Export (CFE) as per **Annexure 19 (Page No. 115)** 2. The approved facility shall itself issue a Certificate for Export (validity for which shall be 15 days from the date of issue) for every export consignment. 3. .If the validity of CFE is expired, then the same can be revalidated up to another 15 days. 4. Blank books of CFE shall be obtained from Capexil (Competent Authority) against payment of requisite charges. Each certificate will consist of original intended for Indian Customs; duplicate to be forwarded to the concerned regional office of Capexil and the triplicate copy for the use of the establishment. Capexil shall maintain proper record of these certificates. 5. In case of lost certificates, exporter shall submit an indemnity bond to that effect to the concerned regional office of Capexil . Capexil in turn, shall inform the Customs to ensure that the certificates bearing those numbers have not been presented to them. Further, Customs shall be informed not to accept those specific certificates in future. 6. In case of cancellation or damage of CFE, the establishment shall submit the original of the cancelled CFE to Capexil along with other two copies (full set) and original Health Certificate (HC) (if already issued) pertaining to the cancelled CFE.
14	**Complaint Handling Procedure: Procedure to be followed for complaints received from importing countries (EU and Non-EU)**
14.1	**General**
	a) When a complaint is received from the importing country or a consignment is detained or specific control measures are imposed by b) the importing countries on food safety or quality grounds, such as product contamination with micro organisms or with harmful residues or due to other reasons including spoilage, incorrect labelling, the CCA will follow the procedure as given below. c) The CCA shall inform the same to CA. d) In turn CA shall put the processing facility under internal alert, collect necessary information about the consignment in question from the processor and get the facility assessed by the panel to determine the

	root cause of the complaint. Based on the panel report CA shall take appropriate action.
14.2	CA shall scrutinise the complaint received from the foreign countries or any other source. EIC may seek clarification from the importing country / Health Authorities, if required.
14.3	**Action by CA**
	a) Placing the unit under "internal alert"
	CA shall place the processing unit under '**Internal Alert**' immediately after the receipt of the information about the rejection and shall collect any of or all the following information, based on the nature of rejection / complaint, from the processor concerned: i. Full particulars of the consignment such as product name, quantity, batch code / grade along with attested copies of related documents such as purchase order / letter of credit, certificate for export, health certificate, bill of lading, etc. and also source of raw materials used for processing and export. (*Details regarding prices need not be furnished by the exporter/processor).* ii. Test reports of raw materials, finished products, pertaining to the consignment. iii. Details of the whereabouts of the consignment. iv. The particulars of products held in stock by the processor. v. Details of investigation carried out by the unit vi. If the processor has got his consignment subjected to a confirmatory test in the country where it was detained or got it surveyed by an independent surveyor in the country where it was detained, copies of such test / survey reports shall be made available to the competent authority for examination. vii. Additional information, if any, relevant to the complaint / rejection.
	b) Information to the laboratories which had tested the product in question: Every laboratory involved with the product in question by way of sampling and / or testing etc., as applicable, in respect of the contaminant(s) which caused the rejection, shall be informed by CA about the complaint with a request to investigate into the matter to determine the root cause for non-detection of the contaminant in its laboratory when the samples were tested and to send a detailed report on the root cause analysis, proposed corrective actions and measures to prevent the recurrence. The CA shall examine the report of root cause analysis done by the laboratory and forward it to CCA with its comments.
14.4	Meanwhile, the following actions shall be initiated by the CA depending on the nature of complaint / rejection, as decided by CA.
14.5	**Testing of consignments**
	In case of rejections to **EU** the next 3 consecutive consignments meant for export to EU and one in two consignments meant for Non-EU shall be tested by CA for the specific contaminant(s) at EIA Lab and got cleared. Frequency of testing for **non-EU consignments** will be one in three till such

	time 3 consecutive consignments to EU or 2 to non-EU are cleared. If any sample tested fails during the period of testing 3 consecutive consignments meant for EU, two more consecutive consignments will be tested for the specific contaminant (s) in EIA labs, till such time two consecutive consignments get cleared after testing. Similarly, if any Non-EU consignment fails, testing of Non EU consignments shall continue till two consecutive Non EU consignments get cleared after testing. Cost of testing, deputation shall be borne by the processor on actual basis.
14.6	**Assessment of the approved facility**
14.6.1	Based on the assessment, the team shall prepare a detailed objective report and submit to the CA within three working days after completion of assessment. The report shall address the possible root cause(s) of rejection and the remedial measures to prevent contamination / rejection.
14.6.2	The CA shall scrutinise the assessment report and test report(s) of samples drawn during assessment and take following actions depending on the outcome of the assessment, after obtaining the necessary approval of CCA. a) In the case of rejections due to food safety / quality issues where the assessment team has opined that the unit is capable of producing safe / quality products based on satisfactory performance of the unit evidenced by proper HACCP implementation and adequacy of the own check system of the unit to prevent further contamination / rejection, CA shall forward a copy of the assessment report along with test report(s) to CCA for information. b) In the case of rejection for reasons other than food safety/ quality issues and if the performance of the unit is satisfactory based on the assessment report, CA shall recommend to CCA to grant approval to **revoke the 'Internal alert'** imposed on the EU listed unit. c) If the assessment report indicates satisfactory performance of the unit subject to rectification of minor deficiencies to prevent the recurrence of contamination / rejection, CA shall communicate the deficiencies to the unit for time bound rectification, with a copy marked to CCA. The corrective actions shall be verified by CA and if satisfied, shall take action as in sub clause a) or b) above, as the case may be. d) In case the test result of any sample drawn during the assessment is found not in conformity with the requirements applicable for the specific contaminant or quality parameters, next five consecutive consignments meant for export shall be subjected to testing / inspection by CA for the specific contaminant / quality parameters at EIA lab and the consignments will be permitted for export only after satisfactory test /

	inspection results. The cost of testing and deputation charges shall be borne by the processor on actual basis. e) In case the investigation team has observed the non-conformity in the areas of primary production, then the same shall be dealt with by taking suitable action on these links. f) In case the performance of the unit is found unsatisfactory during assessment based on improper HACCP implementation and / or inadequate controls by the unit to prevent non-conformity / contamination in the unit, the CA shall take the following actions with intimation to CCA.
14.7	**Action in case of unsatisfactory assessment report**
	(a) Processor is required to show cause within 10 days as to why the approval granted to the facility should not be withdrawn for the lapse(s) brought out in the assessment report. (b) Export to all countries shall be stopped till the approved facility rectifies all the deficiencies pointed out by the assessment team and proper steps are taken to prevent further rejection.
14.7.1	Once the processor informs the CA that the corrective actions have been carried out, verification, of the corrective actions will be done by a CA. The processor may be allowed to resume export only if the CA & in turn CCA is satisfied about the rectification of the deficiencies after verification.
14.7.2	If the CA is not satisfied with the reply of the processor to the show-cause notice, or with the corrective actions taken by the processor and verified as at 16.4.1. above, the approval granted to the facility shall be withdrawn with the approval of the Director (I&Q/C), EIC.
14.8	**Dealing with returned consignments**
14.8.1	If the processor wants EIC to issue a letter to the concerned Health Authority of the importing country for bringing back the rejected consignment, he may request in writing for the same through the CA concerned along with full details of rejected consignment, including type of product, quantity, FOB value, container no, Health Certificate no, & date , reason for rejection etc. A copy of invoice and the name and full address with phone number, fax number and email address of the proper officer of the Health Authority of the importing country to whom the letter should be addressed shall also be provided.
14.8.2	When a consignment has been brought back to India after rejection at the importing country, the processor / exporter shall, well in advance of the date of taking delivery of the consignment, inform the CA the details of the consignment including the reasons for rejection, date and port from where delivery will be taken for enabling the CA to arrange for inspection of the returned cargo and to collect necessary samples for testing.

	On receiving the intimation of return of consignment, the following action shall be taken by CA: a) The CA shall arrange to get the consignment inspected and or tested as soon as it arrives at the port. If the consignment has to be taken to an approved storage where facilities for inspection and sampling exist, the CA shall undertake the same at the establishment.
14.8.3	1. If all the samples tested from the brought back consignment meet the specification, the CA may take decision to release the consignment for export to countries other than EU and other than the non-EU country where the consignment had originally got rejected provided it meets the requirements of the importing country. 2. CAPEXIL may allow to reprocess the consignment
14.9	**Revocation of 'Internal alert'**
14.9.1	If any one of the following points are satisfactory: a) The rejected consignment, if brought back to India and tested for the contaminant / defect is found free of the contamination; b) The assessment report of the unit indicates satisfactory performance of the processing facility based on proper hygienic conditions and implementation of HACCP principles. c) The periodical monitoring conducted by CA during the past three months indicates satisfactory performance of the unit and previous HACCP audit report is satisfactory; d) Samples tested during the assessment visit pass; e) 3 consecutive consignments passes f) Audit Report on the primary linkages, done by CA, is satisfactory and suggestions are implemented by the unit. then, CA (after obtaining the approval of CCA) shall revoke the 'Internal alert' imposed on the unit.
15	**Appeal**
15.1	Any person aggrieved by : a) Decision of the competent authority not to accord approval to the facility as per sub rule (1) of rule 5 of Notification No. S.O. 726 (E) dated 3rd April 2012; b) Decision of the competent authority to withdraw approval as per sub rule (5) of rule 5 of the said Notification; and c) Refusal of the central competent authority to issue health / veterinary certificate as per Rule 6 of the said Notification may prefer an appeal within 45 (forty-five) days of receipt of such communication to an appellate authority appointed from time to time by the Central Government. The appeal may be sent to CCA for forwarding the same to the Chairman, Appellate Authority.
15.2	At least two-thirds of the total membership of the Appellate Authority shall consist of non-officials.
15.3	The quorum for any meeting of the Appellate Authority shall be three.
15.4	The appeal shall be disposed of within 30 days of its receipt.

15.5	The non-official members would be eligible for TA / DA as admissible to them from time to time for attending the meetings of the Appellate Authority. The expenditure on this account will be borne by the CA
16	**POWER TO RELAX**
	In case any situation arises, which is not covered by the executive instructions, the CA may make a suitable recommendation(s) to CCA for decision by Director (I&QC), EIC.

Appendix A

REQUIREMENTS AND CHECK LIST FOR APPROVAL/REGISTRATION OF INDEPENDENT BONE/ HIDE COLLECTION CENTRES

REQUIREMENTS FOR INDEPENDENT COLLECTION CENTRES

Sl No.	Requirement	Observation of APE
1.	They must have covered place to receive bones, hides, skin, tendons and sinews of animals and their transportation to the establishments.	
2.	They must have adequate facilities for cleaning and disinfection of the containers in which bones, hides, skin, tendons and sinews of animals are received as well as the vehicles used for their transportation.	
3.	They must have storage rooms with hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, provided with refrigeration facilities.	
4.	The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.	

CHECK LIST FOR APPROVAL / REGISTRATION OF INDEPENDENT BONE COLLECTION CENTRES

Sl No.	Clauses	Remarks
1.	Name of the establishment	
2.	Address	
3.	Raw bones storage capacity	
4.	Are you registered with local panchayat / zilla parishad/ State Govt. for bone contracts	
5.	Do you store/receive/supply slaughtered cattle bones	
6.	Do you store/receive/supply butcher shop bones	
7.	If you receive bones from butcher shops, Do you keep valid copy of licence/permit issued to butcher shops:	
8.	Do you receive and maintain certificate as per **Annexure A-1** duly signed by state govt. veterinarian	

9.	Do you also deal in fallen / kitchen cattle bones (if yes, you are not eligible for approval)	
10.	Do you have separate place to segregate and store SRM to meet requirements of the buyers (if applicable)	
11.	If yes, Do you maintain records of srm disposal **(for Documentary evidence)	
12.	What is the raw bone quantity received by weight during last 2 month/	
13.	Do you have hard washable floor to store bones	
14.	Do you keep the storage rooms in a satisfactory state of cleanliness	
15.	Do you have adequate arrangement for protection against pests and birds	
16.	Do you take necessary measures to prevent insects in the bones	
17.	Do you take necessary measures to prevent insects in the bones	
18.	Do you have covered premises to receive raw ones/hides/skins/tendons/sinews	
19.	Do you have adequate facilities for cleaning and disinfecting the containers of receptacles in which raw bones are received and the vehicles in which they are transported	
20.	Do you maintain record of cleaning as per **Annexure A-2**	
21.	Does the vehicle carrying srm free raw bones supplied to bone mill bear the label "srm free"	
22.	Are you in a position to provide certificate as per **Annexure A-3** required under the executive instructions for transportation of material:	
23.	Do you provide uniform, hand gloves, shoes head wears and mask to your workers	
24.	Whether you have been maintaining record as per **Annexure A-4** of the executive instructions for a minimum period of past 2 months (for new applicants)	

** Ref definition in the Indian standards of SRM

Document No. EIC/CBOG/Ex.Inst./November/2012/Issue1

DECLARATION

I.....Do hereby declare that the above information is complete and correct and that I agree to abide by the conditions and standards laid Down in the Executive Instructions from time to time.

