Sl No	As per DG(SANCO)2013-6885-Mr DRAFT	Comments of CA
1	**INTRODUCTION**	
	The audit took place in India from 23 January to 31 January 2013 as part of the planned audit programmed of the FVO. The audit team comprised two auditors from the FVO.	
	The FVO audit team was accompanied by representatives from the CCA, the Export Inspection Council (EIC).	The FVO audit team was accompanied by representatives from the Export Inspection Council (EIC).
	The opening meeting was held on 23 January 2013 with the CCA in New Delhi. At this meeting the FVO audit team confirmed the objective of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.	The opening meeting was held on 23 January 2013 with the EIC in New Delhi. At this meeting the FVO audit team confirmed the objective of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.
2	**OBJECTIVES**	
	The objective of the audit was to evaluate the operation of official controls over the production of casings for human consumption destined for export to the EU as well as certification procedures.	
	In pursuit of these objectives, the audit itinerary included the following:	
	COMPETENT AUTHORITIES Competent Authorities Central 1 Opening and closing meeting Regional 2 One regional office was visited and the responsible officials were always present during the visits to individual establishment Local 4 **FOOD PRODUCTION / PROCESSING / DISTRIBUTION – ACTIVITIES** Slaughterhouses 1 Casings establishment 4	
3	**LEGAL BASIS**	
	The audit was carried out under the general provisions of EU legislation and, in particular Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.	
	N.B. Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the latest amended version.	

4	**BACKGROUND**	
	The current audit took place as a follow-up to the FVO audit DG(SANCO) 2011-6137 which was carried out from 07 to 19 September 2011 (hereinafter referred as the previous FVO audit). This report is accessible at:	
	Due to the outcome of the previous audit all the establishments listed for the export of casings for human consumption to the EU were de-listed.	
	In response to the recommendations of the previous FVO audit, the CCA of India submitted an action plan which was considered to be satisfactory by the FVO.	In response to the recommendations of the previous FVO audit, the EIC submitted an action plan which was considered to be satisfactory by the FVO
	As a consequence India was authorized to re-list casings establishments. Four casings establishments have been listed so far.	
	Since the previous audit India has kept the status as a country with negligible risk for Bovine Spongiform Encephylopathy (BSE).	
5	**FINDINGS AND CONCLUSIONS**	
5.1	**LEGISLATION AND COMPETENT AUTHORITIES**	
5.1.1	*Legal basis*	
	Article 46.1 of Regulation (EC) No 882/2004 stipulates that official controls by Commission experts in third countries shall verify compliance or equivalence of third country legislation and systems with EU feed and food law, and EU animal health legislation. These controls shall have particular regard to points (a) to (e) and (g) of the aforementioned Article.	
5.1.2	*Findings*	
5.1.2.1	*Legislation*	
	In response to recommendation 7 of the previous FVO audit ("*To strengthen the system of official controls over the production of casings destined to be exported to the EU to guarantee that the relevant requirements of Commission Decision 2003/779/EC are met")* the Export of Animal Casings Rules (1997) was amended by - Notification S.O 1315(E) dated 8th June 2012. The competence for official controls in relation to the export of casings intended for human consumption to the EU was transferred to the EIC. The EIC was established by the Government of India under The Export (Quality Control & Inspection) Act of 1963 and belongs to the Ministry of Commerce & Industry.	In response to recommendation 7 of the previous FVO audit ("*To strengthen the system of official controls over the production of casings destined to be exported to the EU to guarantee that the relevant requirements of Commission Decision 2003 /779 /EC are met")* the Export of Animal Casings Rules (1997) was amended by - Notification S.O 1315(E) dated 8th June 2012. The competence for official controls in relation to the export of casings intended for human consumption to the EU was transferred to the EIC. The EIC was

