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MANAGEMENT MANUAL FOR JIANGXI DOHR CASING CO., LTD.

Thesis

CENTRAL OSTROBOTNIA UNIVERSITY OF APPLIED SCIENCES

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**ABSTRACT**

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The purpose of thesis is to develop a management manual according to the guideline of ISO 9001:2008 for Jiangxi Dohr Casing Co., Ltd. The management manual is based on the ISO9001: 2008 quality standard system and with reference of the conditions of Jiangxi Dohr Casing Co.,Ltd. This manual aims to provide continuous improvement and foundation for better customer satisfaction, to regulate the internal management and to enhance employee quality awareness and improve operational efficiency.

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1. INTRODUCTION

Jiangxi Dohr Casing Co., Ltd is a sub-company of Jiangxi Animal By-products IMP&EXP Co., Ltd. Jiangxi Dohr Casing Co., Ltd is a food processing plant in Jiangxi province of China.

Jiangxi Dohr Casing Co., Ltd was founded in October of 1995, and its Sanitary Registration Number is 3600/050005. The production plant is located in northern Nanchang nong da road. Jiangxi Dohr Casing Co., Ltd’s main business is purchasing Natural casing (see APPENDIXES 2) and exporting it after processing according to customers' requirement to Italy, Netherlands, Brazil and Germany.

Jiangxi Dohr Casing Co., Ltd has a production staff of 45 and 15 technical staff members. The plant occupies 14,000 square meters, total building area is 1700 square meters, production workshop area is 432 square meters, cold storage area is 324 square meters and other warehouse area is 120 square meters. Since I have some internship experience in Jiangxi Dohr Casing Co., Ltd, its management manual was chosen as the topic of this thesis.

This thesis aims at developing a management manual according to the guideline of ISO 9001:2008 (International organization for standardization 2008). The management manual is based on the ISO9001: 2008 quality standard system (International organization for standardization 2008) and with reference of the conditions of Jiangxi Dohr Casing Co., Ltd. This manual aims to provide continuous improvement and foundation for better customer satisfaction, to regulate the internal management and to enhance employee quality awareness and improve operational efficiency.

The management manual can be divided into five parts. The fist part is a quality
management system. It states what an organization requires to operate its quality management system including the organization's quality management document, implementing, maintaining and continuing improvement.

The second part is the management responsibility that can provide the main principle of commitment to the business to get continuous improvement of quality so as to satisfy customer's exceptions.

The third part is the resource management that describes what an organization needs to use and illustrates how to improve the management of the company's human resource, infrastructure and working environment so as to maintain the quality management system and continually improve its effectiveness and meet customer's requirements and to enhance customer satisfaction.

The fourth part is about the product realization. It provides the guidelines for how to identify the customer's requirement, how to develop, control and improve the quality of the processing of products.

The last part is the measurement, analysis and improvement. It stipulates that an organization should plan and implement with monitoring, measurement, analysis and improvement processes.
2. QUALITY MANAGEMENT SYSTEM

This section is according the section 4 Quality management system of ISO 9001:2008 (International organization for standardization 2008) which states the basis, structure and composition of documentation in quality management system and the implementation, maintenance and continues improvement of those documentations.

2.1 General requirement

The Quality Management System has been developed according to the guideline of ISO 9001:2008 (International organization for standardization 2008). In strict accordance with the reference of relevant provisions of The People's Republic of China on Import and Export Commodity Inspection Law, People's Republic of China Food Safety Law, Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine, Export Food Production Enterprise Record Management Regulations(AQSIQ Decree No. 142), EU food hygiene regulations. It aims to ensure that all products are stably of high quality and the producing processing is strictly in accordance with the requirements of the importing country and customers.

Those documents are necessary regulations for company’s business. So I use those documents as the basic guide regulations of my quality management system.

2.2 Documentation requirements

It provides the structure and composition documents in my quality management system and the implementation, maintenance and continuing improvement of those documentations.
2.2.1 General

According the section 4.1 general requirement of ISO 9001:2008 (International organization for standardization 2008), the quality management system is guided by two documents.

Quality Manual
The Quality Manual provides the details about the quality policy, structure of the organization and methods for maintaining the Quality Management System.

Process Document
This document gives performance standards and hygiene standards on each step in the processes of purchasing, production and sales.

2.2.2 Control of documents

According to the section 4.2.3 Control of documents of ISO 9001:2008 (International organization for standardization 2008), any document of Jiangxi Dohr Casing Co.,Ltd can only be prepared, distributed, updated, kept and obsoleted by the senior management in appropriate place that can ensure it can be easily recognized and provided when it is requested, and the document is reviewed, approved and re-approved by the president of the Company. The documents and data are generated by senior management and are reviewed for adequacy and submitted for approval by president.

The amendment of the document can be conducted by coordinating with customer and regulatory authorities when it is required by contract or regulations. Review and approval changes to controlled documents or data are subject to the same level of control as the original documents. Amendments to this Quality Manual are to be reviewed by Senior Management and approved by the President.
2.2.3 Control of records

According to the section 4.2.4 Control of records of ISO 9001:2008 (International organization for standardization 2008), the records should be based on the evidence of the effective operation of the requirements and quality management system.

The records must be true, accurate and standardized. To ensure the integrity, confidentiality and traceability of the company files and data the records should be kept by the records and documents custody group which are supervised by the factory director of company.

The group should collect the relative records daily, classify and code them in chronological order, establish the recoding of the recipients, loan and distribution of related records. All information shall not be borrowed by any person who is from outside of organization. For any special needs, it shall be subjected to the general manager for approval before the lending.

The record retention period is three years and in special cases, it may be appropriate to extend the shelf life when the general manager approves it. The books should have long-term preservation. Destruction of the information which is over the custody should be approved by the general manager and this information shall never be used for any other purposes.
3. MANAGEMENT RESPONSIBILITY

According to the section 5 management responsibility of ISO 9001:2008 (International organization for standardization 2008), the management responsibility is providing the main principle of commitment, quality policy and quality object to the business to get continuous improvement of quality so as to satisfy customer's exceptions, and defining the responsibilities and authorities in the organization.

3.1 Management commitment

According to the section 5.1 Control of documents of ISO 9001:2008 (International organization for standardization 2008), management should be actively involved in maintaining the Quality Management System. It shows the vision and strategies for the development of the Quality Management System, and set forth the quality objectives and the quality policy.