SIGNATURE OF APPLICANT

PLACE:

NAME

DATE:

ADDRESS & STAMP

**

Indian standards for SRM based on India 's negligible BSE status is as follows:

1. As per Article 11.5.15 of the Terrestrial Animal Health Code of OIE (2011) no SRM is required to be excluded if gelatine prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biological, or medical devices came from a country posing a negligible BSE risk.

   Since India has been accorded Negligible BSE Status by OIE (at the 78th General Session of OIE held in Paris from 23 to 28 May 2010) no tissues are required to be excluded from bovine bones derived from animals born, reared and slaughtered in India.

2. However all Or any of the following SRM may be removed as per contractual specifications:

   a.The skull excluding the mandible and including the brain and eyes, and the spinal cord .

   b. The vertebral column excluding the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia.

   c. The tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages

   d The lymph nodes, Spleens, Corpus pineales, duramaters, placentas, cerebral fluids, pituitaries, thymus and adrenal glands .

3. For meeting of the above requirements mentioned in para (a) to (d) it is mandatory to maintain appropriate records and separate crushers & the respective storage areas to avoid any cross contamination.

Annexure A-1

Format of Certificate of origin cum Health certificate required to accompany raw bone supplies to Independent Bone Collection Centers , Collection Centre-Cum-Bone Mills and Rendering Plants

Document No.:

Date:

Type of Products: Raw Bovine Bone
Type of Packaging: Bulk

.....tons raw bones carried in Truck No....., belonging to Mr./M/s..... has originated from butcher shops detailed below falling under slaughter house/s located at .....These bones have been produced from healthy bovine animals born and bred in India only, and fit for human consumption. This consignment has been sold/dispatched to M/s.....(Name and address of consignee)
.....

Name of butcher shops	Quantity (Kg)	License No.
1.		
2.		

Signature
Name and address of consigner:

Signature of State Govt. Veterinary Officer
Name
Address
Official stamp

(Note : This Certificate should be maintained at the bone collection centre.)

Raw Bones supplied direct to Bone Mills/Rendering Plants by Meat packing establishments / Slaughter houses.

The Bone Millers/Rendering Plants buying raw bones from meat packing establishments / slaughter houses will obtain a letter at least once in a year from such establishments certifying that they only process bones of healthy slaughtered bovine animals fit for human consumption which were born and bred in India.
The raw bones procured directly from such meat packing establishments / slaughterhouses must be accompanied with bills /challans/documents mentioning quantity.

Annexure A-2

DETAILS OF CLEANING OF TRANSPORTATION VEHICLES AND COLLECTION CENTRE

Name of Collection Centre:

CLEANING OF TRANSPORTING VEHICLE					CLEANING OF COLLECTION CENTRE		
Date	Supplier	Vehicle No.	Driver's Signature	Remark	Date of cleaning	Signature of Supervisor	Remarks

Annexure A-3

Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY DESPATCHES OF SRM FREE /NORMAL BONES FROM INDEPENDENT BONE COLLECTION CENTRE TO BONE MILLS/RENDERING PLANTS

1. Certificate sl. No. And date :

2. Name of establishment :

3. Address :

4. Registration no.
Issued by CAPEXIL :

5. Name and address of consignee :

6. Quantity :

7. Place of origin of material (source of supply: I.e slaughter house/meat processing plant/ Butcher shop/authorized agent) (as per details at Sr. no. ..... of page no. ..... of register as per Annexure –A4)

8. Name of the transporter :

This is to certify that the above consignment of raw bone has originated from a slaughterhouse and from healthy bovine animals whose carcasses have been found fit for human consumption following ante and post mortem inspection , which were born and bred in India and necessary records are being maintained by us in register as per Annexure –A4

Signature

Name

Stamp

Annexure A-4

FORMAT OF RECORD TO BE MAINTAINED BY INDEPENDENT BONE COLLECTION CENTRES IN A BOUND REGISTER

NAME OF THE ESTABLISHMENT
REGISTRATION NO.
ISSUED BY CAPEXI

RECEIPT (INPUT)						ISSUE (OUTPUT)					
Date of Receipt	Document No. of **Annexure-A-1**	QUANTITY (Kg)			SOURCE OF SUPPLY (Name & addresses of the relevant source should be indicated against this column).	Date	Quantity (kg)		To whom Despatched	Deli-Very challan no.& date	Certificate no. As per **Annexture-A-3** (only For Srm Free Bones)
		Qty. received	SRM	SRM Free			SRM Free	SRM*			
	Monthly Total	Balance Brought forward									

Annexure A-5

CHECKLIST FOR INSPECTING INDEPENDENT HIDE COLLECTION CENTRES

SI No.	Clauses	Remarks
1.	Name of the establishment	
2.	Address	
3.	Raw hide storage capacity	
4.	Are you registered with local Panchayat/zilla parishad state govt	
5.	Do you store/receive/supply slaughtered cattle hides a. Do you store/receive/supply b. Butcher shop hides c. If you receive hides from butcher d. Shops, do you keep valid copy of e. Licence/permit issued to butcher shops:	
6.	Do you receive and maintain certificates As per format **Annexure A-6 & A-7** furnished below	
7.	Do you also deal in fallen Cattle hide (if yes, you are not eligible for registration)	
8.	What is the raw hide/hide cutting quantity Received by weight during last two months	
9.	Do you have hard washable floor to store hides/hide cuttings	
10.	Do you keep the storage area in a satisfactory State of cleanliness	
11.	Do you have adequate arrangement For protection against pests and birds	
12.	Do you take necessary measures to prevent insects In the hides	
13.	Do you have adequate facilities for Cleaning and disinfecting the containers	
14.	In which raw hide are received and the vehicles in which they are transported?	
15.	Do you maintain record of cleaning	
16.	Whether you have been maintaining Record as per format **Annexure A-8** Furnished below of the executive instructions For a minimum period of past 2 months (for new applicants)	

Annexure A-6

Format of Certificate of origin cum Health certificate required to accompany Bovine Hides from slaughter house to independent hide Collection Centre

Type of Products: Bovine Hides

Type of Packaging: Bulk

Document No.: Date:

This is to certify that .....tons of raw Bovine Hides carried in Truck No..... , has originated **from** following Slaughter houses . This consignment has been sold to M/S (Name and address of the **consignee**) on..... vide delivery challan No. dated.....**OR** invoice No.. Dated.....

It is further certified that these raw hides have been derived from healthy bovine animals born and bred in India only, and found fit for human consumption following ante and post-mortem inspection.

Name of slaughterhouse	Quantity (Kg)	slaughterhouse Reg/Licence. No.
1.		
2.		
3.		

Signature
Name and address of the **consigner**
Seal

Signature of State Govt. Veterinary Officer
Name

Address
Official stamp

(Note: This Certificate should be maintained at the independent hide Collection Center)

Annexure A-7

Format of Certificate of origin required to accompany Hide cuttings from hide collection centre to Gelatine Plants

Document No: Date

Type of Products: Bovine Hide cuttings

Type of Packaging:

CAPEXIL Registration Certificate No:

This is to certify that .....tons of un tanned Bovine Hide cuttings carried in Truck No..... has been sold to M/S (Name and address of the gelatine plant) on..... vide delivery challan No. Dated.....**or** invoices No... Dated.....

We further certify that raw hides were procured by us from (Name and address of the slaughter house) vide Certificate of origin No. Dated....

Signature

Name and address of the **consigner**

Seal

Annexure A-8

FORMAT OF RECORD TO BE MAINTAINED BY INDEPENDENT HIDE COLLECTION CENTRES IN A BOUND REGISTER

NAME OF THE ESTABLISHMENT

REGISTRATION NO. ISSUED BY CAPEXIL

RECEIPT (INPUT)				ISSUE (OUTPUT)				
Date of Receipt	Document No. of **Annexure A-6** & Date	QUANTITY (Tons)	SOURCE OF SUPPLY (Name & addresses of The Slaughter House	Document No. of **Annexure A-7**	QUANTITY (Tons)	TO WHOM DESPA-TCHED (Name& address of Gelatine Plant	DELI-VERY CHALLAN NO.& DATE	

Appendix B

REQUIREMENTS AND CHECK LIST FOR APPROVAL/REGISTRATION OF COLLECTION CENTRE-CUM-BONE MILL

Requirements for collection centres located within the bone mill premises

Sl No.	Clauses	Remarks
1.	They must have covered place to receive Bones, hides, skin, tendons and sinews of animals and their transportation to the establishments	
2.	They must have adequate facilities for Cleaning and disinfection of the containers In which bones, hides, skin, tendons and Sinews of animals are received as well as The vehicles used for their transportation.	
3.	They must have storage rooms with Hard floors and smooth walls that are easy to clean and disinfect and, where appropriate, Provided with refrigeration facilities.	
4.	The storage rooms must be kept in a Satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.	

Requirements for bone mills processing crushed bones:

The establishment shall have:

Sl No.	Clauses	Remarks
1.	No stagnant water or signs of any rodent harbourage inside the premises;	
2.	Roads tarred or turfed	
3.	Adequate covered place to receive raw bones	
4.	Hard, smooth and washable floor to store the raw bones	
5.	Proper drainage facility in the raw bone storage area	
6.	Permanent structure to store Crushed Bones	
7.	The walls smooth, light colored and without crevices	
8.	Waterproof and cleanable switches and other installation of the wall;	
9.	Adequate lavatories, changing rooms and wash basins for staff and these shall be away from the main processing portions	

10.	Adequate arrangement for protection against pests such as insects, rodents and birds	
11.	Drainage facility to meet hygiene requirements	
12.	Adequate facility for cleaning and disinfecting the container vehicles carrying bones;	
13.	Adequate facilities for cleaning and disinfecting the containers or receptacles in which raw bones are received and the vehicles in which they are transported.	