		established by the Government of India under **Section 3 of** The Export (Quality Control & Inspection) Act of 1963 and belongs to the Ministry of Commerce & Industry.
	According to this amendment the EIC and the Export Inspection Agencies (EIA) which operate under the technical and administrative control of the EIC now have the full responsibility for casings establishments regarding approvals, renewal of approvals, official controls, monitoring of compliance with hygienic conditions, as well as the issuance of the EU export certificates.	
	The EIC established a standardized documented procedure for approval of establishments - *Executive Instruction for approval and monitoring of animal casings for export* hereafter referred to as the EIC Executive Instruction – which came into force in November 2012. This instruction also lays down which type of official control has to be carried out by the CA, as well as the requests for necessary documentation and procedures for certifications.	
	The Food Safety and Standards Authority of India (FSSAI) published a new regulation in August 2011. Based on this regulation the FSSAI is responsible for slaughterhouses supplying raw materials for the casings establishments. The FSSAI has to register establishments slaughtering small quantities of animals or has to issue a licence to the medium or large capacity slaughterhouses. The deadline to get this licence or registration was prolonged to 4 February 2013. At the final meeting the FSSAI stated that this deadline was prolonged again by a further six months.	
	Observations:	
	According to the EIC Executive Instruction the primary responsibility for meeting the health requirements of importing countries lies with the food business operators (FBOs) themselves. FBOs are now required to put in place and implement a HACCP based procedure and an own check system, to keep and maintain records.	
	The definition of intestines was also modified and now means small and large intestines, throat or the oesophagus of animal.	
	Procedures for approval of casings establishments laid down in the instruction have already been applied for the re-approval of the four establishments listed.	
5.1.2.2	*Competent Authorities*	
5.1.2.2.1	*Organisation of Competent Authorities*	

	Under the EIC there are 5 regional and approximately 30 sub/district EIA offices to carry out official controls over the establishments in their territory.	
	There is an ad-hoc information exchange and consultation between the FSSAI and the EIC.	
	On the basis of the modified national legislation the EIC may seek assistance and set up an audit team of representatives from the Ministry of Agriculture at state or central level or from the FSSAI regarding approval and/or renewal of approval of establishments (see details under chapter 5.6).	
	There is no delegated official control task regarding the production and export of casings for human consumption.	
5.1.2.2.2	*Competent Authorities' powers, independence and authority for enforcement*	
	The powers and independence as well as the authority for enforcement are laid down in the national legislation.	
	Detailed rules are laid down in point 7 of the EIC Executive Instruction regarding actions to be taken in the case of minor deficiencies observed (do not effect the wholesomeness) or against violations (major deficiency/effect on the food safety, or a number of minor deficiencies or repeated minor deficiencies).	
	Both in the EIC and in the EIA the OVs are all employed full-time and are not allowed to carry out other work activities.	
5.1.2.2.3	***Supervision***	
	The EIC executive instruction sets up the official control system in such a way that officials carrying out controls at establishment level are monitored and supervised by the deputy director of the competent EIA office once a year. In addition, the monitoring and supervision carried out by the EIA officials is evaluated by the EIC once every two years ("Corporate Audit").	
	of the monitoring inspections and effectiveness. As the instruction entered into force only in November 2012 the full implementation of this system cannot be evaluated yet.	
	The check-lists set up for the supervisory visit by the EIA contain a separate point for the evaluation of the monitoring inspections and effectiveness. As the instruction entered into force only in November 2012 the full implementation of this system cannot be evaluated yet.	
5.1.2.2.4	*Training of staff in performance of official controls*	
	Recommendation 8 of the previous audit *("to train the staff responsible for official controls of casings establishments*	