The company’s management commitment is to provide continuous improvement and foundation for better customer satisfaction, to regulate the internal management and to enhance employee quality awareness and improve operational efficiency.

The management should transmit the importance of meeting customer, statutory and regulatory requirements to the organization through seasonal communication meetings and conducting management reviews to ensure the availability of relative resources.

3.2 Customer focus

According to the section 5.2 customer focus of ISO 9001:2008 (International organization for standardization 2008), we can see that understanding the requirements and expectations
of customers and providing them with products that can meet or exceed all of their satisfaction is the main purpose through the processes described (see section 5.2 Customer-related Process), and that these requirements are met. The customer satisfaction measurement is described (see section 6.2.1 Customer Satisfaction) “monitoring and measurements of customer satisfaction”.

3.3 Quality policy

According to the section 5.3 quality policy of ISO 9001:2008 (International organization for standardization 2008), the Quality policy is compatible with the purpose of the organization that understanding the requirements and expectations of customers and providing them with products that meet or exceed all of their satisfaction and continuously improves the effectiveness of the quality management system.

The quality policy should be provided and explained to every employee by seasonal meetings and employee training, so that it is implemented and maintained at all levels of the organization. It is included in new employee training on the quality management system. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at management review meeting and at each updated of the Quality Manual to determine the policy’s continuing suitability for our organization.

3.4 Planning

According to the section 5.4 planning of ISO 9001:2008 (International organization for standardization 2008) Quality management system should be basis on the quality objectives and the planning of quality management system should meet the quality objectives and the requirement of quality management system.
3.4.1 Quality objectives

According to the section 5.4.1 quality objectives of ISO 9001:2008 (International organization for standardization 2008), management should ensure the establishment of quality objectives in the relevant functions and all levels of the organization. The quality objectives should meet the product requirements of the desired content. The quality objectives should be measurable and consistent with the quality policy.

Different departments have different quality objectives. It can be set by season and update in seasonal meeting.

3.4.2 Quality management system planning

According to the section 5.4.2 quality policy of ISO 9001:2008 (International organization for standardization 2008), the planning of quality management system should meet the quality objectives and the requirement of quality management system.

In the planning and implementation of changes to the quality management system, management should maintain the integrity of the quality management system.

3.5 Responsibility, authority and communication

According to the section 5.5 Responsibility, authority and communication of ISO 9001:2008 (International organization for standardization 2008), It should clearly provides the responsibilities and authority of each department in the organization, and the communication through the organization.
3.5.1 Responsibility and authority

According to the previous conditions of Jiangxi Dohr Casing Co., Ltd. and requirements of quality management system, I developed organization structure of Jiangxi Dohr Casing Co., Ltd (see GRAPH 1), responsibility and authority of each department.

GRAPH 1. Organizational structure of Jiangxi Dohr Casing Co., Ltd (modified by author)

In order to ensure the company's normal production and business activities, the company established the Board of Directors and the functional departments which are under the leadership of general manager: Office, Finance department, Quality management department, Production department, and Sales department and Logistics department. See GRAPH 1. Organizational structure of Jiangxi Dohr Casing Co., Ltd.
GRAPH 2. Production process flow chart (modified by author)

3.5.1.1 Board of Director

Responsibilities:

a. Determining the company's production and operation plans and investment programs;
b. Determining the company's internal management structure;
c. Approving the company's basic management system;
d. Reviewing the reports from the general manager and make a resolution;
e. Developing the company's annual financial budget, final accounts program, profit
distribution plan and recovery of losses;
f. Determining the increase or decrease of registered capital, division, merger, termination
and liquidation;
g. Determining the appointment or dismissal of general manager, factory director, finance
department person in charge, and determine its rewards and punishments.

3.5.1.2 General manager

Responsibilities:
a. Archiving the implementation of the State Administration Entry-Exit Inspection and
Quarantine and other relevant laws, regulations, standards and related requirements, to
develop of the company's quality policy, objectives, to establish and improve the
quality management system;
b. Developing according to the resolution of the board, the company's annual production
plan and organize the implementation of overall responsibility for quality inspection,
the day-to-day operation and management, and to accept the inspection and
supervision of the board of directors;
c. Providing all kinds of resources that are required by the business activities of company;
d. Being responsible for reviewing the performance and effectiveness of the quality system.

3.5.1.3 Factory director

Responsibilities:
a. Supervising of production plan, layout and production scheduling. Assisting the general
manager's daily operations and management;
b. Implementing of personal responsibility system of levels of organization;
c. Developing employee training programs and annual training plan. Determining the
related rules and regulations and organizing the implementation;
d. Being responsible for work with regard of office, human resource, security, logistical support and environmental sanitation;
e. Being responsible for the daily transactional communication inside and outside the company;
f. Leading the records and documents custody group which is responsible for archiving and custody of the company's records and documents;
g. Implementing of the company employees' health check;
h. Assisting the general manager's daily work.

3.5.1.4 Director of financial department

Responsibilities:
a. Providing all sources of Finance;
b. Providing all budgeting and cost accounting processes and services;
c. Managing all aspects of Treasury;
d. Managing the Company’s internal and external financial auditing processes;
e. Accurately reporting and filing all necessary documents pertaining to the Company’s operations;
f. Managing investor relationships.

3.5.1.5 Director of purchasing department

Responsibilities:
a. Being responsible for the procurement of raw materials, auxiliary materials, apparatus, equipment and other supplies;
b. Controlling the market information, developing new sources, optimizing the purchase channels, reducing procurement costs;
c. Determining the procurement plan with financial department and production department.
   Report to General Manager for approval;
d. Investigating the supplier that the effectiveness of quality system and ability to meet the
quality requirements of the company, select merit-based selection of qualified suppliers. And report to General Manager for approval;
e. Reviewing and signing the supply contract, implementing procurement activities;
f. Establishing the procurement contract accounting, and supervising the contract implementation;
g. Making refundment and replacement of unqualified raw material in the procurement process;
h. Establishing the file for qualified suppliers. Custody and regularly archiving of purchasing contract, supplier file and relate documents;
i. Being responsible for the security work of procurement.