Check list for approval/registration of collection centre-cum-bone mill

Sl No.	Clauses	Remarks
i.	Name of the establishment a. Address (works) b. Telephone no. c. Fax no. d. Emails	
ii.	SSI approval no./licence no MSME acknowledgement no	
	Check list for collection centres located within the bone mill premises	
1.	Raw Bones Storage Capacity	
2.	Are you registered with local Panchayat/Zilla parishad, State govt	
3.	Do you store/receive/supply slaughtered cattle bones a) Do you store/receive/supply butcher shop bones b) If you receive bones from butcher shops, Do you keep valid copy of licence/permit issued to butcher shops:	
4.	Do you receive and maintain certificate as per **Annexure- B-1** duly signed by state govt. veterinarian	
5.	Do you also deal in fallen/kitchen cattle bones (if yes, you are not eligible for approval)	
6.	Do you have separate place to segregate and store srm to meet requirements of the buyers. (if applicable if yes, Do you maintain records of SRM disposal ** (for Documentary evidence)	
7.	What is the raw bone quantity received by weight during last 2 months	
8.	Do you have hard washable floor to store bones	

9.	Do you keep the storage rooms in a satisfactory state of cleanliness	
10.	Do you have adequate arrangement for protection against pests and birds	
11.	Do you take necessary measures to prevent insects in the bones	
12.	Do you have covered premises to receive raw bones/hides/skins/tendons/sinews	
13.	Do you have adequate facilities for cleaning and disinfecting the containers of receptacles in which raw bones are received and the vehicles in which they are transported?	
14.	Do you maintain record of cleaning as per **Annexure B2**	
15.	Does the vehicle carrying srm free raw bones supplied to bone mill bear the label "SRM free"	
16.	are you in a position to provide certificate as per **Annexure B-3** required under the executive instructions for transportation of material	
17.	Do you provide uniform, hand gloves, shoes head wears and mask to your workers	

Check List for Bone Mills

Sl No.	Clauses	Remarks
1.	Production capacity for crushed bones: (per month in m.t)	
2.	Do you maintain relevant record as per executive instructions to trace the source	
3.	Do you maintain cleaning record as per **Annexure- B-4**	
4.	Do you have separate premises and equipments for receipt, processing and storage of SRM free bones and normal bones (if applicable)	
5.	Whether raw bones are derived from healthy animals slaughtered in a slaughterhouse	
6.	Are you using new or sound (good condition)non-contaminated used bags for supplying crushed bones to Domestic ossein & gelatine plants	
7.	Whether you have been maintaining record as per **Annexure- B5, B6 and B7** of the executive instructions for a minimum period of past 2 months (for new applicants)	
8.	Hygiene requirements for bone mills	
9.	Do you have hard, smooth, cracks free	

	washable floor to store the raw bones.	
10.	Do you have covered building to store crushed bones?	
11.	are the walls properly plastered and painted	
12.	Do you have adequate covered place to receive raw bones	
13.	Do you provide uniform, hand gloves, shoes head wears and mask to your workers	
14.	Do you have hygienic lavatories, wash basins with running water, and changing rooms for staff	
15.	Does your establishment have adequate arrangement for protection against pests and birds	
16.	Do you have a drainage facility to meet hygiene requirements	
17.	Do you have adequate facility for cleaning and disinfecting the equipment, Containers and vehicles carrying bones?	
18.	Do you take precautions to avoid any risk of propagation of pathogens during sorting and storage	
19.	Do you have documented pest control program against, rodents, or other vermin such as insects, rats, cockroaches	
20.	Do you have established and Documented cleaning procedure for all parts of the premises	
21.	Do you take necessary measures to prevent insect in the bones	
22.	Have you put in place, implemented and maintained a permanent written procedure based on haccp principles consisting the following as applicable	
23.	(a)Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; (b)Identifying 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 (c)Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (d) Establishing and implementing effective	

	monitoring procedures at critical control points (e) Establishing corrective actions when monitoring indicates that a critical point is not under control; (f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and (g) Establishing Documents and records commensurate with the nature and size of the bone mill to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f)	

** ref definition in the Indian standards of SRM

DECLARATION

I,..... partner/ proprietor/ Director of m/s.....do hereby declare that the above information is complete and correct and that i agree to abide by the conditions and standards laid down in the executive instructions from time to time. I also declare that if the production figures are found to be incorrect my plant approval certificate may be cancelled.

Signature Of Applicant

Place:

Name

Date:

Address

Stamp

**

Indian standards for SRM based on India 's Negligible BSE status is as follows:

1.As per Article 11.5.15 of the Terrestrial Animal Health Code of OIE (2011) no SRM is required to be excluded if gelatine prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biological, or medical devices came from a country posing a negligible BSE risk.

Since India has been accorded Negligible BSE Status by OIE (at the 78th General Session of OIE held in Paris from 23 to 28 May 2010) no tissues are required to be

excluded from bovine bones derived from animals born, reared and slaughtered in India.

2. However all Or any of the following SRM may be removed as per contractual specifications:

a. The skull excluding the mandible and including the brain, eyes and the spinal cord

b. the vertebral column excluding the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia.

c. the tonsils, the intestines from the duodenum to the rectum and the mesentery of animals of all ages

d. the lymph nodes, Spleens, Corpus pineales, duramaters, placentas, cerebral fluids, pituitaries, thymus and adrenal glands .

3. For meeting of the above requirements mentioned in para (a) to (d) it is mandatory to maintain appropriate records and separate crushers & the respective storage areas to avoid any cross contamination.

Annexure B-1

FORMAT OF CERTIFICATE OF ORIGIN CUM HEALTH CERTIFICATE REQUIRED TO ACCOMPANY RAW BONE SUPPLIES TO INDEPENDENT BONE COLLECTION CENTERS, COLLECTION CENTRE-CUM-BONE MILLS AND RENDERING PLANTS

Document No.:

Date:

Type of Products: Raw Bovine Bone
Type of Packaging: Bulk

.....tons raw bones carried in Truck No....., belonging to Mr./M/s..... has originated from butcher shops detailed below falling under slaughter house/s located at .....These bones have been produced from healthy bovine animals born and bred in India only, and fit for human consumption. This consignment has been sold/dispatched to M/s.....(Name and address of consignee)

.....

Name of butcher shops	Quantity (Kg)	License No.
1.		
2.		

Signature
Name and address of consigner:

Signature of State Govt. Veterinary Officer
Name
Address
Official stamp

(Note : This Certificate should be maintained at the bone collection centre.)

Raw Bones supplied direct to Bone Mills/Rendering Plants by Meat packing establishments / Slaughter houses.

The Bone Millers/Rendering Plants buying raw bones from meat packing establishments / slaughter houses will obtain a letter at least once in a year from such establishments certifying that they only process bones of healthy slaughtered bovine animals fit for human consumption which were born and bred in India.
The raw bones procured directly from such meat packing establishments / slaughterhouses must be accompanied with bills /challans/documents mentioning quantity.

Annexure B-2

DETAILS OF CLEANING OF TRANSPORTATION VEHICLES AND COLLECTION CENTRE

Name of Collection Centre:

CLEANING OF TRANSPORTING VEHICLE					CLEANING OF COLLECTION CENTRE		
Date	Supplier	Vehicle No.	Driver's Signature	Remark	Date of cleaning	Signature of Supervisor	Remarks

Annexure B-3

Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY DESPATCHES OF SRM FREE /NORMAL BONES FROM INDEPENDENT BONE COLLECTION CENTRE TO BONE MILLS/RENDERING PLANTS

1. Certificate sl. No. And date :

2. Name of establishment :

3. Address :

4. Registration no.
Issued by CAPEXIL :

5. Name and address of consignee :

6. Quantity :

7. Place of origin of material (source of supply: I.e slaughter house/meat processing plant/ Butcher shop/authorized agent) (as per details at Sr. no. ..... of page no. ..... of register as per Annexure –B5)

8. Name of the transporter :

This is to certify that the above consignment of raw bone has originated from a slaughterhouse and from healthy bovine animals whose carcasses have been found fit for human consumption following ante and post mortem inspection , which were born and bred in India and necessary records are being maintained by us in register as per **Annexure B-5**

Signature

Name

Stamp

Annexure B-4

DETAILS OF CLEANING OF PLANT AND MACHINERY TO BE MAINTAINED BY THE APPROVED ESTABLISHMENT IN BOUND REGISTER

Name of the approved Establishment :

Date of Cleaning	Cleaning Activities undertaken	Signature of Supervisor	Remarks If any

Annexure B-5

FORMAT OF RECORD TO BE MAINTAINED BY INDEPENDENT BONE COLLECTION CENTRES IN A BOUND REGISTER

NAME OF THE ESTABLISHMENT
REGISTRATION NO.ISSUED BY CAPEXI

RECEIPT (INPUT)						ISSUE (OUTPUT)					
Date of Receipt	Document No. of Annexure-B1	QUANTITY (Kg)			SOURCE OF SUPPLY (Name & addresses of the relevant source should be indicated against this column).	Date	Quantity (kg)		To whom Despatched	Deli-Very challan no.& date	Certificate no. As per Annexture-B3 (only For SRM Free Bones)
		Qty. received	SRM	SRM Free			SRM Free	SRM*			
	Monthly Total	Balance Brought forward									

Annexure B-6

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RENDERING PLANT IN A BOUND REGISTER FOR SRM FREE BONES

NAME OF THE ESTABLISHMENT:
PLANT APPROVAL/ REGISTRATION NO. ISSUED BY CAPEXIL

INPUT (RECEIPT) SRM FREE BONES					PRODUCTION				ISSUE				
Dt of receipt	Quantity SRM Free (Kg.)	Source of Supply & Document no.of **Annexture B-1**	Regn. No. of Capexil	Certificate No. as per **Annexture B-3**	Date	Quantity	Lot No.	Cumulative Total	Invoice No.	Qty.	Lot No.	Supplied to	Certificate No. as per **Annexture B-8/** Health Certificate No. & date
	Balance B/F					Balance B/f.							
	Monthly Total												

Note: Buyer's name, contract No and date, quantity and kind of SRM removed to be furnished

Annexure B-7

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RENDERING PLANT IN A BOUND REGISTER FOR NORMAL BONES

Name of the Establishment:
Plant approval/ registration No. issued by CAPEXIL :

Receipt (Input)				Issue (output)		
Date of Receipt & Document no.of **Annexure-B-1**	Qty of raw bones received (Kg.)		Source of Supply	Crushed bones Supplied to	Quantity Sold (Kg.)	Invoice No. & Date/Health Certificate No. & date
	Quantity					
	Balance Brought forward					
Monthly Total						

Annexure B-8
Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY NORMAL CRUSHED BONES /SRM FREE CRUSHED BONE DESPATCHES FROM BONE MILLS / RENDERING PLANTS TO OSSEIN AND GELATINE ESTABLISHMENTS / SUPPLY TO MERCHANT EXPORTERS**

1. Certificate sr. No. And date :
2. Name of establishment :
3. Address
4. Certificate of approval/ registration no issued by CAPEXIL
5. Place of origin of material (as per lot no., page. No. of register as per **AnnextureB-6** for SRM free bones only)
6. Date of manufacture
7. Invoice no. & date
8. Quantity (net weight in tonnage)
9. Type of packaging & number of packages
10. Name of the transporter
11. Name and address of consignee

This is to certify that the above consignment derived from raw bones of healthy slaughtered animals of Indian origin whose carcasses have been found fit for human consumption following ante and post mortem inspection. During the process of transportation, storage and crushing all necessary precautions have been taken to avoid cross contamination. Necessary records are being maintained by us in register as per **Annexure- B-6 & B-7** of the check list for collection centre cum bone mills.