	in relation to the respective EU requirements as laid down in Commission Decision 2003/779/EC and Council Directive 96/93/EC to ensure that these requirements are met in relation to the approval of casings establishments and export certification") was satisfactorily addressed and staff involved in official controls over the casings establishments received specific training in relation to respective EU requirements.	
	The EIC organised two training sessions regarding casings production:	
	• One was held on 25 and 27 January 2012 for officials and FBOs from the casings sector. The training programme included group exercises and field visits.	
	• On 17 December 2012 another training session was organised in New Delhi in which seven officials responsible for casings establishments and six representatives of the EU approved establishments participated.	
	Observations:	
	The officials' and the FBOs' understanding of the EU requirements has improved in most cases - the FBOs regarding keeping and maintaining records, as well as the carrying out of own checks, the official veterinarians (OVs) regarding documented control procedures.	
5.1.2.2.5	*Resources*	
	The FVO audit team visited one EIA office and the Joint Director (head of the agency) stated that sufficient human resources are available to carry out the official control tasks in their area including the casings establishments.	
	The Export Veterinary Certificate can be issued only for animal casings processed in establishments approved and monitored by the relevant EIA office. The EIC Director stated that EIA offices in the New Delhi area need to recruit OVs to ensure that certificates to the EU are signed and issued by an OV in charge of casings establishment in this area (see more details under chapter 5.8).	The Animal Health Certificate can be issued only for animal casings processed in establishments approved and monitored by the relevant EIA office. The EIC Director stated that EIA offices in the New Delhi area need to recruit OVs to ensure that certificates to the EU are signed and issued by an OV in charge of casings establishment in this area.
5.1.2.2.6	*Organisation of control systems*	
	The casings establishments approved for EU export are officially controlled according to the following system:	
	• After the initial approval of establishments monitoring inspections have to be carried out every three months by an EIA official. If the results remain satisfactory during a year the frequency can be reduced to once every six months and,	

	finally, to once a year.	
	• A supervisory visit has to be carried out once a year by an experienced official at the level of deputy director of the EIA or higher.	
	• At least once in every two years a "corporate audit" has to be carried out by the EIC over the EIA's activities.	
	During these different types of official controls check-lists have to be filled in and reports have to be written. If non-conformities are identified a "Non Conformity Report" has to be prepared and a copy should be provided to the FBO. When corrective action is requested the FBO has to rectify shortcomings within the assigned time period.	
5.1.2.2.7	*Documented control procedures*	
	Staff met in the states visited were all using the templates and check-lists developed for approval, renewal of approval as well as for official controls over the production of casings.	
	The approval and official control files relating to the four establishments visited were complete as laid down in the EIC instruction.	
	Examples of non-conformity reports, action plans provided by the FBOs and follow-up inspection reports were presented to the FVO audit team.	
5.1.3	*Conclusions*	
	The new CCA made considerable efforts to rectify shortcomings found during the previous FVO audit. The legal framework for official controls over the production of casings for human consumption for export to the EU is in place and standardised documented procedures for approval, supervision and certification have been elaborated.	The EIC made considerable efforts to rectify shortcomings found during the previous FVO audit. The legal framework for official controls over the production of casings for human consumption for export to the EU is in place and standardised documented procedures for approval, supervision and certification have been elaborated.
	The definition of an intestine is wider than in the EU legislation and also covers throat and oesophagus, which according to Regulation (EC) No 853/2004 cannot be exported using the model certificate for casings.	
	Progress was noted in different areas, especially in the organisation of official controls. Furthermore training sessions were provided on the EU requirements both for officials responsible for the official controls and for operators in the casings sector.	
5.2	**APPROVAL OF CASINGS ESTABLISHMENTS**	
5.2.1	*Legal Requirements*	
	Commission Decision 1999/120/EC draws up provisional	

	lists of third country establishments from which the Member State authorise imports of animal casings, stomach and bladders.	
	In line with Article 4(c) of Council Directive 92/118/EEC, the establishments must be registered by the CA on the basis of assurance from the establishments guaranteeing compliance with requirements of this Directive.	
	The animal health attestation sets out in point 9 of the model health certificate "CAS" in Annex IA to Commission Decision 2003/779/EC that animal casings must come from establishments approved by the CA.	
5.2.2	*Findings*	
	Recommendation 9 of the previous audit *("To ensure that the establishments are only authorized for EU exports when the relevant EU requirements laid down in Council Directive 92/118/EEC and Regulation (EC) No 852/2004 are met")* was addressed and the following new system for approval was elaborated in the EIC executive instruction:	
	• The FBO has to send an application for approval to the competent EIA office and has to fill in the form in the Annex to the EIC Executive Instruction. Documents requested for the application are also listed in the Annex.	
	• After the evaluation by the EIA and additional documentation or information received when needed, the complete application is forwarded for evaluation to the "Assessment Panel of Experts" (audit team), which is an ad-hoc appointed audit team. The audit team comprises representatives from the EIA, EIC, Ministry of Food Processing Industry, DMI, Bureau of Indian Standards, Agricultural Processed food products Export Development Authority, Animal Husbandry Department, Ministry of Agriculture and the FSSAI. The composition of the team is decided by the competent EIA on the basis of the EIC executive instruction.	
	• The assessment of the establishment has to be carried out by the audit team within 15 working days of receipt of the application. The assessment report has to be written and the check-list annexed to the EIC executive instruction has to be filled in.	
	• In case the audit team finds deficiencies, a non-conformity report has to be filled in and deadlines have to be set for the FBO to remedy the situation. Three months is the maximum time period which can be given to the FBO.	
	• The audit team forwards the report and recommendations to the competent EIA office which carries out the follow-up inspection when needed.	

