Kingdom of Saudi Arabia

Saudi Food and Drug Authority
Operations Sector

Manual of Procedures: Export of Processed Animal Protein (Poultry) to European Union for Pet Feed production

(Export Legislation)

2nd Edition
01 Nov 2022

Date: 01 Nov 2022

Saudi Drug and Food Authority

Kingdom of Saudi Arabia.

The official regulation and procedures concerned with export of Processed Animal Protein of poultry origin to the European Union shall abide with the following stipulations:

- Saudi Food & Drug Authority (SFDA) has been assigned as the Competent Authority in dealing with all matters related to the export of food products and food by-products from Saudi Arabia (Feed Law issued by Council ofMinisters (Decree No. 377 dated 17/9/1435H)

- Formation of Saudi Food and Drug Authority to manage food and drug sectors of Saudi Arabia – Council of Ministers resolutionNo:1 dated 07/01/1424 H, 4693/R dated 26/01/1428H

- Executive Department of AnimalFeed (EDAF) ofSaudi Food & Drug Authority (SFDA) onbehalf of SFDA shall supervise, manage and coordinate the system of export of Processed Animal Protein(Poultry)to European Union .

- The High Level Coordination Committee, comprises of Vice-president of Operations Sector, SFDA and the Director General, Animal Resource Services, Animal Resources Sector, Ministry of Environment, Water and Agriculture (MEWA)shall facilitate the effective implementation of legal stipulations, norms .and procedures

- The Import and Export of Food & Pesticides Permission Section (IEFPPS). shall, on behalf of SFDA supervise and coordinate the system of export of Poultry Products European Union.
- The Food Factory Inspections Section (FFIS) shall coordinate all audits and inspections in the Establishments with the help of SFDA Branches. The auditors from the SFDA Branches shall carryout audits and inspections.
- All stipulations and controls shall be in line with the applicable EU regulations and guidelines, which shall be implemented, monitored and verified by Import and Export of Food & Pesticides Permission Section (IFFPPS)
- Any changes or amendments in the EU Regulations, communicated to the Competent Authority shall be endorsed and incorporated in the “Manual of Procedures - Export of Poultry Products to European Union”.
- Interim decisions shall be taken by Technical Committee (TC) in accordance with national regulation, other applicable standards etc. shall be incorporated in subsequent revisions of this manual
- The revisions and changes shall be approved by the Vice President Operations Sector, SFDA.

- The term ‘Poultry’ referred in this manual is restricted to ‘chicken’ only

SFDA hereby approves the export legislations and content of “Manual of Procedures: Export of Processed Animal Protein(Poultry)to European Union” to be followed in all matters related to the said export.

……..

Sami Al Sager
Vice-president, Operations Sector
Saudi Food and Drug Authority

Contact details of major Government Departments that are involved in the Export of Processed Animal Protein (Poultry) to European Union:

1. **The Competent Authority:**

   A. The Office of Executive Department of Support inspection Executive Department of Support inspection– Operations Sector

   Saudi Food and Drug Authority
   P.O. Box SFDA – 3292
   Northern Ring Road, Hitteen Area unit (1)
   Riyadh – 13513 – 7148, KINGDOM of SAUDI ARBIA
   Tel: 00966 11 2038222 Ext.5368, Fax: 00966 11 2751367

   B. Department of Imports and Exports

   The Head
   Import and Export of Food & Pesticides Permission Section (IFFPPS)
   P.O. Box SFDA – 3292
   Northern Ring Road, Hitteen Area unit (1)
   Riyadh – 13513 – 7148, KINGDOM of SAUDI ARBIA
   Tel: 00966 11 2038222 Ext. 3312, Fax: 00966 11 2751367
   Email: MSNeghamshi@sfda.gov.sa

2. **The Animal Resource Services(ARS),Animal Resources Sector, Ministry of Environment, Water and Agriculture**

   The Director General
   The General Administration of Animal Resource
   Services, Animal Resources Sector
   Ministry of Environment, Water and
   Agriculture King Abdulaziz Street, Riyadh
   Zip code 11195, Saudi Arabia
   Tel: +966-114172000, +966-114016666 Ext: 3100
   Fax: +966-114055851
   Email: i.qasim@mewa.gov.sa

Index

Annexures

Part #1

Working Procedures & Structure

1. Subject Matter, Scope and Definitions

1.1. Subject Matter

1.1.1. These stipulations lay down the general working procedure and administrative structure of the Saudi Arabian government system for the export of Processed Animal Protein(Poultry)to European Union .

1.1.2. The administrative framework and unified procedures are adopted to ensure a harmonised system to implement and monitor the export of said processed .animal protein to EU

1.2. Scope

1.2.1. This administrative structure and procedures shall apply only to the exportof ProcessedAnimal Protein (Poultry) which is "NOT FIT FOR HUMAN CONSUMPTION".

1.2.2. These administrative structure, procedures and stipulations shall cover all the requirements of producing a safe product complying with the applicable EU .regulations

1.3. Definitions - The definitions shall be applicable for Export system for Poultry by- .products to European Union

1.3.1. .**Animal**' - Any invertebrate or vertebrate animal'

1.3.2. Animal By-Products - Entire bodies or parts of animals, products of animal origin ' or other products obtained from animals, which are not intended for human .consumption

1.3.3.' ARS' – Animal Resource Services, Animal Resources Sector, Ministry of Environment, Water and Agriculture. The full organisational name is 'The General .'Administration of Animal Resource Services

1.3.4.‘ Associating Department’ – a government department associated with the Competent Authority in the management of export of processes animal protein .to European Union

1.3.5.‘ Batch’ – A unit of production produced in a single plant using uniform production parameters, such as the origin of the materials, or a number of such units, when produced in continuous order in a single plant and stored together .as a shipping unit

1.3.6. ‘ **Bird’** – The term Bird is generally used for Poultry unless stated otherwise.

1.3.7. **'Blood**’ – Fresh whole blood**‘**.

1.3.8. **CA** – The Competent Authority.

1.3.9.‘ Carcase’– The dead body of the animal as defined in point 1.9 of Annex I to Regulation(EC)No 853/2004

1.3.10. ' **Category1 Material**’ – Animal by-products as described in Article 8 .EU no , 1069/2009

1.3.11. ' **Category2 Material**’ – Animal by-products as described in Article 9 .EU no , 1069/2009

1.3.12. **Category3 Material**’ – Animal by-products as described in Article 10 .EU no , 1069/2009

1.3.13. **Competent Authority**’ – The central authority of Saudi Arabia competent to ‘ ensure compliance with the requirements of this Regulation or any authority to which that competence has been delegated. Saudi Food and Drug Authority – SFDA shall be the Competent Authority of Saudi Arabia which is the corresponding office to European Union for all matters concerning export of Processed Animal Protein9.(Poultry)

1.3.14. **Derived Products**‘ – Products obtained from one or more treatments, ‘ .transformations or steps of processing of animal by-products

1.3.15. .**EDAF**’ – Executive Department of Animal Feed, SFDA‘

1.3.16. **‘IEFPPS’** – Import and Export Food and Pesticide Permission Section, SFDA

1.3.17. ‘**FFIS’** – Food Factory Inspections Section, SFDA

1.3.18. ‘**EDIS’** – Executive Department of Inspection Support and Branches, SFDA.

1.3.19. '**EDRL'** – Executive Department of Research and Laboratories, SFDA.

1.3.20. '**EDSPA**' – Executive Department for Standards and Product Assessments.

1.3.21. **Establishment**' – Any place where any operation involving the handling of animal by-products and/or production of derived products is carried out (In other word it is the Rendering Plant that produces Processed Animal Protein from Category 3 poultry by-production. The term 'Establishment' also implies the Establishment or management of the Establishment

1.3.22. Executive Body/Agency – government agency involved in the program of .export of Processed Animal Protein of poultry origin to European Union

1.3.23. **Export**' – Product movement from Saudi Arabia to the European Community .(or to other countries if specified)

1.3.24. **Farmed Animal**' – Any animal that is kept, fattened or bred by humans and used for the production of food, wool, fur, feathers, hides and skins or any .other product obtained from animals or for other farming purposes

1.3.25. **Feed' or 'Feeding Stuff'** – Feed or feeding stuff as defined in Article3(4)of Regulation(EC)No .178/2002

1.3.26. **Food' or 'Foodstuff**' – Food or foodstuff as defined in Article 2 of Regulation (EC)No . 178/2002

1.3.27. **Incineration**'- The disposal of poultry by-products/derived products as waste, in an incineration plant, as defined in point4 of Article 3 of Directive 2000/76/EC

1.3.28. **Manure**' – Any excrement and/or urine of farmed animals other than farmed .fish, with or without litter

1.3.29. **MEWA'** - Ministry of Environment, Water and Agriculture, Saudi Arabia

1.3.30. **PAP'** – Processed Animal Protein – Animal protein derived entirely from Category 3 material which has been treated in accordance with Section ,1 ofChapter II .of Annex X of EU no1069/2009 so as to render them suitable for direct use as feed material or for any other use in feeding stuff, including pet food, or for use in organic fertilisers or soil improvers

1.3.31. **Poultry'** – In this manual, the word 'poultry' is used only to refer to 'Chicken

1.3.32. **Processed Animal Protein(Poultry)**It is the animal protein derived from – ' poultry by-product (originated from poultry slaughtered for human consumption) - Category3.The Processes Animal Protein (Poultry) is not intended for .human consumption

1.3.33. **Pet Animal**' – Any animal belonging to species normally nourished and kept but '

.not consumed, by humans for purposes other than farming

1.3.34. **Placing on the Market**' – Any operation with a purpose of selling animal by- ' products or derived products to a third party in the European Community or any other form of supply against payment or free of charge to such a third party or .storage with a view to supply to such a third party

1.3.35. **Pressure Sterilisation**' – The processing of animal by-products, after reduction in ' particle size to not more than 50 mm, to a core temperature of more than 133 C for at least 20 minutes without interruption at an absolute pressure of at least ° .bar 3

1.3.36. **Processing Plant (Poultry Processing Plant)**' – is the place where the poultry ' birds are processed for human consumption and the by-products (Category 3 material as per Article 10 Regulation 1069/2009) is sent to the Establishment .(Rendering plant) for the production of PAP- Processed Animal Protein

1.3.37. **Products of animal origin**' – Products of animal origin as defined in point 8.1 of ' Annex I to Regulation (EC) No. 853/2004.

1.3.38. .**SFDA** – Saudi Food and Drug Authority

1.3.39. **Transit**' – The movement through the European Community from the territory of ' .a third country to another third country, other than by sea or by air

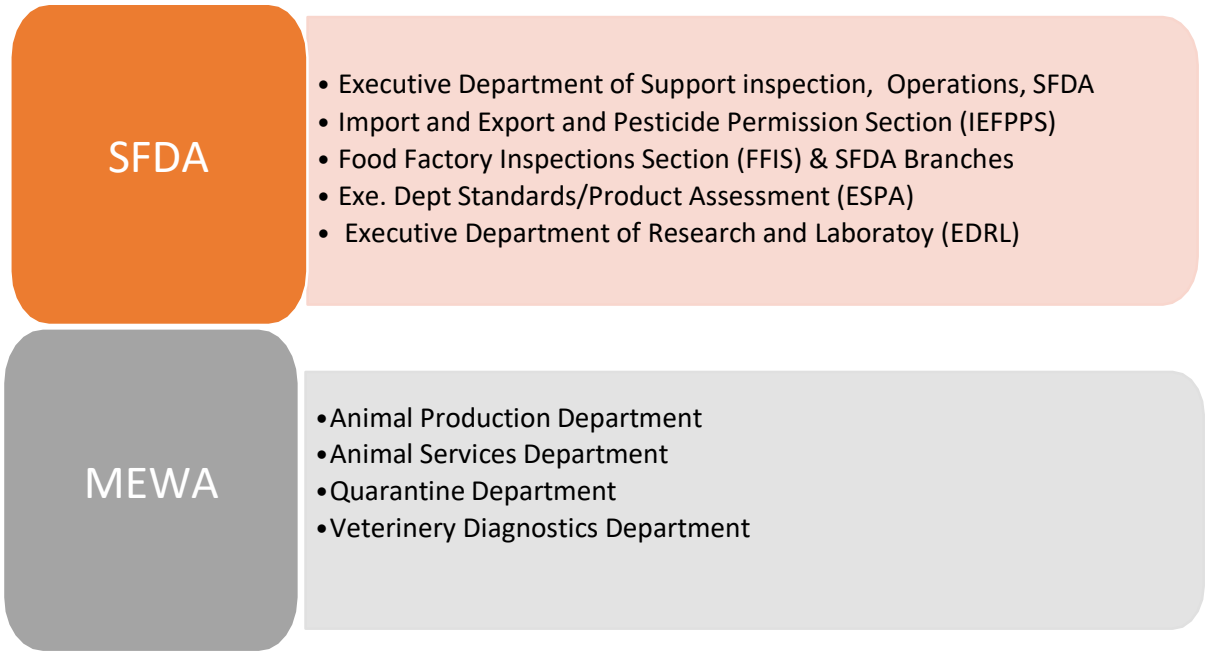
1.3.40. **User**' – The natural or legal persons using animal by-products and derived ' .products for special feeding purposes, for research or for other specific purposes

1.3.41. **Waste**' – It is the waste as defined in point 1 of Article 3 of Directive'2008/98/ EC.