** The above consignment does not contain SRM namely the following:
(SRM removed as per the contract may be mentioned here)
** delete if not applicable

Signature

Name & address of consigner:
Stamp

Appendix C

REQUIREMENTS AND CHECK LIST FOR APPROVAL OF RENDERING PLANTS

REQUIREMENTS FOR RENDERING PLANTS

Sl No.	Clauses	Remarks
	The establishment shall have	
1.	No stagnant water or signs of any rodent harbourage inside the premises	
2.	Roads tarred or turfed	
3.	Adequate covered place to receive raw bones	
4.	Hard, smooth and washable floor to store the raw bones	
5.	Proper drainage facility in the raw bone storage area	
6.	Permanent structure to store Crushed Bones	
7.	The walls smooth, light colour and without crevices	
8.	Waterproof and cleanable switches and other installation of the wall	
9.	Adequate lavatories, changing rooms and wash basins for staff and these shall be away from the main processing portions	
10.	Adequate arrangement for protection against pests such as insects, rodents and birds	
11.	Drainage facility to meet hygiene requirements	
12.	Adequate facility for cleaning and disinfecting the container vehicles carrying bones	
13.	Adequate facilities for cleaning and disinfecting the containers or receptacles in which raw bones are received and the vehicles in which they are transported	

CHECK LIST FOR RENDERING PLANTS

Sl No.	Clauses	Remarks
	The establishment shall have	
1.	Name Of The Establishment A. Address (Works) B. Telephone No. C. Fax No. D. Emails	
2.	A. Address (Office) B. Telephone No. C. Fax No. D. Emails	
3.	SSI approval no. /licence no	
4.	Production capacity of gel bones (per month in m.t)	
5.	Do you maintain relevant record as per executive instructions to trace the source	
6.	Do you maintain cleaning record as per **Annexure C-1**	
7.	Do you have separate premises and equipments for receipt, processing and storage of srm free bones and normal bones.(if applicable)	
8.	Whether raw bones are derived from healthy animals slaughtered in a slaughterhouse.	
9.	Are you using new or sound(good condition) non-contaminated used bags for supplying gel bones to domestic ossein & gelatine plants	
10.	Whether you have been maintaining record as per **Annexure C-2,C-3 and C-4** of the executive instructions for a minimum period of past 2 months (for new applicants)	
11.	Hygiene requirements for bone mills:	
12.	Do you have hard, smooth, cracks free washable floor to store the raw bones	
13.	Do you have covered building to store gel bones	
14.	Are the walls properly plastered and painted	
15.	Do you have adequate covered place to receive raw bones	
16.	Do you provide uniform, hand gloves, shoes head wears and mask to your workers	
17.	Do you have hygienic lavatories, wash	

	basins with running water, and changing rooms for staff.	
18.	Does your establishment have adequate arrangement for protection against pests and birds	
19.	Do you have a drainage facility to meet hygiene requirements	
20.	Do you have adequate facility for cleaning and disinfecting the equipments, containers and vehicles carrying bones?	
21.	Do you take precautions to avoid any risk of propagation of pathogens during sorting and storage?	
22.	Do you have documented pest control program against, rodents, or other vermin such as insects, rats ,cockroaches	
23.	Do you have established and documented cleaning procedure for all parts of the premises	
24.	13 Do you take necessary measures to prevent insects in the bones	
25.	Have you put in place, implemented and maintained a permanent written procedure based on HACCP principles consisting the following as applicable a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; b) Identifying 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 c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; d) Establishing and implementing effective monitoring procedures at critical control points; e) Establishing corrective actions when monitoring indicates that a critical control point is not under control; f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and g) Establishing documents and records	

	commensurate with the nature and size of the bone mill to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f)	
27.	Have you mentioned time and temperature in HACCP programme:	

Declaration

I,..... Partner/ proprietor/ Director of M/S.....do hereby declare that the above information is complete and correct and that i agree to abide by the conditions and standards laid down in the executive instructions from time to time. I also declare that if the production figures are found to be incorrect my plant approval certificate may be cancelled.

Date

Place

Signature of Applicant

Name& Address

Stamp

Annexure C-1

DETAILS OF CLEANING OF PLANT AND MACHINERY TO BE MAINTAINED BY THE APPROVED ESTABLISHMENT IN BOUND REGISTER

Name of the approved establishment :

Date of Cleaning	Cleaning Activities undertaken	Signature of Supervisor	Remarks If any

Annexure C-2

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRES IN A BOUND REGISTER

Name of the establishment:

Registration no. Issued by CAPEXIL :

RECEIPT (INPUT)						ISSUE (OUTPUT)					
Date Of Receipt	Document No. of **Annexure-C-7**	QUANTITY (Kg)			Source of supply (Name & addresses of the relevant source should be indicated against this column).	Date	Quantity (kg)		To whom Despatched	Deli-Very challan no.& date	Certificate no. As per **Annexure-C-5** (only For Srm Free Bones)
		Qty. received	SRM	SRM Free			SRM Free	SRM*			
	Monthly Total	Balance Brought forward									

AnnextureC-3

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RENDERING PLANT IN A BOUND REGISTER FOR SRM FREE BONES

Name of the establishment
Plant approval/ registration no. Issued by CAPEXIL

INPUT (RECEIPT) SRM FREE BONES					PRODUCTION				ISSUE				
Date Of receipt	Quantity SRM Free (Kg.)	Source of Supply & Document no.of **Annexure-C-7**	Regn. No. of Capexil	Certificate No. as per **Annexure-C-5**	Date	Quantity	Lot No.	Cumulative Total	Invoice No.	Qty.	Lot No.	Supplied to	Certificate No. as per **Annexure C-6**/Health Certificate No. & date
	Balance B/F					Balance B/f.							
	Monthly Total												

Note: Buyer's name, contract No and date, quantity and kind of SRM removed to be furnished

Annexure C-4

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RENDERING PLANT IN A BOUND REGISTER FOR NORMAL BONES

Name of the Establishment:
Plant approval/ registration No. issued by CAPEXIL :

Receipt (Input)				Issue (output)		
Date of Receipt & Document no.of **Annexure-C-7**	Qty of raw bones received (Kg.)		Source of Supply	Crushed bones Supplied to	Quantity Sold (Kg.)	Invoice No. & Date/Health Certificate No. & date
	Quantity					
	Balance Brought forward					
Monthly Total						

Annexure- C-5

Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY DESPATCHES OF SRM FREE/ NORMAL BONES FROM COLLECTION CENTERS TO BONE MILLS/ RENDERING PLANTS

1. Certificate sr. No. And date
2. Name of establishment
3. Address
4. Certificate of approval/ registration no issued by CAPEXIL
5. Name and address of consignee
6. Quantity
7. Place of origin of material (Source of supply i.e. slaughter House/ meat processing plant Butcher shop/ authorized agent) (as per lot no. ..... page. No. ..... of register as per **Annexture-C-2** for SRM free bones only)
8. Name of the transporter

This is to certify that the above consignment raw bones has originated from a slaughter house and from healthy bovine animal whose carcasses have been found fit for human consumption following ante and post mortem inspection. Which were born and bred in India and necessary record are being maintained by us in register as per **Annexture-C-2**

Signature

Name & address of consigner:

Stamp

Annexure C-6
Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY NORMAL CRUSHED BONES /SRM FREE CRUSHED BONE DESPATCHES FROM BONE MILLS / RENDERING PLANTS TO OSSEIN AND GELATINE ESTABLISHMENTS / SUPPLY TO MERCHANT EXPORTERS**

1. Certificate No. and date
2. Name of establishment
3. Address
4. Certificate of approval/ registration no.
5. Issued by CAPEXIL
6. Place of origin of material

   (as per lot no. .....
   Page. No. .....
   of register as per **Annexure-C3)**
   for SRM free bones only)
7. Date of manufacture
8. Invoice no. & date
9. Quantity (net weight in tonnage)
10. Type of packaging & number of packages
11. Name of the transporter
12. Name and address of consignee

This is to certify that the above consignment derived from raw bones of healthy slaughtered animals of Indian origin whose carcasses have been found fit for human consumption following ante and post mortem inspection. During the process of transportation, storage and crushing all necessary precautions have been taken to avoid cross contamination. Necessary records are being maintained by us in register as per **AnnextureC-3 and C-4** of the check list for collection centre cum bone mills

** The above consignment does not contain srm namely the following: (srm removed as per the contract may be mentioned here)
** delete if not applicable

Signature

Name & address of consigner:

Stamp

Annexure C-7

FORMAT OF CERTIFICATE OF ORIGIN CUM HEALTH CERTIFICATE REQUIRED TO ACCOMPANY RAW BONE SUPPLIES TO INDEPENDENT BONE COLLECTION CENTERS, COLLECTION CENTRE-CUM-BONE MILLS AND RENDERING PLANTS

Document No.:

Date:

Type of Products: Raw Bovine Bone
Type of Packaging: Bulk

.....tons raw bones carried in Truck No....., belonging to Mr./M/s..... has originated from butcher shops detailed below falling under slaughter house/s located at .....These bones have been produced from healthy bovine animals born and bred in India only, and fit for human consumption. This consignment has been sold/dispatched to M/s.....(Name and address of consignee)

.....

Name of butcher shops	Quantity (Kg)	license No.
1.		
2.		

Signature
Name and address of consigner:

Signature of State Govt. Veterinary Officer
Name
Address
Official stamp

(Note : This Certificate should be maintained at the bone collection centre.)

Raw Bones supplied direct to Bone Mills/Rendering Plants by Meat packing establishments / Slaughter houses.

The Bone Millers/Rendering Plants buying raw bones from meat packing establishments / slaughter houses will obtain a letter at least once in a year from such establishments certifying that they only process bones of healthy slaughtered bovine animals fit for human consumption which were born and bred in India.
The raw bones procured directly from such meat packing establishments / slaughterhouses must be accompanied with bills /challans/documents mentioning quantity.

Appendix D

REQUIREMENTS AND CHECK LIST FOR APPROVAL OF SLAUGHTER HOUSE INTEGRATED WITH ESTABLISHMENT

Sl No.	Clauses	Remarks
1.	The construction, layout and equipment of slaughterhouse shall comply with the following	
2.	Slaughterhouses shall have adequate and hygienic lairage facilities or climate permitting, waiting pens that are easy to clean and disinfect. These facilities shall be equipped for watering the animals and, if necessary, feeding them.	
3.	They shall also have separate facilities for sick or suspect animals to avoid contamination of other animals.	
4.	The lay out of the lairage shall facilitate ante-mortem inspections	
5.	The floor shall be water proof, easy to clean and disinfect and laid Down in such a way as to facilitate the drainage of the water easily or provided with equipment to remove water. There shall be no water stagnation on the floor.	
6.	The walls of the meat handling area shall be durable and have smooth surface which are easy to clean, and impermeable waterproof and light colored.	
7.	Walls shall be free from projection, all pipes and cables shall be neatly covered. Wall to wall and wall to floor junctions shall be rounded off to facilitate proper cleaning.	
8.	Ceiling shall be free from cracks, open joints and shall be smooth, free from rafters other than carcasses hanging devices, waterproof, light colored and easy to clean	
9.	All Doors and windows shall be durable and made of corrosion resistant material and shall be of self-closing type and easy to clean with fly proofing arrangements.	
10.	All entry points shall be provided with Feet washing pit of suitable size. The pit shall be provided with water and disinfectant. The pit–water shall be changed at frequent interval.	
11.	Instruments and working equipments such as tables, containers, conveyor belts, knives and other utensils used shall be of smooth	

	corrosion resistant materials, easy to clean, wash with water and disinfectants	
12.	They must have facilities for disinfecting tools with hot water supplied at not less than 82 °C, or an alternative system having an equivalent effect.	
13.	The equipment for washing hands used by the staff engaged in handling exposed meat must have taps designed to prevent the spread of contamination. There must be lockable facilities for the refrigerated storage of detained meat and separate lockable facilities for the storage of meat declared unfit for human consumption	
14.	To avoid contaminating meat, the slaughterhouses must have a) Sufficient number of rooms, appropriate to the operations being carried out; b) Separate room for the emptying and cleaning of stomachs and intestines; c) Installations that prevent contact between the meat and floors, walls and fixtures; and d) Slaughter lines (where operated) that are designed to allow constant progress of the slaughter process and to avoid cross-contamination between the different parts of the slaughter line. Where more than one slaughter line is operated in the same premises, there must be adequate separation of the lines to prevent cross-contamination.	
15.	**Slaughter Hygiene**	
16.	Live animals brought in to the slaughter house shall comply with the followings: i. Only live, healthy animals shall be brought for slaughter except that met with an accident. ii. During their collection and transportation, the animals shall be handled carefully without causing unnecessary distress. iii. Animals showing symptoms of	

	disease or originating in herds known to be contaminated with agents of public health importance may only be transported to the slaughterhouse when the competent authority so permits.	
17.	After arrival in the slaughterhouse, the slaughter of the animals must not be unduly delayed.	
18.	Animals must be clean.	
19.	Every animal to be slaughtered shall undergo ante-mortem inspection by the veterinarian.	
20.	Stunning, bleeding, skinning, evisceration and other dressing shall be carried out without undue delay and in a manner that avoids contaminating the meat	
21.	Post-mortem inspection of all slaughtered animals shall be carried in accordance with the instructions issued by the competent authority.	
22.	After post-mortem inspection: 1. parts unfit for human consumption must be removed as soon as possible from the clean sector of the establishment; 2. (b) Meat detained or declared unfit for human consumption and inedible by- products must not come into contact with meat declared fit for human consumption; and 3. (c) Viscera or parts of viscera remaining in the carcass, except for the kidneys, must be removed entirely, if possible, and as soon as possible, unless otherwise authorized by the competent authority.	
23.	After inspection and evisceration, slaughtered animals must be cleaned and chilled to not more than 4 °C as soon as possible, unless the meat is cut while warm.	
24.	The carcasses must not contain visible fecal contamination and other dressing must be carried out without undue delay and in a manner that avoids contaminating the meat.	
25.	Carcasses and offal must not come into contact with floors, walls or work stands	

Declaration

I,..... Partner/ proprietor/ director of M/s.....do hereby declare that the above information is complete and correct and that i agree to abide by the conditions and standards laid down in the executive instructions from time to time. I also declare that if the production figures are found to be incorrect my plant approval certificate may be cancelled.