	• The EIA allocates the approval number to the establishment and informs the FBO. In parallel, the documentation is sent to the EIC which notifies the European Commission.	
	• On receiving this letter, the FBO can start to process casings for export to the EU, but consignments can only be loaded when the establishment appears on the EU list.	
	The approval is valid for two years and before the expiry date the FBO has to apply for the renewal of the approval. The procedure to be followed for granting the renewal is the same as the previous one and is also valid for two years.	
	In order to be able to supply intestines to establishments approved for export to the EU any slaughterhouse in India should be authorised by the EIC. The EIC authorises slaughterhouses which are registered according to the previous system by the Agricultural and Processed food products Export Development Authority (APEDA) or licensed/registered by the FSSAI according to the new Food Safety and Standards Regulation (details are under chapter 5.1.2.1).	In order to be able to supply intestines to establishments approved for export to the EU any slaughterhouse in India should be authorised by the EIC/ FSSAI/ State/ Central Authority. The EIC authorises slaughterhouses which are registered according to the previous system by the Agricultural and Processed food products Export Development Authority (APEDA) or licensed/registered by the FSSAI according to the new Food Safety and Standards Regulation (details are under chapter 5.1.2.1).
	Observations:	
	The EIC Executive Instruction was issued in November 2012 but the new approval procedures were already applied before this date as the officials followed the instructions received during the training sessions. The draft version of templates and check-lists were also available and were used before November 2012.	
	Audit teams were set up and carried out pre-approval audits in all the four establishments visited.	
	The FVO audit team detected the following shortcomings in the evaluation procedure:	
	• In one establishment according to the check-list filled in by the audit team, documented procedures for cleaning, disinfection, and maintenance were satisfactory but the FBO could not make available these documents to the FVO audit team.	
	• In the same establishment the HACCP manual, flow diagram, hazard analysis, Critical Control Points (CCP), critical limits, and monitoring of CCPs was satisfactory according to the evaluation of the pre-approval audit team. Nevertheless the FVO audit team found that the HACCP	

	plan was very basic and did not refer to the procedures applied in the establishment.	
	• In another establishment visited, information about the APEDA registration of the slaughterhouse (not yet licensed by the FSSAI) supplying bovine intestines was not available at the time of the FVO audit but was provided by the EIA official later. Though its validity expired on 31 January 2012 no documentation of its extension was available.	
	• In the same establishment the first declaration about the ante- and post-mortem inspection for sheep from which raw material originated was sent on 23 January 2013. However, at the time of the pre-approval audit carried out in September 2012 to the specific question concerning availability of this documentation the answer was "yes".	
	• The pre-approval audit evaluation results were nearly identical for two establishments. Nevertheless the FVO audit team found considerable differences between these two establishments. One was in principle satisfactory while the other one had serious noncompliances regarding maintenance, cleanliness and operational hygiene. These were not noted either by the EIC composed audit team or by the EIA official during the monitoring inspection.	
5.2.3	*Conclusions*	
	Standardised documented procedures for approval of casings establishments have been put in place but they have not yet been implemented satisfactorily. In some cases the pre-approval audit reports did not reflect the reality seen and several shortcomings detected by the FVO audit team were not noted or recorded by the pre-approval audit team which questions the ability of the CA to evaluate rightly the EU compliances of the establishments.	
5.3	**IMPORT CONTROL OVER CASINGS**	
5.3.1	*Legal Requirements*	
	Article 46 of Regulation (EC) No 882/2004 stipulates that Community controls in third countries shall verify compliance with equivalence and control system with Community feed and food law and Community animal health legislation. Point 1 (g) of the above Article sets out that such controls shall have particular regard to the extent and operation of official controls on imports of animals and their products.	
	The applicable requirements for additional animal health attestation for imports of intestines from a country or a region with an undetermined BSE risk are laid down in	