3.5.1.6 Director of production department

Responsibilities:
a. Developing the company's production and processing plan and organizing the implementation;
b. Being responsible for production, process technology, product quality, equipment (testing equipment), safe production management to ensure the effective operation of the health quality management system in the production department;
c. Being responsible for the organizing and providing training to new employees and employees according to process requirements;
d. Being responsible for monitoring the production process, and making records;
e. Being responsible for coordinating works that are related to the production and processing. Assisting the factory manager's daily work;
f. Being responsible for the production of finished natural casings (see APPENDIXES 2) with the requirement of the factory director;
g. Being responsible for the production plant's hygiene, maintaining cleanliness and sanitation of the production environment;
h. To convene the regular meeting of quality review and timely solve the problems with regard of quality and hygiene issues, to analyze and develop corrective measures.
3.5.1.7 Leader of each production line

Responsibilities:

a. Being responsible for production safety, quality, hygiene management of each production line;

b. Organizing the implementation of the production that strictly follows the quality system requirements;

c. By urging employee strictly enforces the disciplinary process, the product self-test and mutual inspection;

d. Organizing employees to analyze the cause of the problem and provides the appropriate corrective measures;

e. Being responsible for the civilization, safety and hygiene of each production line that to meet the requirements.

3.5.1.8 Director of quality management department

Responsibilities:

a. Developing quality management systems and internal quality standards. Directly affected by the leadership of general manager, has the veto power on the quality of products;

b. Inspecting and verifying the quality and hygiene of semi and finished product;

c. Being responsible for production, technology, process management, and organize the preparation of process procedures to ensure that its work to meet the requirements of the quality management system;

d. Being responsible for the test program of measuring instruments, test implementing and establishing the records of the accounting and verification for measuring instruments;

e. Evaluating and depositing the nonconforming product, organizing the investigation and analysis on unqualified issues, and putting forward solution. The major hygiene and quality problems should be promptly reported to the General Manager;
f. Inspecting and appraising the quality of product, sampling the procedures, and the establishing the quality records;
g. Promoting hygiene quality knowledge. Supervise sanitary of factory, workshop internal workplace, and personal hygiene;
h. Detecting the production water;
i. Being responsible for the supervision and inspection of the company workshop of environmental sanitation and personal hygiene.

3.5.1.9 Director of sales department

Responsibilities:

a. Making and reviewing the conventional and special contracts;
b. Checking the performance of the contract, and timely delivery to customers;
c. Being responsible for market research, communication with customers, collecting of customer feedback and suggestions and provision of high quality after-sales service;
d. Establishing the file for customers. Custody and regularly archiving of order contract, customer file and related documents;
e. Being responsible for the investigation of customer satisfaction with the quality of the company's products hygiene conditions, and providing statistical analysis as input to management review:
f. Developing the product identification, quality tracking and recovery control procedure.

3.5.1.10 Director of logistics department

Responsibilities:

a. Being responsible for the inventory management of raw materials, auxiliary materials, packaging materials and finished products;
b. Being responsible for the maintenance of the environmental infrastructure in the field area and processing facilities in the workshop;
c. Being responsible for transportation;
3.5.2 Internal communication

According to the section 5.5.3 internal communication of ISO 9001:2008 (International organization for standardization 2008), data regarding the performance and effectiveness of the Quality Management System should be shared by different functional departments and levels of company. The factory director has the responsibility to provide and organize the appropriate communication tools to promote the communication inside the company, such as bulletin boards, internal publications, presentations, meetings, telephone, slogans and broadcasting. See section 3.5.1.3 Factory Director’s responsibilities.

3.6 Management review

According to the section 5.6 management review of ISO 9001:2008 (International organization for standardization 2008), the review includes evaluating the effectiveness of the quality management system which is operated by company including the suitability of quality policy and objectives, such as the demand of improving and updating.

3.6.1 General

According to the section 5.6 management review of ISO 9001:2008 International organization for standardization 2008, I suggest general manager reviews the quality system at least once per year to ensure its continuing suitability, adequacy and effectiveness. In special circumstances, it may increase at any time. See section 3.5.1.2 General Manager’s responsibilities. Records of management reviews are archived and kept by the records and documents custody group which is responsible for of the company's records and documents. See section 3.5.1.3 Factory Director’s responsibilities.
3.6.2 Review input

The Management Review input includes:

a. The audit results; See section 3.5.1.2 General Manager’s responsibilities.
b. Customer expectations, feedback and communication activities; See section 3.5.1.9 Director of sales department’s responsibilities.
c. The results from the monitoring of process and product compliance; See section 3.5.1.6 Director of production department’s responsibilities.
d. Preventive and corrective actions; See section 3.5.1.8 Director of quality management department’s responsibilities.
e. The previous management reviews, tracking measures; See section 3.5.1.8 Director of quality management department’s responsibilities.
f. The changes that may affect the quality management system;
g. Recommendations for improvement.

3.6.3 Review output

The Management Review input includes.

a. Improvement of the effectiveness of the Quality Management System;
b. Improvement of the product and production process related to customer requirements;
c. Resources needed;
d. Improvement of the company's quality policy and objectives.
4 RESOURCE MANAGEMENT

According to the section 6 resource management of ISO 9001:2008 (International organization for standardization 2008), The resource management that describes what an organization needs to use and illustrates how to improve the management of the company’s human resource, infrastructure and working environment so as to maintain the quality management system and continually improve its effectiveness and meet customer's requirements and to enhance customer satisfaction.

4.1 Provision of resource

According to the section 6.1 provision of resource of ISO 9001:2008 (International organization for standardization 2008), resources include human resources, information resources, infrastructure and work environment. The company's management should be able to promptly identify and provide the resources which are required by the following activities: to establish, implement, maintain and update the quality management system:

a. Implementing and maintaining the quality management system, its continuous improvement and effectiveness;

b. Meeting customer requirements and enhance customer satisfaction;

c. Meeting requirements of food safety and hygiene, environmental protection regulations.

The aim is to ensure that the product realization and production can meet the quality requirements and customer requirements, and as a result, enhance customer satisfaction. The Company should make provision of a good personnel, infrastructure and working environment management and establish needed documents.
4.2 Human resources

According to the section 6.2 human resource of ISO 9001:2008 International organization for standardization 2008), I suggest that company should make the requirements in terms of education, training, skills, experience and ability of health for all positions that affect product quality, to ensure that the company has high-quality workforce that are competent for the work.

4.2.1 Competence, training and awareness

Factory director is responsible for the formulation of Employee Training Programs and related operational documents that provide the necessary abilities, working standards and requirements of skill for all kinds of employees that may affect the quality product and service.