Date
Place
Signature of applicant
Name& address
stamp

Appendix E

REQUIREMENTS AND CHECK LIST FOR APPROVAL OF OSSEIN AND GELATINE PLANTS

Requirements for approval of Ossein plants

Sl No.	Clauses	Remarks
	The establishment shall have following facilities	
1.	Defined cartilage and clean area	
2.	No stagnant water or signs of any rodent harbourage inside the premises	
3.	Roads tarred or turfed	
4.	Designed in such a way to prevent accumulation of dirt, contact with toxic materials, the shedding of particles into food and formation of condensation or undesirable moulds on the surfaces	
5.	Separate covered area to receive Crushed Bones, which is easy to clean and disinfect	
6.	Adequate lavatories, changing rooms and wash basins for staff	
7.	Separation between receiving area, processing area and storage of finished products	
8.	Adequate provisions for degreasing and for receiving degreased and dried bone	
9.	Sufficient production capacity for hot water / steam for processing of Crushed Bones	
10.	Measuring equipment to monitor temperature against time, if necessary, pressure at critical points with adequate safety system to prevent insufficient heating	
11.	Adequate storage facility for cleaning materials and disinfectants	
12.	Adequate drainage facility to avoid risk of contamination	
13.	Waste water disposal system meeting the central / state pollution control board requirements	
14.	Well-equipped in-house laboratory to conduct analyses or make use of services of external laboratories approved by Central Competent Authority	
15.	Established control for movement of personnel between clean and unclean area	
16.	Documented pest control program	
17.	Hygiene control program, which include inspections of environment, equipment and inspection schedules and its results	

	maintained for at least two years	
18.	Storage area for storing of finished product to preclude contamination	
19.	Established and documented cleaning procedure for all parts of the establishment	
20.	System to dispose any material suspected or known to be contaminated	
21.	Provision for separately storing the Ossein intended and not intended for 22. human consumption and are identifiable during production and transportation	

Requirements for approval of gelatine plants

Sl. No.	Clauses	Remarks
A	**Raw Material**	
1.	For the production of Gelatine, any of the following raw material / materials shall be used: a) Ossein; b) Crushed bones c) Hides and skins of bovine animals, provided they have not undergone any tanning process; d) Pig skins; e) Poultry skin; f) TenDons and sinews; and g) Fish skin, scales and bones.	
2.	Ossein shall be procured from approved ossein establishments, crushed bones from bone mills and other raw materials from collection centres registered with CAPEXIL or any other authority designated for the purpose by the Central Competent Authority.	
3.	3 Raw material procured by the establishment shall be accompanied by a Document containing their origin and related information essential to maintain traceability	
B	**Hygiene Requirements**	
4.	have a covered space to receive the raw material for processing gelatine	
5.	have a clean and unclean sector, adequately separated	

6.	be constructed in such a way that it is easy to clean and disinfect	
7.	have smooth floor surface and the floor laid Down in such a way so as to facilitate the draining of liquids	
8.	have adequate lavatories, changing rooms and wash basins with hand washing facilities with running water;	
9.	have appropriate arrangements for protection against pests, such as insects, rodents and birds	
10.	have a waste disposal system	
11.	have its own laboratory or make use of the service of an external laboratory approved by the Central Competent Authority to carry out necessary analysis	
12.	ensure that persons working in un-cleaned sector Do not enter the clean sector without changing their working clothes and footwear	
13.	ensure that equipment and utensils are not taken from the un-cleaned sector to clean sector without cleaning and disinfection	
14.	ensure that plant hygiene is controlled through regular inspection of the environment and equipments;	
15.	ensure that installations and equipments are kept in good state of repair and measuring equipments are calibrated at regular intervals	
C	**Production process:** The production process of gelatine shall ensure that	
16.	All bone material is crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4% and pH<1.5) over a period of at least 2 days. This treatment shall be followed either by i) An alkaline treatment of saturated lime solution (pH>12.5) for a period of at least 20 days with a heat treatment step of 138 °C minimum during at least four seconds; or ii) An acid treatment (PH<3.5)during ten hours minimum with a heat treatment step of 138-140 °C minimum at least four seconds, or iii) Any approved equivalent process.	
17.	Other raw materials are subjected to a treatment with acid or alkali, followed by one or more rinses. The pH shall be adjusted	

	subsequently. Gelatine shall be extracted by heating one or more times in succession, followed by purification by means of filtration and heat treatment.	
18.	Gelatine, whether intended for human consumption or not intended for human consumption, is produced and stored in the same establishment provided that the raw materials and production process comply with requirements applying to gelatine intended for human consumption.	
19.	The use of preservatives other than sulphur dioxide / hydrogen peroxide is prohibited.	
D	**Requirements for finished products:** Each production batch of gelatine shall be subjected to tests to ensure that it meets the following criteria	
20.	**Microbiological criteria:** Salmonella-	 Absent in 25 gms
21.	**Residues**	
	Element	**Limit**
	Arsenic (As)	1 ppm
	Lead (Pb)	5 ppm
	Cadmium (Cd)	0.5 ppm
	Mercury (Hg)	0.15 ppm
	Chromium (Cr)	10 ppm
	Copper (Cu)	30 ppm
	Zinc (Zn)	50 ppm
	Sulphur dioxide (SO_2)	50 ppm
	Hydrogen Peroxide ($H_2 O_2$)	10 ppm
E	**Identification**	
22.	The processor shall ensure that Gelatine intended for human consumption is kept separately and is identifiable during production, storage and transportation. During storage and transportation, a label	

	shall be affixed / attached to the container, carton or other packaging material, clearly indicating whether it is 'intended for human consumption' or 'not intended for human consumption'. Packages containing Gelatine fit for human consumption shall also indicate the date of minimum durability	
23.	Each export package shall be legibly and indelibly marked with the following: I. Name and address of establishment with approval number; II. Name and address of exporter, if different from the establishment; III. Batch or lot number; IV. Year, month of processing or manufacturing; V. Date of minimum durability; VI. Gross weight and net weight; VII. GELATINE INTENDED FOR HUMAN CONSUMPTION" or "GELATINE SUITABLE FOR ANIMAL CONSUMPTION / TECHNICAL PURPOSES", depending upon the end use; and VIII. Product of India.	
F	**Gelatine made from fish scales/fish skin /fish bones for export production**	
24.	The facility manufacturing Gelatine from fish scales/fish skin /fish bones for export production shall procure fish scales/fish skin /fish bones only from fish processing establishments approved /registered by EIA(Export Inspection Agency)/ MPEDA(Marine Products Export Development Authority)	
25.	Fish scales/fish skin /fish bones procured from EIA/ MPEDA approved establishment shall be accompanied by Certificate of origin as per the format given in **AnnextureE-1** in the check list for Establishments manufacturing Ossein & Gelatine and self certified copy of valid certificate of approval issued by the EIA/ MPEDA	
26.	Fish scales/fish skin /fish bones procured from abroad shall be accompanied by Certificate of origin and Health Certificate and other document if any as per the import policy.	

Check list for approval of Ossein and Gelatine plants

Sl No.	Clauses	Remarks
1.	Name of the Approved Establishment a. Address (Works) b. Telephone No. c. Fax No. d. Email	
2.	a.Address (Office) b. Telephone No. c. Fax No. d. Emails	
3.	Factory Approval /License No	
4.	Products/Capacity for which facilities exists A. Ossein MT/annum B. Gelatine MT/annum	
5.	Technical facilities that exist in the processing plant to process the products mentioned in Sl.No.5 above	
	OSSEIN	
6.	Do you purchase Crushed Bones/gel bones only from the approved Bone Mills	
7.	a) Do you also purchase Bones from Non-approved Bone Mills b) If yes, Do you segregate Bones of non approved Bone Mills throughout the period of receipt, storage Processing and dispatch and record thereof Maintained as per **Annexure E-2**	
8.	Hygiene requirements for Ossein	
9.	Have you put in place, implemented and maintained a permanent written procedure based on HACCP principles as applicable consisting the following (a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels (b) Identifying 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 (c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;	

	(d) Establishing and implementing effective monitoring procedures at critical control points (e) Establishing corrective actions when monitoring indicates that a critical control point is not under control; (f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;	
10.	Establishing Documents and records commensurate with the nature and size of the Ossein plant to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).	
11.	Are your personnel trained on hygiene system based on HACCP principles and record thereof maintained	
12.	Do you have separate covered area, which is easy to clean and disinfect to receive crushed bones?	
13.	Is there a separation between receiving area, processing area and storage of finished products?	
14.	Is your facility designed in such a way to prevent accumulation of dirt, contact with toxic materials, the shedding of particles into food and formation of condensation or undesirable moulds on the surfaces.	
15.	(a) Do you receive degreased bones (b) If not , Do you have the facility for degreasing	
16.	Do you provide Uniform, Hand gloves, Shoes Head wears and Mask to your workers	
17.	Is there gap between floor and the shutter of the entrance of your premises to prevent entry of rodents /pests.	
18.	Do you take necessary measures to prevent insects in the bones	
19.	Do you receive crushed bones in new or non-contaminated Sound(good condition) used bags	
20.	Does your plant have adequate arrangement or protection against pests and birds .	
	Processing requirements for Ossein	

21.	Do you have sufficient production capacity for hot water and steam for processing of animal by-products?	
22.	Do you have measuring equipment to monitor temperature, against time, if necessary pressure at critical points with adequate safety system to prevent insufficient heating?	
23.	Do you have adequate facilities for cleaning and disinfecting the containers or receptacles in which Ossein is received and the vehicles (including wheels) in which they are transported?	
24.	Do you have adequate storage facility for cleaning Materials and disinfectants.	
25.	Do you have a waste water disposal system meeting the local authority's requirements?	
26.	Do you have adequate drainage facility to avoid risk of contamination	
27.	Do you conduct analyses in own laboratory OWN/OUTSIDE/BOTH or make use of services of external accredited laboratory.	
28.	Do you have hygienic lavatories, changing rooms and wash basins for staff?	
29.	Do you have established control for movement of Personnel between clean and unclean area?	
30.	Do you have Documented pest control program	
31.	Do you have hygiene control program, which include inspections of environment and equipment and inspection schedules and its results maintained for at least two years?	
32.	Do you have storage area for storing finished Product to preclude recontamination?	
33.	Do you have established and Documented cleaning procedure for all parts of the premises?	
34.	Do you maintain the record of cleaning of facilities handling food products	
35.	Has your product undergone Acidulation with dilute Hydrochloric Acid (with min. conc. 4% at less than PH 1.5) for at least two days	
36.	Whether you have been maintaining Record as per **Annexure E-2 & E-3** of the Executive Instructions for minimum past 2	

	batches (For new applicants)	
37.	Please submit the description of the Process (including flow chart).	
	GELATINE	
38.	Do the conditions for the process for manufacture of Ossein to be used for Gelatine meet the above requirements	
39.	Does the Ossein undergo an alkaline treatment of saturated lime solution (pH>12.5) for a period of at least 20 days	
40.	Does the process involve sterilization Step of 138-140 degree C for min.4 Seconds	
41.	Do you use any preservative other than Sulphur dioxide/hydrogen peroxide	
42.	Whether you have been maintaining Record as per **Annexure E 3** for minimum Past 2 batches (For new applicants)	
43.	Do you maintain proper records for traceability	
44.	Do the packages containing Gelatine carry the words "Gelatine suitable for human consumption/ animal consumption/ technical Purpose and date of manufacturing"?	
45.	Whether Gelatine manufactured in your facility meets Microbiological Criteria and residue elements limits as mentioned in requirements for finished products.	
46.	Do you have a room for storing Wrapping and packaging materials	
47.	Do you have designated area for Wrapping / packaging of gelatine	
48.	Do you have system to dispose the Matter suspected or known to be contaminated	
49.	Do you use calibrated gauges to monitor continuous processing conditions? If yes Do you maintain records for at least two years?	
50.	Do you also manufacture gelatine from Fish scales/fish skin /fish bones	
51.	If yes do you procure Fish scales/fish Skin /fish bones only from fish processing establishments approved by EIA(Export Inspection Agency)/ MPEDA(Marine Products Export Development Authority)	
52.	Are these raw materials accompanied by Certificate of origin as per **Annexure E-1** and self-certified copy of valid certificate of Approval issued by the EIA/ MPEDA.	