	Section D, of Chapter C of Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council. These requirements include the conditions for the products sourced from a country or region with a controlled, undetermined or negligible BSE risk.	
5.3.2	*Findings*	
	There are different CAs involved in import controls of live animals and their products in India. The Department of Animal Husbandry, Dairy and Fisheries of the Ministry of Agriculture is responsible for disease control and the FSSAI carries out import controls over products for human consumption.	
	The FSSAI representatives stated that no specific import rules were set up for casings. In case of import, rules for control of meat products would be applied for casings. The FSSAI also stated that India has no import of casings.	
5.4	**OFFICIAL CERTIFICATION**	
5.4.1	*Legal requirements*	
	Council Directive 96/93/EC lays down the rules and principles on the certification of animals and animal products.	
	Commission Decision 2003/779/EC lays down animal health requirements and the veterinary certification requirements for the import of casings from third countries.	
	Additional attestations in relation to animal health requirements, to be included in the animal health certificates for imports of casings concerning the BSE risk status of the country of origin, are given in Section D, Chapter C, of Annex IX to Regulation (EC) No 999/2001 of the European Parliament and of the Council.	
5.4.2	*Findings*	
	In order to address recommendation 11 of the previous FVO audit - *"To ensure that the certification rules and principles laid down in Council Directive 96/93/EC are respected and that supporting documentation necessary for issuing certificates for export to the EU is available for the certifying officer"* - EU export certificate can only be issued for animal casings processed in establishments approved and monitored by the relevant EIA. Following the certification system elaborated in the EIC executive instruction the FBO has to send a request to the competent EIA office providing all the necessary information together with the following documents:	
1.	Copy of the Certificate for Export (strictly controlled document provided by the CA) filled in and issued by the	

	FBO (validity is 45 days).	
2.	Laboratory analysis report of the final product batch intended to be exported.	
3.	Ante- and post-mortem inspection declaration for raw materials.	
4.	Invoice and packing list.	
5.	Proof that the fees were paid.	
	The new certification system does not include physical pre-export inspection (however, it is still required for export to other countries).	The new certification system for export to EU is based on Food Safety based management system (FSMS). However these plants are approved and regularly monitored by CA based on Food Safety based management system.
	Observations:	
	• The export certificate is issued by the EIA office with a reference number and is valid for 90 days in case of dried animal casings and 45 days in case of salted casings. According to the instruction the validity can be extended (45 days for dry and 15 days for salted casings) if the consignment could not be shipped within the period of validity.	
	• The FVO audit team evaluated five export certification files and found all of them to be complete.	
	• All five export certificates issued for establishments in the New Delhi area were signed by an OV who is based in Mumbai EIA regional office. The establishments were not inspected/monitored by him and no evidence could be provided that when signing the EU export certificates for casings produced in these establishments all necessary documents required by the EIC executive instruction and sent to the competent New Delhi sub-office has been in his possession. The CCA stated that according to the national legislation only an OV can sign and issue export certificates and at the time of the application for the EU export certificates OVs were not employed by the EIA offices in the New Delhi area.	All five Animal Health certificates issued for establishments in the New Delhi area were signed by an OV who is based in Mumbai EIA regional office. The establishments were not inspected/ monitored by him and no evidence could be provided that when signing the EU export certificates for casings produced in these establishments all necessary documents required by the EIC executive instruction and sent to the competent New Delhi sub-office has been in his possession. The CA stated that according to the national legislation only an OV can sign and issue export certificates and at the time of the application for the EU export certificates OVs were not employed by the EIA offices in the New Delhi area.
	• The EIC instruction under point 9.1 (iv) regulates the system for giving the reference number of the export health	