All employees should be aware of the importance of their activities and how they contribute to achieving quality objectives and conformity to product. The qualifications of personnel performing are specialized in operations, processes, tests or inspections which are evaluated and documented.

The training needs are to be identified and the annual training plan is developed based on past education level, working experience and skills of the employees. The annual training plan is updated at least once a year.

Training records are maintained by factory director, including proof of certification for special processes, as applicable. Additional documented education and experience records are maintained in the employee personnel files. It is the responsibility of the relevant management to ensure that their employees are aware of the quality objectives and of the importance of their activities in achieving these objectives. See section 3.5.1.3 Factory director’s responsibilities.
4.3 Infrastructure

General manager is responsible for provision of the resources which meet the requirements of the production and The People’s Republic of China on Import and Export Commodity Inspection Law, People’s Republic of China Food Safety Law, Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine, Export Food Production Enterprise Record Management Regulations (AQSIQ Decree No. 142), EU food hygiene regulations. See section 3.5.1.2 General manager’s responsibilities. In my opinion, general manager should be involved in those three parts:

a. To ensure that the design of plant construction and process are scientific and reasonable;
b. Ground and design of sewage are conducive to cleanliness, and hygiene facilities to meet the requirements of production;
c. Logistics department and production department develop facilities, increase equipment and maintenance plan according to the company production capacity and marketing plan, and report to the general manager for approval. See section 3.5.1.10 Director of logistics department’s responsibilities.

Production department has the responsibility to control and manage the infrastructure and equipment, to establish the equipment accounting, safety operation manual and routine maintenance items and maintenance plan. See section see section 3.5.1.6 Director of production department’s responsibilities.

The logistics department is responsible for day-to-day management of buildings, greening, transportation and office facilities. See section 3.5.1.10 Director of logistics department’s responsibilities.

Quality management department is responsible for the filing of the testing equipment and documents, the standard of operation, routine maintenance, calibration and verification work. See section 3.5.1.8 Director of quality management department’s responsibilities.
4.4 Work environment

General Manager is responsible for the planning and providing environmental resources to producing products that can achieve the product requirements and the requirements of the laws and regulations, and focus on the employee's requirements as to psychology, society, environment and matter, to create a good atmosphere of work environment and improve productivity of the staff. See section 3.5.1.2 General manager’s responsibilities.

4.4.1 Responsibilities

a. Production department is responsible for identifying, recognizing and managing of the various elements of the production workshop environment; See section see section 3.5.1.6 Director of production department’s responsibilities.

b. Factory director is responsible for the plant, office areas and public places environmental management; See section 3.5.1.3 Factory director’s responsibilities.

c. The quality management department is responsible for the implementation, supervision and inspection of whole company's environmental sanitation. See section 3.5.1.8 Director of quality management department’s responsibilities.

4.4.2 Plant and environment

a. The environment of plant is clean and sanitary. It is not allowed to concurrently produce and storage the product which is incompatible with food hygiene;

b. Factory road is flat and there is no ponding and bare ground;

c. Production and living area is separate. It is not allowed to have livestock, poultry, harmful gas or other facilities that are incompatible with food hygiene in the plant area;

d. The layout of plant is reasonable. And the workshop, storage area of all materials, and other ancillary facilities are built to adapt with the capacity and meet the requirements of hygiene;
e. Plant should equip toilet flushing, hand washing, fly-proof and pest control facilities;
f. Production area has flies and pest control, mouse proof facilities, such as mosquito lamps, screens and water seal. The wall panels are using light-colored, smooth, impervious and corrosion-resistant materials to build and keep clean;
g. The production sewage, waste and garbage are timely removed out of plant. The garbage temporary storage area should away from the production area as far as possible, and the sewage should be purified;
h. The production of water pipes and sewage pipes are designed reasonably.

See section 3.5.1.3 Factory director’s responsibilities and GRAPH 4. Production layout of Jiangxi Dohr Casing Co.,Ltd in APPENDIXES 1.

4.4.3 Workshop and environment

a. There is a disinfection pool in front of the raw material warehouse;
b. The size of workshop area should be adaptive to the production capacity, and the production layout should be reasonable. The workshop should have unimpeded drainage, adequate light, good ventilation, sanitation and hygiene;
c. Workshop floor should be stagnant water prove, non-slip, wearing resistance, corrosion resistance and flat with a certain inclination. It is easy to clean and disinfect. The outlet that connects workshop and outside should have mesh cover to prevent mice and pets;
d. Workshop walls are paved with light-colored tile. Ceiling is made of plastic board that is non-toxic light-colored, waterproof, mildew, not falling and easy to clean. The corners should be curved with an angle;
e. Workshop has plastic Door Curtain and insect screens on windows. Doors and windows are made by steel material that is light-colored, smooth, easy to clean, waterproof and corrosion-resistant. The inside and outside of sills are downward-sloping into a 45 degree angle with corner;
f. Lighting system at the top of the workshop should have protection by explosion-proof shade. The illumination of workshop must meet the requirements of production, not less than 450Lux;
g. The workbench made by stainless steel. Tools and equipments are made by PE material that is non-toxic, non-rust, durable, easy to clean and disinfect;
h. Air conditioning keeps the workshop production temperature within range 15-20 degrees Celsius, and maintains good ventilation;
i. The supply of electricity, gas and water meet production needs;
j. A disinfected pool for the footwear and wheels at the entrance of workshop;
k. Enough equipment for hand washing, drying, cleaning and disinfection at the entrance of workshop. The sink faucets with foot switch;
l. Changing room, toilet and shower room are connected with workshop, equipped the aluminum and plastic closet, dressing mirror and ozone generators to meet the needs;
m. The hand disinfection room and the equipment disinfection room are close to workshop, reasonable layout without cross-contamination.

See section see section 3.5.1.6 Director of production department’s responsibilities and GRAPH 4. Production layout of Jiangxi Dohr Casing Co.,Ltd in APPENDIXES 1.


5 PRODUCT REALIZATION

According to the section 7 product realization of ISO 9001:2008 (International organization for standardization 2008), Product realization provides the guidelines as how to identify the customer’s requirements, how to develop, control and improve the quality of the processing of products.

5.1 Planning of product realization

According to the section 7.1 planning of product realization of ISO 9001:2008 International organization for standardization 2008, The company should develops a control procedure for production process and business processes. Also company shall make provision for the process, the sequence and interface of the process that are needed by product realization, control and manage those processes.