1.3.42. .**Wild Animal**' - Any animal not kept by humans

Chart 1

Government Departments Involved in the Export of PAP



1. Government Agencies Involved in Export of Processed Animal Protein (Poultry) to EU

1.1. Saudi Food and Drug Authority-SFDA shall be the Competent Authority of Saudi Arabia in the export of Processed Animal Protein (Poultry) to European Union, headed .by the office of Vice-President, Food Sector

1.1.1 The SFDA consists of five main sectors including Operations, Food, Drug, Medical Devices and Research and Laboratories.

1.1.2 The Operations sector of SFDA handles all matters connected with import and exports of food, feed, drugs and medical devises (except live animals).

1.1.3 Refer **Annexure-1** for the organisational structure – EU Export System for Processed Animal Protein(Poultry).

1.1.4 Among the SFDA departments the following departments are involved in export control of Poultry Products as follows:

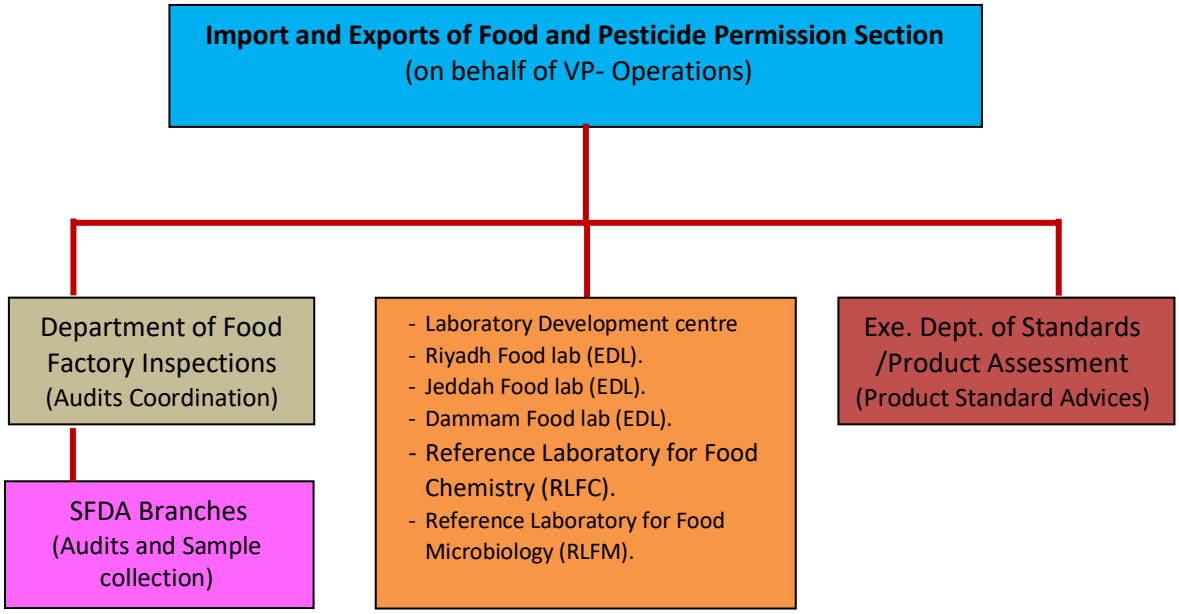
1.1.4.1 Import and Export of Food & Pesticides Permission Section (IEFPPS).
1.1.4.2 Food Factory Inspections Section (FFIS) and SFDA Branches.
1.1.4.3 Executive Department of Standards/Product Assessment (ESPA).
1.1.4.4 Executive Department of Laboratories (EDL) – Research and Laboratories Sector.
1.1.4.5 Reference Laboratory for Food Chemistry (RLFC).
1.1.4.6 Reference Laboratory for Food Microbiology (RLFM).
1.1.4.7 Laboratory Development Canter (LDC).

1.1.5 IEFPPS shall be, on behalf of SFDA, coordinating and supervising all activities related to Poultry Products Export.

1.1.6 Other Departments shall function as other 'Associating Departments' from SFDA

Chart-2

Interactions of SFDA Departments



1.2. The Animal Resources Servic (ARS)of Animal Resources Sector, Ministry of Environment, Water and Agriculture**(MEWA)**shall be the other associating department that participate in management of export of Processed Animal Protein .of poultry origin

2.2.1 Animal Resources Sector of MEWA which is responsible for all veterinary related matters of the country concerning animal resources, animal production, animal health, .animal welfare, animal biosecurity and laboratory analysis

2.2.2 There shall be four major sections of Animal Resources Sector involved in this export namely:

2.2.2.1 Animal Production
2.2.2.2 Animal Resources Services
2.2.2.3 Quarantine
2.2.2.4 Veterinary Diagnostics

2.2.3 The Animal Resources Services – ARS, on behalf of the Animal Resource Sector, hall supervise all the matters related to export of Processed Animal Protein to European Union. The Deputy Director of Animal Health shall be the coordinator for this assignment

2. Roles and Responsibilities of the Competent Authority - SFDA and its Departments

2.1. The Office of Executive Department of Support inspection, Operations Sector – This office shall be responsible for matters such as:

2.1.1. Final approval of all matters related to export of food, feed products, by-products and derived products.

2.1.2. Standing as the communication link point between the Kingdom of Saudi Arabia and the importing countries.

2.1.3. Providing guarantees to importing countries and its official bodies that food products, by-products, derived products and feed exported from the Kingdom of Saudi Arabia has undergone strict official controls to meet the consumer safety, animal health and quality stipulations.

2.1.4. Sending list of Approved Establishments to the importing countries.

2.2. Import and Export of Food & Pesticides Permission Section (IEFPPS).

2.2.1. The IEFPPS shall be responsible for coordination and supervision of all activities and assignments related to exports of Poultry Products, on behalf of the office of the Vice-president, Operations Sector.

2.2.2. Responsibilities of IEFPPS in the Export of Poultry Products

2.2.2.1. The overall supervision of activities related to the said export.

2.2.2.2. Receiving reports and recommendation from the Technical Committee for further action.

2.2.2.3. Communication with other committees and Establishments about different matters related to food export as well as for the product standards.

2.2.2.4. Coordination between different committees, Competent Authority (CA) and Establishment**.**

2.2.2.5. Proper distribution of documents, directives, communications and other relevant information among the committees.

2.2.2.6. List the tests/analyses to be conducted by Government agencies and Establishment laboratory through the Manual.

2.2.2.7. Ensure that the Technical Committee meetings and other meetings are held as per schedule.

2.2.2.8. Making necessary arrangements to convene deferent committee meetings.

2.2.2.9. Regular monitoring of overall activities of the Establishment to ensure that the Establishments meet the government stipulations

2.2.2.10. Ensuring “Manual of Procedures - Export of Poultry Products” meets applicable national and international stipulations.

2.2.2.11. Coordinating for the final approval of Establishments for exports to various countries. Refer **Annexure -2** for Establishment Approval.

2.2.2.12. Allocation of ‘Approval Number’ to Approved Establishments that exports food products, (in consultation with the office of Vice President and other departments involved in other food exports).

2.2.2.13. Identifying external (national/international) laboratories, to conduct tests and analysis, as the need arises to meet the analysis requirements for food and feed exports.

2.2.3. Work Procedures Developed and Proposedby IEFPPS

2.2.3.1. .Import permit procedures for non-medicated feed additives

2.2.3.2. .Export permit procedures for non- medicated feed additives

2.2.3.3. .Procedures for issuing a health certificate for temporary export

2.2.3.4. Procedures of Animal Feed National Registry

2.2.4. Different Divisions of EDAF and their Responsibilities

2.2.4.1. Division 1: Registration, Licensing and Follow-Up

2.2.4.1.1. .Electronic data updating

2.2.4.1.2. Issue export(health certificates for export).

2.2.4.2. Division 2: Feed Control

2.2.4.2.1. .Annual audit and inspection planning

2.2.4.2.2. .Inspection of Regional Offices

2.2.4.2.3. .Monitoring programs on animal feed products

2.2.4.2.4. .Training of auditors/inspectors

2.2.4.2.5. .Performance evaluation of auditors

2.2.4.3. Division 3: Enforcement

2.2.4.3.1. .Enforce food laws and applicable regulations

2.2.4.3.2. Resolve all issues related to the inspection in coordination with .legal and other concerned departments

2.3. The Food Factory Inspections Section (FFIS) and SFDA Branches

3.3.1 The FFIS is responsible for coordination of Establishment inspection and audits (including GLP audits) and sample collection for analysis

3.3.2 The FFIS shall coordinate with the SFDA Branch offices to assign auditors for Establishment audits.

3.3.3 The FFIS shall Participate in the Approval, Renewal audits

3.3.4 The FFIS shall issue formats/checklists to be used during Establishment inspections.

3.3.5 Auditors/inspectors of the SFDA Branches shall visit Establishments to ensure that the all the assigned tasks are carried out as per schedule through regular inspections and audits.

3.3.6 The Branches shall collect samples for analysis as per test requirements

2.4. Research and of Laboratories – (EDL) (Research and laboratories Sector):

2.4.1. shall be responsible for all the lab tests and analyses of Poultry Products intended for export.

2.4.2. Divisions under the sector:

2.4.2.1. Executive department for Laboratories (EDL)

2.4.2.2. Riyadh Food Laboratory (RFL)
2.4.2.3. Jeddah Food Laboratory (JFL)
2.4.2.4. Dammam Food Laboratory (DFL)
3.4.2.2. Reference Laboratory for Food Chemistry (RLFC)
3.4.2.3. Reference Laboratory for Food Microbiology (RLFM)
3.4.2.4. Laboratory Development Center (LDC).

2.4.3. The General Functions of the Research and Laboratories Sector in SFDA

2.4.3.1. Development of integrated system of accredited Food Laboratories.
2.4.3.2. Conduct tests and analysis of food items (both produced in the local market and also imported food).
2.4.3.3. Coordinate among different SFDA Food Laboratories.
2.4.3.4. Supervision and follow-up of all laboratories.
2.4.3.5. Ensure food safety through lab tests and analyses.
2.4.3.6. Implement surveillance programs.
2.4.3.7. Provide scientific, technical recommendation in case of dispute on test results between SFDA labs and declare the final decision.
2.4.3.8. Coordinate with other SFDA departments for laboratory supplies.
2.4.3.9. Meet the requirements of ISO 17025.
2.4.3.10. Capacity building for needed equipment and trained manpower.
2.4.3.11. Method development and validation.
2.4.3.12. Allocate necessary resources for continuous laboratory analysis.
2.4.3.13. Conduct annual proficiency testings (PTs) to evaluate the competency of the subsidiary laboratories.
2.4.3.14. Perform periodic Audits on private laboratories to assess their compliance against ISO 17025.
2.4.3.15. Conducted studies and researches in the area of interest to the SFDA

2.4.4. The specific functions of EDL as the National Reference Laboratory Department in the export of Poultry Products is explained in Article # 7 - 'Details of Laboratory System' of this manual.