53.	Whether you process imported scales, skin, and bones of fish origin and partially processed fishery products.	
54.	If yes whether you have obtained health certificate, certificate of origin from the importing country and other document if any as per the import policy.	
55.	Do you receive fish scales/fish skin /fish bones / hide cuttings in new or non-contaminated Sound (good condition) used bags	
56.	Whether you have been maintaining Record as per **Annexure E-4** for Processing hide cuttings And /OR as per **Annexure E-5** for processing fish scales/fish skin /fish bones furnished below (New applicants need to maintain these records for the past two batches)	
57.	**Specific Hygiene Requirements for gelatine** Have you put in place, implemented and maintained a permanent written procedure based on HACCP principles consisting the following as applicable. (a) Identifying any hazards that must be prevented, eliminated or reduced to acceptable levels; (b) Identifying 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. (c) Establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; (d) Establishing and implementing effective monitoring procedures at critical control points (e) Establishing corrective actions when monitoring indicates that a critical control point is not under control; (f) Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and (g) Establishing Documents and records commensurate with the nature and size of the Gelatine plant to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).	

58.	Have you mentioned Time and temperature in HACCP programme for sterilization?	
59.	Do you follow procedure, practices and methods to ensure that gelatine is produced, handled, packed, stored and Transported under appropriate hygienic conditions.	
60.	Do you have records for all cleaning taking place in the plant?	
61.	Do you have established and Documented Cleaning procedure for all parts of the premises?	
62.	Do you have pest and rodent control programme and records thereof maintained?	
63.	Do you have hygienic lavatories, changing Rooms	
64.	Whether adequate facilities are provided for Hand washing and drying .	
65.	Whether drainage facility is adequate to prevent Cross contamination	
66.	Whether adequate facilities are provided wherever necessary for cleaning and disinfecting equipments	
67.	Do you have the facility to provide potable water for manufacturing	
68.	Whether floors are in good condition and easy to clean	
69.	Do you have a system in place that a person suffering from a disease or afflicted with infected wounds, skin infections or diarrhoea report immediately and the person shall not be allowed to enter product handling area .	
70.	Do you comply with all the above requirements for storage and manufacture of Gelatine not intended for Human consumption also?	
71.	Do you provide distinctive identification mark for each batch of gelatine	
72.	Do you provide Uniform, Hand gloves, Shoes Head wears and Mask to your workers	
73.	Is there gap between floor and the shutter of the entrance of your premises to prevent entry of rodents /pests.	
74.	Does your plant have adequate arrangement for protection against pests and birds?	

DECLARATION

I,..... Partner/Proprietor/Director of M/s..... Do hereby declare that the above information is complete and correct and that I agree to abide by the conditions and standards laid down in the Executive Instructions from time to time

SIGNATURE OF APPLICANT

PLACE:

NAME

DATE:

ADDRESS

Annexure E-1

FORMAT OF CERTIFICATE OF ORIGIN REQUIRED TO ACCOMPANY FISH SCALES/FISH SKIN/BONES FROM FISH PROCESSING ESTABLISHMENTS TO GELATINE PLANTS

1. Document No.: Date:

2. Name & address of the Fish Processing Establishment.

3. Plant approval No. issued by
EIA/MPEDA

4. Type of Products: **Fish scales/fish skin /fish bones**

5. Type of Packaging:

This is to certify that

.....tons of fish scales/fish skin/fish bones carried in Truck No..... has been sold to M/S (Name and address of the gelatine plant) vide delivery challan No. dated..... /invoice No... Dated.....

Signature

Name of person

Seal

Annexure E-2

FORMAT OF RECORD TO BE MAINTAINED BY AN OSSEIN/GELATINE PLANT IN A BOUND REGISTER FOR PROCESSING NORMAL CRUSHED BONES FOR EXPORTS

Name of the establishment

Plant approval no. Issued by CAPEXIL

Receipt (input)					**Issue(output)**		
Date Of Receipt	Invoice No.	Qty. **(MT)**	Lot Nos.	Supplier's Name & address	Date of Charging Into Acidula Tion vat	Date Batch No.& quantity of Finished Product	Invoice No & Date Health certificate no & date

Annexure E-3

Format of record to be maintained by an Ossein / Gelatine Plant In a Bound Register for processing SRM FREE Bones for exports

Name of the establishment

Plant approval no.

. Issued by CAPEXIL

Receipt (input)					**Issue(output)**		
Date Of Receipt	Certificate No and date & invoice no. &date **(Annexture-E6)**	Qty. **(MT)**	Lot Nos.	Supplier's Name & address	Date of Charging Into Acidulation vat	Date Batch no. & quantity of Finished Product	Invoice No & Date & health certificate no & date

Annexure E-4

FORMAT OF RECORD TO BE MAINTAINED BY GELATINE PLANT IN A BOUND REGISTER FOR PROCESSING HIDE CUTTINGS FOR EXPORT PRODUCTION

Name of the establishment

Plant approval no.

Issued by CAPEXIL

Receipt (input)				Issue (output)		
Date of Receipt	Document no. of & Date **(Annexure-E-6)**	Quantity **(MT)**	Source of supply (name & addresses of Hide collection centre)	Date of charging for manufacturing	Date Batch No.& quantity of finished product	Invoice No &Health certificate no & date

Annexure E-5

FORMAT OF RECORD TO BE MAINTAINED BY GELATINE PLANT IN A BOUND REGISTER FOR PROCESSING FISH SCALES/FISH SKIN /FISH BONES

Name of the establishment

Plant approval no.

Issued by CAPEXIL

Receipt (input)				Issue (output)		
Date of Receipt	Document no. of &Date **(Annexure-E-1)**	Quantity**(MT)**	Source of supply (name & addresses of Processing centre)	Date of charging for manufacturing	Date Batch No.& quantity of finished product	Invoice No &Health certificate no & date

Annexure E-6

Original for Consignee
Duplicate copy for transporter
Triplicate for Consignor

FORMAT OF CERTIFICATE OF ORIGIN TO ACCOMPANY NORMAL CRUSHED BONES /SRM FREE CRUSHED BONE DISPATCHES FROM BONE MILLS / RENDERING PLANTS TO OSSEIN AND GELATINE ESTABLISHMENTS / SUPPLY TO MERCHANT EXPORTERS**

1. Certificate sr. No. And date
2. Name of establishment
3. Address
4. Certificate of approval/ registration no. issued by CAPEXIL:
5. Place of origin of material (as per lot no. page. No. of register as per **Annexure E-7** or SRM for bones only)
6. Date of manufacture
7. Invoice no. & date
8. Quantity (net weight in tonnage)
9. Type of packaging & number of packages
10. Name of the transporter
11. Name and address of consignee

This is to certify that the above consignment derived from raw bones of healthy slaughtered animals of Indian origin whose carcasses have been found fit for human consumption following ante and post mortem inspection. During the process of transportation, storage and crushing all necessary precautions have been taken to avoid cross contamination. Necessary records are being maintained by us in register as per **AnnexureE-7 &E-8** of the check list for collection centre cum bone mills

** the above consignment does not contain SRM namely the following:
(SRM removed as per the contract may be mentioned here)

** delete if not applicable

Signature

Name & address of consigner:

Stamp

Annexure E-7

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RENDERING PLANT IN A BOUND REGISTER FOR SRM FREE BONES

Name of the establishment:
Plant approval no. Issued by CAPEXIL

INPUT (RECEIPT) SRM FREE BONES					PRODUCTION				ISSUE				
Date Of receipt	Quantity SRM Free (Kg.)	Source of Supply & Document no.of Annexure E-9	Regn. No. of Capexil	Certificate No. as per Annexure E-6	Date	Quantity	Lot No.	Cumulative Total	Invoice No.	Qty.	Lot No:	Supplied to	Certificate No. as per Annexure E-6 /Health Certificate No. & date
	Balance B/F					Balance B/f.							
	Monthly Total												

Note: Buyer's name, contract No and date, quantity and kind of SRM removed to be furnished

Annexure- E-8

FORMAT OF RECORD TO BE MAINTAINED BY COLLECTION CENTRE-CUM-BONE MILL/RendERING PLANT IN A BOUND REGISTER FOR NORMAL BONES.

Name of the establishment:
Plant approval no. Issued by CAPEXIL :

Receipt (Input)				Issue (output)		
Date of Receipt & Document no.of Annexure-E9	Qty of raw bones received (Kg.)		Source of Supply	Crushed bones Supplied to	Quantity Sold (Kg.)	Invoice No. & Date/Health Certificate No. & date
	Quantity					
	Balance Brought forward					
Monthly Total						

Annexure E-9

FORMAT OF CERTIFICATE OF ORIGIN CUM HEALTH CERTIFICATE REQUIRED TO ACCOMPANY RAW BONE SUPPLIES TO INDEPENDENT BONE COLLECTION CENTERS , COLLECTION CENTRE-CUM-BONE MILLS AND RENDERING PLANTS

Document No.:

Date:

Type of Products: Raw Bovine Bone
Type of Packaging: Bulk

.....tons raw bones carried in Truck No....., belonging to Mr./M/s..... has originated from butcher shops detailed below falling under slaughter house/s located at .....These bones have been produced from healthy bovine animals born and bred in India only, and fit for human consumption. This consignment has been sold/dispatched to M/s.....(Name and address of consignee)

.....

Name of butcher shops	Quantity (Kg)	License No.
1.		
2.		

Signature
Name and address of consigner:

Signature of State Govt. Veterinary Officer
Name
Approval Number.
Address
Official stamp

(Note : This Certificate should be maintained at the bone collection centre.)

Raw Bones supplied direct to Bone Mills/Rendering Plants by Meat packing establishments / Slaughter houses.

The Bone Millers/Rendering Plants buying raw bones from meat packing establishments / slaughter houses will obtain a letter at least once in a year from such establishments certifying that they only process bones of healthy slaughtered bovine animals fit for human consumption which were born and bred in India.
The raw bones procured directly from such meat packing establishments / slaughterhouses must be accompanied with bills /challans/documents mentioning quantity.

(Note: Requirements of these documents is not applicable to integrated plant comprising slaughter houses, meat packing and rendering establishments)

Annexure 1

Format Of Application For Approval /Registration /Renewal Of Independent Bone/Hide Collection Centres, Collection Centres Cum Bone Mills, Rendering Plants, Integrated Slaughter Houses With Establishments, Establishments Manufacturing Crushed Bones, Ossein & Gelatine/ Approval/Registration For Additional Facilities / Activities Such As Additional Product, New Process Activities Etc.

1.	Name and address of the registered office along with Tel, fax no and email id	
2.	Date of establishment	
3.	Address of the processing facilities along with Tel, Fax no and email id	
4.	Factory licence number and date or SSI Regn no.,	
5.	A) products/ facility for which approval/registration is sought B) weather approval is sought for export to EU and / or non EU countries C) whether registration is sought for supply of crushed bones / gel bones/hide cuttings to ossein & gelatine plants to be used for production and export to EU and/ or Non EU countries.	
6.	Additional facilities / activities such as additional product, new process activities etc. Required to be included in the certificate of approval/registration. (if applicable)	
7.	Production capacity / month (product-wise)	
8.	Name(s) of the contact person(s) with phone numbers	1) 2) (two persons)
9.	Name and address of the owner/CEO of the processing plant/establishment, if he/they are different from the above contact person	
10.	Details of bank draft/cheque payable as	

	application fee: (draft/cheque should be in the name of CAPEXIL payable at Kolkata)	

DECLARATION

I,..... Partner/ Proprietor/ Director of M/s.....do hereby declare that the above information is complete and correct and that I agree to abide with the conditions and standards laid down in the Executive Instructions from time to time. I also declare that if the production figures are found to be incorrect my Certificate Of Approval may be cancelled.