	certificate for the EU. According to it each sub-office has to give a serial number prefixed for each health certificate containing the code of the issuing sub-office. In the case of the five EU export certificates the code of the sub-office in New Delhi was missing. In addition, the EIA did not clarify how a certifying officer can sign and issue an export certificate on behalf of an EIA office from another state.	
	• The export certificates that accompanied casings originated from ovine animals and had no statements regarding BSE (Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001).	
5.4.3	*Conclusions*	
	Some improvements have been made in the certification system and controls over the casings consignments for human consumption destined for export to the EU.	
	The principles of certification as laid down in Articles 3 and 4 of Council Directive 96/93/EC as well as the national system for issuing the EU export certificate have not been fully respected.	
	In addition the BSE statement was not included as required by Section B of Chapter C of Annex IX to Regulation (EC) No 999/2001.	
5.5	**APPLICATION OF HYGIENE RULES AT THE ESTABLISHMENTS LEVEL AND OFFICIAL CONTROLS**	
5.5.1	*Legal requirements*	
	Article 9 of Council Directive 92/118/EEC lays down that the requirements applicable to imports of casings must offer at least the guarantees of the provisions applicable to intra-Union trade. These provisions foresee that casings must come from establishments which:	
	• comply with the specific production requirements laid down in Council Directive 92/118/EEC;	
	• establish and implement methods for monitoring and checking of critical points on the basis of the processes used;	
	• keep records of the information obtained, guarantee the administration of marking and labelling; and	
	• the establishment must be under the supervision of the CA to ensure that the FBO or manager of the establishment complies with the requirements of Council Directive 92/118/EEC	
5.5.2	*Findings*	
5.5.2.1	*General and specific hygiene requirements*	
	The FVO audit team visited all four casing establishments re-approved for export to the EU.	
	Observations:	

	• One establishment which has recently moved to entirely new premises, presented good structures and maintenance, adequate flows and satisfactory hygiene of operations and only minor deficiencies were noted by the FVO audit team.	
	• The three other establishments presented in principle satisfactory structures and flow of operations but a number of deficiencies were found regarding maintenance and cleanliness. In particular the presence of rust, dirty ceilings and walls, dirty doors and handles was noted by the FVO audit team. In addition, non-dust proof windows, floor and wall damages made it difficult to keep the areas clean. Separation between street and working clothes was in general insufficient in the changing rooms.	
	• In two establishments gaps under the doors and unprotected drains allowing possible access to rodents was noticed by the FVO audit team.	
	• In one out of the three establishments severe maintenance, cleanliness and hygiene of operation deficiencies were found (general poor cleaning, absence of soap and toilet paper, towels for drying hands in the whole establishment, no separation between street and working clothes). The existing Standard Operating Procedures were not respected. For example, regarding personal hygiene, washing of hands with soap was required, but soap was not available. The required and documented frequency for cleaning of the water storage tank was every three months but in reality it was very dirty and had been neglected for a long period. Temperature records were also not reliable. The CA immediately requested corrective actions and suspended the export certification.	
	None of the deficiencies outlined above was identified by the CA during the official controls at any stage.	
	All parameters listed in Council Directive 98/83/EC shall be tested once in every two years. The laboratory results were included in the pre-approval files for all establishments visited and complied with the Directive mentioned beforehand.	
5.5.2.2	*HACCP-based systems*	
	In all the establishments visited, a HACCP based system was in place, but the manuals were very theoretical and had never been adapted, or not enough, to the specific situation of the establishment concerned.	
	Repeated mistakes in the description of the same CCP, found by the FVO audit team in two establishments indicated that a general model has been mechanically copied.	