In planning of product realization, the company shall determine appropriate contents of the following areas:

a. The product quality indicators and resources required by indicators (including the requirements of the exporting country); See section 3.5.1.2 General manager’s responsibilities.

b. The acceptance criteria and inspection procedures and requirements for raw materials, auxiliary materials and semi-finished products; See section 3.5.1.8 Director of quality management department’s responsibilities.

c. The verification, validation, monitoring, inspection and test activities in production; See section 3.5.1.8 Director of quality management department’s responsibilities.

d. Production Department shall prepare the key processes operating instructions, and provide all the records of the realization process; See section see section 3.5.1.6 Director of production department’s responsibilities.
e. Quality management department provides and saves all records so that products are qualified. See section 3.5.1.8 Director of quality management department's responsibilities.

5.2 Customer-related process

According to the section 7.2 customer-related process of ISO 9001:2008 (International organization for standardization 2008), company should identify customer’s requirement and solve customer’s dissatisfaction.

5.2.1 Determination of requirements

a. Before signing the contract, company should fully identify and understand the customers' explicit and implicit requirements, food safety regulations, additional requirements of the exporting country, and to confirm these requirements;
b. Sales department is responsible for organizing the assessment of the contract to ensure that the Company has the ability to meet contractual demands, and retain the records of the assessment and follow-up measures.

See section 3.5.1.9 Director of sales department’s responsibilities.

5.2.2 Solution of customer's satisfaction and dissatisfaction

a. Sales department is responsible for the communication with customers through a variety of ways (such as market research, telephone, fax, product fairs, to visit) to understand customer needs, the contract or order processing, answering customer's inquiries and modifying the contract or order;
b. The contract changes, product standards changes and customer feedback (including complaints) as well as the after sales service of product are to be prescribed by company, and it also should establish channels of communication with customers, the timely exchange of information about products and services;

c. If customer gives written or verbal complaints or suggestions, the sales department (coordinating with other departments) should immediately track down the reason, give proper solution and explanation (or apology) to the customer, and recall the product when it is necessary;

d. The records of customers' written or verbal complaints or suggestions and the situation should be made indicating the product name, batch number, quantity, factor, date and manner. The records shall be circulated to the relevant departments as reference to help them improve their performance.

See section 3.5.1.9 Director of sales department’s responsibilities.

5.3 Product identification and traceability

I suggest the Sales department should develop the product identification, quality tracking and recovery control procedure, establish traceability system to ensure that will be able to identify the relationship between the records of product batches, processing and distribution.

The traceability system should be able to identify the source of semi-final products and final products.

The traceability records shall be maintained on the base of the final products' shelf life time, so it can be adequate for system evaluation, disposal and recall of potentially unsafe products. Also it should meet the requirement of customer, legislation and regulations.

See section 3.5.1.9 Director of sales department’s responsibilities.
5.4 Purchasing

In my opinion, company shall develop a procurement control procedure to ensure that the procurement of material can meet the requirement.

a. Purchasing department is responsible for quality control of supplier, the preparation of procurement plans and implementation of the procurement process;
b. The raw materials should be purchasing from non-infected areas and supplier should have the certification of inspection and quarantine. Each batch of raw materials must be approved by the drug residue inspection before feed production;
c. The procurement staff must be trained and have the knowledge and skills to identify the quality and hygiene of natural casing;
d. Quality management department and purchasing department are responsible for the detection of drug residues and heavy metal residue to suppliers 1 or 2 times for one year. Company shall implement non-scheduled inspections to monitor the supplier at least once a year, develop the conformity assessment and the monitoring rating scale for suppliers (see the pesticide and veterinary drug residue monitoring system);
e. Quality management department is responsible for the preparation of the procurement technical standards (or requirements) and acceptance criteria, the validation of raw materials and technical standards. The raw material acceptance criteria: fresh, clean, color, smell normal;
f. After raw materials pass the inspection, paste inventory number and identifies should be put on it and it will be stored in the warehouse, and records are made. Packaging materials must be non-toxic, harmless, no potentially polluting and can meet the hygiene requirements;
g. Purchasing department is also responsible for the procurement of auxiliary materials, apparatus, equipment and other supplies based on the procurement control procedures;
h. Transport vehicles must meet the hygiene requirements that should have rain and dust-proof facilities. Transport vehicles should be disinfected by the epidemic prevention department;
i. Transportation should be prevented from pollution, and nothing should be shipped with the toxic and hazardous materials at any time;

j. The raw materials should be stored in cold storage warehouses with specified temperature;

k. The raw materials should be stored in batches, each batch of raw material must be identified and shall not be stored with other substances that may affect the quality of raw material;

l. If the raw materials stored in the warehouse that do not meet quality and hygiene standards must be promptly removed so as to prevent pollution.

See section 3.5.1.5 Director of purchasing department’s responsibilities and section 3.5.1.8 Director of quality management department’s responsibilities.

**5.5 Production process control**

The company should identifies the production process, develops and implements work instruction, controls materials, processing, personnel, workshop environment, packaging, storage, toxic, hazardous substances, delivery, and production equipments.
5.5.1 The production process flow chart

GRAPH 3. The production process flow chart (Xiong Kun, 2010)

5.5.2 The development and implementation of work instructions

Company should develop SSOP hygienic standard operating procedures to control the hygiene of equipment, environment and person. The production department is responsible for organizing and scheduling of production, process control, management and maintenance of the production facility, and preparation of the necessary operating instructions or operating procedures.
The production department should educate and train staff to operate in accordance with the operating instructions to make the products consistent with the requirements of production, hygiene and quality.

See section see section 3.5.1.6 Director of production department’s responsibilities.

### 5.5.3 Control of raw materials and auxiliary materials

a. Raw materials, auxiliary materials shall comply with the requirements of safety and hygiene, to avoid pollution of pesticides, veterinary drugs or harmful substances from air, soil, water and fodder;
b. Raw materials (natural casing) should be purchased from non-affected areas, and it should be small, fresh, without other unclean substances and with veterinary health and quarantine certification;
c. Auxiliary materials are the natural casings (see APPENDIXES 2) dedicated salts that can meet the hygiene requirements of the production, without impurities;
d. Casings salt should be in packaging bags in a plastic barrel, and stored in the special area of warehouse. The auxiliary materials must have inspection certificates;
e. Production water is the city drinking water from the county water utility, its quality shall comply with 《national drinking water hygiene standards》. The epidemic prevention station must test the water samples from the plant before the water used into production.