We undertake that our facility meets all the requirements stipulated in the export of crushed bones, ossein and gelatine (quality control, inspection and monitoring) rules 2012 and also the other requirements specified by competent authority from time to time in the executive instruction.

PLACE :

DATE :
Seal

AUTHORISED SIGNATORY

Enclosures: An application shall be submitted along with the following documents, as applicable;

1. Demand draft or cheque as per **Annexure 3**
2. Attested / Certified copy of legal identity of the new facility.
3. Self-certified copy of the IE code
4. Copy of HACCP Manual
5. PCB certificate

Annexure 2

Address of CCA & CA

CENTRAL COMPETENT AUTHORITY

EXPORT INSPECTION COUNCIL OF INDIA

Export Inspection Council of India (Corporate Office) (Department of Commerce) (Ministry of Commerce & Industry, Government of India), 3rd Floor - NDYMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi – 110 001. Tel: +91 – 11 – 23341263 / 23748189 , 23365540 Fax: 011 - 23748024 E - mail: eic@eicindia.gov.in	**Export Inspection Agency-Mumbai** Aman Chambers - 4th Floor, 113, Maharshi Karve Road, Mumbai - 400 004. Tel: 022 - 2363 0311 / 2363 0312 / 2363 0113 Fax: 022 - 2368 3927 E – mail: eia-mumbai@eicindia.gov.in
Export Inspection Agency-Kolkata World Trade Centre, 14/1B Ezra Street, Kolkata - 700 001. Tel: +91-33 - 22355004 / 22352651 / 22352652 Fax :+91-33 - 22354562 E – mail: eia-kolkata@eicindia.gov.in	**Export Inspection Agency-Kochi** 27/1767 A, Shipyard Quarters Road, Panampilly Nagar (South),Kochi - 682 036 Tel: 0484 - 2314645 / 2316946 / 2316949 Fax: 0484 - 2316948 E – mail: eia-kochi@eicindia.gov.in
Export Inspection Agency-Delhi (Ministry of Commerce & Industry, Govt. Of India) Thakkar Bapa Smarak Sadan, 2nd Floor, Dr. Ambedkar Marg, (Link Road) (Behind Jhandewalan Metro Station) New Delhi - 110 055 Tel: 011 – 23626320/21/22/23/24/25/26/27 Fax: 23626328 E-mail: eia-delhi@eicindia.gov.in	**Export Inspection Agency-Chennai** 6th Floor CMDA Tower II, No: 1 Gandhi Irwin Road, Egmore, Chennai - 600 008 Tel: +91-44 - 2855 2841 / 42 Fax: + 91-44 - 2855 2840 E – mail: eia-chennai@eicindia.gov.in

COMPETENT AUTHORITY
CAPEXIL
(Ministry of Commerce & Industry, Government of India)
H.O.: "VANIJYA BHAVAN" (3RD FLOOR)
INTERNATIONAL TRADE FACILITATION CENTRE
1/1, WOOD STREET, KOLKATA-700 016.
PHONE: 033-2289-0524/25, 2289-1721/22/23/25
FAX : 033-2289-1724
Email: Capexil@capexil.in Web: www.capexil.com

NORTHERN REGION	**WESTERN REGION**
"VANDANA BUILDING" 11, TOLSTOY MARG, FLAT NO 4B, 4TH FLOOR, NEW DELHI-110 001. PHONE : 011-2335-6703, 237-1479,2375-2282 FAX : 011-2331-4486 e.: capexiln@bol.net.in, Capexil@bol.net.in	"COMMERCE CENTRE" 4TH FLOOR, BLOCK NO.D-17, TARDEO ROAD, MUMBAI-400 034. PHONE: 022-2352-3410, 2352-0084 FAX : 022-2351-6665 e.: capexilm@vsnl.com, capexilm@mtnl.net.in
SOUTHERN REGION	**EASTERN REGION**
" RASHEED MANSION" 408 (OLDE NO. 622) ANNA SALAI CHENNAI-600 006. PHONE : 044-2829-2310, 2829-4713 FAX : 044-2829-5386 e.: capexils@dataone.in	"VANIJYA BHAVAN" (3RD FLOOR) INTERNATIONAL TRADE FACILITATION CENTRE 1/1, WOOD STREET KOLKATA-700 016. PHONE : 033-2289-0524/25, 2289-1721/22/23/25 e.: rdero@capexil.in

FEE STRUCTURE

ANNEXURE 3

1. All fees are in Rs. & to be paid by demand draft / pay order.
2. Testing fee at EIA labs shall be as per EIC instructions.

Activity	Independent bone/ hide collection centres	Collection centres cum bone mills	Rendering plants	Integrated slaughter houses with establishments	Establishments manufacturing Ossein	Establishments manufacturing Gelatine
Assessment/Inspection	3000	3000	5000	5000	5000	5000
Original/Duplicate - Health/ Veterinary Certificate (intended for human consumption)*		1000	1000		5000	5000
Original/Duplicate - Health/ Veterinary Certificate (intended for Technical end use) *		500	500		2500	2500
Endorsement of any change in the Certificate of Approval	1000	1000	1000	1000	1000	1000
Issue of Duplicate Certificate of Approval	1000	1000	1000	1000	1000	1000
Merchant Exporter Approval	3000	3000	3000	3000	3000	3000

NOTE: The assessment fee is payable by demand draft/pay order in favour of CAPEXIL payable at Kolkata.

1.Fee for issuance of Health Certificate is payable to Central Competent Authority by demand draft/pay order in favour concerned Export Inspection Agency

2.No fee shall be payable for Health Certificate for export of bonafide samples not exceeding five kilograms net weight .

ANNEXURE 4

ASSESSMENT REPORT FORMAT TO BE USED BY THE ASSESSMENT PANEL OF EXPERT

Name of the Processing Establishment	
Representative of the establishment present at the time of Inspection	
Products	
Composition of Inspection Team	
Type of Inspection	New approval / Monitoring Visit / Casual Inspection
Date of Inspection	

Coverage of Inspection	As per applicable checklist given in Appendix A to E
Observations/Suggestions	
Sampling and Recording of evidence	If PAC finds SRM in the SRM free area they may draw samples and record evidence by taking photographs, etc. (wherever applicable as per the contract)
Recommendation of panel	Recommended / not recommended for approval Recommended / not recommended for renewal of approval Recommendation subject to fulfilment of deficiencies within 30 days.
Name, signatures with stamp of the authorized person of the inspecting establishment who was present at the time of inspection	

Name				
Designation				
Organisation				
Date				
place				

* Delete whichever is not applicable

Annexure 5

CERTIFICATE OF REGISTRATION FOR INDEPENDENT BONE /HIDE COLLECTION CENTRES

This is to certify that the Bone Collection Centre described below has been inspected by a Plant Approval Committee constituted by CAPEXIL and existing facilities are considered adequate to meet the relevant requirements as laid down in the Executive Instructions.

1.	Name of the Bone Collection Centre	
2.	Location of the Bone Collection Centre	
3.	Year of Establishment of Bone Collection Centre	
4.	Products for which Registered	RAW BONES , RAW HIDES , ETC
5.	Capacity of the Bone Collection Centre (mention Quantity which can be stored in the Collection Centre)	
6.	Bone Collection Centre's Approval No. &Date	
7.	Date of First approval	
8.	Date of Revalidation	
9.	Certificate valid up-to	

SIGANTURE
NAME
DESIGNATION

DATE
PLACE
SEAL

ANNEXURE 6

FORMAT OF REGISTRATION CERTIFICATE FOR COLLECTION CENTRE CUM BONE MILLS, RENDERING PLANT,INDEPENDENT HIDE COLLECTION CENTRES FOR SUPPLY OF CRUSHED BONES/GEL BONES/HIDE CUTTINGS TO DOMESTIC OSSEIN AND GELATINE PLANTS FOR EXPORT PRODUCTION

This is to certify that the establishment described below has been inspected by the plant approval committee constituted by CAPEXIL and existing facilities are considered adequate to meet the technical requirements as laid down in the executive instructions for domestic sale

Name & address of the establishment	
Location of the processing facility	
Date of establishment	
Products authorized for supply to ossein and gelatine plants to be used for production and export of ossein and gelatine to EU countries	
Capacity of each product product wise	
Registration no. & date	
Date of first registration	
Certificate valid up to	

Signature:

Name:

Designation:

Seal

Date

Place

ANNEXURE 6A

CERTIFICATE OF APPROVAL FOR COLLECTION CENTRE CUM BONE MILL, RENDERING PLANT, OSSEIN AND GELETINE PLANT.

This is to certify that the processing plant described below has been inspected by a Plant Approval Committee constituted by CAPEXIL and existing facilities are considered adequate to meet the relevant requirements as laid down in the Executive Instructions for export.

Name & address of the exporter location of the processing plant	
Date of establishment	
Products authorised for Exports **a)** Products authorised for exports to EU countries **b)** Products authorised for exports to non EU countries **c)** Products authorised for supply to ossein and gelatine plants to be used for production and export of ossein and gelatine to EU countries. **d)** Products authorised for supply to ossein and gelatine plants to be used for production and export of ossein and gelatine to non EU countries.	
Capacity of each product Product wise	
Plant approval no. & date	
Date of first approval	
Date of revalidation	
Certificate valid up to	

Date, Place and Signature:
Name,
Designation
Seal

ANNEXURE 7

(Format of non-approval letter)

No. / Date: ____

To

Dear Madam / Sir,

Sub: Non approval of independent collection centres / collection centres cum bone mills / rendering plants/integrated slaughter houses with establishments / establishments manufacturing crushed bones/Ossein & Gelatine

Ref: Your application dated

The Assessment Panel visited your facility, particulars of which are given below, for adjudging its suitability for approval as per Order and notification S.O. 725(E) & 726(E) both dated 3rd April,2012 for export of Crushed Bones, Ossein & Gelatine.

Name and location of the facility	Date of APE visit

The Assessment Panel has observed certain defects / deficiencies in your facilities, which are given in the duly signed attached Annexure. In view of the nature of defects / deficiencies, it is regretted that your facility cannot be approved at present.

You may, however, rectify all the defects / deficiencies, ensure that your facility fully meets the requirements for approval and apply for approval afresh.

Please acknowledge receipt.

Yours faithfully,

CAPEXIL

Encl: Annexure

Copy to:

1. The Officer In-charge, EIA _____
2. The Director (I&Q/C), EIC, New Delhi –110 001 – for kind information
3. Co-ordinating office of CAPEXIL New Delhi
4. Party file

ANNEXURE 8

PERMISSION TO PROCESS AND PACK CRUSHED BONES, OSSEIN AND GELATINE ON BEHALF OF MERCHANT EXPORTER

(To be typed on company letterhead)

To

CONCERNED REGIONAL OFFICE OF CAPEXEL- _____

Sir,

Sub: Request by facility for permission to process and pack Crushed Bones,/Gel Bones ,Ossein / Gelatine for export through merchant exporter.

Ref.: Approval Number of the unit _____

We request that permission may kindly be granted to us to process and pack Crushed Bones/,Gel Bones /,Ossein /Gelatine in our approved processing establishment for export by the following merchant exporter(s).

1. Name & Address of the merchant exporter(s)

2. Countries to which exports are proposed to be made and products for which registration is sought

3. Production capacity of the unit as fixed by Capexil

4. Capexil registration no. and validity of Merchant exporter

We hereby state that we, as approved processor, shall be responsible for the quality and safety of the processed and packed Crushed Bones,/Gel Bones ,Ossein / Gelatine 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 Capexil and assure that the production capacity fixed by Capexil for our establishment will not be exceeded at any time.

We also assure you that Crushed Bones,/Gel Bones ,Ossein / Gelatine 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 premises 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 :

Enclosure:

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 Capexil and EIC.
3. Certified true copy of Capexil registration given to the merchant exporter(s) concerned.

ANNEXURE 9

PERMISSION TO PROCESS AND PACK CRUSHED BONES,/GEL BONES, OSSEIN / GELATINE FOR EXPORT THROUGH MERCHANT EXPORTER

CONCERNED REGIONAL OFFICE OF CAPEXEL- _____

No. Date :

Dear Sir,

Sub.: Permission to process and pack Crushed Bones,/Gel Bones ,Ossein / Gelatine export through 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 Crushed Bones,/Gel Bones ,Ossein / Gelatine for export by merchant exporter: M/s. *(Name and address of merchant exporter)*, to any country including EU/Russia/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 processor)*, with approval No. .....) shall be responsible for the quality and safety of the Crushed Bones,/Gel Bones ,Ossein / Gelatine processed by it for export by the merchant exporter;

3. The approved processor shall ensure that the consignments of Crushed Bones,/Gel Bones ,Ossein / Gelatine 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 Crushed Bones,/Gel Bones ,Ossein / Gelatine products processed by it for the merchant exporter and such records shall be made available to the monitoring officials of the CAPEXIL, for verification.

5. The approved processor shall ensure that the CERTIFICATE FOR EXPORT issued by it in favour of the merchant exporter shall be counter signed by the concerned CAPEXIL Office.

6. The approved processor shall be responsible for obtaining health certificate for consignments prior to shipment.

7. The validity of the permission granted by CAPEXIL for processing and packing Crushed Bones,/Gel Bones ,Ossein / Gelatine 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 / validity of the registration as merchant exporter with CAPEXIL WHICHEVER IS EARLIER.

Please acknowledge receipt.

Yours faithfully,

In charge of
CAPEXIL

Copy to:

a) The Director, EIC, New Delhi-110001.
b) Coordinating office of CAPEXIL, New Delhi

ANNEXURE 10

WITHDRAWAL OF PERMISSION TO PROCESS AND PACK CRUSHED BONES/GEL BONES, OSSEIN / GELATINE THROUGH MERCHANT EXPORTER

To,

CONCERNED REGIONAL OFFICE OF CAPEXEL- _____

No. Date:

To,

Dear Sirs,
Sub: Withdrawal of permission to process and pack Crushed Bones,/Gel Bones ,Ossein / Gelatine through merchant exporter.

Ref: (1) Your letter No. dated .

(2) Our letter No./ dated: .

In pursuance of your request cited above and also the request of the Merchant Exporter, the permission given to your facility to process and pack **CRUSHED BONES,/GEL BONES ,OSSEIN / GELATINE** products for the following merchant exporter(s) is hereby withdrawn:

Name & Address of Merchant Exporter	

Yours faithfully,

In charge of
CAPEXIL

Copy to:

a) The Director, EIC, New Delhi-110001.
b) Coordinating office of CAPEXIL, New Delhi

ANNEXURE 11

NON-CONFORMITY REPORT (NCR)

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

1. Earlier *NCR* pending rectification:	
2. Details of non-conformities observed:	
3. Comments / Agreed action:	

---

1. Acknowledgement of report copy
2. Non-conformities have been fully explained and understood by the establishment. Confirmation of implementation of the agreed or proposed corrective actions to be made to EIA within .....(7/15/30 etc.) days.

Signature	Signature :	
Name	Name :	
Designation	Designation :	
(EIC / EIA officer)	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 12

SUGGESTIONS FOR IMPROVEMENT

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

Suggestions

1.
2.
3.
4.
5.

Agreed action by the processor:

Signature		Signature	
Name		Name	
Designation		Designation	
EIC/ EIA officer		Representative of the establishment	

Annexure: 13

CORPORATE AUDIT REPORT

EXPORT INSPECTION COUNCIL, New Delhi
(MINISTRY OF COMMERCE)
GOVERNMENT OF INDIA

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

7. OBSERVATION FORM

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

8. NON-CONFORMITY REPORT (NCR)

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

9. General Observations

1.	
2.	
3.	
4	
5.	
6.	

Team Leader Auditor

Proposed Corrective actions

Probable Date of Completion

Auditee

NC cleared/down graded/statuesque

Auditor Team Leader

ANNEXURE 14

Quarterly report of monitoring / supervisory visits to the approved facilities

EUROPEAN UNION

	Monitoring							Supervisory						
Type of the facility	No. of visits planned	Number of visits actually conducted	Number of units which are satisfactory based on the visits	Number of units which are unsatisfactory based on the visits	Reasons for short fall, if any in monitoring /monitoring visits	Action taken in case of each unsatisfactory unit	Details of verification of corrective action taken by the processing units reported unsatisfactory in the earlier statements.	No. of visits planned	Number of visits actually conducted	Number of units which are satisfactory based on the visits	Number of units which are unsatisfactory based on the visits	Reasons for short fall, if any in supervisory /monitoring visits	Action taken in case of each unsatisfactory unit	Details of verification of corrective action taken by the processing units reported unsatisfactory in the earlier statements.
Independent Collection Centers (Bone / Hide)														
Collection Centers Cum Bone Mills														
Rendering Plants														
Establishments Manufacturing Crushed Bones														
Integrated Slaughter Houses With Establishments														
Ossein & Gelatine Plants														

ANNEXURE 15

LIST OF APPROVED INDEPENDENT COLLECTION CENTERS CUM BONE MILLS, RENDERING PLANTS, INTEGRATED SLAUGHTER HOUSES WITH ESTABLISHMENTS, ESTABLISHMENTS MANUFACTURING CRUSHED BONES, OSSEIN & GELATINE PLANTS

(SUBMISSION THROUGH ELECTRONIC MEDIA ONLY)
(SEPARATE LIST TO BE SENT FOR EU AND NON EU)

NO.	APPROVAL NO.	NAME AND CONTACT DETAILS OF THE FACILITY	SCOPE OF THE APPROVAL	DATE OF APPROVAL (DD/MM/YYYY)	DATE OF EXPIRY (DD/MM/YYYY)

ANNEXURE 16

STATUS REPORT OF ESTABLISHMENT AGAINST WHICH COMPLAINT WAS RECEIVEDFROM EU, AND NON-EU COUNTRIES

1.	Name and Address of the approved facility	
2.	Approval No.	
3.	Details of Complaints: (a) Nature of complaint (b) Product (c) Health Certificate No. (d) Complaint Country (e) Whether this is the first / second / third complaint in the current calendar year (Specify category of contaminants / deficiencies such as "residue / microbiological repeated rejections)?	
4.	Date of placing the unit under ' "internal 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 (pl. mention the actual test results obtained, name of the lab. & name of the sampler) ➢ Test results by other EIC approved lab (pl. mention the actual test results obtained, name of the lab., and name of the sampler) ➢ Action taken, if any c) If not brought back, status of the consignment:	
6.	Assessment of the establishment a) Date of assessment b) Composition of assessment team c) Outcome of the Assessment 1) Whether the unit meets the requirements of S.O 730(E) and that of importing country? 2) Implementation of HACCP 3) Routine testing by the unit 4) Traceability and the source of raw material used for the consignment in question.	

	5) Details of the in-house testing, if applicable (Pl. specify the actual test results found and the name of the approved technologist who tested) 6) Whether the consignment has been tested prior to shipment for the contaminant(s)_ in question (Pl. specify the actual test results found and the name of the lab. and the sampler) 7) Test result of the reference sample which was drawn for the pre export testing (specify the test result, test method, which EIA lab it was tested and if found positive then whether the lab was audited and what is the outcome that audit report) 8) Test results found by the importing country (name of the lab and actual test results) 9) Test results of samples drawn during assessment (with details like number of samples, test methods, name of the Lab etc.) 10) In case of 2nd / 3rd complaint – the outcome of lab. audit and the action taken 11) Root cause of the contamination / rejection 12) Corrective action suggested / implemented, if any.	
7.	Current status of Sanitation/Hygiene of the unit(after placing the unit ' on alert') No. of Monitoring Visits (MV) conducted No. of unsatisfactory reports with details of non-compliance	
8.	Details of consignment inspection/Batch number tested (with details of testing method, Lab etc.) (a) EU Consignent ▪ No. of consignments tested ▪ No. of consignments passed ▪ No. of consignments failed ▪ Reason for failure/other remarks (b) Non EU consignent ▪ No. of consignments tested ▪ No. of consignments passed ▪ No. of consignments failed(state reason)	

	(c) In case of 2nd & 3rd rejections of same category ▪ No. of additional consignments tested ▪ No. of additional consignments passed ▪ No. of additional consignments failed (state reason) Present status: ▪ Change in Frequency of Monitoring (F.M.), if any ▪ Date of Revocation of 'Internal alert' ▪ Action pending, if any	

Signature
(Name & designation)

ANNEXURE 17

Appendix II to Annex VI of EC regulation 2074/2005 as amended

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
35.03

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Gelatine intended for human consumption**

Part II: Certification

II. Health attestation	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the gelatine described above was produced in accordance with those requirements, in particular that it:

— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— has been produced from raw material which met the requirements of Section XIV, Chapters I and II of Annex III to Regulation (EC) No 853/2004,

— has been manufactured in compliance with the conditions set out in Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004,

— satisfies the criteria of Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

and (1)

— if from ruminant origin, does not contain and is not derived from:

either (1)

specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in .....(2) (3).

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Treatment type: date of manufacture (dd/mm/yyyy).

Part II:

(1) Delete as appropriate.
(2) Insert the name of the country.
(3) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

ANNEXURE 18

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS FOR THE PRODUCTION OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Raw materials for the production of gelatine intended for human consumption**

Part II: Certification

II. Health attestation	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the raw material described above complies with those requirements, in particular that:

— bones, hides and skins of domestic and farmed ruminant animals, pig skins, poultry skin and tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (1)

and/or

— wild game hides and skins described above derive from killed animals whose carcases have been found fit for human consumption following post-mortem inspection (1)

and/or

— fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export (1)

and (1)

— if from ruminant origin, the raw material does not contain and is not derived from:

either (1)

specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in.....(2) (3).

Notes

Part I:

— Box reference I.8: Region of origin: if appropriate.
— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.19: Use the appropriate HS codes: 05.05, 05.06, 05.11.91, 05.11.99.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Nature of commodity: (hides), (skins), (bones), (tendons) and (sinews);
Manufacturing plant: includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant.

Part II:

(1) Delete as appropriate.
(2) Insert the name of the country.
(3) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

ANNEXURE 19

SEAL of CAPEXIL

CERTIFICATE FOR EXPORT
(Shipment clearance certificate for Indian Customs)

1. Certificate No: Date of issue: Date of Validity: (15 days from the date of issue)	2.Name and address of the exporter	3.Name and address of the approved Processing Unit
4.Plant approval No. issued by CAPEXIL: Date of validity:	5.IEC No. of Exporter	6. Buyer's Order No. & Date
7.Description of goods	8. Invoice No. & date 9.Quantity	

10.Shipping marks	11. No. and kind of pkgs.	12. Port of Loading	13.Port of discharge	14. Country of destination
15.Number of Containers ----------	16.Specification reference: ---------- Order No.S.O 725 (E) dated 3rd April 2012 & Notification No.S.O. 726 (E) dated 3rd April 2012 issued by Ministry of			

	Commerce and Industry (Dept. of Commerce), Govt. of India ,for export of Crushed Bones, Ossein & Gelatine	

Declaration

The undersigned hereby declares

(I) that the above consignment has been processed in our processing establishment which has valid approval and is under continuous monitoring by CAPEXIL---------- as per the Export of Crushed Bones, Ossein and Gelatine (Quality Control, Inspection and Monitoring) Rules, 2012:

(II) that the consignment is export worthy

(Signature)

(Name)

Designation

(Seal of Processing unit)

Place..... Date.....

NOTE: This certificate is to be filled in triplicate

Original(white) copy to be submitted to concerned Customs Dept.

Duplicate(yellow)copy to be submitted to the CAPEXIL(Competent Authority)

Third(pink) copy to be retained by the exporter.