	During the re-approval audit of the establishments, the audit team composed of three or four experts did not identify these shortcomings. Moreover, in the check-lists filled in by the officials it was stated that all elements of the HACCP based system were in place and were properly implemented.	
	Documentation on pest control had only started before the re-approval. When the FVO audit team checked information about substances used, the map of bait stations was available, but the documentation seen was incomplete regarding the monitoring and result.	
5.5.2.3	*Microbiological testing*	
	According to the EIC Executive Instruction FBOs are obliged to carry out microbiological tests for salt once in six months, for water, final products, contact surfaces and workers' hands the required frequency is once in two months. The parameters and maximum limits are also available in the EIC executive instruction.	
	During each monitoring inspection officials have to take samples and send them for microbiological testing to the relevant regional EIA laboratory. The laboratory network comprises five state laboratories operating under the regional EIA. There are 19 private laboratories authorised by the EIC also involved in the official controls.	
	The places, products and parameters for "sample taking" are listed in the EIC Executive Instruction.	
	Observations:	
	• In all the establishments visited own control systems were in place, including contact surfaces, workers' hands and final products. Samples were taken at the stage of production and for parameters stipulated in the EIC Executive Instruction.	
	• In addition water has to be tested for Coliforms at least once in two months.	
	• When a monitoring inspection was carried out the laboratory test results of official samples were attached to the report.	
	• The laboratory testing methods used for the detection of different pathogenic agents were in most cases the relevant ISO reference methods. They were mentioned on the document communicating the laboratory test results to the FBO, together with the limits of acceptability.	
5.5.2.4	*Traceability and identification marking*	
	The four establishments visited had traceability system in place. Records for incoming and outgoing products were	

	available and systematically maintained.	
	A traceability system necessary to guarantee the statement for certification regarding the 30 day salting period was also established.	
	Observations:	
	• The raw materials came from slaughterhouses which have been authorised for this purpose by the EIC.	
	• In all the establishments visited raw materials were supplied from the slaughterhouses in crates or barrels without any labelling. The consignments were accompanied by a gate pass (laisser passer) from the slaughterhouse and a trader's declaration.	
	• In one chiller for final products 9 barrels out of 50 had no identification. The EIA requested corrective actions and took immediate action to exclude these barrels from EU export.	
	• In another establishment visited one out of three consignments exported to the EU was not recorded.	
	Section XIII of Annex III to Regulation No (EC) 853/2004 requires that the raw materials for casings exported to the EU have to come only from animals having undergone and being approved for human consumption after ante- and post-mortem inspection. Particular problems were identified by the FVO audit team regarding the official documentation relating to this requirement:	
	• Raw materials are brought to the casings establishments by transporters or casings traders. The intestines brought by them are accompanied by their statement/guarantee indicating that the intestines come from animals which have undergone ante- and post-mortem inspection and are fit for human consumption.	
	• The CAs in charge in the slaughterhouses supplying intestines to the casings establishments have not delivered any document with this statement.	
5.5.2.5	*Official controls at establishment level*	
	Documented control procedures were established by the EIC for official controls over the production of casings for export to the EU. Templates and check-lists were also made available.	
	During the official controls the procedures were followed, and the relevant check-lists were used. Official samplings were carried out in accordance with the required frequency and for the required parameters.	
	When non-conformities were found, non-conformity reports were filled in, action plans were provided and follow-up inspection reports were also filled in. However,	

	many of the deficiencies observed by the FVO audit team had not been identified during the official controls.	
5.5.2.6	*Ante mortem and post mortem inspection*	
	The FVO audit team visited one slaughterhouse supplying intestines to casings establishments which was authorised by the EIC to provide raw materials for production of casings intended to be exported to the EU.	
	The OVs (municipality employed) carried out the ante-and post-mortem inspections correctly and maintained the records satisfactorily.	
5.5.3	*Conclusions*	
	The four casings establishments visited presented in principle satisfactory structures and flow of operation. Extensive control procedures have been put in place with instructions and check-lists but they were not properly implemented. Deficiencies related to maintenance, general hygiene and traceability, some of them significant, were found in three out four establishments visited. In all of them some shortcomings related to the HACCP were detected. That these deficiencies had not been detected during official controls, indicates that the training provided has not been fully effective.	
	Certification was suspended for one establishment due to serious non-compliances found in maintenance, cleanliness and hygiene of operation.	
	Deficiencies were identified in the traceability systems in place.	
	The declaration that raw materials/intestines originated from animals which have been subjected to ante- and post-mortem inspection and being approved for human consumption is issued by a trader which is not in line with the requirements of Article 3 of Council Directive 96/93/EC.	
	Regarding water control the frequency for physical and chemical analyses as well as the microbiological controls carried out according to the EIC Executive Instruction are not in line with the requirements laid down in Council Directive 98/83/EC.	
	Progress was noted in keeping and maintaining records and carrying out own checks.	
6	**OVERALL CONCLUSION**	
	The EIC made efforts to improve the organisation of official controls in relation to the processing and production of casings intended for export to the EU. However, implementation is not yet satisfactory. Improvements are necessary in the approval of	