See section 3.5.1.8 Director of quality management department’s responsibilities.

### 5.5.4 Control of processing

Processing operations should be consistent with the principles of hygiene and safety to reduce pollution.
a. Production equipment should have rational layout in accordance with the production process, and kept clean and in good condition;
b. Production equipment, tools, containers, venues should be strictly implemented according to the provisions of the cleaning and disinfection, and the containers shall not be directly contacted with the ground;
c. Air disinfection: the workshop should be disinfected by ozone sterilization for 1-2 hours, every morning and night;
d. Production facilities, equipment, tools and instruments store should be cleaned and disinfected in required frequency and method. And the quality management personnel should check and make records at location;
e. Raw materials, auxiliary materials, semi-finished and finished products are stored separately in unpolluted areas;
F. In accordance with the priorities of the casing production process and product characteristics, the equipments and tools of raw material processing and processing of semi-finished products, industrial equipment cleaning and disinfection of finished products such as packaging, product packaging, finished product testing and finished product storage area of different hygiene requirements should set separately to prevent cross-infection.

See section see section 3.5.1.6 Director of production department’s responsibilities, section 3.5.1.8 Director of quality management department’s responsibilities and section 3.5.1.10 Director of logistics department’s responsibilities.

5.5.5 Control of personnel

a. All employees must have medical clearance from Health and Epidemic Prevention Station before appointment;
b. The health records for all employees should be developed. Production and quality management personnel should annually conduct a health check. New employees must have medical clearance before appointment;
c. The employees who have following diseases should be removed from the position: dysentery, typhoid, viral hepatitis and other gastrointestinal diseases (including pathogen carriers), active tuberculosis, suppurative or exudative dermatitis and other diseases incompatible with requirements of food hygiene;

d. Production, quality management personnel shall maintain personal cleanliness and shall not bring any items into the workshop that have nothing to do with the production, such as wearing jewelry, watches, and make-up. Before entering the workshop, all personnel should disinfect hands and wear special clothes, shoes and hats. Clothes, shoes and hats should be disinfected regularly;

e. Production, quality management personnel must be educated with hygiene knowledge and given skills training, and have past the examination before appointment;

f. Production, quality management personnel should accept the inspection of the quality management officers on their own initiative, participate in the food hygiene knowledge special teaching activities organized by the Quality management department, and should be an expert in terms of hygiene knowledge and requirements in the production;

g. According to company needs, company shall equipped suitable number of professionals with corresponding qualifications in health management.

See section 3.5.1.3 Factory director’s responsibilities and section 3.5.1.8 Director of quality management department’s responsibilities.

5.5.6 Control of plant environment

a. It is not allowed to concurrently produce and storage the product which is incompatible with food hygiene;

b. There is no ponding and bare ground;

c. Production and living area is separate. It is not allowed to have livestock, poultry, harmful gas or other facilities that are incompatible with food hygiene in the plant area;
d. The layout of plant is reasonable;

e. Toilet flushing, hand washing, fly-proof and pest control facilities;

f. Production area has flies and pest control, mouse proof facilities, such as mosquito lamps, screens and water seal. The wall panels are using light-colored, smooth, impervious and corrosion-resistant materials to build and keep clean;

g. The production sewage, waste and garbage are timely removed out of plant. The garbage temporary storage area should be placed away from the production area as far as possible, and the sewage should be purified.

See section 3.5.1.3 Factory director’s responsibilities and GRAPH 4. Production layout of Jiangxi Dohr Casing Co., Ltd in APPENDIXES 1.

5.5.7 Control of workshop environment

a. A disinfection pool in front of the raw material warehouse;

b. The workshop should be unimpeded drainage, with adequate light, good ventilation, sanitation and hygiene;

c. The outlet that connects workshop and outside should have mesh cover to prevent mice and pets;

d. Lighting system at the top of the workshop should have protection of explosion-proof shade. The illumination of workshop must meet the requirements of production, not less than 450Lux;

e. Air conditioning can keep the workshop production temperature range 15-20 ° C, and maintain good ventilation;

f. There is a disinfected pool for the footwear and wheels at the entrance of workshop;

g. There is enough equipment for hand washing, drying, cleaning and disinfection at the entrance of workshop. The sink faucets should have foot switch;

h. Changing room, toilet and shower room are connected with workshop, equipped the aluminum and plastic closet, dressing mirror and ozone generators which can meet the needs;
i. The hand disinfection room and the equipment disinfection room are connected with workshop and have reasonable layout to avoid cross-contamination.

See section 3.5.1.6 Director of production department’s responsibilities and GRAPH 4. Production layout of Jiangxi Dohr Casing Co., Ltd in APPENDIXES 1.

5.5.8 Control of packaging and storage

a. Plastic barrel and the inner bag must be conforming to the hygiene standards, it shall not contain toxic and hazardous substances. It must be strictly inspected according to the requirements of hygiene standards during purchasing;
b. Plastic barrels and bags are separately placed in a clean, dry and ventilated warehouse, without pollution;
c. Transportation should be met the requirements of hygiene, and equipped with rain and dust refrigeration, insulation and other facilities;
d. Raw materials storage and cold storage shall be equipped with temperature and hygrometer display unit. Items shall maintain a certain distance with the walls. The storage shall not be stored items that could be harmful to the food hygiene or may cause mutual contaminated each other;
e. The cold storage of finished natural casings (see APPENDIXES 2) should not store other items that could be harmful to the casings hygiene. Finished natural casings (see APPENDIXES 2) should be kept in the plastic barrel and with 0-10 Degrees Celsius in the cold storage, raw materials and semi-finished products shall not be stored with finished products;
f. The cold storage of the finished product is equipped with automatic temperature recorder and a digital thermometer, curators make daily temperature check and record for future reference purposes;
g. The cold storage of finished natural casings (see APPENDIXES 2) should be regularly cleaned and disinfected to eliminate odor and it have anti-mouse and anti-pest facilities;
h. The finished natural casings (see APPENDIXES 2) should be maintained a 10 cm gap with walls, 50 cm gap with the ceiling;

i. Company should use refrigerated containerized to shipping the export products, the container shall be clean and past the quarantine inspection from CIQ inspection.

See section 3.5.1.10 Director of logistics department’s responsibilities.

5.5.9 Control of toxic and hazardous substances

Company should strictly implement the storage and use toxic and hazardous materials regulations to ensure that the use of detergents, disinfectants, lubricants, additives, chemical reagents and other toxic and hazardous materials in the workshops that can be effectively controlled to avoid the pollution to foods, food containing surfaces and food packaging materials. See section 3.5.1.8 Director of quality management department’s responsibilities.

5.5.10 Control of delivery

Sales department:

a. Signing an outsourcing agreement with the transport company, to ensure product quality.

b. Being responsible for the organizing and coordinating of product after-sales service;

c. Being responsible for communication with customer, properly solve customer's complaints and make of relevant records;

d. Being responsible for measurement of customer satisfaction to identify customer's needs and expectations;

e. Establishing customer file (including name, address, contact and order specifications and quantity of each batch of product models) in order to understand the tendency of customer's ordering in a timely manner and get prepared for future supply;
5.5.11 Control of monitoring and measuring equipment

a. Quality management department develops the inspection and management procedures. The quality inspector should be qualified with training and examinations, before appointment;

b. Company should have a laboratory that can be adapted to production capacity, and with appropriately qualified inspectors;

c. Laboratory should have enough standard information that is needed by the inspection work. Inspection facilities and equipment, testing equipment required to measure and test, and make inspection records;

d. The county epidemic prevention station is responsible for the test items that cannot be tested by the company laboratory;

e. The detection equipment and thermometers need timing calibration;

f. Sampling and testing of raw materials, auxiliary materials, semi-finished products should be strictly in compliance with relevant provisions of the State. Sampling and testing of finished products should be strict compliance with national standards or customer's requirements, with testing results and verification report;

g. Quality Management Department has veto to quality of natural casings; see APPENDIXES 2.

h. Product testing standard should be strict compliance with GB GB/T7740-2006 export salted casings test methods or customer requires;

i. Inspectors should be able to provide accurate, standardized system records and keep them for more than three years for reference purposes.

See section 3.5.1.8 Director of quality management department’s responsibilities.
6 MEASUREMENT, ANALYSIS AND IMPROVEMENT

According to the section 8 measurement, analysis and improvement of ISO 9001:2008 (International organization for standardization 2008), the last section stipulates that an organization should plan and implement monitoring, measurement, analysis and improvement processes.

6.1 General

With the established and documented quality management system to provide planning, implementation of the required measurement and monitoring activities, it can ensure
a. To confirm the conformity of the products;
b. To ensure the effectiveness of the quality management system;
c. To continuously improve the effectiveness of the quality management system.

6.2 Monitoring and measurement

According to the section 8 measurement, analysis and improvement of ISO 9001:2008 (International organization for standardization 2008), It is very important to be measure target data in company which includes customer satisfaction, measurement of process, control of products, control of nonconforming products.

6.2.1 Customer satisfaction

Whether a company can monitor and measure the customer satisfaction or not is the measurement of the performance of the quality management system.

The company determines the method of investigation and calculation of the customer
satisfaction. When the customers are not satisfied, the company should develop some correction and preventive improvements.

The information of customer satisfaction should be monitored in order to evaluate the effectiveness of the quality management system and identify the opportunities for improvement and enhancing customer satisfaction.

Sourcing: investigating from customers, the feedback on the relevant products (quality, price, delivery and service) and the changing of customer's requirements or needs.

Forms of information gathering: gathering information through market research, industry exchanges and customer communication, such as visits to the customer, telephone interviews, issuing a questionnaire and fax letters to investigate and monitor the customer's complaints.

Sales department should regularly collect information on customer satisfaction, the information can be verbal or written. Analysis can be done with the collected information by using appropriate statistical techniques, and it can draw the trends of customer satisfaction to identify customer requirements and the differences with competitors, so that necessary improvement can be conducted.

See section 3.5.1.9 Director of sales department’s responsibilities.

6.2.2 Monitoring and measurement of processes

The company develops appropriate files to measure and monitor the identified process. It should be focused on the measurement and monitoring of the product realization process.

In Monitoring and measurement of processes, the company shall determine appropriate contents of the following areas:
a. Purchasing

Quality management department and purchasing department are responsible for the detection of drug residues and heavy metal residue to suppliers 1 or 2 times for one year. Company shall implement non-scheduled inspections to monitor the supplier at least once a year, and develop the conformity assessment and the monitoring rating scale for suppliers;

b. Production

Production facilities, equipment, tools and instruments storing should be cleaned and disinfected in required frequency and method. And the quality management personnel should check and make records at location;

c. Personnel

Production, quality management personnel should accept the inspection of the quality management officers on their own initiative, participate in the food hygiene knowledge special teaching activities organized by the Quality management department. Developing the training records which maintained by factory director.

The health records for all employees should be developed. Production and quality management personnel should annually conduct a health check. New employees must have medical clearance before appointment.

6.2.3 Monitoring and measurement of products

a. Quality management department is responsible for the inspection of raw materials, semi-finished and finished products that are made according to raw materials acceptance requirements, product performance standards and associated procedures of the product realization plan, to ensure that the product’s features meet customer requirements and ensure the food hygiene meets requirements of the exporting country;
b. Raw materials and semi-finished products that are without inspection or acceptance cannot be input to production. The finished products shall not enter the warehouse and shall not be sent out of factory without inspection certification;

c. The company should develop quality control standards and implement requirements, such as raw materials acceptance requirements, finished product standard and the key process control. Company should equip the relevant information of existing regulations and standards, or access method, to measure and monitor the quality of raw material, the quality in processing and the quality of the finished products.

6.2.4 Control of nonconforming product

Control aim: To ensure nonconforming product is identified and controlled so as to prevent unintended use or delivery.

Control object: nonconforming raw materials, nonconforming processes, nonconforming finished products and the discovery of the nonconformity after delivery to the customer.

Control activities:

a. Quality management department should monitor and control the non-conforming raw materials, auxiliary materials to ensure the company's products meet the export requirements;

b. Inspector must strictly control the quality of raw materials of each purchase, reject raw materials or semi-finished products from the infected areas, reject raw natural casing of sickness and death of livestock;

c. Rejecting non-consumption of refined salt or non-dedicated casings salt, packaging materials should be suitable for packaging food;

d. The non-conforming water should not be used as the production water;

e. Company should seriously assess and timely handle the nonconforming product and waste that appear in the production process.
6.2.5 Internal audit

a. The management representative is responsible for the implementation of internal audit. It can determine whether the quality management system is conforming to the planned arrangements and the requirements of the standard, and ensure the suitability, compliance and effectiveness of the quality management system. The internal audit should be implied at least once a year;

b. The management representative appoints the internal auditor and forms an internal audit team, designates a team leader responsible for the implementation of auditing and the developing of audit plan;

c. The documents of output Audit are the internal audit report and the correction and preventive measures request form. The unqualified are required by the relevant department to develop the corrective and preventive measures to prevent the recurrence of unqualified activities. The internal auditor is responsible for tracking and verifying the corrective measures.

6.3 Analysis of data

In summary, the company shall record the data in the quality management process by using appropriate statistical methods, analyze the various data of product and process from monitoring activities to provide the following information:

a. Customer satisfaction;

b. Data related to product quality;

c. Quality of raw materials.

I suggest company should summarize the data collected from various departments at least twice each year, analyze with the relevant departments to find opportunities for improvement and submit the results of analysis to management.
6.4 Improvement

The company should continually improve the effectiveness of the quality management system through the appropriate way to achieve the company's quality policy and objectives, to provide customers with satisfactory products. It should analyze all aspects of applicable data, identify the problems, determine the quality improvement program, supervise the implementation process and evaluate the results of implementation.

6.4.1 Corrective and prevent action

Company develops the corrective and preventive measures and control program, to correct or prevent the occurred or possible occurred nonconformity, to eliminate the actual or potential nonconformity causes and to avoid similar nonconformity.

a. Identification and review of nonconformity: the nonconformities of product quality part (including customer’s complaining) are assessed and analyzed by the quality management department. If there are recurring or significant nonconformities, the corrective action notice should be filled in and the concerned department should be noticed. The nonconforming report should be sent to the management representative of concerned department; (see section 3.5.1.8 Director of quality management department’s responsibilities)

b. When the supervising department receives the corrective action notice or nonconforming report, it should investigate and analyze the reasons of nonconformities, recording investigating results, and develop targeted corrective action to responsible departments, implemented and records;

c. Company should develop documented corrective action for each critical control point and the necessary control process, so that corrective action can be implemented when monitoring results show that a critical control point deviates from the deviation limits of critical or process.
Production layout of Jiangxi Dohr Casing Co., Ltd.
GRAPH 5. Product examples of Natural casing
Casing, sausage casing, or sausage skin is the material that encloses the filling of a sausage.

Sausage is known to be the oldest and most enduring form of processed meat. In some respects, it may even be considered the world's very first "convenience food."

Natural casings are made from the sub-mucosa, a layer of the intestine that consists mainly of collagen. They are edible and bear a close resemblance to the original intestine after processing.

The history of sausage production parallels the recorded history of man and civilization. In fact, for as long as man has been carnivorous, the intestinal tract of meat animals has been used for sausage casings - not to mention a variety of other uses as well. A large variety of sausage is produced world-wide using the processed intestines of pigs, sheep, goats and cattle (and sometimes horses).

It is often assumed that sausages were invented by the Sumerians in the region that is Iraq today, around 4000 BC. Reference to a cooked meat product stuffed in a goat stomach like a sausage was known in Babylon and described as a recipe in the world's oldest cook book 3750 years ago (Yale Babylonian collection, New Haven Connecticut, USA).

The Chinese sausage Lachang, which consists of goat and lamb meat, was first mentioned in 589 BC. The Greek poet Homer mentioned a kind of blood sausage in his Odyssey (book 20, poem 25); Epicharmus (ca. 550 BC- ca. 460 BC) wrote a comedy entitled "The Sausage". Numerous books report that sausages were already popular among the ancient Greeks and Romans.

It's only during the last thousand years, however, that Sausage Making has come into its own as a venerable and highly developed craft. The practitioners of this trade have fostered a rich tradition - at once sophisticated and yet personal. In many cases, families handed down their particular sausage making art over several generations and across dozens of nations, with each "wurstmacher" contributing his taste and heritage to the art. Of course, the art was also influenced by the demand of the marketplace and by the availability of the various ingredients which went into the sausage.

The twentieth century brought on the Industrial Revolution - exploding onto the scene with new technology - and adding billions to the world's population. This "one-two punch" generated a need for mass production in virtually all industry segments... especially food! At first, the goals of mass production were primarily "quality" and "speed." But gradually, "quality" struggled
toward the forefront of this new technology. The meat processing industry faced its own inherent challenges in slaughter, processing, and food safety. "Efficiency" and "quality" became the norm for those processors who rose to the challenge and managed to withstand the test of time.

Sausage making has now evolved into a highly specialized business, with processors ranging in size from independent "mom & pop" shops producing one-of-a-kind gourmet sausages, to multi-million dollar "mega-processors" producing millions of pounds of product each and every week.

Today there are numerous types of sausage casings including: Natural and artificial such as Collagen, Cellulose and Plastic. Collagen, Cellulose and Plastic casings are relative newcomers to the artificial field, mainly born out of market demand during the technological maelstrom of the early twentieth century. Much information and instruction about these man-made products is available through the major manufacturers of these casings and it is not our place to delve into them here. As for Natural Sausage Casings, however, surprisingly little qualitative or quantitative information is readily available to processors about these products.

(The international natural sausage casing association 2012)
APPENDIXES 3

GB/T7740-2006 export salted casings test methods

*Translation:

Title: The national standard of the People's Republic of China, Natural Casings.
Published By: The People's Republic of China Administration of Quality Supervision, Inspection and Quarantine and China National Standardization Management Committee
(Translate by author: Hu Yuanyang)
APPENDIXES 4

The production process flow chart

*Translation:
Title: Hygiene Management Handbook
Written By: Xiong Kun
Approved By: Wang Lanzhen
Audited By: Liang linna
(Translate by author: Hu Yuanyang)
LIST OF REFERENCES

Administrative provisions on registration of export food production enterprises (AQSIQ Decree No. 20) 2002 http://en.ciqcid.com/Laws/Department/sp/45910.htm


GB/T7740-2006 export salted casings test methods 2006 (See appendix 3)


National drinking water hygiene standards 2006 http://www.docin.com/p-57717937.html


The production process flow chart 2010 (See appendix 4)