2.5. Executive Department for Standards and Product Assessment - EDSPA

2.5.1. EDSPA shall be responsible for setting up product specifications, standards and technical regulations

2.5.2. Structure of EDSPA

2.5.2.1. .Technical Regulations and Standards Setting
2.5.2.2. .Technical Committees
2.5.2.3. .Regional and International Department
2.5.2.4. .Conformity Department

2.5.3. General Functions of EDTRS

2.5.3.1. Setup standards and technical regulations of ,food agricultural goods/products, feed, pesticides, and food packaging .materials

2.5.3.2. Contact point and representing Saudi Arabia in Regional and international organizations that related to food standards and technical regulations, such as Codex, WTO (SPS & TBT) and GSO … etc

3. Authority and Central/regional organisation of the Competent Authority

3.1. .Competencies, prerogatives and powers of SFDA as the Competent Authority

3.1.1. .SFDA shall have overall responsibility for Export to EU

3.1.2. SFDA shall frame the legal, procedural, analytical requirements of export to .poultry by-products to EU from Saudi Arabia

3.1.3. SFDA shall be responsible for Overall supervision and final decisions of veterinary .Drug registration, use, prohibition and Residue Control in Saudi Arabia

3.1.4. SFDA shall maintain well equipped, technically qualified, adequately trained .manpower to handle audits, tests, legal formalities etc

3.1.5. SFDA as CA, shall be the ultimate authority for approval, dismissal, suspension, .and withdrawal of export sanctions to European Union

3.1.6. The CA shall have full authority to levy penalties/disciplinary steps, other action on Establishments that export poultry by-products to EU

3.2. Organisation of the Competent Authority at Central, Regional and Local Level

3.2.1. Saudi Food and Drug Authority represented by the office of the Vice President, Food Sector, SFDA, has its head office in Riyadh.

3.2.2. The Riyadh Office shall head the Competent Authority Functions and responsibilities.

3.2.3. The Executive Department for Animal Feed (EDAF) carries out the coordination and management of EU export activities (of PAP) with its head office in Riyadh.

3.2.4. The head office of EDAF in Riyadh shall monitor and manage the work activities of its regional/local offices in different locations in Saudi Arabia.

3.2.5. EDAF shall be headed by an Executive Director.

3.2.6. All directions for control and instruction for system procedures and changes shall originate from the Riyadh office of EDAF to ensure and guarantee harmonised system in the whole country through its regional offices.

3.2.7. The Executive Department for Laboratories that carries out the analyses for EU exports has its head office in Riyadh headed by the Executive Director of EDL.

3.2.8. EDL has regional laboratories to meet the national analyses requirements.

3.2.9. The Executive Department for Technical Regulation and Standards (EDTRS) headed by the Executive Director has its head office in Riyadh.

CHART – 2
Regional Structure of Competent Authority

Competent Authority	Offices	Responsibilities
Office of Executive Department of Support inspection, Operations	**Riyadh**	**The overall responsibility of export of food products.**
Import and Export of Food & Pesticides Permission Section (IEFPPS)	**Riyadh**	**Coordination of Food Exports**
Food Factory Inspections Section (FFIS) and Branches	**Riyadh (H.O)**	**1. Routine Establishment inspection**
	All Branches	**2. Issuing Health Certificate**
		3. Collecting samples for analysis
Research and Laboratories Sector	**Riyadh (H.O)**	**1. Supervision on SFDA lab tests.**
		2. Supervision on Private Labs.
		3. Supervision on Establishment Labs.
Exe. Department of Standards & Product assessment-EDSPA	**Riyadh Office**	**Responsible for Standards and Regulations**

4. Responsibilities of Animal Resource Services(ARS)of Ministry Of Environment, Water and Agriculture (MEWA)

4.1. The Animal Resource Services of MEWA shall be one of the two executive bodies of the High Level Coordination Committee (HLCC) working together with CA to ensure .Poultry by-products export to EU meet the requirements

4.2. ARS shall be responsible to provide all information about the general health status of .the livestock, and domestic animals

4.3. ARS shall provide all information about the existence status of infectious animal diseases in Saudi Arabia, which is listed in the Terrestrial Animal Health Code of the .World Organization for Animal Health

4.4. In addition, ARS shall provide other regulations on the prevention and control of infectious animal diseases in Saudi Arabia, including rules of imports of live animals .from other third countries

4.5. The main focus of ARS shall be on the primary sector (environment, poultry (hatcheries, poultry farms, and harvested birds [from farm] before processing etc).

4.6. ARS shall be responsible for the National Residue Monitoring Program, Animal Health Monitoring, Disease/pathogen control Program, Vaccination Program etc. and authorised to conduct all related inspections, , audits, sample collection, lab tests etc.

4.7. ARS also shall take necessary corrective/legal actions in the primary sector to combat noncompliant results.

4.8. The specific functions and responsibilities of the ARS in official controls are as follows:

4.8.1. Regulation on Poultry Farming

4.8.2. Regulation on poultry drug residue program in the primary sector

4.8.3. Regulation on general poultry farming operation

4.8.4. Regulations and requirements of poultry diseases

4.8.5. Regulation on usage of veterinary drugs/chemicals

4.8.6. Regulation on veterinary drug/chemical supply

4.8.7. Ensure that the Establishment laboratory meets requirements

4.8.8. "Sampling for "National Residue Monitoring Program- NRMP

4.8.9. Fixing frequency of sample collection

4.8.10. Fixing types of samples, sampling methods and securing procedures

4.8.11. Collecting and sending samples for NRMP to Laboratories

4.8.12. Receive and review residue test results

4.8.13. Set measures, take action when residues are detected above admissible limits

4.8.14. Collect background information and details of production and products exported to Europe

4.8.15. Define the scope of "National Residue Monitoring" plan

4.8.16. Set sample collection / testing frequencies and levels of controls

4.8.17. Set targeting criteria (if any)

4.8.18. Send copy of all reports of routine audits conducted by ARS to the Competent Authority before last day of every calendar year

4.8.19. Provide all information about the general health status of poultry

4.8.20. Provide all information about the existence status of infections animal diseases (OIE listed) in Saudi Arabia

4.8.21. Manage regulations on the prevention and control of infectious animal diseases in Saudi Arabia

4.8.22. Manage, control and monitor rules of poultry imports (live chicks, eggs, birds) from other countries

4.8.23. Establish strategies and regulations on animal disease control

4.8.24. Develop and establish strategies and regulations for poultry vaccination program

4.8.25. Develop strategies for control on Salmonella & Campylobacter

4.9. Organisation of the Animal Resources Sector, Ministry of Environment, Water and Agriculture at Central, regional and local level

4.9.1. The office of the Animal Resources Sector with its head office in Riyadh carries out functions under the Ministry of Environment Water and Agriculture. The head office of ARS in Riyadh is responsible for managing all the activities related to animal resources, animal welfare and animal health. This office coordinates the work activities of its regional/local offices in different locations in Saudi Arabia. All such offices shall be under the direct control of the head office of .Animal Resources Sector

4.9.2. The Animal Resources Sector shall be headed by the Deputy Minister whose .office is stationed in Riyadh

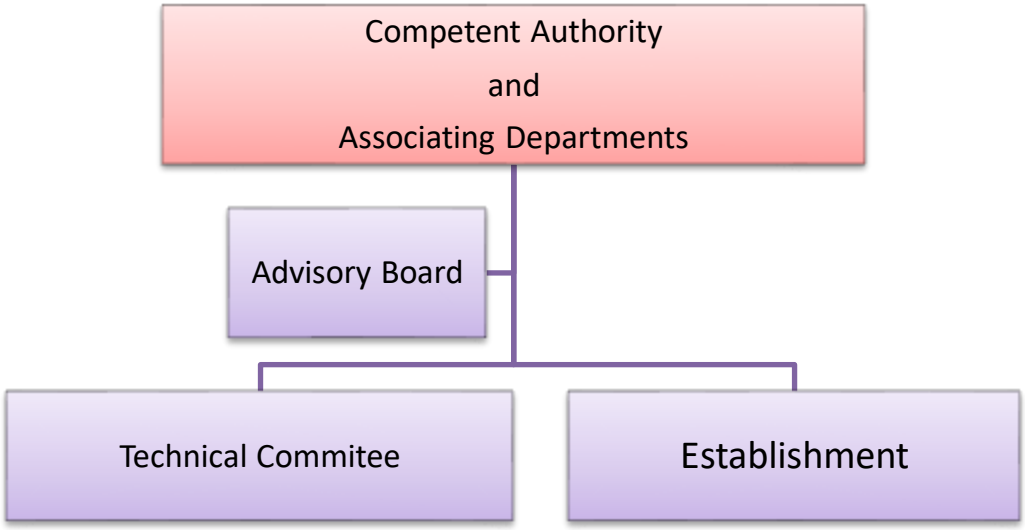
4.9.3. The Animal Resource Services, one of the departments of Animal Resources Sector, is assigned to carry out all matters concerning export of Processed Animal Protein of poultry origin to EU.

4.9.4. Under the Director General of Animal Resource Services, the Deputy Director Animal Health shall coordinate and supervise all the assigned responsibilities – related to the Export of Processed Animal Protein.

4.9.5. All directions for control, system procedures and changes shall originate from the Riyadh office of ARS to ensure and guarantee harmonised system in the whole country through its regional offices.

5. Basic Administrative Structure of EU Export Control System - The agencies that form part of the Administrative structure for Export of Processed Animal Protein (Poultry) are Competent Authority (along with the Associating Departments), High Level Coordination Committee, Advisory Board, Technical Committee and Establishments.

CHART – 3
Organisational Structure – EU Exports Control System



5.1. Competent Authority and Associating Departments

5.1.1. Structure of the Competent Authority – The structure of CA shall be as follows:

5.1.1.1. The office of the Vice President ,Opration Sectorshall head the Competent Authority

5.1.1.2. The Executive Department of Animal Feed(EDAF)shall be the executing body who act on behalf of the Vice-President of Food Sector in all matters of Export of Processed Animal Protein (Poultry)

5.1.1.3. Other associating departments such as Executive Department for Laboratories (EDL) and Executive Department for Technical Regulations and Standards (EDTR) support EDAF in said assignments

5.2. High Level Coordination Committee (HLCC)

5.2.1. :Structure - The HLCC shall have the following members

5.2.1.1. Vice-President Food Sector, SFDA

5.2.1.2. The Director General, Animal Resource Services (ARS), Animal Resources Sector, Ministry of Environment Water and Agriculture (MEWA)

5.2.1.3. The Executive Director, Executive Dept. for Animal feed (EDAF), SFDA

5.2.1.4. The Deputy Director, Animal Health, Animal Resource Services, Ministry of Environment Water and Agriculture (MEWA)

5.2.2. The Functions of HLCC

:The Functions of HLCC shall include

5.2.2.1. Evaluation and approval of suggestions/observation/recommendations of the 'Technical Committee' before it is forwarded to the Competent .Authority for final approval

5.2.2.2. Recommending amendments in the "Manual of Procedures – Export of Processed Animal Protein (Poultry) to European Union" suggested by the .Technical Committee

5.2.2.3. This committee shall convene meeting at least once a year, but CA can call .for special meetings as required

CHART – 4
High Level Coordinating Committee

Members of High Level Coordination Committee	
SFDA	***MEWA***
1. Vice-President Opration Sector, SFDA	**3.** ,Director General Animal Resources Services, MEWA
2. Executive Director, EDAF	**4.** Deputy Director - Animal Health

5.3. Advisory Board – The Advisory Board shall be the body, which provide proactive advice to the EU export system. This body shall also help in solving problems and shall handle issues that require special attention.

5.3.1. Structure of the Advisory Board – The advisory board shall include the following members:

5.3.1.1. One member (minimum) from Executive Department for Animal Feed (EDAF)

5.3.1.2. One member (minimum) from Animal Resource Services (ARS) – Ministry of Environment Water and Agriculture (MEWA)

5.3.1.3. One member (minimum) from Executive Dept. of Laboratory (EDL)

5.3.1.4. One member (minimum) from Executive Department for Technical Regulations and Standards (EDTRS)

5.3.1.5. One representative from the Establishment

5.3.1.6. Consultants / advisors as nominated

5.3.2. Functions of the Advisory Board – Functions of Advisory Board shall include:

5.3.2.1. Give pieces of advice on specific issues related to EU export of processed poultry by-product.

5.3.2.2. Give specific suggestion/review/update for the EU export system of processed poultry by-product.

5.3.2.3. Evaluate proposals for changes in EU export system and give advice.

5.3.2.4. Other advisory tasks as assigned by Technical committee/HLCC.

5.4. Technical Committee

5.4.1. Technical Committee (TC) shall comprised the following:

5.4.1.1. Technical Representatives from SFDA (three members from the Executive Department Animal Feed [EDAF]; one representative from EDTRS and one representative from laboratory Dept.)

5.4.1.2. Technical Representatives from Animal Resource Sector of MEWA (Three representatives)

5.4.1.3. Establishment Representative (One technical representative from each Establishment exporting Processed Animal Protein [Poultry] to EU). The Establishment shall not involve in Governmental Decision Making.

CHART – 5
Technical Committee

SFDA	• Two representatives from IEFPPS • One representative from FFIS • Branch Representatives (as required) • One representative from Research and Laboratories Sector
ARS	• Three representatives from ARS
ESTABLISHMENT	• One technical representative from each EU approved Establishment

5.4.2. Functions of the Technical Committee - The Functions of Technical Committee shall include:

5.4.2.1 Conducting detailed analysis and discussion on procedural, scientific and Technical matters connected with food exports.

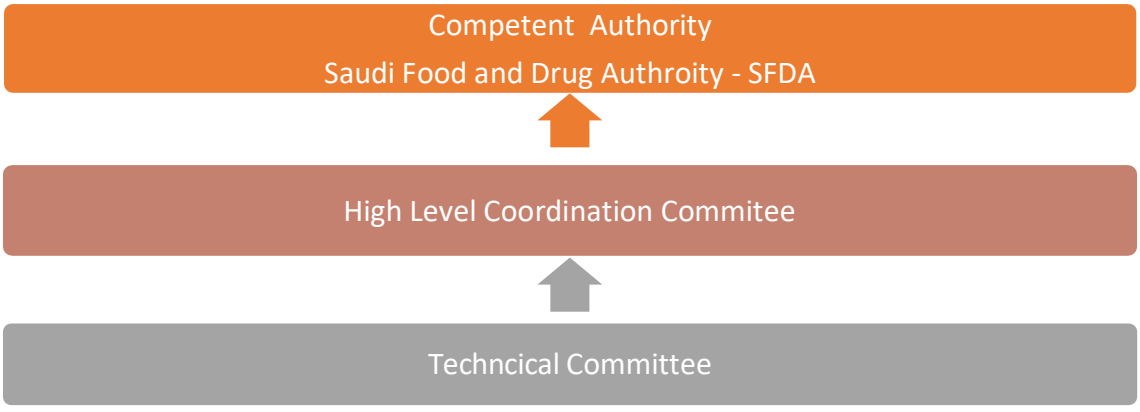
5.4.2.2 This committee through Establishment audits, shall ensure that the Establishment follows procedures and meet stipulated standards.

5.4.2.3 This committee shall review Poultry Product exports carried out by approved Establishments, their issues related to primary production, processing, storage, export, inspections, laboratory analysis etc.

5.4.2.4 This committee also shall be responsible for suggesting amendments in the Manual of Procedures: Export of Poultry Products" and update the manual as needed.

5.4.2.5 This committee shall convene meeting at least once a year.

CHART – 6
Reporting line of Committees



5.5. :Establishments - The Establishment shall be responsible for

5.5.1. Accept and implement directions and advice officially issued by the Competent .Authority

5.5.2. Follow all conditions and procedures specified in the 'Manual of Procedures: .'Export of Processed Animal Protein (Poultry) to European Union

5.5.3. The direct implementation of the standards and procedures prescribed by the .Competent Authority

5.5.4. Receive the assigned Government auditors and coordinate with them for .conducting inspections/audits

5.5.5. .Abide by the national rules and regulations

5.5.6. Develop and maintain required infrastructure facilities as stipulated and .required for production of safe food/food products/by-products

5.5.7. .Maintain adequate qualified manpower for the export procedures

5.5.8. Keep all necessary documents and records to a required period as stipulated .by the CA

5.5.9. .Maintain hygiene and sanitation requirements in the Establishment

5.5.10. .Get all audits registered in the 'Establishment Audit Register' after every audit

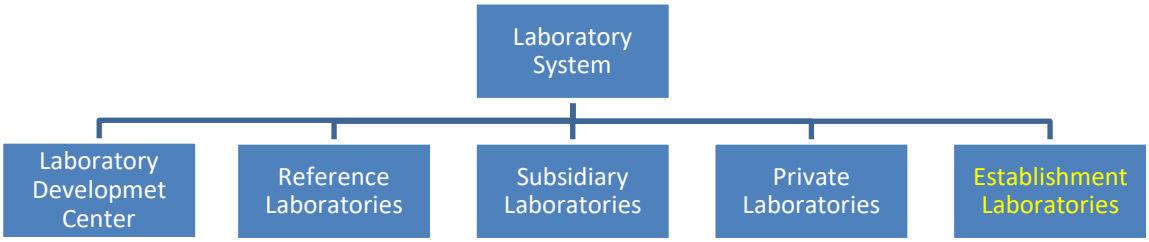
5.5.11. Give a Guarantee Letter at the time of Approval Audit and during every Annual Renewal Audit stating that "There is no possibility of any type of contamination to the products produced in the Establishment resulting in any public health or animal health risks. And there is a scientifically designed full traceability system for all products and processes." signed by the person in charge of the .Establishment

5.5.12. The Establishment shall not involve in making legislative procedures or in 'law .making' in any way, unless suggestions are specifically invited by the CA

5.5.13. To send samples (self-monitoring) to only CA approved laboratories for .analysis

6. **Details of the 'Laboratory System' -** The EDL Laboratory of SFDA in Riyadh shall be the National Reference Laboratory for all analyses concerned with the export of Processed Animal Protein (Poultry) to European Union. Subsidiary Reference Laboratories (Government owned) and Approved External Reference Laboratories shall function under the National Reference Laboratory to meet the analysis requirements of the said .EU exports

CHART – 7
Laboratory System



6.1. The Working Structure of Laboratories: As shown in the above figure, the Laboratory Working Structure shall comprise a National Reference Laboratory, Subsidiary .Reference labs, External Reference Labs and Establishment Labs

6.1.1. National Reference Laboratory – SFDA Laboratory in Riyadh (under EDL) shall .function as the National Reference Laboratory

6.1.2. Subsidiary Reference Laboratories – The Subsidiary Reference Laboratories that conduct analyses for Processed Animal Protein (Poultry) shall include the :following laboratories

6.1.2.1 Riyadh Food Laboratory (RFL)
6.1.2.2 Jeddah Food Laboratory (JFL)
6.1.2.3 Dammam Food Laboratory.
6.1.2.4 Central Laboratory of MEWA (Ministry of Environment, Water and Agriculture) in Riyadh
6.1.2.5 Regional Laboratories of MEWA in Jeddah, Medina, Al Hassa, Abha, Hail, Jezan and Al Qassim

6.1.3. External Reference Laboratory – External Reference Laboratories are one kind of Subsidiary Reference Laboratory of this system, but not owned by the Government of Saudi Arabia. The External Reference Laboratories shall be

approved by the Competent Authority to meet the analysis requirements of Export of Processed Animal Protein (Poultry) to European Union. External .Reference Laboratories include both national and international labs

CHART – 8
Laboratory Working Structure

6.2. Responsibilities of Reference Laboratories

6.2.1.National Reference Laboratory - The SFDA Central Laboratory (of EDL) in Riyadh shall be the National Reference Laboratory. This Laboratory shall be responsible for the coordination of all matters related to Laboratory tests and analyses. The :other responsibilities of this laboratory shall be as follows

6.2.1.1. Receive the list of analyses and tests to be conducted in connection with export of processed poultry by-products from the Competent .Authority

6.2.1.2. Assigning of tests and analyses to different National/International .Reference Laboratories

6.2.1.3. Ensure that the analytical methods used in different laboratories for .tests/analyses are valid and scientifically accepted

6.2.1.4. .Conducting analysis for samples received in the SFDA Laboratory, Riyadh

6.2.1.5. .Receiving lab reports of tests from all Reference Laboratories

6.2.1.6. .Compilation of reports received from Reference Laboratories
6.2.1.7. Dispatch of compiled test results to the Establishment with copy to .other associating government bodies
6.2.1.8. Record keeping of lab results for all tests/analyses conducted in all .reference Laboratories
6.2.1.9. .Keep GLP in the National Reference Laboratory
6.2.1.10. Maintenance of GLP Compliance Program for all laboratories as per the .'Good Laboratory Practice Manual'
6.2.1.11. .Audit of Establishment Laboratories to check the adherence to GLP
6.2.1.12. Keep a separate file for every Establishment and keep all tests/analyses .reports concerned with that Establishment

6.2.2.Subsidiary Reference Laboratories – The EDL Laboratories in Dammam and Jeddah, Animal Resources Sector Laboratories owned by Ministry of Environment, Water and Agriculture (MEWA) in Riyadh are assigned as Subsidiary Reference Laboratories. The responsibility of these laboratories shall :be as follows

6.2.2.1. Receive samples dispatched by the government auditors .from Establishment
6.2.2.2. Conduct the tests and analyses as per the assignment given by the .National Reference Laboratory
6.2.2.3. .Send the test results to the National Reference Laboratory
6.2.2.4. ,Keep confidentiality of all lab tests and results
6.2.2.5. Keep a file for each Establishment and keep all tests/analyses reports .concerned with that Establishment
6.2.2.6. .Keep GLP in the Subsidiary Reference Laboratory

6.2.3.External Reference Laboratories – The External Reference Laboratory shall be approved by the Competent Authority from time to time based on the analysis requirement. The Competent Authority shall identify, evaluate and engage such .reliable laboratories located in Saudi Arabia or abroad for analysis

:The responsibilities of the External Reference Laboratories shall be as follows

6.2.3.1. Receive samples for analysis as advised by the Executive Bodies that .functions under the supervision of SFDA
6.2.3.2. Conduct test/analysis as per the analysis requirement communicated by .the Executive Bodies
6.2.3.3. Send test/analysis reports to the concerned executive body from where .the analyses request was received

6.2.3.4. .Keep confidentiality of all lab tests and results
6.2.3.5. .Keep GLP in the External Reference Laboratory

6.2.4.Establishment Laboratory – There shall be an own laboratory for the Establishment to carry out regular analyses and tests. The responsibilities of this :Laboratory shall be as follows

6.2.4.1. .Conduct regular tests/analyses as per the list issued by CA
6.2.4.2. .Keep record of all tests/analyses conducted
6.2.4.3. Send tests/analyses reports to the Competent Authority along with other documents to get health certificate (from Competent Authority) for each .consignment to be exported to EU
6.2.4.4. .Keep GLP in the Establishment Laboratory

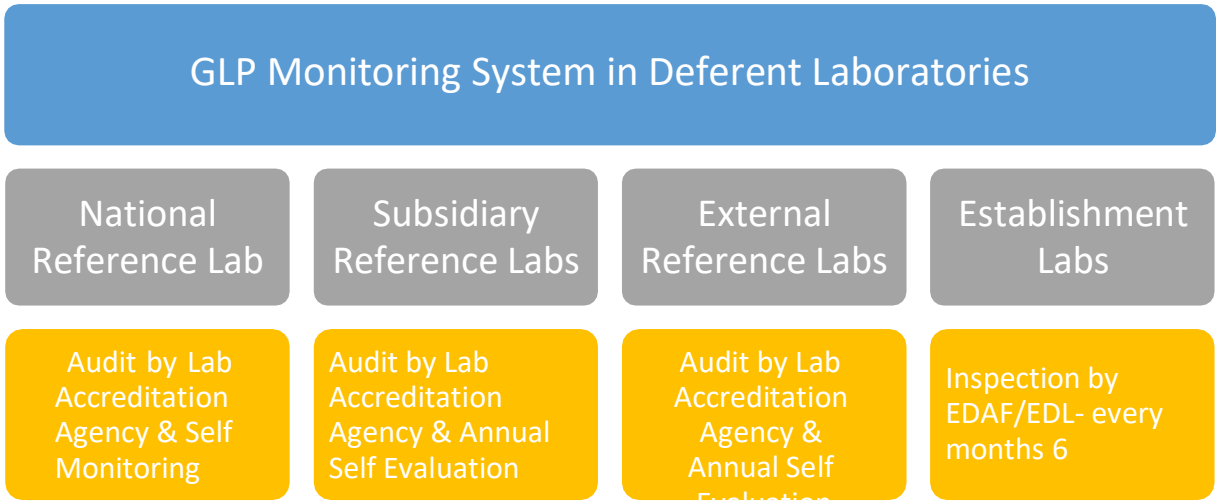
6.3. GLP Monitoring System

6.3.1. .The Good Laboratory Practices of all laboratories shall be monitored

6.3.2. The Government Laboratories where there are hurdles for an external agency to conduct GLP monitoring shall be carried out though the accreditation .agency. Such labs shall also conduct internal audits (self-assessment)

6.3.3. The government auditors (from SFDA and MEWA) shall carry out GLP audits in the Establishment laboratory along with the other audits or separately as .convenient

CHART – 9
Good Laboratory Practice Monitoring



6.4. Type of samples collected and tested – Various samples collected for analysis to ensure compliance to EU export requirements are of the following groups:

6.4.1. Samples drawn during routine /surveillance programs by EDAF.

6.4.2. Drinking water sample drawn by EDAF once a year from each Establishment.

6.4.3. Samples collected for chemical contaminants (veterinary drug & heavy metals residues) and for biological contaminants, etc. for National Residue Monitoring Program.

6.4.4. Self-monitoring samples collected and analysed by the Establishment.

6.4.5. Other relevant samples as required (need based).

6.5. Sample Collection and Dispatch

6.5.1. Collection of samples shall be done by auditors/inspectors of the Competent Authority and Animal Recourses Sector based on the type of samples.

6.5.2. Approved scientific sample collection methods (Sample number, Sample Collection, Sample Preparation, Sample Dispatch) shall be adopted according to GSO 999/1998 "Methods of sampling for animal feeding stuff".

6.5.3. The sample shall be directly dispatched to the assigned Reference Laboratories (National Reference Laboratory and/or Subsidiary reference laboratories).

6.5.4. The Dispatch of test results to Establishments – The lab test results shall not be sent to Establishment unless there is a nonconforming results in the report.

6.6. Verification of the Appropriateness of Methods of Sampling, Methods of Analysis and Detection Tests

6.6.1. The appropriateness of the methods of sampling, analysis etc. shall be verified initially by the Competent Authority.

6.6.2. The review of the methods of sampling, analysis, etc. shall be again carried out during the time of revision of manual.

6.6.3. Verification shall be carried out also when a new sampling/analysis method is adopted.

6.7. Actions Taken Following Unsatisfactory Results of Analyses (of samples drawn during official audits and visits)

6.7.1. Step 1 – The information shall be immediately communicated to the following agencies as given below.

6.7.1.1. Competent Authority

6.7.1.2. Farm/Establishment

6.7.1.3. Other associating government bodies

6.7.2. Step 2 – The lot from which the final product samples were collected and kept aside from sales/export shall be re-sampled. In any case, if any such product found already released, communication shall be sent to hold the product pending retest results.

6.7.3. Step 3 – If the second sampling (retained samples) also reveals the unsatisfactory results, the lot from which the sample was collected, decision shall be taken to reprocess or discard the lot based on the type, nature and level of the residue detected. However, if the second sample reveals the results are normal then the product shall be released.

6.7.4. Step 4 – The CA shall investigate the reason for such incidents and necessary corrective and preventive measures shall be taken and the Farm/Establishment shall be advised accordingly.

6.7.5. Step 5 – All information regarding potential incidents (with history, action taken and future plans etc.) shall be communicated to concerned agencies.

6.7.6. The action taken on high residue levels reported higher than the admissible limits as per the "National Residue Monitoring" shall be as per the procedure described in the "National Residue Monitoring Program".

6.8. Allocation of Tests to Laboratories – Procedure by which laboratories are designated by the CA to carry out the analysis of samples taken during official audits, inspection etc. shall be as follows:

6.8.1. As much as possible the tests shall be conducted by the National Reference Laboratory and Subsidiary Reference Labs owned by the government.

6.8.2. CA shall be responsible for identifying and approving external competent laboratories (national and international) to meet the analysis/test requirements as needed.

6.8.3. Tests shall be allocated to labs based on its capability, efficiency, time taken for completion of analysis, professional/scientific credentials etc.

6.9. Criteria for Ensuring Lab Competency, Reliability and Accuracy

6.9.1. The selection of laboratory is carried out only if they comply with standard reference methods. This is ensured by the following:

6.9.1.1. Selecting labs with organised systems/certifications to conduct test and analysis (like ISO/IEC 17025 or equivalent) to comply with the requirements.

6.9.1.2. Site visit to the laboratories and inspection as needed.

6.9.1.3. Writing down the test methods in the test result report as a proof of methods adopted in the analyses and tests.

6.10. List of Approved External reference Laboratories

SN	Name of Reference Laboratory	Accreditation status
1	LUFA-ITL GmbH, Germany	DIN EN ISO/IEC 17025:2005
2	IDAC Laboratory, Riyadh, Saudi Arabia	ISO 17025:2005
3	SGS Gulf Limited, Dubai	ISO 17025:2005
4	CIFT Lab, Indian Council of Agricultural Research, Cochin. India	ISO 17025:2005
5	TUV SUD South Asia, Bangalore, India	ISO 17025:2005

Part # II

Compliance of Saudi Arabia to European Union Regulation (EC) No. 1069/2009 of 21 October 2009

1. Subject Matter, Scope and Definitions

1.1. Subject Matter

1.1.1. These stipulations lay down public health and animal health rules for the production of Processed Animal Protein of poultry origin produced and exported from Saudi Arabia to European Union.

1.1.2. The rules and regulation also aims to prevent and minimise risks to public and animal health arising from those products, and, in particular, to protect the safety of the food and feed chain.

1.2. Scope

1.2.1. These stipulations shall apply to production 'Processed Animal Protein (Poultry)' not fit for human consumption, which form raw materials for animal feed and has the intention of controlling and eradicating applicable animal diseases.

2. Obligations – Starting Point in the Manufacturing Chain and Obligations

2.1. As soon as Establishments (which exports Processed Animal Protein of Poultry origin) to European Union) generate animal by-products or derived products falling within the scope of this manual, they shall identify them and ensure that they are dealt with in accordance with the stipulations of this manual

2.2. Establishments shall ensure at all stages of collection, the transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use and disposal within the businesses under their control that animal by-products and derived products satisfy the requirements of this Manual which are relevant to their activities.

2.3. The Competent Authority shall monitor and verify that the relevant requirements of all EU regulation are fulfilled by the Establishments /Establishments along the entire chain of animal by-products and derived products.

2.4. The Competent Authority shall maintain a system of official controls in accordance with relevant EU regulations and national legislations.

2.5. The Competent Authority shall ensure that an adequate system is in place ensuring that animal by-products are:

2.5.1. Collected, identified and transported without undue delay;

2.5.2. Treated, used or disposed of in accordance with the applicable EU Regulations.

3. Animal Health Restrictions

3.1. Animal by-products and derived products from susceptible species (with transmittable diseases to animals or humans) shall not be received from holdings/areas or processed in Establishments which are subject to restrictions and such by-products shall not be stored in the Establishments

4. Categorisation of Poultry By-Products and Derived Products

4.1. Poultry by-products shall be categorised into specific categories which reflect the level of risk to public health and animal health arising from those animal by-products.

4.2. Category 1 Material - Category 1 material shall comprise the following poultry by-products:

4.2.1. Entire bodies and all body parts, including feather of diseased poultry unfit for human consumption.

4.2.2. Poultry suspected of being infected by highly infectious animal disease.

4.2.3. Poultry killed in the context of disease eradication measures.

4.2.4. Poultry used for experiments.

4.2.5. Entire bodies or parts of dead poultry containing specified risk material.

4.2.6. Entire bodies or parts of dead poultry subjected to illegal treatments.

4.2.7. .Entire bodies or parts of dead poultry with undesirable residues

4.2.8. Entire bodies or parts of dead poultry with contaminants or other substance .not permitted as per EU regulations

4.3. Category 2 material - Category 2 material shall comprise the following poultry by-:products

4.3.1. Poultry by-products collected during the treatment of waste water/slaughter .houses

4.3.2. Poultry by-products containing residues of authorised substances or .contaminants exceeding the permitted levels

4.3.3. Products of animal origin which have been declared unfit for human .consumption due to the presence of foreign bodies in those products

4.3.4. Poultry died other than by being slaughtered or killed for human consumption, .including animals killed for disease control purposes

4.3.5. .Mixtures of Category 2 material with Category 3 material; *Article 9 (g)*

4.4. Category 3 Material - Category 3 material shall comprise the following poultry by-:products

4.4.1. Carcases and parts of poultry slaughtered which are fit for human consumption in accordance with EU regulation, but are not intended for human .consumption for commercial reasons

4.4.2. Carcases or bodies and parts of poultry which are rejected as unfit for human consumption in accordance with Community legislation, but which did not .show any signs of disease communicable to humans or animals

4.4.3. Carcases, trimmings, bones, body parts, heads, feather, feet etc. originating from poultry that have been slaughtered in a slaughterhouse and were considered fit for slaughter for human consumption following an ante-mortem .inspection

4.4.4. Poultry products, which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects .or other defects from which no risk to public or animal health arise

4.4.5. .Other poultry by-products meet EU regulations for Category 3 materials

5. Disposal and Use of Animal By-Products and Derived Products

5.1. Restrictions on Use

5.1.1. Category 3 material which has changed through decomposition or spoilage so as to present an unacceptable risk to public or animal health, shall not used in .the processing of animal Protein (poultry) export to EU

5.2. Disposal and Use

5.2.1. The disposal and use of Category-1, Category-2 and Category-3 poultry by-products shall be as per the stipulations of Article 12, 13 & 14 of Regulation .(EC) No 1069/2009

5.2.2. Only applicable Category 3 material shall be used for the production of the .Processed Animal Protein intended for export to European Union

5.2.3. Any objectionable material (as per EU regulation) even birds dead on arrival (in .the poultry processing plant) shall not be used for the production of the PAP

5.2.4. Any birds/its body parts which cause chances for transmission of risks to public and animal health due any reason shall be safely disposed following the .stipulated procedures abiding with EU regulation under official supervision

5.2.5. In the case of burning or burial of poultry by-products as provided for in Article of Regulation (EC) No 1069/2009, the person responsible for such (1)19 incineration shall keep records of the quantities, categories and species of .poultry by-products burnt along with the place and date of incineration

6. Collection and Identification As Regards to Category and Transport

6.1. The Establishment shall collect, identify and transport animal by-products of poultry origin without undue delay under conditions which prevent risks arising to public and .animal health

6.2. The Establishment shall ensure that animal by-products and derived products from poultry are accompanied during transport by necessary documents as prescribed by .the EU regulation (including the Health Certificate as applicable)

6.3. Commercial documents, health certificates accompanying animal by-products or derived products from poultry during transport shall include all relevant information including information on the origin, the destination and the quantity of such .products, and a description of the animal by-products or derived products

6.4. The Establishment shall meet the product labelling requirements of Processed Animal .Protein as stipulated in applicable EU regulations

7. Microbiological Standard of the Final Product

7.1. Samples of the final products taken during or on withdrawal from storage at the :processing plant shall comply with the following standards

.Sl No	Criteria	Stipulation
1	*Clostridium perfringens*	Absent in 1 g (sample directly after process treatment)
2	Salmonella	absence in 25 g n = 5, c = 0, m = 0, M = 0
3	Enterobacteriaceae	n = 5, c = 2, m = 10, M = 300 in 1 g

:where

;n = number of samples to be tested

m = threshold value for the number of bacteria; the result is considered satisfactory if the ;number of bacteria in all samples does not exceed m

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more samples is M or more; and

c = number of samples the bacterial count of which may be between m and M, the sample still being considered acceptable if the bacterial count of the other samples is m or less

8. Packaging

8.1. Packaging shall be carried out under satisfactory conditions of hygiene, to preclude .contamination of the poultry by-products

8.2. Packaging materials used for poultry by-products shall comply with all the EU .stipulations of hygiene

8.3. .The material shall be strong enough to protect the poultry by-products adequately

8.4. .Packaging materials shall not be re-used

8.5. Unused packaging material shall be stored in premises away from the production .area and be protected from dust and contamination

8.6. The transportation of packaging material shall be carried out in such a way to avoid .possibility of contamination

9. Labelling

9.1. The product label shall include Product name, Product Type, List of ingredients (if applicable), Net weight, Date of production/Batch number, Date of Expiry (period of expiry), Special storage conditions, Name and address of the processor, Special declaration or buyers specifications (if any).

9.2. The minimum durability of the product shall be mentioned in the label of individual pack and the expiry date/month shall be preceded by "Use By …" as applicable.

9.3. The label shall include the specific statement "not fit for human consumption".

9.4. The labelling details shall be printed clearly so that information is legible.

9.5. The labelling details shall meet all applicable EU labelling requirements.

10. Storage

10.1. Processed Animal Protein of poultry origin shall be packed and stored properly in constructed bulk bins, bags.

10.2. Products in conveyors, elevators and bins shall be protected from casual contamination.

10.3. All storage facilities shall be emptied and cleaned on regular basis, to the extent necessary to prevent contamination.

10.4. The product shall be kept dry in storage.

10.5. Leakages and condensation in the storage area shall be prevented.

10.6. The PAP shall be stored properly, under appropriate temperature conditions, until dispatched.

10.7. The permitted duration of storage / 'product expiry period' shall be as per the EU standards as applicable.

11. Traceability

11.1. Establishments producing, storing, and transporting Processed Animal Protein (Poultry) shall keep all details and records of the raw material, other incoming .materials, certificates, commercial documents, health certificates etc

11.2. There shall be a system to trace the final product (PAP) back to the hatcheries and .ensure a strong traceability system

11.3. The raw material arrived, material on line, final product in the store and product in .the market shall be covered under the traceability system

11.4. Establishment shall ensure that animal by-products and derived products are traceable at all stages of the chain of manufacturing, use and disposal. Refer ."**Annexure-3** for the detailed procedure of "Traceability

11.5. Establishment shall keep all production details and documents pertaining to the .daily production of PAP

11.6. All details and information shall be made available to the Competent Authority on .request

11.7. There shall be a documented Product Recall Program to recall products in case of an emergency situation. Refer to **Annexure-13** for the detailed Product Recall .Program

11.8. The Establishment shall keep all information and documents for a period equivalent .to the expiry period of the product

12. Registration of Establishment

12.1. All Establishments intending to export Processed Animal Protein (Poultry) shall be .registered in the office of the Competent Authority

12.2. .On registration the Establishment shall provide full details about its operation

12.3. The Competent Authority shall inspect the premises and grant/deny approval .based on the inspection outcome

12.4. The Establishment, before commencing operations, notify the Competent Authority of details of activity such as production, transport, handling, processing, .storage, placing on the market, distribution etc. of PAP

12.5. The registered Establishment shall provide the Competent Authority with up-to-date information including any significant change in activities such as any closure .of an existing Establishment or plant

12.6. There is an on-line registration in SFDA for establishments that produces food and .food products in Saudi Arabia as well as third country food exporters

13. Approval of Establishments or Plants

13.1. Establishment intended to export Processed Animal Protein (Poultry) to European .Union shall get their rendering plants approved by the Competent Authority

13.2. Only those Establishments (Rendering Plants) which own poultry meat processing plant and poultry farm and hatchery (fully integrated) shall be approved for exports .Processed Animal Protein (Poultry) to EU

13.3. No raw material (poultry by-product) shall be sourced by the Establishment, except .from own Poultry Facilities

13.4. The Establishments shall carry out processing of poultry by-products, employing a .manufacturing process stipulated in the applicable European Union regulations

13.5. Approved Establishment shall produce Processed Animal Protein (Poultry) only .from Category 3 material

13.6. The intended use of the produced Processed Animal Protein (Poultry) shall be manufacturing of aquaculture feed and pet food' and other permitted animal ' :feeds including special feeding purposes as follows

(a) ;zoo animals
(b) ;circus animals
(c) ;reptiles and birds of prey other than zoo or circus animals
(d) ;fur animals
(e) ;wild animals
(f) ;dogs from recognised kennels or packs of hounds
(g) ;dogs and cats in shelters
(h) .maggots and worms for fishing bait

13.7. .Refer to **Annexure-2** for detailed Establishment Approval procedures

14. General Sanitation Requirements – To ensure proper Sanitation in operation, the Establishment shall ensure that:

14.1. The premises have sufficient size for work to be carried out under adequate hygiene conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building.

14.2. The construction of the facility shall be a permanent structure.

14.3. The premises shall be constructed in a way permitting their effective cleaning and disinfection and where appropriate the construction of floors is impermeable to water facilitates the draining of liquids.

14.4. There shall be adequate natural/artificial lights (with proper protection), ventilation facility with proper air filtration system and temperature control system in the production area.

14.5. The production premises shall have access to adequate facilities for personal hygiene such as number of lavatories, rest rooms, changing rooms and washbasins for staff.

14.6. The doors shall be self-closing type and foot dips with sanitizing agents at doors.

14.7. The premises, production and connected areas shall have appropriate arrangements for protection against pests, such as insects, rodents and birds and there shall be a documented pest control program – implemented regularly monitored and records kept.

14.8. The Establishment shall keep all installations and equipment in good condition with documented maintenance plans and schedules and records kept.

14.9. There shall be adequate separation for dirty and clean areas (Raw material handling area, processing area, finished product handling areas) inside the Establishment.

14.10. There shall be appropriate arrangements for the cleaning and the disinfection of containers and vehicles in place to avoid risks of contamination.

14.11. There shall be appropriate documented cleaning procedures established, practised and documented for all parts of the Establishment and/or plant.

14.12. The Establishment shall use sanitising agents & detergents (chemical agents, soap solutions etc.) approved by the Competent Authority for effective cleaning and .sanitation

14.13. The plant surrounding shall be concreted, asphalted or compressed, in order to .prevent windblown dust contamination

15. Hygiene Requirements

15.1. Any person working in the Establishment shall wear suitable, clean and, where .necessary, protective clothing

15.2. Persons working in the unclean sector shall not enter the clean sector without first .changing their work clothes and shoes or without having disinfected them

15.3. Equipment and machinery shall not be moved from the unclean to the clean sector .without first being cleaned and disinfected

15.4. The Establishment shall establish a procedure relating to the movements of persons in order to monitor their movements and describe the correct use of foot-.baths and wheel baths

15.5. .Training shall be given to employees on Hygiene and Sanitation procedures

15.6. Smoking, spitting, eating and drinking in work and storage premises shall be .prohibited

15.7. All the employees who work in the product handling area shall obtain Health Certificates from a Government agency, as proof of fitness to work in the .Establishment

15.8. .Hand swab tests need to be conducted as factor of verification of staff hygiene

16. General Precautions and Conditions

16.1. In the Establishment, poultry by-products shall be handled in such a way as to avoid .risks of contamination

16.2. The Category 3 Material (Poultry by-products) shall be processed as soon as .possible

16.3. After processing, derived products shall be handled and stored in such a way as to avoid risks of contamination

16.4. Wherever appropriate, during any processing applied to Processed Animal Protein (Poultry) every part of the animal by-product (CAT 3 Material) and derived products (PAP) shall be treated to a given temperature for a given period of time and risks of .re-contamination shall be prevented

16.5. Establishment shall check regularly the applicable parameters, particularly .temperature, pressure, time, size of particles

16.6. The applicable parameters shall be monitored manually or using automatic devices .as required by the process

16.7. That measuring equipment are calibrated regularly and calibration records are .kept

17. Handling of Animal By-Products Within Food businesses

17.1. The treatment, processing or storage of Category 3 poultry by-products and Processed Animal Protein in Establishments approved by Competent Authority for export of Processed Animal Protein (Poultry) shall be carried out under conditions which prevent cross-contamination and if appropriate in a dedicated part of the .Establishment or plant

17.2. The Establishment shall abide by all the specific requirements laid down in .Community veterinary legislation

18. Implementing measures – For the implementation of all applicable stipulations of the :EU regulation, necessary measures shall be laid down relating to the following

18.1.1. Infrastructure and equipment requirements applicable within the .Establishment

18.1.2. Hygiene requirements applicable to all types of handling of Processed Animal Poultry (Poultry) including “General Hygiene Requirements” stated in previous .clauses for Establishments

18.1.3. Conditions and technical requirements for the handling, treatment, .transformation, processing and storage of Processed Animal Protein (Poultry)

18.1.4. .Conditions for treatment of waste water

18.1.5. Evidence (from the Establishment) of validation of the treatment, transformation and processing of Processed Animal Protein (Poultry), on their ability to prevent public and animal health risks.

18.1.6. Conditions for the handling of Animal Protein (Poultry) or its derived products of more than one category (Category1,2, 3 etc.) in the same Establishment where compulsorily such operations are carried out separately.

18.1.7. Conditions for the prevention of cross-contamination when animal by-products are stored, treated or processed in a dedicated part of an Establishment.

18.1.8. Conditions for the disposal (including 'Incineration'(of raw material (Poultry by-products) or final product (derived products including Processed Animal Protein), if suspected/discovered causing animal health or public health implications.

18.1.9. Other measures, stipulations and conditions required for the implementation of applicable EU regulation.

19. Own Checks and HACCP System

19.1. Own Checks

19.1.1. The Establishment shall have a quality and safety controlling department to ensure quality, safety and regulatory compliance of the product, process and the facility.

19.1.2. The Establishment shall put in place, implement and maintain own checks in the production of Processed Animal Protein (Poultry) in order to monitor compliance with all applicable EU Regulations.

19.1.3. The Establishment shall ensure that no poultry by-products or Processes Animal Protein suspected or discovered not complying with EU Regulations leave the Establishment, unless destined for disposal.

19.2. Hazard Analysis and Critical Control Point System

19.2.1. Establishments that carry out processing, handling and storage of Processed Animal Protein of poultry origin shall put in place, implement and maintain a permanent written procedure or procedures based on the hazard analysis and critical control points (HACCP) system principles.

19.2.2. To comply with the "**7 Principle**" requirements of HACCP system, the Establishment shall:

19.2.3. Identify any possible hazards that are likely to occur shall be prevented, .eliminated or reduced to acceptable levels (**Principle # 1**)

19.2.4. Identify the critical control points (CCPs) at every step at which control is essential to prevent or eliminate hazards or reduce it to acceptable levels .(**Principle # 2**)

19.2.5. Establish Critical Limits (CLs) at critical control points which separate acceptability from unacceptability, for the prevention, elimination or .reduction (to the acceptable level) of identified hazards (**Principle # 3**)

19.2.6. Establish and implement effective monitoring procedures at every critical .control point (**Principle # 4**)

19.2.7. Establish corrective action when monitoring indicates deviation of critical .limit (CL) and the critical control point is not under control (**Principle # 5**)

19.2.8. Establish specific procedures to verify that the measures outlined are .complete and working effectively in controlling hazards (**Principle # 6**)

19.2.9. .Carryout verification procedures regularly

19.2.10. Prepare required documents and maintain adequate records commensurate with the nature and size of the businesses to demonstrate the effective application of the measures set out in above said points .(**Principle # 7**)

19.2.11. To ensure that the HACCP system is effectively established, the :Establishment shall

19.2.11.1. Form a HACCP team with members from different departments of .the Establishment who are directly involved in food safety

19.2.11.2. Describe the product in order to have detailed information to .facilitate the implementation of HACCP system

19.2.11.3. .Specifically identify and record the intended use of the product

19.2.11.4. Construct a flow-diagram of the step-by-step process involved in the .production of Processed Animal Protein of poultry origin

19.2.11.5. Verify every step of the process inside the processing area of the Establishment to ensure that every process step of the production is .listed in the flow-diagram

19.2.12. To ensure that the HACCP performs efficiently, the Establishment shall design and adopt prerequisite/foundation programs as follows:

19.2.12.1. Good Manufacturing (Production) Practices/Standard Operating Procedures for every operation.

19.2.12.2. Good Hygiene Practices/Sanitation Standard Operating Procedures to ensure product/personnel hygiene.

19.2.13. When any modification is made to a product, process or any stage of production, processing, storage or distribution, the Establishment shall review their procedures and make the necessary changes.

19.2.14. Implementation of HACCP in Establishment that exports Processed Animal Protein (Poultry) shall be in accordance with all applicable EU regulations

20. National Guides to Good Practises

20.1. The Competent Authority and associating Government agencies shall prepare national guides for Good Practices for the Establishment that produce Processed Animal Protein (Poultry) to follow in relevant areas including HACCP, biosecurity, Good Laboratory Practices, hygiene procedures etc. as needed.

20.2. The Competent Authority shall ensure that such National Guidelines are relevant and to the best interest of the country as well as of the Establishments. The Competent Authority shall also make sure that the suggestions and guidance given are relevant and pragmatic.

21. Placing on the Market - Processed Animal Protein (Poultry) shall be proposed for placing in EU Markets relating to the following:

21.1. Safe Sourcing – Safe sourcing shall include the use of material from which no unacceptable risks to public and animal health arise. Processed Animal Protein (Poultry) produced in the Establishment destined for European Union Markets shall be produced only from Category 3 material. The raw material (poultry by-products) shall be accepted only from Poultry Meat Processing Plant owned by the same Establishment approved by the Competent Authority.

21.2. Safe Treatment – Safe treatment shall include application of a manufacturing process to the material used which reduces to an acceptable level risks to public and animal health arising from the material used or from other substances resulting from the manufacturing process. The Processed Animal Protein (Poultry) destined

for EU markets shall be processed in accordance with the conditions for pressure sterilisation or other conditions to prevent risks arising to public and animal health .in accordance with applicable EU Regulations

21.3. Safe End Use – Safe end uses shall include the use of Processed Animal Protein (Poultry) under conditions which pose no unacceptable risks to public and animal health. The end use for the product is defined as it is not for human consumption .but for manufacturing of pet feed

22. Import of Poultry and Poultry Product

22.1. The Competent Authority shall impose strict measures on the import of Poultry and Poultry products to Saudi Arabia in view of prevention of possible introduction of .infectious animal disease through imports

22.2. The countries importing Processed Poultry Product shall be screened by a designated office of the Competent Authority – Executive Department for Imported .Food Control

22.3. The import control of poultry products shall be ensured through a detailed questionnaire, country visit and inspection. Please see **Annexure-4a** for the .questionnaire

22.4. Import of live poultry is prohibited in to the kingdom except for day old chicks and .fertilised eggs

22.5. The import of day old chicks and fertilised eggs are carried out though strict control measures by Animal Recourses Sector of Ministry of Environment, Water and .Agriculture (MEWA)

22.6. The Competent Authority has documented guide line published for inspectors who inspect third country Competent Authorities and Establishments and the process .of approval. Refer to **Annexure 4b and 4c**

22.7. .No Processed Animal Protein of poultry origin is permitted import to Saudi Arabia

23. Saudi Arabia, Meeting Requirements as Third Country

23.1. Saudi Arabia as third country intending export of Processed Animal Protein ((Poultry) to European Community as per the Article 41 (4) of EC No. 1069/2009.

23.1.1. Shall develop, adopt, maintain and monitor adequate legislation for the production, handling, storage and export of Processed Animal Protein (Poultry) meeting the EU requirements.

23.1.2. Shall ensure a strong organisation for the Competent Authority, with:

23.1.2.1. Effective inspection services in the country

23.1.2.2. Well-defined powers/responsibilities

23.1.2.3. Adequate supervision to which they are subject to

23.1.2.4. Delegated authority to monitor effectively the application of legislation

23.1.3. Shall ensure effective measures for safe production, manufacture, handling, storage and dispatch of Processed Animal Protein (Poultry) intended for the export to European Community warranting no risk for public or animal health.

23.1.4. Shall provide assurance that Saudi Arabia abides by applicable requirements of EU in compliance with relevant health conditions. Refer to **Annexure-5**.

23.1.5. Has food products marketing experience in European Union since 2005 (Refer **Annexure-6**) without any quality or other issues.

23.1.6. Had been inspected by DG (SANCO) in the year 2013 and was found the current organisation of the Saudi Arabian CA and the control system implemented can offer adequate guarantees for EU export. Refer to **Annexure-7**.

23.1.7. Ensure that Saudi Arabia shall not pose any risk to public or animal health in the European Community through the managing the health status of the livestock, other domestic animals and wildlife in the third country, having particular as regards to exotic animal diseases and general health situations in the country.

23.1.8. Has system in place for quick transmission of information about the existence of infectious poultry diseases in its territory, in particular the diseases listed in the Terrestrial Animal Health Code and the Aquatic Animal Health Code of the World Organization for Animal Health.

23.1.9. Has strict regulations implemented for the prevention and control of infectious poultry diseases in force in Saudi Arabia including rules on imports from other third countries.

24. Export

24.1. The Processed Animal Protein (Poultry) exported to EU shall be complying to the requirements of applicable EU regulations in order to make sure that the stipulations are at least as strict as the production and marketing of such Processed Animal Protein (Poultry) within the European Community.

24.2. All necessary documentation shall be done for every export taking place to EU countries. Every consignment shall be accompanied by Health Certificate, other commercial documents, declarations etc. as required to the fulfilment of import requirements of Processed Animal Protein (Poultry) in the European Community.

24.3. The process of issuing the Health Certificate shall follow the steps as given in **Annexure-8**.

24.4. Please see the model health certificate – **Annexure-9**.

24.5. In case of transit of Processed Animal Protein (Poultry) of Saudi origin in European Community, shall meet all requirements stipulated in the applicable EU regulations.

25. Procedure for Approval

25.1. The Competent Authority shall approve Establishments only where an on-site visit, prior to start-up of any activity, has demonstrated that they meet the relevant requirements laid down in accordance with applicable EU regulations including:

25.1.1. Good Manufacturing (Operating) Practices in the Establishment

25.1.2. Hygiene and Sanitation procedures and practices (Good Hygiene Practice)

25.1.3. Own check (HACCP) system

25.1.4. Laboratory and Analytical system

25.1.5. Animal Health Monitoring System

25.1.6. Disease Control and Prevention System

25.1.7. Vaccination Program

25.2. The Competent Authority may grant conditional approval if it appears, from the on-site visit, that the Establishment or plant meets all the infrastructure and equipment requirements with a view to ensuring the application of the operational .procedures in compliance with applicable EU Regulations

25.3. The Competent Authority shall grant full approval only if it appears, from another on site visit carried out within three months of granting conditional approval, that .the Establishment or plant meets all the stipulated requirements

25.4. The Competent Authority shall test/ evaluate the competency/ adequacy of Lab .technicians, HACCP system, Laboratory facility etc. and approve if found qualified

25.5. If the Establishment plant still does not meet all of these requirements, the .Competent Authority shall terminate the conditional approval

25.6. .The step by step procedure to approve an Establishment shall follow **Annexure-2**

26. Official Controls

26.1. The Competent Authority shall at regular intervals carry out official controls and supervision of the handling of Processed Animal Protein (Poultry) for the export to .European Union

26.2. The Competent Authority shall apply stipulations of relevant EU regulations to .verify compliance

26.3. The Competent Authority may take into account adherence to guides to good .practice, when carrying out its official controls

26.4. The Competent Authority shall ensure the right reference methods are employed .in microbiological, chemical and other analyses

26.5. The audits, inspections and monitoring carried out as part of official control shall .follow the details given in **Annexure-10**

27. Impositions, Suspensions, Withdrawals and Prohibitions on Operations - If the official controls and supervision carried out by the Competent Authority and other associating government agencies reveal that one or more of the requirements of this Regulation are not met, the Competent Authority shall take appropriate action.

27.1. Impositions – The Competent Authority, based on the inspection and audits as part of official controls shall impose specific conditions on Establishments or plants in order to rectify existing deficiencies.

27.2. Suspensions – The Competent Authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health suspend approvals of Establishments or plants approved pursuant to this Regulation, in following situations:

27.2.1. The conditions for approving or operating the Establishment or plant are no longer fulfilled.

27.2.2. The Establishment can be expected to remedy the deficiencies within a reasonable period of time.

27.2.3. The potential risks to public and animal health do not require withdrawal of approval.

27.3. Withdrawals – The Competent Authority shall in particular, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health withdraw approvals of Establishments approved pursuant to this Regulation, in the following situations:

27.3.1. The conditions for approving or operating the Establishment are no longer fulfilled.

27.3.2. The Establishment cannot be expected to remedy the deficiencies within a reasonable period of time.

27.3.2.1. For reasons relating to the infrastructure of the Establishment or plant;

27.3.2.2. For reasons relating to the personal capacity of the Establishment or the staff under his supervision; or

27.3.2.3. Because of serious risks to public and animal health requiring major adjustments to the operation of the Establishment before the Establishment may apply for re-approval.

27.4. Prohibitions – The Competent Authority shall, as appropriate to the nature and to the gravity of the deficiencies and to the potential risks for public and animal health, temporarily or permanently prohibits Establishments from carrying out operations, as appropriate, following receipt of information indicating:

27.4.1. Unacceptable and unjustifiable noncompliance demonstrating that the requirements of EU regulations/legislation are not met; and

27.4.2. Potential risks to public or animal health arising from such operations to a dangerous level.

28. Re-Approval of Establishments

28.1. If the approval of the Establishment is suspended/withdrawn/terminated due to a reason, the Establishment could export products again to European Union only once the Establishment is reapproved by the Competent Authority.

28.2. The re-approval of the Establishment shall depend on the suspension/withdrawal/ termination of the approval; adequacy of the corrective action taken; confidence of the Competent Authority to re-approve the Establishment etc.

28.3. The decision for re-approval shall be under the sole discretion of the Competent Authority.

28.4. The procedure of re-approval shall follow the details provided in **Annexure 11**.

29. Listing of Approved Establishments

29.1. The Competent Authority shall draw up a list of Establishments which have been approved in accordance with the relevant EU Regulations in the country.

29.2. The Competent Authority shall assign an official number to each approved Establishment, which identifies the Establishment with respect to the nature of its activities.

29.3. The Competent Authority shall make details of the Establishment(s) along with the relevant details to DG- SANTE for the approval from the European Union and listing for official purposes.

30. Keeping Establishments in the Approved List

30.1. .The establishments shall be given approval to export to EU for one year

30.2. After one year and thereafter every year the establishment shall be audited for renewal of the approval status by the audit team comprised of auditors/inspectors of SFDA and MEWA .as assigned by the Competent Authority

30.3. Those Establishments that are qualified in the renewal audit shall be retained in the Approved List of Establishment qualified for export of Processed Animal Protein (Poultry) .to European Union

31. :Removal of Establishment from the Approved List of Establishments

31.1. If an establishment fails to comply with EU regulation, posing major risk to public/animal health/consumer safety/casing critical system damage/report of fraud/legal violations; name of such Establishment shall be removed from the Approved List of Establishments .exporting processed animal protein to EU by the CA after a thorough investigation

31.2. Removal from the Approval List shall be communicated to concerned offices of the .European Union

31.3. The decision of the Competent Authority on the removal of the Establishment from the list .of approved Establishment shall be final in this matter

32. National Provisions

32.1. The Competent Authority shall develop, review and adopt regulations on a national level in Saudi Arabia to comply with the Commission requirements for the export .of Processed Animal Protein (Poultry) to European Union

32.2. The Competent Authority shall communicate to the European Commission (DG – SANTE) of the national regulations Saudi Arabia adopts in areas under their competence which directly concerns the proper implementation of applicable EU .Regulations

33. Infringements and Penalties

33.1. The Competent Authority shall lay down the rules on penalties applicable to infringements of the stipulation of this legislation – Manual of Procedures: Export .of Processed Animal Protein (Poultry) to European Union

33.2. .The penalties provided for shall be effective, proportionate and dissuasive

33.3. The Competent Authority without prejudice shall ensure that the penalties are .imposed as appropriate

33.4. Details of action taken by the Competent Authority on infringements and violations of this legislation are given in **Annexure-12**

34. General Clauses

34.1. Measures to Eliminate Conflict of Interest and Biased Decision – In order to ensure that that staff or members of the official control system are devoid of any conflict .of interest or biased decision the following precautionary measures are taken

34.1.1. Distribution of Responsibilities - Specific responsibilities allotted to the each inspection agency such as the Competent Authority (Food Sector – SFDA), EDAF-Executive Department for Animal Feed, Executive Department for Laboratories – EDL, Animal Recourse Services (ARS) of Ministry of Environment, Water and .Agriculture *etc.,* as explained in this Manual

34.1.2. Mosaic Audit Pattern – The government agencies such as EDAF, EDL, and ARS shall conduct separate routine audits. EDAF audit shall be carried out every three months which is a general supervisory audit which cover elements of EU export system and cross verifies other audit details. EDL audit shall be every 6 months .whereas ARS shall carry out the audit every week

34.1.3. Audit Interlink – As an inter-link between these three audits, the Competent Authority shall convene a Technical Committee meeting every three months to .discuss all matters concerned with Official Control

34.1.4. Combination of Officials for Common Consensus – The approval audit of an establishment and renewal audit of an already approved establishments shall be carried out by a combined audit team comprise of auditors of different .government bodies

34.1.5. The comprehensive network of audits and pattern of inspections designed for monitoring shall ensure elimination of conflict of interest and biased decisions of .staff performing Official Controls

34.2. Provisions to Guarantee a Harmonized System in the Whole Country

34.2.1. The Competent Authority operates all activities from head office in Riyadh, .Saudi Arabia and responsibilities as described in this Manual

34.2.2. The head office of CA shall directly monitor and coordinate the EU export .system activities

34.2.3. The relevant clauses and stipulations of the 'Manual of Procedures' are communicated to all concerned executive bodies and staff who carry out .Official Control procedures

34.2.4. Changes, amendments *etc.,* in procedures/documentation shall be discussed in the Technical Committee meeting where all associating government .agencies participate

34.2.5. The High Level Coordination Committee (HLCC) comprise Heads of apex government agencies as described in this Manual shall help in the implementation and evaluation of systems and procedures of export of .Processed Animal Protein (Poultry) to EU across Saudi Arabia

34.2.6. Training shall be given to auditors and inspectors on procedures to ensure .unified and harmonised methods are adopted across the country

34.3. Internal Control' Provisions in the CA and EU Export Monitoring System'

34.3.1. The head office of the Competent Authority shall responsible for ensuring .legal compliance and adherence to the written procedures

34.3.2. During 'Renewal Audit' of the Establishment, CA auditor shall verify the process of audit carried out by the auditors (from all government agencies) .to ensure compliance to legalisation and written procedures

34.3.3. Representatives of head office of the Competent Authority shall visit offices of the associating government agencies as well as local/regional offices of the CA for reviews and evaluation as needed to ensure internal control practices, .system compliance and adherence to specifications and stipulations

34.3.4. The CA, during its direct audit through EDAF in establishments, shall inspect the records of audits carried out by different inspectors of different associating government agencies to ensure that the audit schedule is met and a harmonized approach is demonstrated in different audits and compliance .to legalization and written procedures are in place

34.4. .Training program for the EU export system maintenance

34.4.1. The Competent Authority and associating governing departments shall conduct training programs for the EU system Auditors/ Inspectors/ .Technicians and Establishment as required

34.4.2. Each government agency that is associated with EU export of Processed .Animal Protein shall conduct trainings for their inspectors as needed

34.4.3. The Establishments shall conduct training for their technicians and quality control personnel on EU export system procedures and controls at a defined .frequency

34.4.4. The Establishment shall conduct GMP/SOP Training, Hygiene/Sanitation .training, HACCP training *etc.* on a regular basis

34.4.5. .There shall be a documented training program. Refer to **Annexure-14**

35. National Residue Monitoring Program

35.1. The Competent Authority shall make sure that the National Residue Control and .Monitoring is implemented in the country

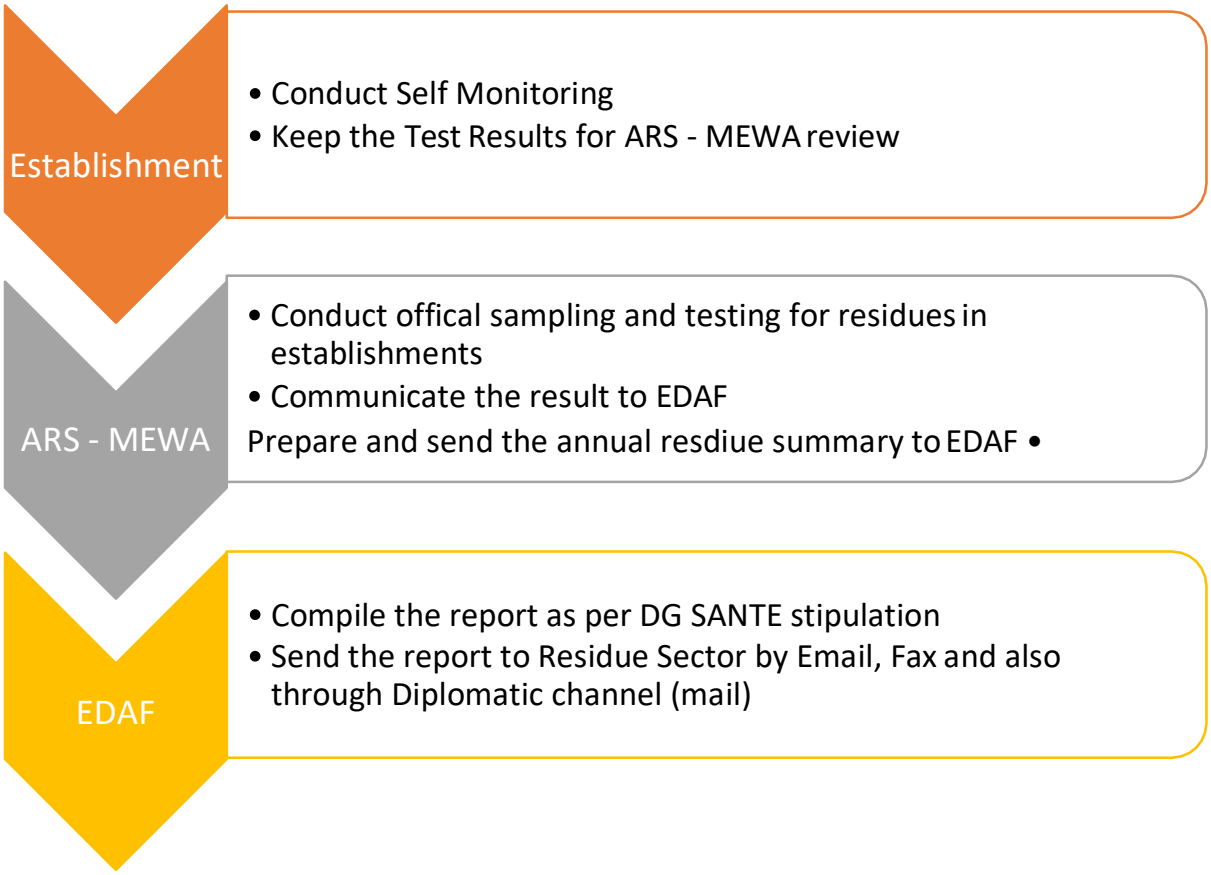
35.2. .ARS – MEWA shall be responsible for National Residue Monitoring Program

35.3. The National Residue Monitoring Program is described in the Poultry Health and .Residue Control Program manual of ARS – MEWA

36. Annual Reporting to EU (DG SANTE)

The Competent Authority shall communicate the status of residues (veterinary drug :residues, contaminants, heavy metals, dyes etc.) to DG SANTE as given below

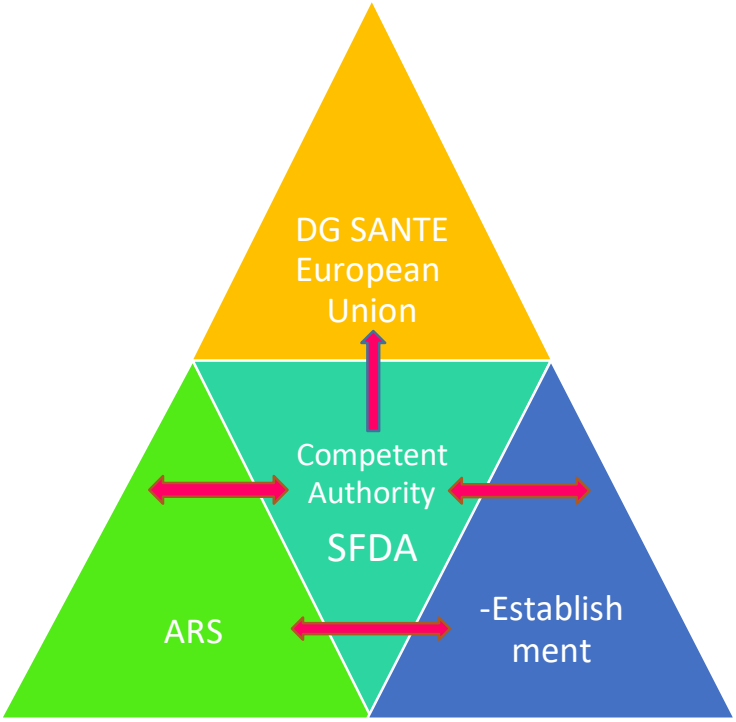
CHART – 10
The Annual Reporting System



37. Communication

The office of the Vice-president of Food Sector, SFDA shall be the only contact point to DG SANTE, FVO and EU from Saudi Arabia for exports of Processed Animal Protein (Poultry). Other associating government agencies shall be authorised to communicate with the establishments and CA (and vice-versa). The general pattern of communication is given in :the figure below

Chart-11
The Communication Pattern



38. Record Keeping

38.1. The Competent Authority, Executive Bodies and Establishments shall keep relevant records concerning with export of Processed Animal Protein (Poultry) to European .Union

38.2. The records shall be available for inspections and verification by concerned official .bodies and European Union representatives

38.3. The checklists for Official Controls shall be prepared and use in audits and .inspections

38.4. The Official Control inspections shall include Hatchery, Farms, Poultry Meat Processing Plant, Rendering Plant (The Establishment) and allied departments and all necessary records and documents shall be kept.

38.5. The Date shall be stored properly with high level of confidentiality and safety. Only authorised persons shall access the records, files and documents. If the data is stored electronically, all security provision such as pass-word, access control, fire-wall, back-ups *etc.* shall be ensured for the data control protection.

38.6. The 'own-check system' based on the HACCP principles shall be compulsorily approved by CA and all the documents and records shall be maintained.

38.7. The records shall be maintained at least for two years.

38.8. Major Audit Forms used are the following:

- **38.8.1.** Combined Audit Form for Establishment Approval and Renewal
- **38.8.2.** Routine audit forms of the EDAF
- **38.8.3.** Routine Audit Form ADR – MEWA
- **38.8.4.** GLP Audit Check-list

38.9. Other Forms

- **38.9.1.** Nonconformity Report
- **38.9.2.** Establishment Audit register
- **38.9.3.** Inspection Summary Report
- **38.9.4.** Sample Dispatch Form