	establishments and traceability to ensure satisfactory guarantees for the export of casings to the EU.	
	Three out of the four establishments visited were in compliance with most of the EU requirements, but some deficiencies were noted. The Indian CA took immediate action in the fourth establishment and suspended the export certification to the EU.	
	Non-compliances were detected in the procedures established for certification and improvements are necessary to fulfil all the requirements of Council Directive 96/93/EC.	
7	**CLOSING MEETING**	
	A closing meeting was held on 31 January 2013 with the CCA, the EIC. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.	A closing meeting was held on 31 January 2013 with the EIC. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CA of the relevant time limits for production of the report and their response.
	The representatives of the CCA acknowledged the findings and conclusions presented by the FVO audit team. In addition, information on action already taken and planned, in order to address particular findings in the establishments visited, was presented.	The representatives of the EIC acknowledged the findings and conclusions presented by the FVO audit team. In addition, information on action already taken and planned, in order to address particular findings in the establishments visited, was presented.
8	**RECOMMENDATIONS**	
	An action plan, describing the action(s) taken or planned in response to the recommendations of this report and setting out a timetable to correct the deficiencies found, should be presented to the Commission within 25 working days of receipt of the report.	
No.	**Recommendation**	
1.	To improve the official control system to guarantee that casings for human consumption intended to be exported to the European Union are only dispatched from establishments that meet all the relevant requirements, as laid down in Article 12 (2) (a) of Regulation (EC) No 854/2004.	
2.	To ensure an adequate traceability system at all stages of production and processing of casings in order to meet all the relevant requirements, as laid down in Article 18 of Regulation (EC) No 178/2002.	
3.	To take action in order to have in place an official system to certify the eligibility of the raw material for the	

	production of casings for human consumption intended for export to the European Union (Chapters I & II, Section XIII, Annex III, Regulation (EC) No 853/2004).	
4.	To ensure that when certifying casings to be exported to the European Union rules and principles of certification equivalent to those laid down in Council Directive 96/93/EC are followed, with particular attention to Article 3 and 4 of this Directive.	
5.	To ensure that water testing is performed in line with the requirements of Council Directive 98/83/EC.	
	ANNEX 1 - LEGAL REFERENCES	
Legal Reference	**Title**	
Reg. 999/2001	Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies	
Reg. 178/2002	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	
Reg. 852/2004	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs	
Reg. 853/2004	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin	
Reg. 854/2004	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption	
Reg. 882/2004	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules	
Reg. 2073/2005	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs	
Legal Reference	**Title**	
Reg. 2074/2005	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council	

	and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004	
Reg. 1162/2009	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council	
Dir. 92/118/EEC	Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC	
Dir. 93/119/EC	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing	
Dir. 96/22/EC	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC	
Dir. 96/23/EC	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	
Dir. 96/93/EC	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products	
Dir. 98/83/EC	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption	
Dir. 2002/99/EC	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption	
Dir. 2004/41/EC	Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC	
Dec. 1999/120/EC	1999/120/EC: Commission Decision of 27 January 1999 drawing up provisional lists of third country establishments from which the Member states	

Dec. 2003/779/EC	2003/779/EC: Commission Decision of 31 October 2003 laying down animal health requirements and the veterinary certification for the import of animal casings from third countries	
Dec. 2004/432/EC	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC	
Dec. 2007/115/EC	2007/115/EC: Commission Decision of 12 February 2007 amending Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC	
Dec. 2007/453/EC	2007/453/EC: Commission Decision of 29 June 2007 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk	
Dec. 2007/777/EC	2007/777/EC: Commission Decision of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC	