UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

HILLSIDE FARMS CORP. | DBA/IOR: SHANGHI ADAMS

Name of FSVP Importer

YANTAI HAO'S PET FOOD TECH. CO., LIMITED

Name of Foreign Supplier

FREEZE DRIED CHICKEN LIVER DOG TREATS

Name of Product

MAY 16, 2019 / MAY 10, 2022

Date of Initial Verification / Reverification

MAY 18, 2023

Date of FSVP Plan Expiration

VERIFICAITON COMPLETE | APPROVED FOR IMPORT

Result of Verification

NUMBER 04

Version

– Confidential –

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OVERVIEW *of* FSVP PLAN

Title 21 of the Code of Federal Regulations requires that *"... for each food you import; you must develop, maintain, and follow an FSVP [Foreign Supplier Verification Program] that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (regarding adulteration) and 403(w) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the Federal Food, Drug, and Cosmetic Act. ..."* for each product *(and each foreign supplier of each product)* that our client imports, United Safety Agents (USA) has been engaged to undertake and successfully complete all requisite actions on our client's behalf; to analyze, verify, build and maintain this FSVP plan, that our client will now use to keep in compliance with FSVP regulations.

INSTRUCTIONS

Please review this FSVP plan in its entirety and sign where indicated. 21 C.F.R., §1.510 requires that this plan be kept on file for a minimum of two years after its use is discontinued. All records must be legible and stored to prevent deterioration or loss. If requested in writing by FDA, you must send records to the Agency electronically, or through another means that delivers the records promptly. Off-site storage of records, including records maintained by other entities in accordance with §1.504, §1.505, or §1.506, is permitted if such records can be retrieved and provided within 24 hours of FDA's request. Electronic records are considered to be on-site if they are accessible from an on-site location. Records obtained by FDA are subject to the disclosure requirements found under Part 20. **Please contact USA immediately** to report a change in a foreign supplier's processes or status, upon contact by FDA, or with any questions that you may have by email at info@unitedsafetyagents.com, or by telephone at +1 (888) 551-7403.

TERMS & DEFINITIONS

FSVP Importer *(Importer)*: The importer, is the U.S. owner or consignee of an article of food that is being offered for import into the United States. **U.S. owner or consignee** means the person in the United States who, at the time of U.S. entry, either owns the food, has purchased the food, or has agreed in writing to purchase the food.

Foreign Supplier *(Supplier)*: The foreign supplier or supplier is the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States.

Qualified Individual *(QI)*: Qualified individual means a person who has the education, training, or experience (or a combination thereof) necessary to perform an activity required under this subpart.

Verified &/or Approved: Verified & approved means only that actions were taken to fulfill regulatory obligations. It does NOT mean that the subject product of this FSVP plan is ready for consumption in its current state.

RULES *of* USE

FOREIGN SUPPLIER VERIFICATION PROCEDURES

21 C.F.R., §1.506 (a), (a)(2), (b), and (c) require that written procedures are established and followed to ensure that food is imported from approved suppliers only and that these procedures provide adequate assurance that the hazards requiring a control in the imported food have been significantly minimized or prevented. 21 C.F.R., §1.506 (d) requires that *"... Except as provided in paragraphs (d)(2) and (3) of this section, before importing a food from a foreign supplier, [an FSVP Importer] must determine and document which verification activity or activities listed in paragraphs (d)(1)(ii)(A) through (D) of this section, as well as the frequency with which the activity or activities must be conducted, are needed to provide adequate assurances that the food [an FSVP Importer] obtain[s] from the foreign supplier is produced in accordance with paragraph (c) of this section. Verification activities must address the entity or entities that are significantly minimizing or preventing the hazards or verifying that the hazards have been significantly minimized or prevented (e.g., when an entity other than the grower of produce subject to part 112 of this chapter harvests or packs the produce and significantly minimizes or prevents the hazard or verifies that the hazard has been significantly minimized or prevented, or when the foreign supplier's raw material supplier significantly minimizes or prevents a hazard). The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign supplier conducted under §1.505."* As an FSVP Agent or Qualified Individual, USA's FDA-mandated goal is to verify that a product's innate physical, chemical and biological hazards are being controlled in a manner that is at least equivalent to the FDA's domestic standards. in order to accomplish this goal, documentation of a foreign supplier's processes, procedures and control methods will be required. Understanding that all foods may not share identical hazards - their control*(s)* also not being identical - USA utilizes a variety of foreign supplier verification activities to verify that a food's hazards have been significantly minimized or prevented. USA's determination of appropriate supplier verification activities is based on an evaluation of a specific food, its relevant hazards, and its corresponding foreign supplier. The following activities may be used to satisfy the requirements of 21 C.F.R., §1.506 (a), (a)(2), (b), (c), and (d):

A foreign supplier's Hazard Analysis and Critical Control Point *(HACCP)* plan may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's HACCP plan will be included within this FSVP plan.

An on-site audit of a foreign supplier's facility may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's on-site audit report will be included within this FSVP plan.

Sampling and testing of a food may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's reviewed sampling and testing results will be included within this FSVP plan.

A foreign supplier's relevant food safety record(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's relevant food safety record(s) will be included within this FSVP plan.

Continued onto next page.

FOREIGN SUPPLIER VERIFICATION PROCEDURES

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Certifying documents for a foreign supplier's Qualified Individual(s) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the certifying documents for a foreign supplier's Qualified Individual(s) will be included within this FSVP plan.

A food's nutritional label(ing) may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the food's nutritional label(ing) will be included within this FSVP plan.

Completion of the FSVP Importer's Supplier Assessment Questionnaire and/or the FSVP Importer's Allergen and Intolerance Questionnaire may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the completed Questionnaire(s) will be included within this FSVP plan.

Documentation that a foreign supplier is in, and under the regulatory oversight of, a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States, and that the food is within the scope of that official recognition or equivalency determination, and that the foreign supplier of the food is in good compliance standing with the food safety authority of the country in which the foreign supplier is located may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.

Documentation that a foreign supplier meets the definition of a qualified facility *(as defined by §117.3 or §507.3)* may be required. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of all substantiating documents will be included within this FSVP plan.

The FSVP Importer may rely upon performance of activities by other entities. If the FSVP Importer relies upon supplier verification activities conducted by another entity, the FSVP Importer will review and assess the results of these activities. Notation and documentation of the FSVP Importer's review and assessment will be recorded in this FSVP plan, including documenting that the determination of appropriate verification activities was made by a Qualified Individual.

When the FSVP Importer determines that a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the FSVP Importer will require a copy of the foreign supplier's annual on-site audit results. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the foreign supplier's annual on-site audit results will be included within this FSVP plan. After initial verification, the FSVP Importer will require that the foreign supplier provide copies of their annual on-site results at least annually thereafter.

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.

It may be required that the FSVP Importer conduct or obtain documentation of other (not previously mentioned) appropriate supplier verification activity(s) based on the foreign supplier's performance and the risk associated with the food. If required, notation will be recorded on the enclosed FSVP Document Checklist and a reviewed and approved copy of the supplier verification activity(s) will be included within this FSVP plan.

FREQUENCY *of* VERIFICATION PROCEDURES

All foreign supplier verification procedures and activities will be conducted and/or re-conducted at a frequency appropriate to the relevant procedure/activity and the corresponding hazard profile for the relevant food. Please refer to document-specific notes found on page eleven, Ongoing Document Requirements found on page twelve, and Ongoing Verification Activities & Frequency of Ongoing Verification Activities found on page fourteen.

USE *of* APPROVED SUPPLIERS ONLY

Food and/or food-related products should only be imported from foreign suppliers that have been verified to the standards of FSVP. Prior to importation, all steps necessary to successful verify that a foreign supplier's food safety processes and procedures meet the requirements of FSVP *(and other applicable regulations)*, must be undertaken. Once complete, the product specific FSVP plan - created by United Safety Agents – will denote a supplier's status on the Title Page of each plan. Importation may occur if the following three parameters are met: 1) the FSVP plan's status does not read "Denied" or other wording denoting that product is not currently approved for import; 2) the date of importation will fall within one calendar year *(365 days)* from the plan's noted "Review End" date, and 3) there are no outstanding issues or changes in the supplier's processes and/or procedures since the noted "Review End" date.

CORRECTIVE ACTIONS

The FSVP Importer will take prompt corrective actions if it determines that a foreign supplier does not produce food consistent with the written assurance, and in compliance with applicable processes and procedures that provide same level of protection as FDA requirements. If the FSVP Importer determines by means other than verification activities that a foreign supplier does not produce food in compliance with applicable processes and procedures that provide the same level of protection as FDA requirements, it will conduct an investigation to determine whether the FSVP should be modified accordingly. Such corrective actions are dependent upon the specific circumstances of the deviation but could include: the complete discontinued use of the foreign supplier, or the discontinued use of the foreign supplier until the cause or causes of noncompliance, adulteration, or misbranding have been adequately addressed.

IDENTIFICATION *of* FSVP IMPORTER

The FSVP Importer will ensure that, for each line entry, the following information is provided to U.S. Customs and Border Protection: 01) FSVP Importer's Business Name; 02) FSVP Importer's Electronic Mail Address; and 03) The FSVP Importer's FDA acceptable UFI *(Unique Facility Identifier)* such as a DUNS number.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

UNITED STATES CODE *of* FEDERAL REGULATIONS

The following are or may be applicable to this product/supplier, FSVP Importer should confirm & comply independently.

- ☐ **101.** §101.1–101.108. Food Labeling.
- ☐ **106.** §106.1–106.160. Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, & Notifications.
- ☐ **110.** §110.3–110.110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
- ☐ **111.** §111.1–111.610. Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
- ☐ **112.** §112.1–112.213. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.
- ☐ **113.** §113.3–113.100. Thermally Processed Low-Acid Foods Pkged in Hermetically Sealed Containers.
- ☐ **114.** §114.3–114.100. Acidified Foods.
- ☐ **117.** §117.1–117.475. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- ☐ **120.** §120.1–120.25. Hazard Analysis and Critical Control Point (HACCP) Systems.
- ☐ **121.** §121.1–121.401. Mitigation Strategies to Protect Food Against Intentional Adulteration.
- ☐ **123.** §123.3–123.28. Fish and Fishery Products.
- ☐ **129.** §129.1–129.80. Processing/Bottle Drinking Water.
- ☐ **131.** §131.3–131.206. Milk and Cream.
- ☐ **133.** §133.3–133.196. Cheeses & Related Products.
- ☐ **135.** §135.3–135.160. Frozen Desserts.
- ☐ **136.** §136.3–136.180. Bakery Products.
- ☐ **137.** §137.105–137.350. Cereal Flours.
- ☐ **139.** §139.110–139.180. Macaroni & Noodle Products.
- ☐ **145.** §145.3–145.190. Canned Fruits.
- ☐ **146.** §146.3–146.187. Canned Fruit Juices.
- ☐ **150.** §150.110–150.160. Fruit Butters, Jellies, Preserves, and Related Products.
- ☐ **152.** §152.126. Fruit Pies.
- ☐ **155.** §155.3–155.201. Canned Vegetables.
- ☐ **156.** §156.3–156.145. Vegetable Juices.
- ☐ **158.** §158.3–158.170. Frozen Vegetables.
- ☐ **160.** §160.100–160.190. Eggs and Egg Products.
- ☐ **161.** §161.30–161.190. Fish and Shellfish.
- ☐ **163.** §163.5–163.155. Cacao Products.
- ☐ **164.** §164.110–164.150. Tree Nut and Peanut Products.
- ☐ **165.** §165.3–165.110. Beverages.
- ☐ **166.** §166.40–166.110. Margarine.
- ☐ **168.** §168.110–168.180. Sweeteners and Table Sirups.
- ☐ **169.** §169.3–169.182. Food Dressings and Flavorings.
- ☐ **170.** §170.3–170.285. Food Additives.
- ☐ **179.** §179.21–179.45. Irradiation in the Production, Processing and Handling of Food.
- ☐ **190.** §190.6. Dietary Supplements.
- ☑ **501.** §501.1–501.110. Animal Food Labeling.
- ☑ **507.** §507.1–507.215. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.
- ☐ **570.** §570.3–570.280. Food Additives.
- ☑ **579.** §579.12–579.40. Irradiation in the Production, Processing, & Handling of Animal & Pet Food.

Note: List is not exhaustive. Other regulations may be applicable.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

21 C.F.R. §1.500–§1.514

The following section(s) of the FSVP regulation is/are or may be particularly relevant to this product/supplier.

- ☒ **§1.500.** What Definitions Apply to This Subpart?
- ☒ **§1.501.** To What Foods Do the Requirements in This Subpart Apply?
- ☒ **§1.502.** What Foreign Supplier Verification Program *(FSVP)* Must I Have?
- ☒ **§1.503.** Who Must Develop My FSVP and Perform FSVP Activities?
- ☒ **§1.504.** What Hazard Analysis Must I Conduct?
- ☒ **§1.505.** What Evaluation for F. Supplier Approval & Verification Must I Conduct?
- ☒ **§1.506.** What Foreign Supplier Verification and Related Activities Must I Conduct?
- ☐ **§1.507.** What Requirements Apply When I Import Food That Cannot Be Consumed Without the Hazards Being Controlled or for Which the Hazards Are Controlled After Importation?
- ☒ **§1.508.** What Corrective Actions Must I Take Under My Foreign Supplier Verification Program?
- ☒ **§1.509.** How Must the Importer Be Identified at Entry?
- ☒ **§1.510.** How Must I Maintain Records of My FSVP?
- ☐ **§1.511.** What FSVP Must I Have If I Am Importing A Food Subject to Certain Requirements in the Dietary Supplement Current Good Manufac turing Practice Regulation?
- ☐ **§1.512.** What FSVP May I Have If I Am A Very Small Importer or I Am Importing Certain Food from Certain Small Foreign Suppliers?
- ☐ **§1.513.** What FSVP May I Have If I'm Importing Certain Food from A Country with An Officially Recognized Food Safety System?
- ☒ **§1.514.** What Are Some Consequences of Failing to Comply with the Requirements of FSVP?

NOTES & COMMENTS

FSVP 21 CFR §1.500–§1.514

This product falls – at least in part – under the jurisdiction of the United States Food and Drug Administration (FDA), and does not qualify for an exemption in Title 21, Code of Federal Regulations, Chapter I, Sub-chapter A, Part 1, Subpart L, §1.501. As the FSVP Importer's Qualified Individual (as the term is defined in §1.503) United Safety Agents – through the actions of this FSVP Plan's identified "Agent(s)" – has performed all actions required by FSVP and has presented this FSVP Plan for the review of this product's FSVP Importer. Please refer to pages twenty-eight through thirty-six for substantiation of the FSVP QI's / PCQI's credentials.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ATTESTATION *of* REVIEW & ASSESSMENT

21 C.F.R., §1.506, (d)(3) provides that *"You may rely on a determination of appropriate foreign supplier verification activities . . . made by an entity other than the foreign supplier if you review and assess whether the entity's determination regarding appropriate activities. . . . You must document your review and assessment, including documenting that the determination of appropriate verification activities was made by a qualified individual."* **Please review this FSVP plan in its entirety and document your review below.**

I, _____ certify that I reviewed this FSVP plan on _____ and found
type name *today's date*

its contents to be acceptable.

Reviewer's Name: _____

Reviewer's Signature: _____

Reviewer's Title: _____

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

DESIGNATION *of* ROLES & SUMMARY *of* REVIEW

FOREIGN SUPPLIER VERIFICATION PROGRAM IMPORTER

Company Name: Hillside Farms Corp. (Importer of Record: Shanghi Adams) FDA FEI: Not Available.

Physical Address: 16330 Bake Parkway DUNS No.: 963721407

City: Irvine State: California, 92618 Country: United States

Mailing Address: 16330 Bake Parkway

City: Irvine State: California, 92618 Country: United States

Phone Number: +1 (949) 208-7988 Email Address: DanieleN@hillside-farms.com

Name *of* Representative*(s)*: Ms. Daniele Nguyen Title: Commercial Rep.

FOREIGN SUPPLIER &/OR MANUFACTURER *as defined by §1.500*

Company Name: Yantai Hao's Pet Food Tech. Co., Ltd. FDA FFR: 12149111738

Manufacturing Address: No.16 Puchang Road, Laishan Economic Development Zone FDA FEI: 3010135110

City: Yantai City Province/Territory: Shandong Province, 264003 Country: China

Office Address: No.16 Puchang Road, Laishan Economic Development Zone

City: Yantai City Province/Territory: Shandong Province, 264003 Country: China

Phone Number: +86-13105275510 Email Address: zhaol@wanpy.com.cn

Name *of* Representative*(s)*: Mr. Zhao Lei Title: QA Manager

QUALIFIED INDIVIDUAL*(s)* & AGENT*(s)*

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: May 10, 2022

Support PCQI: William J. Barber Signature: W. J. Barber

Title: Preventive Controls Qualified Individual.

SUMMARY *of* REVIEW

Details *of* Product(s)	*Is foreign supplier expected to implement controls for*			**Comments**
	Biological Hazards	**Chemical Hazards**	**Physical Hazards**	
Chicken Liver Dog Treats (Freeze Dried). Weight: .88 & 20oz. Packaged for retail distribution.	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	☑ Yes ☐ No ☐ *Undetermined*	Verified & Approved. — See Addendum.
	☐ FSVP Importer	☐ FSVP Importer	☐ FSVP Importer	
	☐ Disclosure	☐ Disclosure	☐ Disclosure	
	☐ Customer	☐ Customer	☐ Customer	

Preventive Control or Disclosure Rqd.: Per §117, §507, §111 and/or §1.507, Notice is required when FSVP Importer or FSVP Importer's customer will be responsible for controlling hazards. *See "Hazard Analysis & Determination" section(s) and "Addendum" section for additional information.* *Required* *Recommended* *Confirm efficacy of previously applied control(s)*

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Yantai Hao's Pet Food Tech. Co., Ltd.'s HACCP Plan received.
Dated: January 03, 2020. Version: No. 4.
Plan Entitled: Dried Pet Food Safety Plan / Freeze Dried Pet Food Safety Plan
Prepared By: Lifeng Yu. Approved by Yishan Jiang.
Contains: Process flow chart, hazard analysis, process preventative controls, sanitation preventative controls, supply-chain preventative control, withdraw and recall procedure, correction procedure, verification procedure, and implementation records.
Yantai Hao's Pet Food Tech. Co., Ltd.'s previous HACCP Plan on file.

ON-SITE AUDIT

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Yantai Hao's Pet Food Tech. Co., Ltd.'s BRC Food Safety Issue 8: August 2018 Audit Report received.
Dated: March 18, 2020.
Re-audit Due Date: March 25, 2021.
Audit Grade: A. Number of Minor Non-conformities: 7.
Previous Audit Grade: A. Previous Audit Date: March 20, 2019 - (Report also on file)
Yantai Hao's Pet Food Tech. Co., Ltd.'s SGS FSMA Gap Assessment Audit received.
Dated: March 23, 2019.
Audit Result: FSMA Certification.

SAMPLING OR TESTING RESULTS

☑ *Requested* ☐ *Required* ☐ *Received* ☐ *Reviewed*

NOTES No substantiating information provided by the supplier.
Note: We respectfully request that recent certificate(s) of analysis be provided for testing conducted to determine that product has been effectively processed to control for all FDA identified biological and chemical hazards (preferably by an ISO 17025-accredited laboratory).

OTHER FOOD SAFETY RECORDS

☑ *Requested* ☐ *Required* ☐ *Received* ☐ *Reviewed*

NOTES Foreign Supplier FSVP Questionnaire requested.

No substantiating information provided by the supplier.

PRODUCT LABELING

☑ *Requested* ☑ *Required* ☑ *Received* ☑ *Reviewed*

NOTES Product Label received. Label clearly identifies all present allergens. Labeling is in compliance with Part 403(w) of the Federal Food, Drug, and Cosmetic Act in so far as it is not misbranded with respect to the presence of food allergens. See Analysis & Determination of Allergenic Hazard(s) for details.

Note: USA's assessment of product(s) labeling is restricted to a label(s)' allergen disclosure statement and should not be interpreted to meant that the label(s) meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or any other applicable section of 21 CFR Part 101.. USA recommends that FSVP Importer independently confirm that product label(s) is in compliance with all regulations prior to import.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

VERIFICATION FREQUENCY *for* UPDATED DOCUMENTS

21 C.F.R., §1.505, §1.506, and §1.510 require that all FSVP records be updated and maintained. Depending on USA's review and determination of the supplier's compliance history and food safety program, receipt of the following food safety documents are recomended accord to their individually-marked time interval.

FACILITY FOOD SAFETY PLAN

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

HACCP PLAN / HARPC PLAN

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

ON-SITE AUDIT RESULTS

- ☑ if a change or update occurs
- ☑ annual basis *(regardless of change)*
- ☐ *other:*_____

LABORATORY TESTING RESULTS

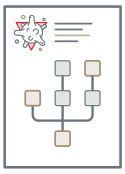
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☐ if inspection occurs
- ☐ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*_____

FDA REGISTRATION

- ☑ if a change or update occurs
- ☑ bi-annual basis *(regardless of change)*

FACILITY LICENSE

- ☐ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☑ *not applicable*



RECALL PLAN

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

PRODUCT LABEL

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

QUALIFICATIONS

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

IMPLEMENTATION RECORDS

- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☐ on an annual basis
- ☐ on a per-batch/shipment basis
- ☐ *other:*_____

FSVP QUESTIONNAIRE

- ☑ if a change or update occurs
- ☐ annual basis *(regardless of change)*
- ☐ *other:*_____

NOTES

All documents used for FSVP verification and approval must be re-acquired at least one every three years or sooner, per above.

unitedsafetyagents.com/documents

Supplier: Yantai Hao’s Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

INITIAL VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control have been significantly minimized or prevented, the below enumerated activities were used to initially verify the products (“product” or “imported product”), supplied by Yantai Hao’s Pet Food Tech. Co., Ltd. (“supplier” or “foreign supplier”), imported by Hillside Farm Corp. (“importer” or “FSVP importer”):

RELEVANT FOOD SAFETY RECORDS, including a review of the foreign supplier's relevant food safety records, including Yantai Hao’s Pet Food Tech. Co., Ltd.'s Hazard Analysis and Critical Control Plan (“HACCP Plan”); food safety plan/program; implementation records; and internal monitoring procedures. Per §1.506(d)(1)(ii)(C) and (e)(1)(iii), documentation of each record, including the dates of review, the general nature of the records reviewed, the conclusions of the review, and documentation that the review was conducted by a FSVP qualified individual were completed.

THIRD-PARTY ON-SITE AUDIT REPORT, including the assessment of Yantai Hao’s Pet Food Tech. Co., Ltd.'s on-site audit report. Per (e)(1)(i)(B) Yantai Hao’s Pet Food Tech. Co., Ltd.'s on-site audit report was not relied upon to approve the supplier because United Safety Agents (“USA”) could not definitively confirm – or rule out – that the report considered FDA food safety regulations.

OTHER APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES, including a review of Yantai Hao’s Pet Food Tech. Co., Ltd.'s compliance history, including whether Yantai Hao’s Pet Food Tech. Co., Ltd. is the subject of an FDA Warning Letters; Import Alerts; or other FDA compliance actions related to food safety. Per §1.506(d)(1)(ii)(D) and (e)(1)(iv)(B), documentation of each activity conducted in accordance with paragraph (e)(1)(iv), including a description of the activity, the date on which it was conducted, the findings or results of the activity, any corrective actions taken in response to significant deficiencies identified, and documentation that the activity was conducted by a FSVP QI were completed.

NOTE

Per §1.506(d)(3), Hillside Farm Corp. relied on the determination of appropriate foreign supplier verification activities made by an entity other than the foreign supplier (USA) and reviewed and assessed whether the determination was appropriate. Hillside Farm Corp. has documented its review and assessment, including documenting that the determination of appropriate verification activities was made by a FSVP QI. Hillside Farm Corp.'s attestation of review and assessment can be found on page number nine of this FSVP. USA's certifications and qualifications can be found on page numbers twenty-eight through thirty-six of this FSVP.

***Note**: see next page for Ongoing Verification Activities.*

Supplier: Yantai Hao’s Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ONGOING VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control, for products (“product” or “imported product”), supplied by Yantai Hao’s Pet Food Tech. Co., Ltd. (“supplier” or “foreign supplier”), continue to be significantly minimized or prevented prior to public distribution, up-to-date versions of all documents used during the initial FSVP verification and approval processes will be re-acquired at least once every three years – or sooner, per the following document-specific requirements:

An updated version of Yantai Hao’s Pet Food Tech. Co., Ltd.'s FOOD SAFETY PLAN will be required if any change or update occurs. Yantai Hao’s Pet Food Tech. Co., Ltd. has been informed of this ongoing requirement and USA will confirm annually that the version on file remains current and faithfully illustrates all processes, monitoring procedures, etc., or acquire and review Yantai Hao’s Pet Food Tech. Co., Ltd.'s most up-to-date copy.

An updated version of Yantai Hao’s Pet Food Tech. Co., Ltd.'s HACCP PLAN will be required if any change or update occurs. Yantai Hao’s Pet Food Tech. Co., Ltd. has been informed of this ongoing requirement and USA will confirm annually that the HACCP Plan on file remains current and faithfully illustrates all supply chain controls and/or process/critical control procedures, or acquire and review Yantai Hao’s Pet Food Tech. Co., Ltd.'s most up-to-date copy.

An updated version of Yantai Hao’s Pet Food Tech. Co., Ltd.'s ON-SITE AUDIT REPORT will be requested annually, or if any change or update occurs prior to year's end. Yantai Hao’s Pet Food Tech. Co., Ltd. has been informed of this ongoing request and USA will acquire and review the updated Report from the supplier annually, or sooner if a change has been made.

Confirmation that Yantai Hao’s Pet Food Tech. Co., Ltd.'s FOOD FACILITY REGISTRATION remains active with FDA will be made annually by USA.

The supplier's COMPLIANCE STANDING/HISTORY will be checked by USA via FDA's Data Dashboard annually – at a minimum ¬– or sooner in the event that USA is made aware of new information.

An updated version of the product's LABELING will be required if any change or update occurs. Yantai Hao’s Pet Food Tech. Co., Ltd. has been informed of this ongoing requirement and USA will confirm annually that the label on file remains current.

NOTE

USA's assessment of the product's labeling is restricted to the label's allergen disclosure statement and should not be interpreted to mean that the label meets all requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food Allergen Labeling and Consumer Protection Act (FALCPA), or all other applicable sections of 21 CFR Part 101. It shall remain Hillside Farm Corp.'s responsibility to independently confirm that the product label follows all regulations prior to import.

FREQUENCY *of* VERIFICATION ACTIVITIES

All Ongoing Verification Activities will be conducted and re-conducted at their individually noted frequency, as appropriate to confirm that each hazards requiring a control continues to be significantly minimized or prevented by the supplier. Or, if not controlled by the supplier, is properly disclosed to the appropriate party. Document frequency-specific determinations can be found on page number twelve of FSVP.

***Note**: It is understood that the above actions are applicable only if USA continues to serve as the FSVP QI.*

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

FDA COMPLIANCE ACTIONS & REGULATORY HISTORY

21 CFR part 1, subpart L, §1.505(a)(1)(iii)(A)(C), and elsewhere requires that a foreign supplier's compliance history be evaluated, including whether the foreign supplier is the subject of an FDA Warning Letter*(s)*, Import Alert*(s)*, or other FDA compliance action(s) related to food safety. The following constitutes the results of this evaluation.

RESULTS *of* EVALUATION

Date *of* Action	Description *of* Action
2019	FDA FACILITY INSPECTION Inspection Id: 1097442 Project Area: Monitoring of Marketed Animal Drugs, Feed, and Devices Classification: NAI FDA Data Dashboard search results indicate that supplier's compliance history does not include FDA Warning Letters, Import Alerts, or other applicable compliance actions.

Covers: Yantai Hao's Pet Food Tech. Co., Ltd. FEI: 3010135110 Date: May 10, 2022

***Note**: Results may not be exhaustive. FSVP Importer should conduct independent inquiry.*

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	May 16, 2019	Product and supplier underwent initial FSVP verification.
No. 02	May 15, 2020	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.
No. 03	May 15, 2021	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.
No. 04	May 10, 2022	Foreign Supplier and product underwent annual verification. Additional and/or updated food safety documents were requested, received, and added to FSVP. FSVP content and format was updated to reflect recent FDA Guidance document(s) and/or regulatory statues that became applicable since initial verification, or previous reverification.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

ANALYSIS & DETERMINATION *of* BIOLOGICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Bacillus cereus*** ☐ ***Clostridium botulinum*** ☐ ***C. perfringens*** ☐ ***Brucella spp.*** ☐ ***Campylobacter spp.*** ☐ ***Pathogenic E. coli*** ☒ ***Salmonella spp.*** ☐ ***S. aureus*** ☐ ***L. monocytogenes*** ☐ ***Trichinella spiralis*** ☐ ***Giardia lamblia*** ☐ ***Shigella spp.*** ☐ ***Other***	1	3	Biological hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the application of a heat and/or chemical kill-step, implementing and following raw material supplier approval procedures, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes raw material supplier approval procedures to control hazards posed by biological contaminates. Details: Supply-chain, The incoming raw materials shall be checked by QC. The supplier shall provide the Animal Inspection and Quarantine Certificate. business license, manufacture permit or other certificate, third party approve certificate, and third party test report required for approval. 02. Supplier utilizes thermally induced drying to help control for the presence of biological contaminates. Details: Drying Temperature: 80°C + Drying Time: 30min + Validation: The drying/sterilization record is checked every day. The pathogen items are tested by the test center. The thermo meter is calibrated every week. The automatic temperature recorder is calibrated every year. 03. Supplier certifies that all raw material and finished product is submitted for laboratory testing by SGS (CNAS accreditation lab based on ISO17025). Test items main include Sensory, TPC, Coli form, pathogenic bacterium, Pb, As and pesticide residue. CNAS lab and internal lab used for finished product testing, raw materials testing.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified biological hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient ——————— ———————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ANALYSIS & DETERMINATION *of* CHEMICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Drug residues*** ☐ ***Heavy metals*** ☒ ***Industrial chemicals*** ☐ ***Pesticides*** ☒ ***Mycotoxins/Toxins*** ☐ ***Radiological*** ☐ ***Unapproved colors & additives*** ☐ ***Chemical hazards due to mis-formulation*** ☐ ***Other***	1	2	Chemical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – implementing and following appropriate raw material supplier approval procedures, and/or subjecting raw material(s) and/or finished product(s) to laboratory testing. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes raw material supplier approval procedures and raw material inspection procedures to control hazards posed by chemical contaminates. Details: Supply-chain, The incoming raw materials shall be checked by QC. The supplier shall provide the Animal Inspection and Quarantine Certificate, business license, manufacture permit or other certificate, third party approve certificate, and third party test report required for approval. Testing conducted for: Drug Residue, Furan metabolite, chloramphenico, diethylstilbestrol, amantadine, sulfamethoxazole, Tilmicosin, Trimethoprime, Sulfaquinoxaline, Enrofloxacin, Sulfaclozine, and Clenbuterol. Validation: Inspection record is checked every day. Raw materials is monitored by the test center according to the monitoring plan. Raw materials factory accredited third test report. 02. Supplier certifies that all raw material and finished product is submitted for laboratory testing by SGS (CNAS accreditation lab based on ISO17025). ———————NOTE——————— We respectfully request a copy of recent laboratory testing results.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified chemical hazards. ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient ——————— ———————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ANALYSIS & DETERMINATION *of* ALLERGENIC HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☐ ***Undeclared allergens - Incorrect label*** ☐ ***Undeclared allergens - Cross-contact*** **ALLERGENS** ☐ ***Milk*** ☐ ***Eggs*** ☐ ***Fish*** ☐ ***Shellfish*** *(Crustacean)* ☐ ***Tree nuts*** ☐ ***Peanuts*** ☐ ***Wheat*** ☐ ***Soybeans*** ☐ ***Sesame****	-	-	Allergens themselves can not be directly controlled. However, the presence of allergens – or a given allergen – can be controlled. The presence of allergenic hazards can be effectively controlled through the utilization of a number of control measures, including – but not limited to – staff training for common food allergens, avoiding cross-contact, and proper food labeling. These may be effective methods to ensure that allergens are not ingested by a person who will be experience a negative reaction. ——— SUPPLIER CONTROL MEASURES ——— Note: Top 8 Human Food Allergens do not apply to pet and animal foods. Label allergen disclosure is not required. See US CVM. ———————NOTE——————— ---------- Labeling Requirements ---------- The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control the hazard posed by allergenic adulteration. As per the US CVM allergens are not considered a hazard with respect to animal food ——————— ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient ———————

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

*Per Food Allergy Safety, Treatment, Education and Research Act, food packages will need to reflect allergen labeling for sesame beginning on January 1, 2023.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ANALYSIS & DETERMINATION *of* ENVIRONMENTAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Recontamination with environmental pathogens.*** ☐ ***Bacterial pathogen survival of a lethal treatment.*** ☐ ***Bacterial growth and/or toxin formation due to lack of time / temperature control.*** ☐ ***Recontamination due to lack of container integrity.*** ☐ ***Bacterial growth and/or toxin formation due to poor formulation control.*** ☐ ***Bacterial growth and/or toxin formation due to reduced oxygen packaging.*** ☐ ***Other***	1	2	Hazards posed by ineffective processes or environmental pathways can be controlled by the utilization of Current Good Manufacturing Practices, positively releasing finished product, avoiding cross-contamination, carefully monitoring production process, subjecting raw material(s) and/or finished product(s) to laboratory testing, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Hazard posed by recontamination with environmental pathogens is controlled through Current Good Manufacturing Practices 02. Products are mechanically sealed in PVC bags. 03. All product is positively released. 04. Supplier utilizes laboratory testing to confirm finished product is free from environmental pathogens. 05. Supplier utilizes an environmental monitoring program, which has been established based on risk. Details: Based on risk assessment, the environmental monitoring program details the following requirements: typical sampling areas, organisms being assessed, frequency and methods of testing, handling for out of specification results; Lab staff is responsible for Environmental monitoring (TPC, coliform, E.coli, salmonella, staphylococcus aureus, Listeria) such as testing the TPC for workshop (processing areas, packing area) every month. No pathogenic bacteria detected, then the monitoring plan will be adjusted. SGS (CNAS accreditation lab based on ISO17025) ———NOTE——— We respectfully request a copy of recent laboratory testing results.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control FDA identified environmental hazards. ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ANALYSIS & DETERMINATION *of* PHYSICAL HAZARDS

FDA Identified Hazard(s)	P.	S.	Control Measure(s)	Hazard(s) Controlled
☒ ***Metal*** ☐ ***Glass*** ☐ ***Extraneous Matter*** ☐ ***Plastics*** ☐ ***Stones*** ☐ ***Wood*** ☐ ***Natural Component of Food*** ☐ ***Other***	1	2	Physical hazards can be effectively controlled through the utilization of a number of different control measures, including – but not limited to – the utilization of an operational and calibrated metal detector during and/or after the production process, sieving raw material and/or finished product, optical sorting machinery, visual inspection, appropriate and consistent raw material supplier approval methods, and/or through the utilization of a number of other appropriate control measures. ——— SUPPLIER CONTROL MEASURES ——— 01. Supplier utilizes an operational and calibrated metal detector to control hazards posed by physical agents. Metal Detector's Critical Limits Ferrous: 1.5 mm. Non Ferrous: 1.5 mm. Stainless Steel: 1.5 mm. Validation: If the products can not pass the metal detector, these products will be separated and take root analysis and take preventive measures, If the metal detector is not working, all the products that have passed since the last calibration, the separated products will pass the metal detector by the repaired machine. The metal detector calibration will be checked every day. The metal detector will be calibrated before production, every 1 hour in the production and after production. Each batch products will be checked by QC.	Based upon the information and documentation provided to USA before the above noted Review End date, this supplier has implemented sufficient measures – or certified that sufficient measures are in place – to effectively control physical hazards. ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient

Legend *for* Hazard Analysis & Determination

M&B: Micro & Biological. Hazards may include bacteria, viruses, parasites, and environmental pathogens.

C: Chemical. Hazards may include radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives.

P: Physical. Hazards may include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects.

Probability (*P.*): Assesses the probability that the hazard will occur in the absence of controls. (§1.503, (c))

Severity (*S.*): Assesses the severity of the illness or injury if the hazard were to occur. (§1.503, (c))

P. & S. Assessment Scale: **1** - Low, **2** - Moderate, **3** - High, **S** - Serious adverse health consequences or death.

Hazard(s) Controlled: Are the supplier's method(s) adequate to ensure that the relevant hazard(s) are controlled.

Source

Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration's Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry. Appendix 1: Potential Hazards for Foods and Processes. (Hazards Tables)

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Yantai Hao's Pet Food Tech. Co., Ltd. 1.2. Supplier country: China

1.3. Products manufactured/supplied: Dried pet foods and treats, packaged in polyethylene terephthalate bags and bottles.

1.4. Is the supplier certified to a Global Food Safety Standard and audited annually? ☑ Yes ☐ No ☐ N/A

Standard: BRC Issue 8, FSMA, ISO22000, ISO9001

2.0 SUPPLIER PROCEDURES, PROCESSES & PRACTICES

2.1. Does supplier follow current GMPs? ☑ Yes ☐ No

2.2. Does the supplier have SOPs in place? ☑ Yes ☐ No ☐ N/A

2.3. Does the supplier have allergen controls in place to prevent cross-contamination? ☑ Yes ☐ No ☐ N/A

2.4. Does the supplier have a HACCP/PC plan for the product manufactured for the importer? ☑ Yes ☐ No ☐ N/A

2.5. Has the supplier's HACCP/PC plan been reviewed and approved by USA's PCQI? ☑ Yes ☐ No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

3.0 SUPPLIER PERFORMANCE HISTORY

3.1. To the best of USA's knowledge, has the supplier been the subject of a public FDA Alert/Warning Letter?

☐ Yes ☑ No ☐ N/A *Description: No, Import Alert & Warning Letter search-results, which were conducted on – or about – the Review End date, have been attached to this FSVP Plan.*

3.2. Has the supplier provided timely and adequate responses to all requests and issues related to food safety?

☑ Yes ☐ No *Description:*

4.0 SUPPLIER APPROVAL

4.1 Have USA's PCQI(s) identified and evaluated the known and reasonably foreseeable hazards for each product imported from the supplier and are there preventive controls in place to adequately control the hazards?

☑ Yes ☐ No *PCQI(s): C. Innocenti (PCQI. Member, USA LLC)*

4.2. After reviewing all hazards and the supplier's performance, have USA's PCQI(s) determined appropriate verification activitie(s) that will be conducted and documented on an ongoing basis to verify the preventive controls are effectively controlling the hazard(s)? ☑ Yes ☐ No

PCQI(s): C. Innocenti (PCQI. Member, USA LLC)

4.3 **Is the foreign supplier approved for import into the United States under FSVP** ☑ Yes ☐ No

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Claims Made Against Product

No claims have been made against the raw materiel / product type.

Overview *of* Foreign Supplier's Commercial Operation

Yantai Hao's Pet Food Tech. Co., Ltd. is responsible for the production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.

Business was established in 1999, and is located at No. 16 Puchang Road, Laishan Economic Development Zone, and Yantai City, Shandong Province, China.

Yantai Hao's Pet Food Tech. Co., Ltd. utilizes one production facility and about 400 contracted staffs. 7 QCs on staff. 1 shift per day, about 8 hours and 6 days per week. Output of roughly 3000 metric tons. Products are exported to North America and Europe. At present, the company holds ISO22000, ISO9001, ISO14001 and MSC certificates.

Testing Program & Accreditation

Supplier states that they send all/most raw materials for laboratory testing. We have not received any substantiation for this claim.

We suggest that copies of the cited testing reports be acquired, reviewed and included in this FSVP plan.

Supplier & Product Allergen Information

Supplier certifies that: A) there are NO allergens handled on site, B) a documented allergen control program is in use, C) a dedicated process line and a documented cleaning procedure are in place to prevent contamination, D) all employees undergo allergen training and processes have been put in place to reduce the likelihood of cross contact or unintentional introduction of allergens into processing area.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires that all animal foods, like human foods, be safe to eat, produced under sanitary conditions, contain no harmful substances, and be truthfully labeled. Top 8 human food allergens do not apply to pet and animal foods. Thus allergens are not considered to be a harmful substance. Label allergen disclosure is not required. See US CVM.

Packaging Type & Shipping / Handling Requirements

Packaging type: polyethylene bags that contains desoxidant and the outer the paper carton. Animal food-contact and non-contact surfaces of utensils and equipment cleanable and maintained. Utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. The purchasing of the raw materials and the auxiliary materials and the packaging materials used in the pet food processing and the suppliers management. The product packaging material supplier assessment shall be conducted according to the procurement control procedures, if necessary, will be on-site evaluation.
Storage: room temperature.
Shelf life: 18 months/24 months.
Special transportation requirement: room temperature and use the clean container to ship. Avoid the sunshine and rain. The products cannot shipped with the harmful, foreign smell products.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd.

Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC)

Review Start: April 15, 2022 Review End: May 10, 2022

REVIEW *of* GENERAL FOOD SAFETY PROGRAM

Supplier GFSI Status & Historical Performance

Supplier appears to be following CGMPs and utilizes an established food safety program. Products supplied by this supplier have been verified and are approved for import.

Specify certificate(s) and scope(s): BRC Food issue 7, ISO22000:2005. FSMA Compliance audit. Food safety PRP (HS-CX-42) was established based on ISO22000, BRC, GB14881, CAC GMP & HACCP and other applicable laws e.g. 21CFR 110, issue 8.0, Date on 2016-11-04.

Recent changes including organization, documentation, products, facilities, processes, key personnel, client activities, management system, level of integration etc. during the past 2 years. No obvious change during the past 2 years.

Close Supplier Monitoring

No. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis, or sooner if necessary.

General Comments & Verification Timeline

Products supplied by this supplier have been verified and are approved for import. Supplier/product will be re-assessed and re-verified to the standards of the Foreign Supplier Verification Program on an annual basis (or sooner if necessary). This FSVP will expire one year from its above the above noted "Review End" date.

NOTE

We respectfully request: recent laboratory testings for all identified biological and chemical hazards.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ADDENDUM

TITLE 21 OF THE CODE OF FEDERAL REGULATIONS
CHAPTER I, SUBCHAPTER E, PART 507, SUBPART E, § 507.105, § 507.110, AND § 507.115

---------- Sec. 507.105 Requirement to establish and implement a supply-chain program ----------

(a)(1) Except as provided by paragraphs (a)(2) and (3) of this section, the receiving facility must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control.

(b) The supply-chain program must be written.

(c) When a supply-chain-applied control is applied by an entity other than the receiving facility's supplier (e.g., when a non-supplier applies controls to certain produce (i.e., produce covered by part 112 of this chapter), because growing, harvesting, and packing activities are under different management), the receiving facility must:

(1) Verify the supply-chain-applied control; or

(2) Obtain documentation of an appropriate verification activity from another entity, review and assess the entity's applicable documentation, and document that review and assessment.

---------- Sec. 507.110 General requirements applicable to a supply-chain program ----------

(a) The supply-chain program must include:

(1) Using approved suppliers as required by 507.120; (2) Determining appropriate supplier verification activities (including determining the frequency of conducting the activity) as required by 507.125; (3) Conducting supplier verification activities as required by 507.130 and 507.135; (4) Documenting supplier verification activities as required by 507.175; and (5) When applicable, verifying a supply-chain-applied control applied by an entity other than the receiving facility's supplier and documenting that verification as required by 507.175, or obtaining documentation of an appropriate verification activity from another entity, reviewing and assessing that documentation, and documenting the review and assessment as required by 507.175.

(b) The following are appropriate supplier verification activities for raw materials and other ingredients:

(1) Onsite audits; (2) Sampling and testing of the raw material or other ingredient; (3) Review of the supplier's relevant food safety records; and (4) Other appropriate supplier verification activities based on supplier performance and the risk associated with the raw material or other ingredient.

(c) The supply-chain program must provide assurance that a hazard requiring a supply-chain-applied control has been significantly minimized or prevented.

(e) If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, document review, relevant consumer, customer, or other complaints, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as requiring a supply-chain-applied control, the receiving facility must take and document prompt action in accordance with 507.42 to ensure that raw materials or other ingredients from the supplier do not cause animal food that is manufactured or processed by the receiving facility to be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act.

---------- Sec. 507.115 Responsibilities of the receiving facility ----------

(a)(1) The receiving facility must approve suppliers.

(2) Except as provided by paragraphs (a)(3) and (4) of this section, the receiving facility must determine and conduct appropriate supplier verification activities, and satisfy all documentation requirements of this subpart.

(3) An entity other than the receiving facility may do any of the following, provided that the receiving facility reviews and assesses the entity's applicable documentation, and documents that review and assessment:

(i) Establish written procedures for receiving raw materials and other ingredients by the entity;

(ii) Document that written procedures for receiving raw materials and other ingredients are being followed by the entity; and

(iii) Determine, conduct, or both determine and conduct, the appropriate supplier verification activities, with appropriate documentation.

(4) The supplier may conduct and document sampling and testing of raw materials and other ingredients, for the hazard controlled by the supplier, as a supplier verification activity for a particular lot of product and provide such documentation to the receiving facility, provided that the receiving facility reviews and assesses that documentation, and documents that review and assessment.

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

(1) A determination by its supplier of the appropriate supplier verification activities for that supplier;

(2) An audit conducted by its supplier;

(3) A review by its supplier of that supplier's own relevant food safety records; or

(4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of 507.110(b)(4).

ADDENDUM

NOTE

Hazard Analysis and Risk-Based Preventive Controls for Food for Animals Guidance for Industry

Biological Hazards

Ref. 96.: Food and Drug Administration. 2013. "CPG Sec. 690.800 Salmonella in Food for Animals". Accessed November 9, 2017. https://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM361105.pdf.

Ref. 141.: Food and Drug Administration. 2013. "NutriVet, LLC Recalls NutriVet and Nutripet Chicken Jerky Products Because of Possible Salmonella Health Risk". Accessed January 8, 2018. http://wayback.archive-it.org/7993/20170112111709/http:/www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/-ucm340468.htm

Ref. 142.: Food and Drug Administration. 2015. "Grill-Phoria LLC Recalls Big Bark All Natural Beef Jerky Treats for Dogs Because of Possible Salmonella Health Risk". Accessed January 11, 2018. http://wayback.archive-it.org/7993/20170112074016/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2015/-ucm432561.htm.

Chemical Hazards

Ref. 39.: Food and Drug Administration. 2013. "Pesticide Monitoring Program". Accessed January 8, 2018. https://wayback.archive-it.org/7993/20170723104546/https://www.fda.gov/downloads/Food/FoodborneIllness-Contaminants/Pesticides/UCM508084.pdf.

Ref. 143.: Food and Drug Administration. 2013. "Milo's Kitchen Voluntarily Recalls Chicken Jerky and Chicken Grillers Homestyle Dog Treats". Accessed January 3, 2018. http://wayback.archive-it.org/7993/20170112111715/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/-ucm335621.htm.

Ref. 144.: Food and Drug Administration. 2012. "FDA Investigates Animal Illnesses Linked to Jerky Pet Treats". Accessed January 3, 2018. https://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm319463.htm.

Physical Hazards

Ref. 145.: Leib, M. S., and L. L. Sartor. 2008. "Esophageal Foreign Body Obstruction Caused by a Dental Chew Treat in 31 Dogs (2000–2006)". Journal of the American Veterinary Medical Association 232 (7): 1021-1025. DOI: 10.2460/javma.232.7.1021.

Supplier: Yantai Hao’s Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

ADDENDUM

NOTE

Labeling Requirements

It is the FSVP Importer's responsibility to confirm a product's compliance with Sec. 501 prior to distribution. The following regulatory citations are provided for reference.

Subpart A--General Provisions

§ 501.1 - Principal display panel of package form animal food.
§ 501.2 - Information panel of package for animal food.
§ 501.3 - Identity labeling of animal food in package form.
§ 501.4 - Animal food; designation of ingredients.
§ 501.5 - Animal food; name and place of business of manufacturer, packer, or distributor.
§ 501.8 - Labeling of animal food with number of servings.
§ 501.15 - Animal food; prominence of required statements.
§ 501.17 - Animal food labeling warning statements.
§ 501.18 - Misbranding of animal food.

Subpart B--Specific Animal Food Labeling Requirements

§ 501.22 - Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

Subparts C-E [Reserved]

Subpart F--Exemptions From Animal Food Labeling Requirements

§ 501.100 - Animal food; exemptions from labeling.
§ 501.103 - Petitions requesting exemptions from or special requirements for label declaration of ingredients.
§ 501.105 - Declaration of net quantity of contents when exempt.
§ 501.110 - Animal feed labeling; collective names for feed ingredients.

Animal Products FDA Regulates: Pet Foods

FDA regulations which apply to pet foods as well as other animal feed products are published in Title 21, Parts 501, 573, 579, 582, 584, and 589 of the Code of Federal Regulations. As with human food, pet foods may not be adulterated or misbranded. Pet foods may not contain any poisonous or deleterious substances or residues of pesticides in excess of established tolerances. They may not be stored in any containers which may render the contents injurious to health because of any poisonous or deleterious substance and may not contain any color additives or food additives which are unsafe. To ensure safety, canned pet food must be manufactured and registered in accordance with the FDA regulations for low-acid canned foods. Pet food labeling may not be false or misleading in any particular. Damage or inferiority may not be concealed in any manner. Pet food may not be sold under the name of any other food and may not have any valuable constituents omitted or extracted. Although pet food products do not need to have premarket approval by FDA, these products are subject to the requirements of the Act and pet food manufacturers are subject to individual annual product registration in most States. State laws may require that pet food labels bear, in addition to the mandatory information required by Federal law, a label statement of "guaranteed analysis" for minimum protein and fat content, and maximum fiber and moisture content, a nutritional adequacy statement, and feeding directions. Additional information concerning State registration and labeling requirements may be obtained from the individual states where the products will be distributed or from the Official Publication of the Association of American Feed Control Officials, Inc. c/o Sharon Krebs, Assistant Secretary, AAFCO, P.O. Box 478, 104 East McConnell Street, Oxford, Indiana, 47971. AAFCO’s website is http://www.aafco.org/.disclaimer icon. Pet foods are also subject to the labeling requirements of the Fair Packaging and Labeling Act, which governs certain aspects of consumer product labeling. AAFCO has developed definitions for certain nutrient content claims for calories and fat, such as "low calorie," "less or reduced calories," "low fat," and "less or reduced fat."

Source: https://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm268125.htm

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on
05/13/2021

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

AFDO

Certificate # 31d8ad94

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

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Claudio Innocenti

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Animal Food

delivered by Lead Instructor

Charles Nolan

completed on
07/09/2020

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Susan M. Hays, Executive Director
Association of American Feed Control Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AAFCO
Association of American Feed Control Officials

Certificate # 223faa17

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

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FSPCA

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Foreign Supplier Verification Programs

delivered by Lead Instructor

Bob Bauer

completed on

09/14/2018

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # d2e9c287

Produce Safety
ALLIANCE

AFDO
ASSOCIATION OF FOOD & DRUG OFFICIALS
SINCE 1896

Certificate of Training

is awarded to

Claudio Innocent

in recognition for having successfully completed
the Produce Safety Alliance course:

PSA Grower Training Course

Delivered by PSA Lead Trainers and/or PSA Trainers
Cara Fraver, Laura McDermott, Yolanda Gonzalez, Lindsey Pashow

Class Number
NY-180712-GR
Grower ID Number
50447
Training Date and Location
7/12/2018–7/12/2018
Voorheesville, NY

Joseph Corby
Executive Director, AFDO

Elizabeth A. Bihn, Ph.D.
Produce Safety Alliance Director

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

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delivered by Lead Instructor

Bob Bauer

completed on

05/31/2018

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

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Certificate # d2e9c287

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Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

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Certificate # d2e9c287

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

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CLAUDIO INNOCENTI

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA PREVENTIVE CONTROLS FOR HUMAN FOOD

delivered by Lead Instructor

Amanda Evans

completed on

07/25/2017

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

AFDO

Certificate # 2d697331

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

QUALIFICATIONS *of* SUPPORTING QI

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

WILLIAM BARBER

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

FSPCA Preventive Controls for Human Food

delivered by Lead Instructor

Mirasol Mohal

completed on
06/05/2019

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Steve Mandernach, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti

Certificate # ed6f0b58

AFDO

FSPCA
FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE

CERTIFICATE OF TRAINING

is awarded to

William Barber

in recognition for having successfully completed
the Food Safety Preventive Controls Alliance course:

Foreign Supplier Verification Programs

delivered by Lead Instructor

tina coil

completed on
06/13/2017

Robert Brackett, VP and Director
Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
Association of Food and Drug Officials

IFSH INSTITUTE FOR FOOD SAFETY AND HEALTH
ILLINOIS INSTITUTE OF TECHNOLOGY

ifpti INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

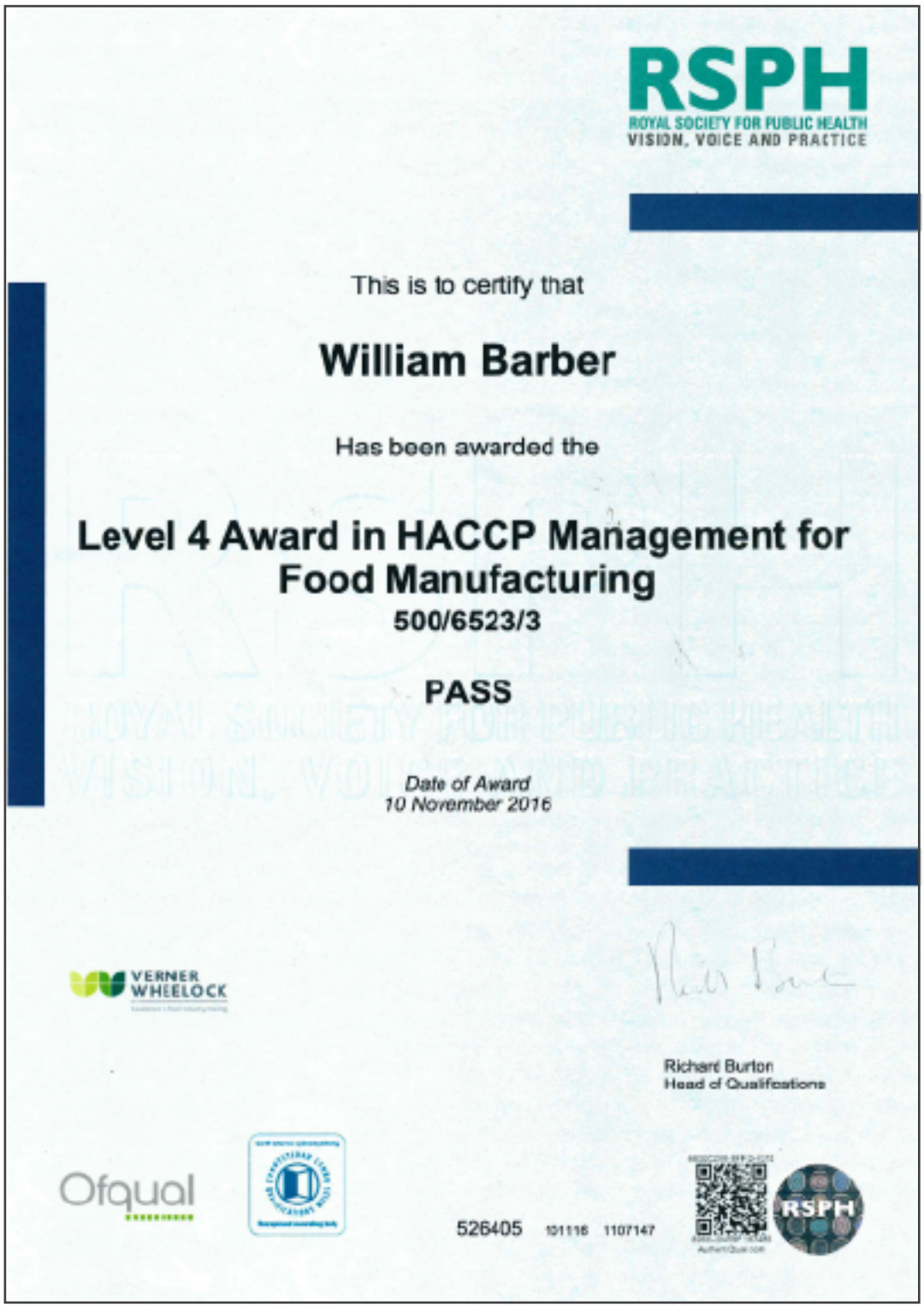
Certificate # 917b0241

AFDO

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

QUALIFICATIONS *of* SUPPORTING QI



RSPH
ROYAL SOCIETY FOR PUBLIC HEALTH
VISION, VOICE AND PRACTICE

This is to certify that

William Barber

Has been awarded the

Level 4 Award in HACCP Management for Food Manufacturing

500/6523/3

PASS

Date of Award
10 November 2016

VERNER WHEELOCK

Richard Burton
Head of Qualifications

Ofqual

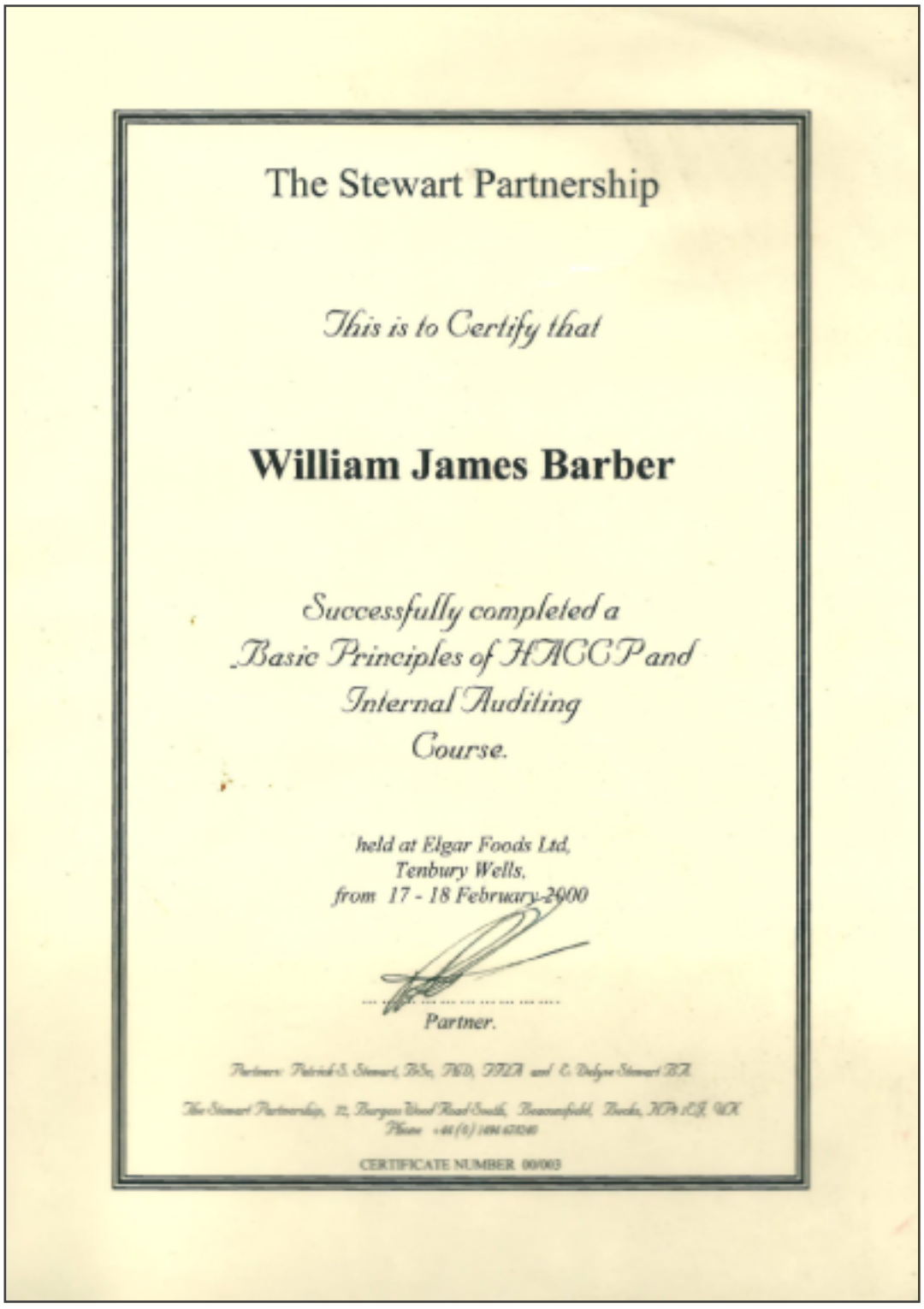
526405 101116 1107147

RSPH

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

QUALIFICATIONS *of* SUPPORTING QI



The Stewart Partnership

This is to Certify that

William James Barber

Successfully completed a Basic Principles of HACCP and Internal Auditing Course.

held at Elgar Foods Ltd, Tenbury Wells, from 17 - 18 February 2000

Partner.

Partners: Patrick S. Stewart, BSc, PhD, FIFST and C. Dalyce Stewart BA

The Stewart Partnership, 12, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 672040

CERTIFICATE NUMBER 00003

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

QUALIFICATIONS *of* SUPPORTING QI

City & Guilds

NATIONAL VOCATIONAL QUALIFICATION

LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS
(Q1054402)

IS AWARDED TO

WILLIAM BARBER

THE HOLDER HAS A NUMBER OF FORMAL UNIT CREDITS BY WHICH THIS AWARD WAS ACHIEVED

AWARDED SEPTEMBER 2007 0739/0243/07A/124203/PXC4025/1/13/03/64

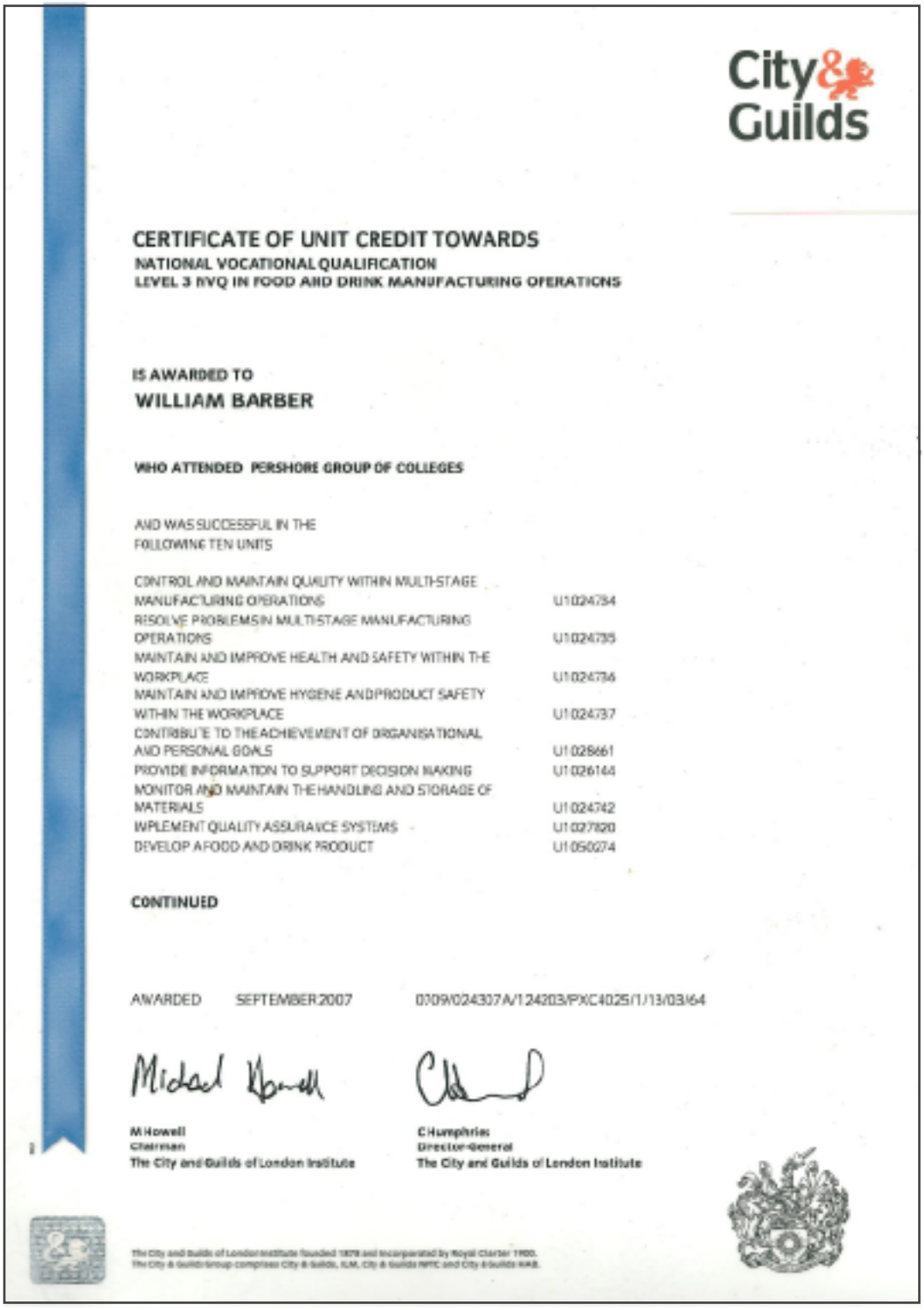
M Howell
Chairman
The City and Guilds of London Institute

C Humphries
Director-General
The City and Guilds of London Institute

QCA
Qualifications and Curriculum Authority

The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.

QUALIFICATIONS *of* SUPPORTING QI



City & Guilds

CERTIFICATE OF UNIT CREDIT TOWARDS
NATIONAL VOCATIONAL QUALIFICATION
LEVEL 3 NVQ IN FOOD AND DRINK MANUFACTURING OPERATIONS

IS AWARDED TO
WILLIAM BARBER

WHO ATTENDED PERSHORE GROUP OF COLLEGES

AND WAS SUCCESSFUL IN THE
FOLLOWING TEN UNITS

CONTROL AND MAINTAIN QUALITY WITHIN MULTI-STAGE MANUFACTURING OPERATIONS	U1024734
RESOLVE PROBLEMS IN MULTI-STAGE MANUFACTURING OPERATIONS	U1024735
MAINTAIN AND IMPROVE HEALTH AND SAFETY WITHIN THE WORKPLACE	U1024736
MAINTAIN AND IMPROVE HYGIENE AND PRODUCT SAFETY WITHIN THE WORKPLACE	U1024737
CONTRIBUTE TO THE ACHIEVEMENT OF ORGANISATIONAL AND PERSONAL GOALS	U1028661
PROVIDE INFORMATION TO SUPPORT DECISION MAKING	U1026144
MONITOR AND MAINTAIN THE HANDLING AND STORAGE OF MATERIALS	U1024742
IMPLEMENT QUALITY ASSURANCE SYSTEMS	U1027820
DEVELOP A FOOD AND DRINK PRODUCT	U1050074

CONTINUED

AWARDED SEPTEMBER 2007 0709/024307/A/124203/PXC4025/1/13/03/64

M Howell
Chairman
The City and Guilds of London Institute

C Humphries
Director General
The City and Guilds of London Institute

The City and Guilds of London Institute founded 1878 and incorporated by Royal Charter 1900.
The City & Guilds Group comprises City & Guilds, ILM, City & Guilds NPTC and City & Guilds KAB.

Supplier: Yantai Hao's Pet Food Tech. Co., Ltd. Product: Chicken Liver Dog Treats (Freeze Dried)

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: April 15, 2022 Review End: May 10, 2022

SUBSTANTIATING DOCUMENTS

This FSVP plan is based – at least in part – on the following foreign supplier-provided food safety documents. All substantiating documents have been reviewed and assessed by United Safety Agents LLC.

Note Foreign supplier-provided documents are considered to be the property of that foreign supplier and may contain information which is privileged, confidential, and protected. Any reproduction, distribution or other use of these documents without the express written consent of the foreign supplier is prohibited. Enclosed documents are meant for review purposes only and are subject to change without notice. Documents may contain non-binding recommendations and are uncontrolled.

No. :HS-FSP-02

Freeze Dried Pet Food Safety Plan

Edition No.: 4

Editor: Lifeng Yu

Auditor: Lei Zhao

Approver: Yishan Jiang

Controlled status: controlled

Implement Date:
2020-01-03

Implement Date:
2020-01-03

YANTAI HAO'S PET FOOD TECH CO., LTD.

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

Claudio Innocenti

1.1Pet Food Safety Team Members:

Name	Degree of education	Position in the company	Position in the team	Responsibility	Training
Yishan Jiang	bachelor	Vice GM	Team leader	Organize to establish, implement and keep the pet food safety and quality management system; The system approve; the internal audit; The pet food safety and quality management system implement, correct and prevent; The flow chart confirmation.	HACCP training in Yantai CIQ in 2003; EU pet food regulation training; ISO9001, HACCP training in Hairid Company.
Lei Zhao	bachelor	Quality Management Manager	Vice team leader	Organize the pet food safety plan, PRP, OPRP and other document to edit, implement, verification and correction. Review the quality system and take correction. The non-compliance decision and handling; The management system document management.	HACCP training in Yantai CIQ in 2003; EU pet food regulation training; ISO9001, HACCP training in Hairid Company. ISO9001:2015 has been trained in 2015.
Lifen Yu	bachelor	Quality Management Manager	Team member	The pet food safety document management and edition. Organize the pet food safety plan ,PRP.,OPRP etc edition and implementation, verification and confirmation. The reviewing quality records; The normal data collection and analysis and correction implementation. The non-compliance decision and handling;	The lab training in 2007; The GM and additives training in SGS in 2009; EU pet food regulation training; ISO9001, HACCP training in Hairid Company; ISO9001:2015 has been trained in 2015;

Claudio Innocenti

Name	Degree of education	Position in the company	Position in the team	Responsibility	Training
					SGS FSMA human preventative control training.
Xue Li	bachelor	Manager of the technology department	Team member	HACCP technology and the flow chart edition and confirmation.	HACCP training in Yantai CIQ in 2003; ISO 9001,HACCP training in Hairid Company
Jicheng Wang	bachelor	Manager of the production department	Team member	Organize the pet food safety plan, PRP, OPRP and other document to implement, verification and correction. flow chart confirmation. traceability label management. Preventative and correction and production records reviewing.	ISO 9001/HACCP training in Hairid Company. ISO9001:2015 has been trained in 2015.
Yunuan Zhang	master	Manager of the international trade department	Team member	The process order review; The customer management; The market survey, the production products collection and analysis. The company introduction.	ISO 9001/HACCP training in Hairid Company.
Tingting Ran	bachelor	Manager of the purchase department	Team member	The raw materials purchasing; the new supplier development; The purchasing contract etc.	The internal training
Cheng Wang	bachelor	Manager of the warehouse department	Team member	The warehouse stock establishment; the warehouse sanitation; the products delivery	ISO 9001/HACCP training in Hairid Company.
Yanxiang Zhang	junior college	Manager of the equipment	Team member	The equipment operation procedure; the facility and equipment repair.	ISO 9001/HACCP training in Hairid Company.
Xiangling Liang	bachelor	Manager of the HR	Team member	The HR management; the company position analysis and adjustment. The employees training	ISO 9001/HACCP training in Hairid Company.
Zhengpeng Zang	bachelor	Manager of the management department	Team member	The dormitory and dining room management. The factory environment check, the safety production and fire safety	ISO 9001/HACCP training in Hairid Company.

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Name	Degree of education	Position in the company	Position in the team	Responsibility	Training
				check. the employee health check	
Lifen Yu	bachelor	Quality Management Manager	Team member	The pet food safety document management and edition. Organize the pet food safety plan ,PRP.,OPRP etc edition and implementation, verification and confirmation. The reviewing quality records; The normal data collection and analysis and correction implementation. The non-compliance decision and handling;	The lab training in 2007; The GM and additives training in SGS in 2009; EU pet food regulation training; ISO9001, HACCP training in Hairid Company; ISO9001:2015 has been trained in 2015; SGS FSMA human preventative control training.
Ling Song	junior college	The incoming materials QC	Team member	The incoming materials check and take correction if exceed the CL.	The internal training
Feng Liu	High school	Metal detector operator	Team member	The metal detector operation and take correction if exceed the CL,	The internal training
Zhengkui Zhang	High school	Drying operators	Team member	The drying operation and take correction if exceed the CL,	The internal training

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1.2 The products characteristic

Freeze Dried Pet Food products

Products Name	Freeze dried pet food
Main ingredients	Chicken breast, chicken liver, duck breast, fish
The products characteristic	The physical and chemical meet the label requirement. NO pathogen
Label	Meet the imported country requirement
Whether contain the allergen	no (for dogs)
process	The frozen raw materials/thawing/cutting the bags/mixing the ingredients/mixing/shaping/putting on the nets/drying/cooling/taking off the drying nets/selecting/metal detecting/weighing/inner packing/weighing on line/sealing/packing inspection/outer packing/putting in the carton/seal the carton/inspection/storage/shipment
Potential usage possibility	Label for the raw materials and auxiliary materials.
Pack type	polyethylene bags that contains the desoxidant and the outer the paper carton.
Eat type	ready to eat
Usage	as the pet food for dogs
Storage	room temperature
distribution	by dealer
Shelf life	18 months/24months
Special transportation requirement	room temperature and use the clean container to ship. Avoid the sunshine and rain. The products cannot shipped with the harmful, foreign smell products.

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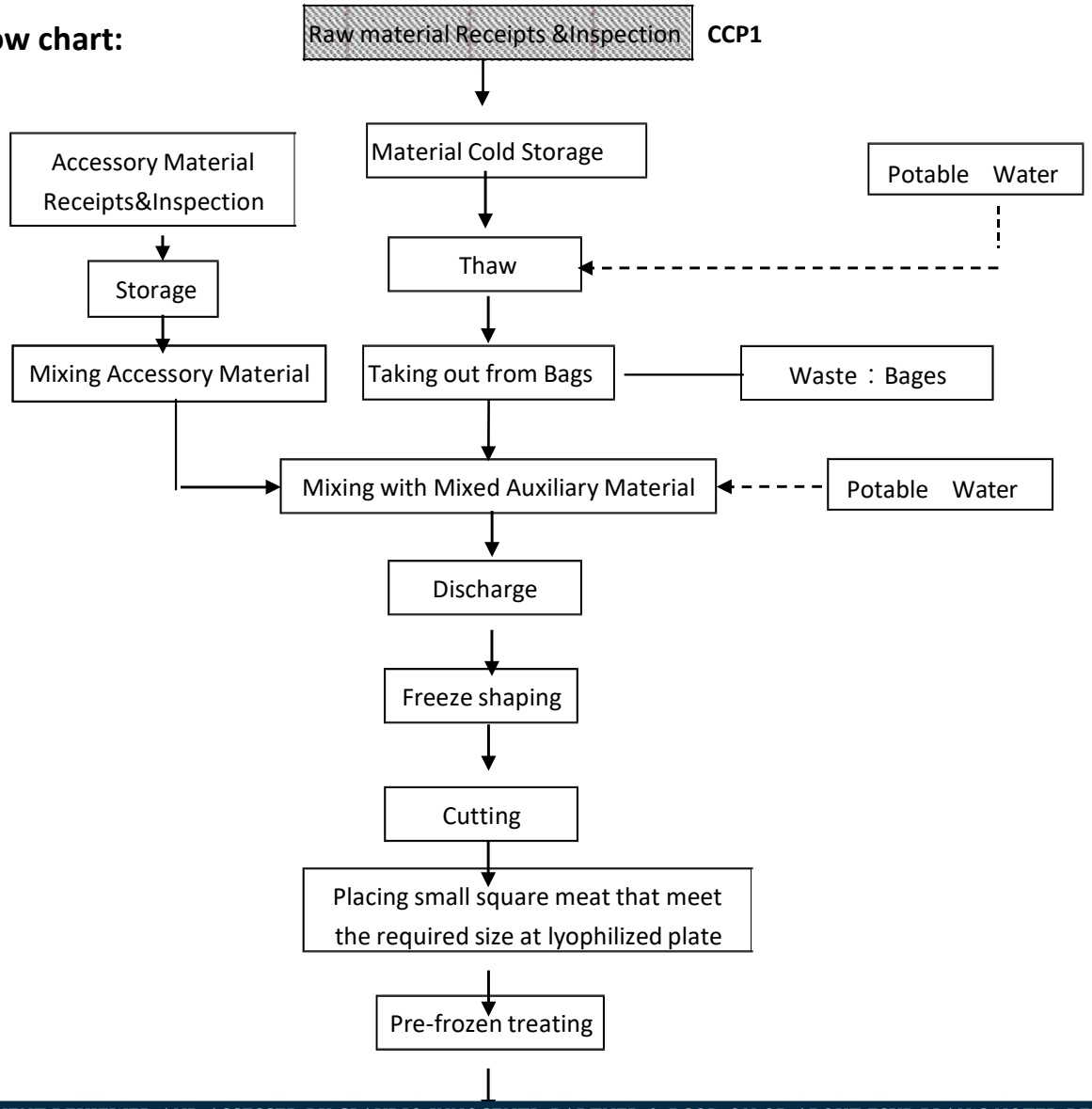
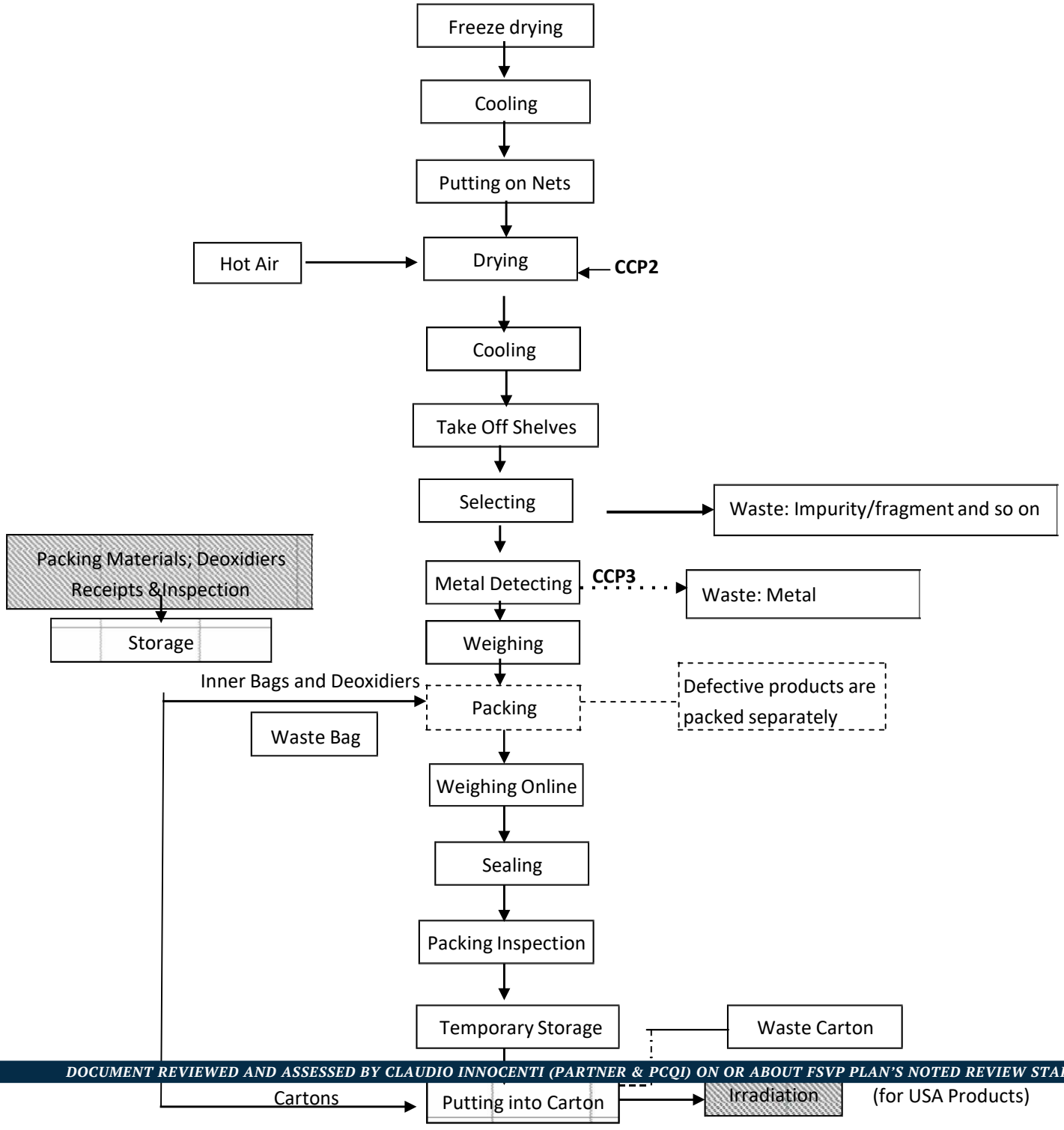
1.3Flow chart:





DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

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2. Hazard Analysis

(1)Ingredients Process Steps	**(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step**	**(3)Do any potential pet food safety hazards require a preventive control**		**(4)Justify your decision for column 3**	**(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control**	**(6)Is the preventive control applied at this step**	
		YES	**NO**			**YES**	**NO**
Raw Materials inspection (chicken breast, duck breast and chicken liver) CCP1	Biological hazards: 1. Epidemic disease and the bird flu 2.Salmonella etc. pathogen	×		In the breed and process, there is epidemic disease happening and may be contaminated by pathogen.	Supply-chain---The incoming raw materials shall be checked by QC. The supplier shall provide the Animal Inspection and Quarantine Certificate.		×
		×				×	
	Chemical hazards: drug residues Furan metabolite, chloramphenicol, diet hylstilbestrol amantadine, sulfamethoxazole, Tilmicosin, Trimethoprime, Sulfaquinoxaline, Enrofloxacin Sulfaclozine	×		In the breed process, the drugs preventing the disease could exceed the limit or used the forbidden drug.	1. Supply-chain---The raw materials supplier shall be audited on site. 2.The process control---raw materials are tested according to the monitoring plan.	×	
	Physical hazards: metal, plastic etc foreign materials	×		The foreign materials may be brought in the slaughter process.	The process control-- The metal detecting		×

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(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Raw Materials inspection (fish meat) CCP1	Biological hazards: Salmonella etc. pathogen	×		-	The process control-- The drying process		×
	Chemical hazards: PCB	×		-	The process control-- take samples to test.	×	
	Physical hazards: metal, plastic etc foreign materials	×		The foreign materials may be brought in the slaughter process.	The process control-- The metal detecting		×
Raw materials storage	Biological hazards: No	-	-	-	-	-	-
	Chemical hazards: NO	-	-	-	-	-	-
	Physical hazards: NO	-	-	-	-	-	-
Deoxidizer Inspection	Biological hazards: pathogen grow		×	It may be contaminated in the process. But the possibility is lower.	-	-	-
	Chemical hazards: heavy metals(lead, arsenic)		×	The supplier improper control can cause the heavy metals exceeding the standard. But the possibility is lower.	-	-	-
	Physical hazards: No	-	-	-	-	-	-

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(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Packaging materials inspection	Biological hazards: no	–	-	-	-	–	–
	Chemical hazards: heavy metals and the soluble materials etc. harmful materials		×	The supplier improper control can cause the heavy metals exceeding the standard. But the possibility is lower.			
	Physical hazards: no	–	-	-	-	–	–
The raw materials thawing	Biological hazards: pathogen growing		×	The long thawing time can cause the meat core temperature too high and then cause the microbe grow. But the possibility is lower.	-	–	–
	Chemical hazards: No	–	-	-	-	–	–
	Physical hazards: metal	×		The meat contacts the thawing shelves that can bring in the metal foreign materials.	The process control-- The metal detecting		×
The bags cutting	Biological hazards: pathogen growing		×	The product may be contaminated in the process.	-	–	–
	Chemical hazards: No	–	-	-	-	–	–
	Physical hazards: metal and plastic foreign materials	×		The broken knife may cause the metal foreign and the bags broken can cause the foreign materials.	The process control-- The metal detecting		×

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(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
The auxiliary materials mixing	Biological hazards: pathogen growing		×	The product may be contaminated in the process.	-	-	-
	Chemical hazards: additives exceed		×	The additive amount exceed the requirement. But the possibility is lower.	-	-	-
	Physical hazards: metal and plastic bags	×		The broken tools and containers may cause the metal foreign and the bags broken can cause the foreign materials.	The process control-- The metal detecting		×
Potable water	Biological hazards: pathogen contamination		×	The potable water company may contaminate the water. But the possibility is lower.	-	-	-
	Chemical hazards: chemical contamination and heavy metals		×	The contamination in the water source cannot be handled completely . But the possibility is lower.	-	-	-
	Physical hazards: foreign materials brought in		×	It may be brought in the process. But the possibility is lower.	-	-	-
Mixing ingredients	Biological hazards: pathogen contamination and grow		×	It may be contaminated in the process. But the possibility is lower.	-	-	-
	Chemical hazards: the chemical used to cleaning		×	The chemicals cleaning is not completely after the equipment cleaning and disinfection. But the possibility is lower.	-	-	-
	Physical hazards: metals	×		The meat contact with the machine that may cause the metal foreign	The process control-- The metal detecting	-	×

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(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Freeze shaping	Biological hazards: pathogen contamination		×	It may be contaminated in the process. But the possibility is lower.	-	-	-
	Chemical hazards: the chemical used to cleaning		×	The chemicals cleaning is not completely after the equipment cleaning and disinfection. But the possibility is lower.	-	-	-
	Physical hazards: metal and plastic bags	×		The meat contact with the machine and packing materials that may cause the metal foreign.	The process control-- The metal detecting	-	×
Cutting	Biological hazards: pathogen contamination		×	It may be contaminated in the process. But the possibility is lower.	-	-	-
	Chemical hazards: the chemical used to cleaning		×	The chemicals cleaning is not completely after the equipment cleaning and disinfection. But the possibility is lower.	-	-	-
	Physical hazards: metal	×		The meat contact with the machine and packing materials that may cause the metal foreign.	The process control-- The metal detecting	-	×
Pre-frozen treating	Biological hazards: pathogen contamination		×	It may be contaminated in the process. But the possibility is lower.	-	-	-
	Chemical hazards: No	-	-	-	-	-	-
	Physical hazards: metal and plastic bags	×		The meat contact with the machine that may cause the metal foreign.	The process control-- The metal detecting	-	×

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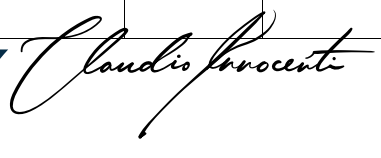
(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Freeze drying	Biological hazards: pathogen contamination and grow		×	It may be contaminated in the process. But the possibility is lower.	-	–	–
	Chemical hazards: no	-	–	–	-	–	–
	Physical hazards: metal and plastic bags	×		The meat contact with the machine and packing materials that may cause the metal foreign.	The process control-- The metal detecting	–	×
Putting on the nets	Biological hazards: pathogen contamination and grow		×	The long production time causes the meat temperature too high and then cause the microbe grow. Bu the possibility is lower.	-	–	–
	Chemical hazards: No	-	–	–	-	–	–
	Physical hazards: plastic foreign materials		×	The broken tools and containers. But the foreign materials can be checked easily. The risk is lower.	-	–	–
Hot air	Biological hazards: pathogen contamination		×	The air is contaminated by microbe.			
	Chemical hazards: No	-	–	–	-	–	–
	Physical hazards: foreign materials		×	The air has the foreign materials.	-	–	–
Drying CCP2	Biological hazards: pathogen contamination	×		The lower temperature and short time cannot kill the pathogen.	Process control- drying . Use the proper temperature and time to kill the pathogen.	×	



(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
	Chemical hazards: No	–	–	–	-	–	–
	Physical hazards: metals and foreign materials		×	Contact with the machine and the tools and containers are broken.	The process control-- The metal detecting	–	×
Cooling	Biological hazards: pathogen contamination again	×		The products are exposed in air and has the second contamination risk.	Sanitation control-prevent the second contamination.	×	
	Chemical hazards: No	–	–	–	-	–	–
	Physical hazards: No	–	–	–	-	–	–
Taking off from the nets	Biological hazards: pathogen contamination	×		The products are exposed in air and has the second contamination risk.	Sanitation control-prevent the second contamination.	×	
	Chemical hazards: No	–	–	–	-	–	–
	Physical hazards: plastic bags		×	The broken tools and containers. But the foreign materials can be checked easily. The risk is lower.	-	–	–
Selecting	Biological hazards: pathogen contamination	×		The products are exposed in air and has the second contamination risk.	Sanitation control-prevent the second contamination.	×	
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: metal and plastic bags			The broken tools and containers. But the foreign materials can be checked easily. The risk is lower.	-	–	–

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(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Metal Detecting CCP3	Biological hazards: pathogen contamination	×		The products are exposed in air and has the second contamination risk.	Sanitation control-prevent the second contamination.	×	
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: metal	×		The raw materials may bring and the process may be contaminated.	The process control-- The metal detecting	×	
Weighing, packing and labeling	Biological hazards: pathogen contamination	×		The products are exposed in air and has the second contamination risk.	Sanitation control-prevent the second contamination.	×	
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: plastic bags		×	The broken tools and containers. But the foreign materials can be checked easily. The risk is lower.	-	–	–
Weighing on line	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
Sealing	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: plastic foreign materials		×	The broken tools and containers. But the foreign materials can be checked	-	–	–

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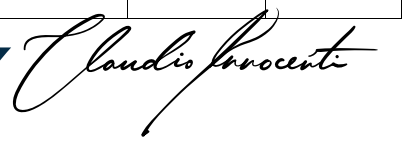
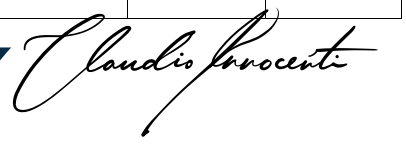
(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
				easily. The risk is lower.			
Packing inspection	Biological hazards: pathogen contamination		×	The bags are broken and the possibility is lower.			
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
Storage temporarily	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
Outer packaging	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards :No	–	-	–	-	–	–
Weighing	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–



(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
	Physical hazards :No	–	-	–	-	–	–
Sealing cartons	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
The finished products inspection	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
Storage	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–
	Physical hazards: No	–	-	–	-	–	–
The finished products leaving the factory	Biological hazards: No	–	-	–	-	–	–
	Chemical hazards: No	–	-	–	-	–	–



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		YES	NO			YES	NO
	Physical hazards: No	–	-	–	-	–	–
radiation	Biological hazards: Pathogen contamination	×		Less irradiation dose can cause the pathogen residues.	Supply-chain control The irradiation factory shall be conducted the audit on site and the irradiation dose shall be verified.	×	
	Chemical hazards: irradiation dose residue	×		More irradiation dose can add the irradiation dose residues.	Supply-chain control--- The irradiation factory shall be conducted the audit on site and the irradiation dose shall be verified. The irradiation dose shall be controlled.	×	
	Physical hazards: No						

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3.1 Process Preventive Control

(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Raw material inspection (chicken, chicken liver, fish)	C chemical hazards: drug residues Furan metabolite, chloramphenicol, diethylstilbestrol amantadine, sulfamethoxazole, Tilmicosin, Trimethoprime, Sulfaquinoxaline, Enrofloxacin Sulfaclozine PCB(fish)	×		In the breed process, the drugs preventing the disease could exceed the limit or used the forbidden drug.	The process control---raw materials are tested according to the monitoring plan.	×	
	B biological hazards: pathogen	×		In the breed process, the products could be contaminated by pathogen.	The process control-- the after drying process		×
Drying	B biological hazards: pathogen residues			The lower temperature and time cannot kill the pathogen and could cause the pathogen grow.	The process control-- the drying process The adequate temperature and time can kill the pathogen.	×	
Metal detecting	P physical hazards: metals			The metal foreign materials could be accompany in the process.	The process control-- The metal detecting	×	

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Process Control Form

CCP	Significant Hazards	CL	Monitor				Correction	Record	Verification
			Target	Method	Frequency	Responsible Persons			
Raw materials Inspection (CCP1)	1. Epidemic disease 2.Drug Residue: Furan metabolite chloramphenico diethylstilbestrol amantadine, sulfamethoxazole, Tilmicosin, Trimethoprime, Sulfaquinoxaline, Enrofloxacin Sulfaclozine 3. contamination: PCB	(1)Animal Inspection and Quarantine Record (2) Drug Residue: ND (3)PCB:ND	(1)Animal Inspection and Quarantine Record (2) Drug Residue (3)PCB	Check and test	Each batch /Each year (Furan metabolite chloramphenico Diethylstilbestrol Clenbuterol,PCB)	Incoming Materials QC	If there is no raw materials factory inspection record and the animal inspection record or the test records do not meet the standard, the raw materials will be rejected.	Raw Materials Inspection Record and Correction Record	①The inspection record will be checked every day. ②The raw materials will be monitored by the test center according to the monitoring plan. ③The raw materials factory accredited third test report.

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Drying (CCP2)	Pathogen	Drying Temperature≥80 ℃, Drying Time≥30min ;	Time and temperature	Check and test	Every10 minutes	Drying Operators	①The time and temperature deviate the operational limit but not the critical limit, adjust the time and temperature. ② If the time and temperature deviate the critical limit, adjust the time and temperature. Then evaluate the dried products by the QC. If the dried products do not meet the quality requirement, these products will be discarded.	Drying/Sterilization Record and Correction Record	①The drying/sterilization record will be checked every day. ②The pathogen items will be tested by the test center. ③The thermo meter will be calibrated every week. ④The automatic temperature recorder will be calibrated every year.
Metal Detecting (CCP3)	Metal Foreign Materials	Fe < ϕ1.5mm SuS < ϕ1.5mm NoN-Fe < ϕ1.5mm	Products and Metal Detector	check	All Products	Metal Detector Operators	①If the products can not pass the metal detector, these products will be separated and take root analysis and take preventive measures ;②If the metal detector is not working, all the products that have passed since the last calibration, the separated products will pass the metal detector by the repaired machine.	Metal detector calibration record and correction record	①The metal detector calibration will be checked every day. ②The metal detector will be calibrated before production, every 1 hour in the production and after production. ③Each batch products will be checked by QC.

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3.2 Sanitation Preventive Controls

(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Cooling	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	
Taking off from the nets	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	
Selecting	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	
Metal detecting	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	
Weighing	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	
Packing	biological hazards: pathogen	×		The products are exposed in air and have the second contamination risk .	Sanitation control-prevent second contamination.	×	

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The clean and disinfection procedure

Cooling, taking off the drying nets, selecting, metal detecting, weighing and packing sanitation control

1. Purpose:

In order to reduce the microbe cross-contamination or the environment pathogen affecting the products safety.

2. Frequency:

clean: after work in the morning, the products category shifting and the after work in the afternoon

disinfection: before work, in the work and the products category shifting and after work: use the 75% alcohol to spray.

3. Procedure:

3.1 The weighing plastic containers

a. Pre-work: disinfect with 75% alcohol

b. after work in the morning, the products category shifting: disinfect with 75% alcohol

c. the after work in the afternoon: clean the broken pieces, disinfect with 75% alcohol

3.2 The taking off plastic containers:

Each recycle: disinfect with 75% alcohol

Each week: clean completely→clean with water→clean with diluent cleanser→ wash with

water→sterilizing with 100ppm~150ppmNaCLO→keep 1 min→wash with water

3.3 The plastic container for tuning:

Each recycle: disinfect with 75% alcohol

Each week: clean completely→clean with water→clean with diluent cleanser→ wash with water→sterilizing with 100ppm~150ppmNaCLO→keep 1 min→wash with water

3.4The stainless steel shelves: clean the broken pieces, disinfect with 75% alcohol

3.5 Work tables:

a. Pre-work: disinfect with 75% alcohol

b. after work in the morning, the products category shifting: disinfect with 75% alcohol

c. the after work in the afternoon: clean the broken pieces, disinfect with 75% alcohol

3.6sealing machine, metal detecting, automatic selecting, transit line, slicing machine and scale:

a. Pre-work: disinfect with 75% alcohol

b. after work in the morning, the products category shifting: disinfect with 75% alcohol

c. the after work in the afternoon: clean the broken pieces, disinfect with 75% alcohol

3.7 Hands disinfecting:

Workers should wash and disinfect hands strictly according to the following washing and disinfecting procedure every time before production or dirtying their hands. The disinfect procedure is the following:

Hand washing with water→hand washing with soap→cleaning soap→s →cleaning with water →disinfect with 75% alcohol

3.8 work clothes:

The work clothes are hang in the dressing room and disinfection with ozone for 1 hour.

3.9 Air disinfection:

Use the ozone to disinfection the process workshop for 1 hour after work. See the Ozone Sterilization Record.

4. Monitor:

Check the table surface to confirm no residues and the clean. See the Workshop Sanitation Checking Record.

And use the test paper to verify the Naclo and alcohol concentration. See the Cleaning and Disinfection Record.

5. Correction:

If there is meat residues on the work table, it need to be cleaned and disinfected again.

If the Naclo and alcohol concentration cannot meet the requirement, it need to be prepared again.

6. Record:

The Workshop Sanitation Check Record

7. Verification:

The workshop supervisor shall check the 7 days sanitation check records and sign.

3.3 Supply-chain Preventative Control

(1)Ingredients Process Steps	(2)Identify potential pet food safety hazards introduced, controlled or enhanced at this step	(3)Do any potential pet food safety hazards require a preventive control		(4)Justify your decision for column 3	(5)What preventive control measures can be applied to significantly minimize or prevent the pet food safety hazard? Process including CCPS, allergen, sanitation, supply-chain, other preventive control	(6)Is the preventive control applied at this step	
		YES	NO			YES	NO
Raw materials Inspection (CCP1)	C chemical hazards Drug Residue: Furan metabolite chloramphenico diethylstilbestrol Clenbuterol amantadine, sulfamethoxazole, Tilmicosin, Trimethoprime, Sulfaquinoxaline, Enrofloxacin Sulfaclozine	×		In the breed process, the drugs preventing the disease could exceed the limit or used the forbidden drug.	Supply-chain---The raw materials supplier shall be audited on site.	×	
	B epidemic disease contamination	×		In the breed and process, there is epidemic disease happening.	Supply-chain---The incoming raw materials shall be checked by QC. The supplier shall provide the Animal Inspection and Quarantine Certificate.	×	
Irradiation	B biological hazards: pathogen	×		Less irradiation dose could not kill the pathogen.	Supply-chain control----The irradiation factory shall be conducted the audit on site and the irradiation dose shall be verified.	×	
	C chemical hazards: irradiation residues	×		More irradiation dose could cause the irradiation residues increasing.	Supply-chain control--- The irradiation factory shall be conducted the audit on site and the irradiation dose shall be verified. The irradiation dose shall be controlled.	×	

Claudio Innocenti

3.2The supply-chain preventative procedure:

1. Purpose:

In order to assure the raw materials and the auxiliary materials quality safety and prevent the raw materials and the auxiliary materials hazards, and the purchasing raw materials and the auxiliary materials and the packaging materials can meet the specification requirement, so the supply-chain procedure has been established.

2. Scope:

The purchasing of the raw materials and the auxiliary materials and the packaging materials used in the pet food processing and the suppliers management.

3.Responsibility:

3.1 The purchasing department is in charge of the suppliers development , survey, and the suppliers document management and purchase the materials according to the specification standard. The purchasing department is also in charge of the supplier management.

3.2The technology development department is in charge of editing of the raw materials and the auxiliary materials inspection standard.

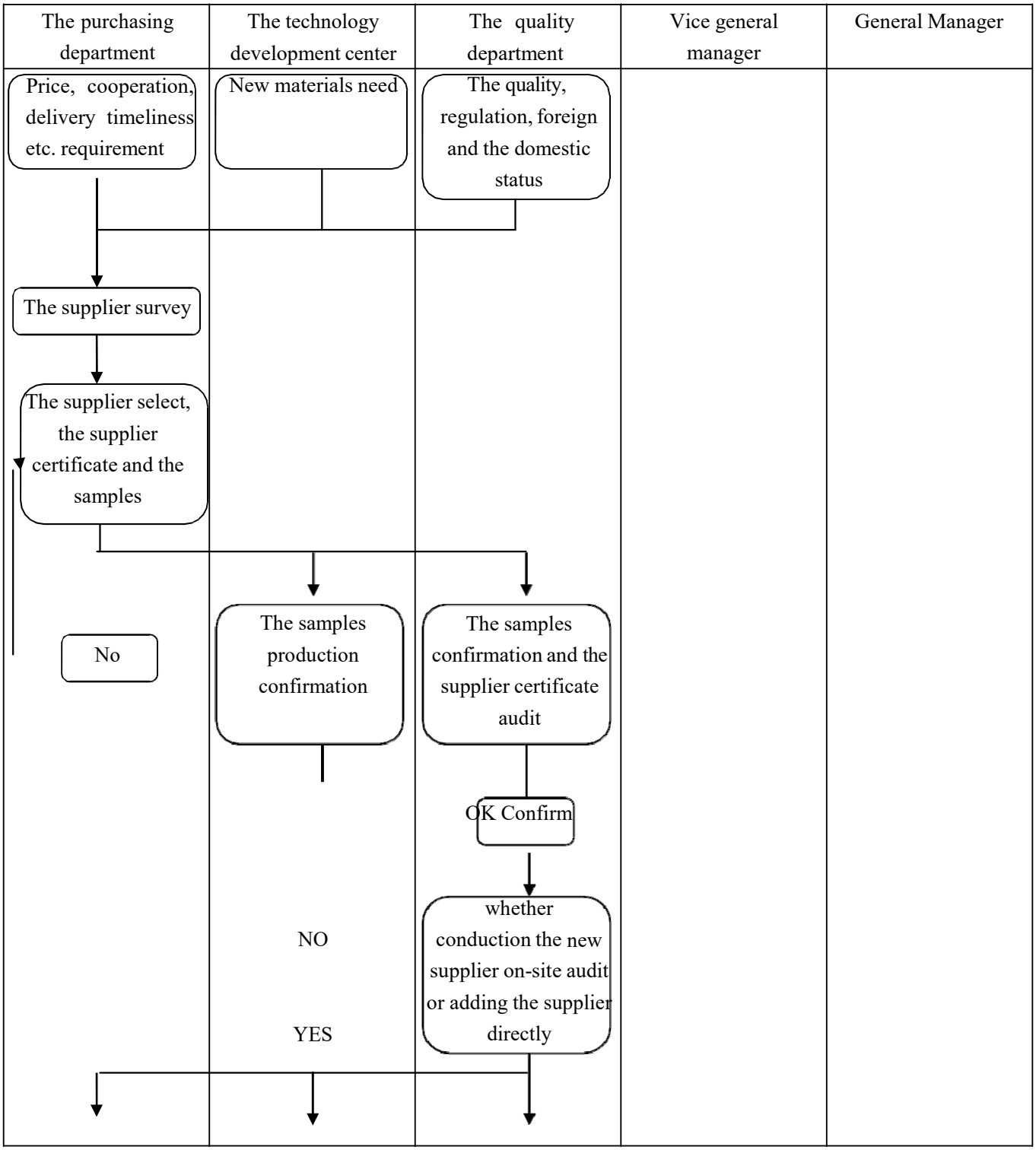
3.3 The quality department is in charge of the quality audit and the review for the suppliers and the incoming materials inspection.

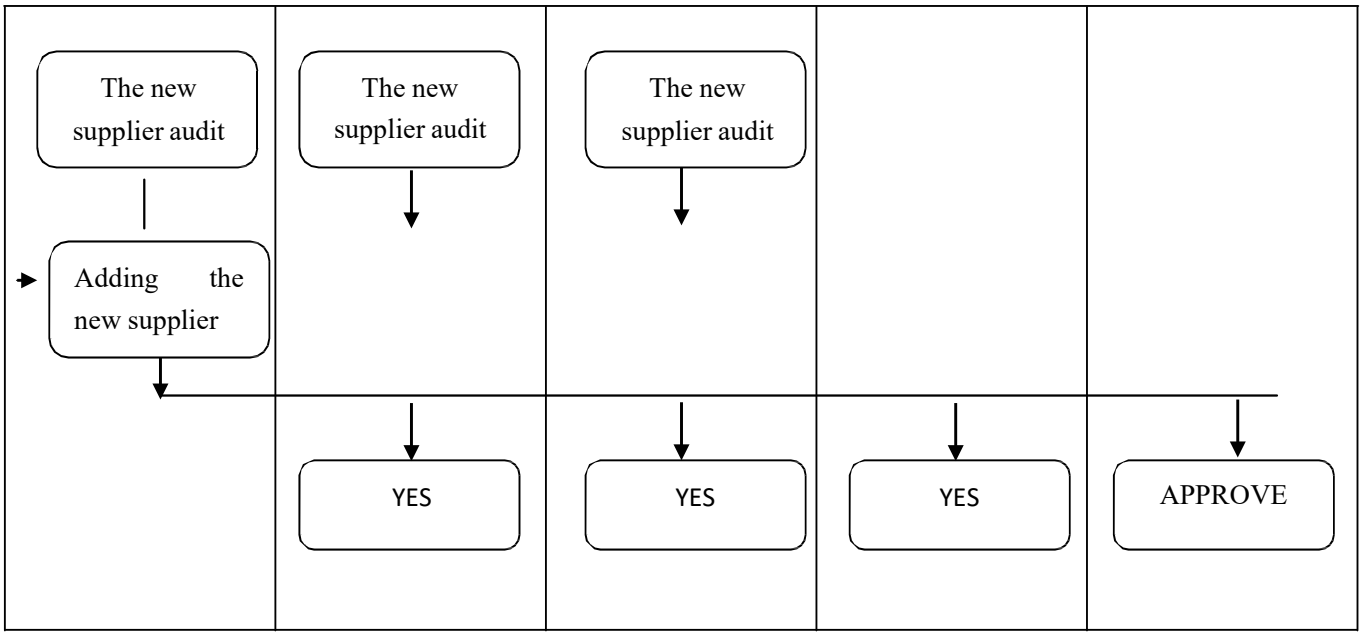
4.0 Content

4.1 The supplier approve flow

4.1.1 The purchasing department can develop the new supplier to meet the process requirement according to the price, the incoming materials quality, the supplier cooperation, the delivery timeliness, the new products development requirement, the regulation and the foreign and the domestic status change.

4.1.2 The new supplier development flow





4.1.2.1 The purchasing department conducts the suppliers survey according to the requirement. Select the supplies that can meet the basic requirement.

4.1.2.2 The purchasing department require the suppliers providing the samples and the supplier document and the third party test report. The document shall include the following:

① The business license

② The manufacture permit or other certificate

③ The third party approve certificate

④ The third party test report

A. The samples shall be confirmed by the technology development center and the samples quality shall be confirmed by the quality department.

B. The quality department is in charge of reviewing the supplier document and the test report.

4.1.2.3 If the samples, the supplier document and the third party test report are all qualified, the management department confirm to conduct the on-site audit according to

the risk assessment.

A. If need the on-site audit, the purchasing department arranges the audit plan. The purchasing department, the quality department and the technology development center conduct the on-site audit. If pass, the purchase department can apply to add the new supplier to the list.

B. If not need the on-site audit, the supplier fill the *The supplier questionnaire Survey* record. And then the supplier can be listed in the *Supplier List.*

C. In principle there shall be two or more suppliers providing the same materials as the approved suppliers in order to purchasing selecting.

D. If the materials only has one supplier, then the supplier can be list as the approved suppliers directly.

E. If the supplier is provided by the customer, the purchasing department must purchase the materials from the designed suppliers.

4.1.2.4 If the purchasing department applies a new suppler, the *New Adding Supplier Application*, the samples confirmation report, the supplier certificate, the third party test report, the on-site report or the supplier survey questionnaire, these document shall be filled in and then the technology development and the purchasing department sign the opinions. And then approved by the vice general manager and the general manger.

4.2 The qualified supplier approved list

4.2.1 According to the new supplier reviewing result, the supplier can be listed as the qualified supplier list then approved by the vice general manager.

4.2.2 The quality department shall made the supplier audit plan for these old suppliers. The audit result can be as the annually review basis. According to the result, the

renewed qualified supplier list shall be signed by the technology development and the quality department and then approved by the vice general manager.

4.2.3 If the raw materials has the serious safety quality problem, the foreign and the domestic regulation has great changes, the new risk early warning has been published, after the quality department reviewing, the qualified supplier list shall be edited timely. The edited qualification supplier list shall be approved by the vice general manager.

4.3 The supplier audit requirement:

4.3.1 For the raw materials, the auxiliary materials and the packaging materials suppliers, the verification activity shall be implemented and then can be as the qualified supplier.

4.3.2 The supplier verification activity includes the following:

A. The on-site audit

B. The raw materials and other ingredients samples test

C. Audit the supplier relevant food safety record

D. Other verification for the raw materials food safety management system and the relevant materials risk.

4.3.3 The supplier verification frequency

4.3.3.1 The quality is in charge of the on- site quality audit. And the audit plan shall be made at the beginning of the year.

4.3.3.2 Need the on-site audit principle: the main raw materials, the auxiliary materials and the packaging materials. These materials can have serious effect for the products quality safety.

4.3.3.3 The audit persons shall be arranged by the quality department. The audit persons shall have the qualification and fully understand the audit standard and can conduct the

audit individually.

4.3.3.4 If the on-site audit result is A grade, the supplier shall be audited per two years. Other audit grades suppliers shall be audited per year.

4.3.5 The raw materials and the auxiliary materials the no need on-site audit, the supplier shall fill in the Supplier Quality Self-check Record. And the record shall be filled and stamped and then transferred to the quality department.

4.3.6 If the incoming materials has the serious quality problem, the supplier shall conduct the root cause survey and take measures . If necessary, the supplier shall be conducted on-site audit temporarily.

4.4 The supplier materials receiving procedure:

4.4.1 All the raw materials, the auxiliary materials and the packaging materials supplier shall be from the approved the qualified Supplier List. The incoming materials shall be inspected by the department. The inspection activity shall include the following:

A. Whether comes from the qualified supplier list

B. Verify the materials inspection certification

C. Verify the vehicle sanitation, packaging and the label

D. Take samples to physical, chemical and the microbe items test

If the above inspection is OK, the incoming materials shall be used in the production.

4.4.2The inspection standard for the incoming materials shall be confirmed by the technology development center. And then transferred to the purchasing department, the quality department and the production department. The purchasing department is in charge of transferring the quality requirement to the supplier in the contract. The quality management is in charge of the incoming materials inspection.

4.4.3 The quality department makes the effective preventative measures according to the raw materials and the auxiliary materials risk analysis and confirms the annually monitoring plan and verification safety hazards in order to meet the regulation and the standard requirement.

4.5 The record management requirement

4.5.1 The supply-chain procedure shall include the following document and the records:

4.5.1.1 The qualified supplier list

4.5.1.2 The supplier qualification certification document

4.5.1.3 The raw materials and the auxiliary materials samples and the test report

4.5.1.4 The raw materials and the auxiliary materials inspection standard

4.5.1.5 The on-site audit supplier list

4.5.1.6 The on-site audit report

4.5.1.7 The implementation record audit supplier list

4.5.1.8 No-compliance items correction report

4.5.1.9 The correction action record of the unqualified supplier

4.5.2 All the supplier management document and the record shall be kept for at least 3 years.

4.5.3 The record shall be paper, photo or the electronic records.

4.5.4 The records shall be truly, acute and understand easily. The record content shall be detailed. The date, the time and the persons shall be traced.

3.3.2 The approved suppliers list

see the approved suppliers list

Products Recall Procedure

1. Purpose:

In order to avoid the safety problem pet food distribution in the market and ensure the pet is safe.

2. Scope:

The Products Recall Procedure is applied to the safety problem pet food that will be distributed and have been distributed in the market.

3. Responsibility:

3.1 The general manager is in charge of the implementation of the Products Recall Procedure.

3.2 The relevant departments are in charge of the products withdraw and the products recall process.

3.3 The quality management department and the production department are in charge of the verification the relevant information accuracy.

3.4 The quality management department manager is in charge of the Products Recall Procedure supervision and implementation.

3.5 The warehouse department is in charge of the recalled products separation storage and label.

4. Terms:

4.1 product withdraw: Product withdrawal is designed to prevent further

distribution, display or provide any measures of dangerous products to consumers.(2001/95 / EC instruction about product safety)

4.2 product recall: Refers to any measures taken to recycling producers or distributors have been supply or consumers are already using unsafe products.(2001/95 / EC instruction about product safety)

4.3 Unsafe food: refers to the food safety laws and regulations banning the production and operation of food and other evidence that may endanger human body health food

5. Procedure:

5.1 The reason of the products withdraw and products recall

5.1.1 Because of the HACCP hazard analysis ignores the significant hazard, it leads to the pet food safety problem.

5.1.2 After the pet food having been delivered, the customer complaints that the pet food has the safety problem after the products investigation.

5.1.3 There is enough information that shows the pet food can cause pet health problem. And the pet food that we manufactured has the significant hazard substances.

5.1.4 After the pet food having been delivered, there is the customer compliant and the outside information that shows the pet food may have the safety problem. And the safety problem can give serious affect to our company.

5.2 The determination of the recall ad withdraw

5.2.1 According to the seriousness of the pet food safety, the recall level can be divided into three categories.

A. The first category recall

After eating, it may result in serious health damage and even death, Food producers and traders shall be conducted the recall within 24 hours and report to the local food and drug supervision and administration department at or above the county level shall recall plan after the recalls;

B. The second recall

After eating, it may lead to general health damage. Food producers should be conduct the recall within 48 hours and be aware to report to the local food and drug supervision and administration department at or above the county level after the recalls;

C. The third recall

Food labels, logo is a false target. After food producers should be aware of food safety risk. The recalls shall be conducted within 72 hours, and report to the local food and drug supervision and administration department at or above the county level for recall plan. Tags, identifying flaws, after eating food won't cause health damage, the food producers should be correct and can be voluntary recall.

D. The market recall

If there is a slight defect products and not need to be restricted by the FDA regulations, the factory must take the product withdrawal from the market or corrective actions for these minor nonconformities

5.2.2 The withdraw and recall coordinator shall review all the got information and take actions and get other ways to resolve these questions.

5.2.3 If the customer complaints contains potential information for the health, the

withdraw and recall coordinator shall discuss with the quality management department and confirm the customer information.

5.2.4The company determines the problems that can cause serious effect and cause serious honor loss.

5.3 withdraw and recall

5.3.1 Emergency withdrawal and recall: pet food in eat process or in a particular danger environment will bring serious negative impact on pet health and lead to the bad effect. It may cause the withdrawal and recall.

5.3.2 Concern of withdrawal and recall: pet food in edible or exposed to some kind of danger. It can cause temporary or cause negative results and the probability of serious cases smaller product withdrawal and recall.

5.3.3 Without danger of withdrawal and recall: the use of pet food or in some situations will not have any negative impact on health, but other factors including product quality will have a negative impact to the company's withdrawal and recall.

5.4 the withdraw and recall preparation

4.4.1HACCP team or the management department finds the defective sectors that can affect the pet safety.

5.4.2 Determine the defective sector has caused the hazard or has the potential hazard. And according to the hazard seriousness and the hazard possibility, determine the recall level. If the defective products are determined, the recall will be started in 10 work days for the first recall level. And the recall will be started in 20 work days for the second recall level. And the recall will be started in 30 work days for the third recall level.

5.4.3 The production department is in charge of the defective products storage amount, transportation amount and delivery amount. If the infective sector belongs to the raw materials and auxiliary materials, the recall content shall include the relevant products that products by the same batch raw materials and auxiliary materials.

5.4.4 The international trade department is in charge of determining the products amount providing the customer.

5.4.5 According to the recall reason, the factory must take correction to keep the pet food safety from now on. And take verification to the correction to close the pet food recall reason.

5.4.6 Withdrawal and recall coordination commission personnel:

Name	Position	Responsibility	Mobile/email
Zhongli Hao	GM	Responsible for monitoring the recall process	14406388609 (hao@wanpy.com.cn)
Yishan Jiang	Vice GM	Coordinate commander, responsible for the organization and coordination of recall commander in chief	13853586969 (jiangys@wanpy.com.cn)
Jicheng Wang	Production department manager	Responsible for tracing back the reason and improve production	13791185226 (wangjc@wanpy.com.cn)
LeiZhao	Quality department manager	Responsible for the organization traced recalled Responsible for tracing back the reason and make the judge of recall	13105275510 (zhaol@ wanpy.com.cn)
Yunnuan Zhang	International trade department	Responsible for the contact customers, products sold to locate.	13002738715 (catherine@wanpy.com.c

	manager		n)
Cheng Wang	Warehouse department manager	Responsible for tracking the goods stored	14463899730 (wangc@wanpy.com.cn)
Lili Yu	CIQ	Responsible for the supervision and management of the product recall	05356693852
Lingshan Pu	SGS(Qingdao)	Responsible for the supervision and management of the product recall	0532-68999258
Aiying Li	CQC	Responsible for the supervision and management of the product recall	13583566963 （0535-6693803）
Wencheng Liang	lawyer		13791246516
	USA FDACVM		AskCVM@fda.hhs.gov 240-402-7002
	EU EFSA		440521036111
The supplier contact see the approved supplier list. The international department provides the customer contact information.			

5.5 The withdraw and recall start

5.5.1 Make the recall plan and discussed and approved by the recall team leader. The approved recall plan will be given to the relevant department.

(1) the food producers, head of the name, domicile, legal representative, concrete, contact information and other basic situation;

(2) the product name, trademark, specifications, production date, batch, quantity, and recall the regional scope;

(3) recall cause and the harmful consequences;

(4) the level of recall, process and time limit;

(5) the recall notice or the content of announcement and release way;

(6) related food operator's obligations and responsibilities;

(7) measure, the expense of food recall;

(8) recall expected effect.

5.5.2 The production provides the recalled products storage amount, transportation amount and the delivery amount. And the recalled storage products will be separated.

5.5.3 The international trade department notices the customer to stop selling the recalled products.

5.5.4 The recall team leader notices the media if necessary.

5.5.5 If the recall reason because of the raw materials and the auxiliary materials, the purchase department is in charge of noticing the relevant supplier. The relevant batch of the raw materials and auxiliary materials and the process products will be separated.

5.5.6 The relevant records in the recall process will be kept and provide the government to check.

5.5.7 The quality management department manager is responsible for the whole withdraw and recall process.

5.6 information disclosed

5.6.1 The information is announced to the media and provide the facts, but only with a proven facts, only to withdraw and co-ordinator or its designated personnel must have the right to recall issued a statement to the media.

5.6.2 The content of issued a notice:

(1) the food producers, head of the name, domicile, legal representative, concrete,

contact phone number, email, etc.;

(2) the product name, trademark, specifications, production date, batch, etc.;

(3) the recall because of starting and ending date, grade, and area;

(4) the relevant obligations of the food producers and traders and consumers return and compensation process.

5.7 The withdraw and recall end

5.7.1 when the product withdrawal and recall of coordinating committee consider withdrawal and recall project has been achieved the effectiveness, only has in the hands of customers and won't be able to withdraw and recalled products. He suggests that the company's mission has been completed and shall notify relevant departments such as employees, customers, wholesalers and retailers.

5.8 The recall conclusion:

5.8.1 The recall report will be given to the recall team leader to find the recall products ratio.

5.9 the company stock

5.9.1 identifying and tracking that has been shipped to the customer.

5.9.2 the back products that wasn't up to the requirements of the contract products or potential harm need to confirm the quantity of products and evaluate the validity of recall and withdraw.

5.9.3 The recalled products have been withdrawn in the case of a quality problem according to the nonconforming product processing program execution, such as security, please qualified department for destruction.

5.9.4 According to the nature of the customer feedback quality problem to decide and

judge to seal for the raw materials, finished products and semi-finished products of concrete by the manufacturing department to avoid unqualified products into other products.

5.10 Avoid the product withdrawal and recall measures

5.10.1 Be strictly in accordance with the quality of the product and the pet food safety requirements for production, for each processing procedure strict inspection checks, truthful and accurate fill in production related records.

5.10.2 The product packaging material supplier assessment shall be conducted according to the procurement control procedures, if necessary, will be on-site evaluation.

5.10.3 Such as production need to use additives, the factory must determine the additive and its dosage was proved to be safe in the current environment, and suppliers are qualified with permission by the department of production or sales.

5.11 The recall process mock test

The recall procedure is mocked at least one time per year to verify the procedure effectiveness. If there is loophole in the mock recall process, the recall process procedure will be revised and reported.

5.12 The whole simulation process must be in strict accordance with the program execution, if found in the process of simulation program of the loopholes, to report immediately and correct the whole process of withdrawal and recall.

5.13 not ex-factory product withdrawal

5.13.1 The quality management department, manufacturing to produce or is expected to produce quality problem within the company or product in transit for confirmation,

and inform the manufacturing timely withdraw.

5.13.2 The manufacturing department is responsible for not ex-factory quality problem or other problems of the product are identified and isolated storage.

5.13.3 The quality management department is responsible for the analysis of the causes of unqualified take corresponding corrective and preventive actions.

6. The records

The product withdrawal and recall exercise plan

The product withdrawal and recall notice

The product withdrawal and recall drill record"

The product withdrawal and recall report

7. The relevant document

Nonconforming product control procedures

6.Correction Procedure

1. Purpose:

Take the correction action procedure to control the pet food hazard when the preventative action derivates or cannot ensure the pet food safety hazard in the acceptable level.

2. Scope:

The potential hazards in the pet food process

3.Responsibility:

3.1 The preventative team members is the main department to implementation correction action.

3.1.1 Take correction actions for each preventative measures deviation.

3.1.2 The problem products shall be isolated and labeled if the derivation happens.

3.1.3 The product that deviates the standard shall be reviewed.

3.1.4 The products shall be disposed according to the review result and keep the relevant records.

3.2 The preventative members shall include other relevant department.

3.2.1 If the critical control points deviates the standard, the preventative members and take actions immediately.

3.2.2The products shall be disposed according to the preventative members review

results.

4. Work procedure

4.1 If the preventative measures cannot be conducted, the correction actions shall be taken. The following shall be taken the correction action procedure.

4.1.1 The pathogens exist in the products.

4.1.2 The pathogens have been tested in the environment samples.

4.2 Correction actions steps:

4.2.1 Take the actions for the problem of the preventative measures control process.

4.2.2 Take adopt measures in order to keep the problems not happen again if necessary.

4.2.3 Review all the affected pet food safety.

4.2.4 All the affected products shall be forbidden shipment if the products cannot be determined whether the products belong to the adulteration food of the Chapter 402 Federal Food, Drug, and Cosmetics.

4.3 If the following happens, the correction actions must be taken.

4.3.1 The preventative measures cannot be implemented correctly, the correction action procedure cannot be made.

4.3.2 The preventative measures and a team preventative measures or the whole pet food plan is not effective.

4.3.3 The record is not completely when the record review and did not take correction actions according to the pet food plan regulated procedure.

4.4 All the correction actions shall be recorded. These recorders shall be verified and reviewed according to the requirement.

7.Verification Procedure

1. Purpose:

In order to the preventative measured has been implemented and verify the pet food safety plan id effective, the preventative control measures verification procedure has been established.

2. Scope:

The procedure applies to the pet food safety plan verification of YANTAI HAO'S PET FOOD TECH. CO., LTD.

3. Responsibility:

The preventative members are in charge of the verification of the pet food safety plan.

4. Content:

4.1 Verification scope includes the following:

4.1.1 Confirm the determined hazards have been controlled by the preventative measures.

4.1.2 The preventative measures :

4.1.2.1 The qualified preventative persons shall conduct the verification:

A. before the pet food safety plan implementation or need to state the preventative measures can implemented.

B. Within 90 days when the pet food first production

C. If the qualified persons can provide a written statement, the validation can be conducted after 90 days when the pet food first production.

D. If the preventative measures have changed, it can affect the preventative measures effective.

E. The pet food safety plan need to analyze again if necessary.

4.1.2.2 Determine the preventative measures whether can control the hazards by getting the scientific and technical evidence.

4.1.3 Verification the preventative measures whether is monitored.

4.1.4 Verification the correction action procedure has been implemented.

4.2 Verification of implementation and effectiveness

4.2.1 The preventative measures are consistently implemented to minimize or preventative the hazards. The verification activities shall be included the following, as appropriate to the facility, the pet food, and the nature of the preventative controls and its role in the facility's food safety system.

4.2.1.1 The calibration of process monitoring and verification instruments(check them for accuracy)

4.2.1.2 The product testing for pathogen or other hazards

4.2.13Environmental monitoring, if contamination of the pet food environment pathogen, the environment samples shall be taken to test.

4.2.1.4 The qualification persons shall review the following records in the specified timeframes in order to keep the records complete. The preventative measures in the records shall be conducted and taken actions according to the implemented preventative measures.

A. After 7 days of the monitoring and correction actions records have been conducts. Or the qualification persons can provide the written statement.

B. After the calibration records, test records, the supplier audit and other verification activities have been conducted.

4.3 Reanalysis

4.3.1The reanalysis of the pet food safety plan as a whole has been conducted at least once every 3 years.

A. Whenever a significant change in the activities conducted creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard.

B. Update the potential hazards

C. When the pet food safety problems happen

D. If a preventative control measures or the combination of preventative hazards or the whole pet food safety is not effective.

4.3.2The new adding preventative control measures shall be confirmed.

A. Before any change in activities at the facility is operative.

B. When necessary to demonstrate the control measures can be implemented as designed.

C. Within 90 days after production of the applicable pet food first begins.

D. The preventative measures qualified individual performs the re-analysis.

E. If a new hazards and the document basis has been renewed, the preventative measures members shall conduct the reanalysis if necessary.

Record to scene with maneuverability, including:

(1) raw material acceptance form

(2) the drying form

(3) the metal detector calibration record

(4) the equipment calibration records

(5) workshop hygiene control records

(6) microbial inspection records

(7) correction records

(8)verification records

(9)training records

(10)the supplier review records

Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Yantai Hao's Pet Food Tech. Co., Ltd.	Site Code	9892347
Site name	Yantai Hao's Pet Food Tech. Co., Ltd.		
Scope of audit	Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2020-03-18		
Re-audit due date	2021-03-25		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
FSMA Preventative Controls and FSVP Preparedness	Passed	Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.	N/A
Choose a module	Choose an item		

Head Office	No

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2019-03-20		
Certificate issue date	2020-04-19	Certificate expiry date	2021-05-06		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	7

Address	No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City, Shandong Province, 264003.		
Country	P. R. China	Site Telephone Number	00865356727937
Commercial representative Name	Ms Zhang Yunnuan	Email	catherine@wanpy.com.cn
Technical representative Name	Mr Yu Lifeng	Email	yulf@wanpy.com.cn

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	One shift x 8 hours (08:00~17:30); 8 hours per shift.
Subcontracted processes	No
Other certificates held	ISO22000, ISO9001, ISO14001, MSC
Regions exported to	North America Europe Choose a region Choose a region Choose a region Choose a region
Company registration number	12149111738
Major changes since last BRCGS audit	No major change since last BRCGS audit.

4.Company Profile

Company Description

Yantai Hao's Pet Food Tech. Co., Ltd. was a joint venture company, which was established in 1999, located at No. 16 Puchang Road, Laishan Economic Development Zone, and Yantai City, Shandong Province, China.
There was one workshop and about 400 contracted staffs in the plant. QCs were 7 persons who take over the quality inspection during the production. There was 1 shift per day, about 8 hours and 6 days per week.
The output of a year was about 3000 ton and main products are exported to North America and Europe.
At present, the company holds ISO22000, ISO9001, ISO14001 and MSC certificate.

5.Product Characteristics

Product categories	15 - Dried food and ingredients VM - FSMA Preventative Controls and FSVP Preparedness Category Category
Finished product safety rationale	Finished product safety rationale ambient stable, 18 months, Sterilization temperature/ time: USA, ≥80℃/ ≥30 minutes; Europe, ≥90℃/ 30 minutes. Ambient (Aw below 0.68).

High care	No	High risk	No	Ambient high care	No

Justification for area	Because all final products were used as pet food, and Aw was below 0.68, so only low risk and enclosed area were in place.
Allergens handled on site	None Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen Choose an allergen
Product claims made e.g. IP, organic	MSC
Product recalls in last 12 Months	No

5.Product Characteristics

Products in production at the time of the audit	Air-dried chicken wrapped with cowhide and calcium bone packed in plastic bag.

6.Audit Duration Details

On-site duration	22 man hours	Duration of production facility inspection	11 man hours
Reasons for deviation from typical or expected audit duration	Time as per BRCGS calculator		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2020-03-16	11:00	17:00
2	2020-03-17	08:00	17:00
3(finished date)	2020-03-18	08:00	17:00

	Auditor (s) number	Name	Role
Auditor Number	176779	Alvin Liu Gaowen	Lead Auditor
Second Auditor Number			Please select

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Guo Jiudong / production manager	X	X		X
Shen Minling / system admin	X	X		X
Wang Qian / storehouse keeper	X	X	X	X

Present at audit				
Xu Xiaolin / technical staff	X	X	X	X
Guo Shifan / maintenance staff	X		X	X
Du Yunli / QC manager	X	X	X	X
Zhao Fei/ QA	X			X
Wang Chun/QA	X	X		X
Sun Yi/QA	X	X		X
Chen Wendong/purchase Dept. staff	X			X

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**

Minor							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Date reviewed**	**Reviewed by**
1	2.5.1	The potential delay point was not recognized on the flow chart.	The potential delay point had been added into the flow chart	To train all relevant staffs and identify when the production and processing process changes; Review the process flow every year and update it timely.	New flow chart after updated and training record dated on 2020-03-19.	2020-04-01	Alvin Liu Gaowen
2	3.5.1.1	Raw material slight fish fillet was not considered in the	Raw material slight fish fillet had been taken risk	To train all relevant staffs and update the	New raw material risk	2020-04-01	Alvin Liu Gaowen

		raw material risk assessment report.	assessment and the report had been updated.	raw material risk assessment report in time.	assessment report and the training record dated on 2020-03-19.		
3	4.4.8	One door in the raw work area was not enclosed well.	The door had been repaired well.	To train all relevant staffs and to check the door condition in time.	The photos of the door and the training record dated on 2020-03-20.	2020-04-01	Alvin Liu Gaowen
4	4.6.1	Some burr edge was found on the SUS container on site.	The SUS container with burr edge had been maintenance well.	To train all relevant staffs and to check the SUS container condition in time.	The photos of the SUS container and the training record dated on 2020-03-20.	2020-04-01	Alvin Liu Gaowen
5	4.9.3.2	The walkie-talkies, plastic brushes, air condition and scales were not recognized as brittle material.	The walkie-talkies, plastic brushes, air condition and scales had been added into brittle material list.	To train all relevant staffs and to check the brittle material and update the list in time.	brittle material list HS02-04-67 and the training record dated on 2020-03-20.	2020-04-01	Alvin Liu Gaowen
6	4.11.1	The hygiene of the bottom and on the top of the SUS cover for steaming was not cleaned well.	The hygiene had been cleaned well.	To train all relevant staffs and to check the hygiene condition in time.	Photos of hygiene condition and the training record dated on 2020-03-20.	2020-04-01	Alvin Liu Gaowen
7	5.1.4	The procedure of acceleration life test required the salmon slices	The site had arranged staff Li NC to set the shelf life test	To train all relevant staffs and to check the shelf life test	Shelf life testing record from 2019-08-	2020-04-01	Alvin Liu Gaowen

		test at least 20 weeks, but the record showed the site only tested 16 weeks.	again and tested for 24 months.	according to the requirement of procedure.	01 to 2019-12-05 and the training record dated on 2020-03-20.		

Comments on non-conformities

Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Continual improvement control procedure was documented and implemented. Its GM demonstrated they were fully committed to the implementation of the requirements of the Global Standard for Food Safety including provision of adequate resources, effective communication, food safety culture, systems of review and actions taken to effect continual improvement, and opportunities for improvement was identified, implemented and fully documented.
The policy was stated as the following: Total employee involvement, ensure customer satisfaction, ensure safety and hygiene, and obey regulation, ongoing improvement.
The food safety and quality policy can be available in its food safety and quality manual. The food safety and quality policy signed by its GM and dated on 2020-01-02. It is defined in quality and food safety manual (HS-SFQM-2020) and displayed on site in the company.
A list of the activities on site that have an impact on food safety and quality culture was in place, such as food safety policy, food safety culture team, action plan, and approved by its GM; the effectiveness had been assessed on 2019-12-01.
The quality objects were established as followed:
Pet food safety incident was 0; Customer satisfaction rate above 96%; Import country inspection qualified rate 100%, customer complaint rate less than 7/year.
Policy and objects management control procedure was documented and implemented.
The policy and objects were communicated among all departments and all staffs by training and showing.
The objectives were reviewed by management on basis. Trend analysis conducted, the results reported to top management quarterly, at present, the objectives of 4th quarter of 2019 achieved, Last reviewed and reported on 2020-01-02.
A list of the activities on site that have an impact on food safety and quality culture was in place, such as food safety policy, food safety culture team, action plan, and approved by its GM; the effectiveness would be assessed from the next audit to Issue 8.
The quality meeting plan approved by GM was in place and the frequency is at least weekly. The meeting records were remained on files, e.g. 2019-11-21 and 2019-12-31.
A confidential reporting procedure (issued on 2020-01-16) is established, documented and implemented, the relevant telephone number for reporting is open to all staff.
The management review procedure was documented and implemented. The frequency of the management review was planned to be yearly.
Latest annual management review conducted on 2020-01-06. The management review is hosted by GM, and related supervisor, such as QC manager, Production manager, admin. manager, trade manager, purchasing manager participated. The management review report was maintained on files covering necessary inputted materials. The KPI of every department has been covered and the report demonstrate that all KPIs have been achieved.
11 decisions were raised in the management review. The action and responsible of the output had been defined, and will be completed on 2019-12-31.
The main products were sold in domestic and the monitoring system for relevant regulations collection was established and the documents of external origin were in place.
Three approaches to obtain the updated regulation. A: communicate with its suppliers and customers to know its raw materials and finished products standards; B: contact potential customs for obtaining the new regulation; C: from web to obtain the new regulation such as China, FDA and EU regulation.
The company has a Chinese version original copy of Issue 8 of the Standard at the audit.
All previous CARs (7 minor CARs) were followed up and effectively improved;
The most senior production/operations managers on site was GM, QA/QC manager, production Manager

available during opening and closing meeting and available for management interview after the opening meeting.
BRCGS logo using policy is in place, and the company knows how to use BRCGS logo.

1.2 Organisational structure, responsibilities and management authority

Organisational chart and responsibilities defined, including those with an impact on product safety, legality and quality.
Clear organization structure was established covering all business processes under Global Standard for Food Safety. The organisation chart is defined in Food safety and Quality Manual (doc. HS-SFQM-01 9.0).
Job descriptions, which clearly defined the assigned duty, appropriate arrangement when absent, qualification, reporting and subordinating lines, were in place for all positions of the current organization structure. Designated staff was expected to 'acting' in case of absence, and this was stated in Job description such as production monitor, QC manager, admin and lab staff.
Work instructions are available, are communicated and are in place for staff who are responsible for every key activity related to product safety, legality and quality.

2 The Food Safety Plan – HACCP

HACCP plan established and maintained based on the codex Alimentarius HACCP principles. HACCP plans for its dried pet foods (HS-HA-01_03) approved by GM.
The multi-disciplinary food safety team was established, members 14 staff: such as GM, Production manager, QC manager, Business manager, Engineering manager, Office, Operator and others.
The team leader is VGM Jiang YS and the other staffs were identified as members. HACCP team leader had over than 20 years' experience in manufacturing of pet foods and had been trained for HACCP system;
Internal HACCP trainings were held yearly. There was a PCQI training cert for Yu LF and Sui SY. the training date on 2017-08-09.
Its HACCP plan scope was Air-dried pet foods, from receiving to delivery.
Documented PRPs were in place, including layout, maintenance of equipment and facilities, purchasing, allergen, cleaning, pest control, personnel hygiene, training and others. PRPs were verified on 2020-03-05.

HACCP plans are established according to Codex standard, scientific literature for pet foods, and nature of product, hazard analysis, food safety legislation, experimental study and customer requirements.
Relevant information such as scientific literature, historical and known hazard (physical-metal, glass, stone, wood, chemical-Furan, chloramphenicol, radiation, heavy metal and microbiological – TPC, Coliform, E. coli, salmonella), code of practice (Codex Alimentarius standard or guideline), legislation (EU, USA) and customer requirements were reference for HACCP analysis conducting.
Full description of the products developed including: Frozen chicken, duck, beef, pork, fish, salt, sugar, starch, soybean wheat flour; drying; Packaging system: PE bag and PE/PA composite bags, cartons, PET bottles; storage and distribution.
conditions (ambient); 18 months, sterilization.
Such as the calcium bones description: ingredients include corn starch, wheat flour starch, soybean protein, calcium carbonate and coloring matter. Packaging: inner was PE bag and outer was cartons, deoxidizer added ambient, shelf life was 18 months.
The intended use was defined as ready to eat after open for pet snacks.

Incoming raw materials/ ingredients receiving- storing- defrosting-cutting or tumbling- moulding- shaping drying/sterilization- cooling- off net-cutting (when needed) - selecting- metal detecting- packing sealing- inspecting-online weigher- storing-irradiating-delivery.
The flow diagrams were verified on site by HACCP teams and were signed off on 2019-12-16 to 18.
irradiating process was subcontracting process.

Minor CAR is raised here under against clause 2.5.1,

The potential delay point was not recognized on the flow chart.

The relevant information needed to conduct the hazard analysis were collected, maintained, documented and updated. The relevant codes of practice and customer requirements and other information were all available for review.
The method of developing the hazard analysis was using the risk grade which consideration matrix the likelihood and severity and the CCP decision tree.
The drug residue (e.g. chloramphenicol and melamine), pathogen and metal fragments were identified as obvious hazards in the production process.
The CCP and CL and monitoring measures were as follows:
The decision tree was used to assess the hazard controls at each process step and the results were documented.
For its air-dried pet foods: CCP1: incoming raw materials receiving; CCP2: sterilization; CCP3: metal detection.
For its air-dried pet foods: CL1: certificate of inspection and quarantine for each batch and residue of veterinary drug test report once a year. CL2: drying room temp≥80℃, OL ≥85℃, time≥ 30 minutes for normal products (to EU: drying room temperature ≥ 90℃, OL ≥92℃, time more than 30 minutes); every 10 minutes.
CL3: Fe Φ≤1.5mm, SUS Φ≤1.5mm, Non-Fe Φ≤1.5mm. Start and end of production per hour.
For CCP1, reject the materials;
For CCP2, adjust the temperature and duration separated and review the products;
For CCP3, Isolate the potential effected products and assess. Re-detect the product by metal detector.
Samples of CCP monitor records were reviewed:
CCP1: Raw chicken meat incoming date 2020-02-25, COA was issued by Yantai Jieke, drug residues were tested, the result is satisfied; Animal inspection certificate (No.3750582219).
Raw chicken meat incoming date 2019-12-31, COA was issued by CTI testing centre, drug residues were tested, the result is satisfied.
CCP2: Sterilization, lamb meat rolled on dried fish fillet dated on 2018-12-05, temperature ≥90℃, duration 30 minutes.
CCP3: Metal detection, dated on 2020-03-16, product name dried chicken, calibration time from 08:10 ~ 10:00, Fe Φ≤1.5mm, SUS Φ≤ 1.5mm, Non-Fe Φ≤1.5mm.

Documents and records review find that there is no deviation for the CCPs.

Critical limit had been agreed and signed off by team. The CCP CLs were based on published data or industry best practice and FDA. CCPs are monitored and recorded regularly. Non-conforming product would be degraded, rework or rejected and kept in hold before releasing by QA. The corrective action was taken by competent person trained fully.
Procedures of validation and verification to confirm that the HACCP system working effectively is in place. And the last verifications were carried out on 2019-04-11, and the verification reports were maintained.
The HACCP records were maintained at least 3 years.

The company operates a formal sign off process for all new products and significant changes and new equipment which includes sign off by the HACCP Team leader to confirm the impact of any changes have been assessed.
The company should be reviewed its HACCP system yearly. latest reviewed on 2020-01-10. considered all related items.

3. Food safety and quality management system

3.1 Food safety and quality manual

The food safety and quality manual (Chinese) was established (Doc. HS-SFQM-01 9.0), valid on 2020-01-02.
Quality manual contained outline of work method, practice reference of BRCGS Food Issue 8 requirements related their processes.

Quality manual was distributed under document control process to main office and each department.

3.2 Document Control

Document control procedures (Doc. HS-CX-01) was established.
Documents have been approved by designed authorized person and distribute to relevant department to ensure the correct version available in place.
All controlled documents were controlled by document controller and share in electronic system; therefore, all documents are readily accessible to relevant staff at all times.
During audit, document observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.
The obsolete documents were recalled back to document control department, stamp cancelled and disposed.

3.3 Record completion and maintenance

Record control procedure (Doc. HS-CX-02) was established.
The requirement of collation, review, maintenance, storage and retrieval of records were defined in it.
Records were kept at least 3 years (shelf life 18-24 months). And the list of quality record was in place.
During audit, record observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.
All electronic form had been kept well.

3.4 Internal audits

Documented internal audit procedure HS04-01-93 is established and implemented.
There were 4 audit dates in the audit programme and throughout the whole year. E.g. the audit date 2020-01-02 and 03, 2019-06-13 and 14, 2019-09-03 and 04 and 2019-12-10 and 11 based on the risk assessment.
The internal auditors included 4 internal auditors Zhang YN, Qi TP, Wang JC and Liang XL, who were competent. The internal auditors included Mrs. Yu LF (team leader) and the members (Wu Du YL, Guo JD, Yu XF) who were competent (HACCP training, BRCGS food issue 8.0 training, food experiences), and they were all independent from the audited department.
The internal audit was conducted followed the plan and relevant standards BRCGS were used and all internal auditors were independent of the areas they audited.

Internal audit plan and internal audit record showed that cross audit conducted.
The internal auditor training record was in file.

Internal auditors are appointed and competent,
Total 6 Minor CARs were raised in this internal audit. (E.g. 4.15.2 no batch No. for one batch of inner bags 4.7.3 adhesive tape was used onsite.) And those non-conformity was followed and the corrective action was verified by internal audit team members.
The internal audit records were retained as following,

- Internal audit plan
- Internal audit check list
- Corrective action record
- Internal audit report

Hygiene inspection to ensure that the factory environment and processing equipment was maintained in a suitable condition was in place, inspection frequency monthly, and the check record dated 2020-03-05 were reviewed.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The documented purchasing control procedure (Doc. HS-CX-12, HS-CX-25) based on risk assessment was in place. The supplier review was carried out by purchasing Dept. and QC Dept. effectively. The grades of suppliers were defined according to the risk of affecting products and onsite audit or questionnaire investigation methods were defined.
The documented risk assessment of each raw materials including foreign body risks, microbiological and chemical contamination, variety or species cross-contamination, legislative control and substitution were in place in the facility and it was updated and reviewed annually. The last assessment was conducted 2020-03-13 and the records were maintained.
Supplier monitoring and evaluation included in purchasing control procedure; For high risk suppliers, on site audit or GFSI certificate. Supplier performance/ monitoring is evaluated on every 12 months and summarized for supplier communication. Primary production control is appropriately controlled based on risk assessment such as onsite verification, or questionnaire updating that reissued at least three years.
Approved suppliers were registered in approved supplier list.
The frequency of supplier evaluation was conducted once a year, the supplier audit is not completed by a second or third party.
Evaluation records were in place. Sample:
Frozen chicken supplier named Penglai Minhe food Co., Ltd., there was a BRCGS cert issued by SGS） Business licenses, COC (No.: NNAQU9SA4F1008484).
Frozen chicken supplier named Fuxin A&F Development Co., Ltd. Business licenses, there was a China HACCP cert for this supplier.
Desoxidant supplier named Jiangsu Oukai Packing Technical Co., Ltd. Business licenses, COC (No.: OK2000786-1, 2020-02-12).
inner supplier named Dalian Rongguan Packing Co., Ltd., Business licenses, COC (No.: W2019045310310340, 2019-04-08). Questionnaire dated on 2019-06-28.
For all suppliers, the relevant certificates or licenses required by authorization were collected and reviewed once a year.
Traceability system of all suppliers was checked by GFSI certificates, on-site audit, questionnaires. Evidences kept.
At present, raw materials e.g.（glycerine, carmine）are purchased from agents named Jianeng.
The trail will be done when they cooperate with new supplier or purchase new material. If there are changes or amendments to the documents, the reasons will be recorded.
Some exceptions (such as any supplier was prescribed by client) have been described in procedure.
The original supplier label and product received were verified through the warehouse storage area for onsite evidence check and records of receiving and dispatch were also verified. COCs were available.
Minor CAR is raised here under against clause 3.5.1.1,

Raw material slight fish fillet was not considered in the raw material risk assessment report.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Product inspection and test procedure is established and implemented. The parameters for acceptance, approved changes to raw materials and frequency of testing are clearly defined in it.
The received materials are verified by authorized person such as QC and store staff prior to receive. The status of passed test material is identified in tag identification for each material for communication with related functions.
And intake records inspected during audit.
Verified incoming materials as Raw chicken meat incoming date 2020-02-25, COA was issued by Yantai Jieke, report No.19W031519001, drug residues were tested, the result is satisfied; Animal inspection certificate (No.3750582219).

Raw chicken meat incoming date 2019-12-31, COA was issued by CTI testing centre, report No. A2190359222101001E, drug residues were tested, the result is satisfied.

3.5.3 Management of suppliers of services

Management service provider was documented as defined in procedure, for implementing.
Evaluation of services providers' performance is also done for every service activities.
Approved service suppliers were registered in approved supplier list.
Those include pest control, waste service, transportation service and lab service.
The related contracts were kept on files, such as pest control service (Yantai Aojie, valid until 2021-03-03).
Evaluation records were kept.
All contract that detailed sufficient requirements to ensure product safety were maintained and reviewed.

3.5.4 Management of Out sourced processing

Irradiating process was sub-contract process. All pet foods export to US must be irradiated. There was a contract with Qingdao Qingmai Gaoneng electron irradiation. The contact was in valid date.

3.6 Specifications

All materials specifications were in place taking into account relevant CN, GB or other regulars and customer requirements, such as:
The specification for raw materials, ingredients and packaging were in place, such as Raw materials (HSQW-01-23 and Q/HS001) –chicken, duck, beef, lamb, pork. Ingredients (HS-QW-01-24 and Q/HS076) –salt, potato starch, corn starch, garlic powder, vitamin E, wheat powder, glycerine, carmine, pet biscuit, cheese, oxygen absorber.
Packaging (HS-QW-01-276) – PE bag, carton.
In-process product –net weight, moisture, temperature and time;
Final specifications (dried pet foods, Q/HS009) were in place.
Specifications cover details of safety parameters (physical, chemical and biological hazard) such as raw materials, ingredients and packaging, finished product.
Formally agreed specification was established, and reviewed up to date to supplier, customer of raw materials and finished product specification.
Specification was reviewed every 3 years.

3.7 Corrective and preventive actions

Corrective actions procedure (Doc. HS-CX-14) is established and implemented.
QA department is responsible for this issue.
Records review finds that the company takes corrective actions in a timely manner for non-conformities, and consider the analysis (root cause) of non-conformities for trends, a non-conformity places the safety, legality or quality of a product at risk.

3.8 Control of non-conforming product

Documented non-conformity control procedure (Doc. HS-CX-20) was established, and the responsibility for decision making on the use or disposal of products was defined, and QA manager was responsible for it and GM could make final decision.
The designated separated storage room for non-conforming products were identified and marked with labels, and the clear process was understood by staff interviewed during the audit. The non-conforming product records were maintained. Non-conforming disposing product records were kept on files.
Corrective actions are implemented to avoid recurrence of non-conformance. No major trends.

3.9 Traceability

The traceability control procedure was established (Doc. HS-CX-20) to ensure the complete traceability for tracing materials from raw material to finished product and vice versa. The traceability testing was conducted at least every year to cover both directions.
The company ensured the traceability of all materials used for its raw materials, ingredients, packaging

and finished products could also be included. The batch number coding system was established.
Mock traceability exercise procedure was established and implemented.
Traceability test carried out 2 times every year to cover both directions (raw material to finished product and vice versa).
The most recent traceability (from raw materials to final products, and vice versa) testing for dried duck fillet on 2020-03-05, and the traceability testing records were maintained on file.
Frozen chicken batch number was aAL2D40, quantity: 34992 kg, finished product batch number was L361AL2D40, quantity: 9847.31 kg, plastic bag batch was also traced in it. The conversion rate was 51.01%, the requirement is 50-53%.
Quantity check and mass balance considered in its traceability testing. The duration was within 2 hours.
For supplier approved based on a questionnaire, considered the product safety, traceability, HACCP review and GMPs; such as packing materials supplier, traceability done on 2019-06-02.
And the company would check its incoming materials batch when receiving.
A test (Finished production duck slices, production date 2019-12-10), initiated by the auditor on the day of the audit involved the following: from raw material to finished products (including package) and vice versa, which was completed within 1.75 hours and mass balance, quantities were accurate, related raw material, frozen duck, batch no. aD120804, 15000kg received on 2019-07-19; finished products (dried duck products), 1 batch (production date are 2019-12-10), total quantity is 80 cartons/440.38kg, The conversion rate was 42.84%, the requirement is 40-44%.
The production records were maintained for every time reworks such as label problems, and the batch numbers were clearly marked and recorded to ensure complete traceability, at present, no rework occurred.

3.10 Complaint-handling

The customer complaint handling procedure was established (Doc. HS-CX-07). Trade Department was responsible for complaints collecting and then discussed with production manager and QC manager. After discussing and analysis, QC department and/or production department will find the cause and make a decision how to take the corrective action. QC manager will verify the corrective actions and preventive actions taken and business department will reply customer.
The complaints are recorded and investigated, take corrective action via root cause to avoid recurrence, and the results of the customer complaint are recorded.
At present, the company declared that 5 complaints were raised from 2019 to now, e.g. the foreign body, and no food safety complaints.
Trend analysis was conducted every year, the last time was dated on 2019-12-30.

3.11 Management of incidents, product withdrawal and product recall

The recall and withdrawal procedure (Doc. HS-CX-22) is in place that contained handing method and responsible person of each stage.
Classifications of product recall:
Class I Recall: This is an emergency involving the removal from marketing and distribution channels those products that, because of a deficiency, pose an immediate or long-term serious threat to health or life. In a Class I Recall, top priority must be given to the complete and immediate removal of the recalled products from all levels in the distribution chain all the way down to the consumer level.
Class II Recall: This is a priority situation in which a product deficiency may cause temporary or medically reversible adverse health consequences and where the probability of serious adverse health consequence is remote. An example of such a product is a food product containing Salmonella enteritis. In a Class II recall, products must be removed from all levels in the distribution chain.
Class III Recall: This is a routine situation in which adverse health consequences of a product deficiency are highly improbable or non-existent. Products are recalled because of adulteration or misbranding not involving a health hazard. Examples of Class III Recalls are situations involving improperly labelled products or products with filth contamination. In a Class III Recall, products must be removed from the wholesale levels of the distribution chain.

The list of key contacts, e.g. suppliers, client, certification body is in place.
Communication plan was defined in the procedure.
The product recall and withdrawal procedures are tested once annually.
The last recall test was conducted on 2020-03-05, for dried duck (batch no. F009AG4D45, 720 cartons), mock cause was salmonella problem. Records (including input and issue warehouse record, inventory record, handling records) were remained and mock recall rate was 100%, within 2 hours.
In the event of a product recall, the company will be informed within three working days of the decision to issue a recall to CB.
No recalls to date.
The emergency preparedness and response procedure (Doc. HS-CX-19) is established and implemented.
The items cover: the equipment broken, water, energy, fire, malicious contamination or sabotage and disease.

4. Site standards

4.1 External standards

The company was established on 1999-07-21.
In normal repair and well maintained with investments regularly planned. Located in an industrial park.
No local activities that would risk product contamination.
No pest harborages found nearly.
Adequate drainage system was in place and no standing water hazard happen.
The additional building (e.g. restaurant, dormitory, power room) were checked, and in normal condition.
Adequate drainage system was in place and no standing water hazard happen.

4.2 Site security and food defence

Food defence procedure (doc. HS-QW-01-11 6.0) and site boundaries have established and clearly defined to prevent access of unauthorized persons to factory.
Access to site of contractors, suppliers and visitor has implemented by registered at main factory gate that defined in its procedure. Visitor cards will be declared and this card must be returned when exit. Identify card must be tagged at all times in factory. In terms of production and storage areas, the staff's uniforms are the system to identify authorized staff who work in that area.
There are security guards 24 hours at every gate of entrance.
Storage procedure, delivery procedure and transportation contract have been defined instruction for product security.
Production, warehouse areas were defined as strictly control areas. They were locked when no activities performed.
The latest annual review for a documented threat assessment plan was conducted on 2020-01-03.
Based on analysis results, the raw materials and products are not particular risk found.
The information that detailed in procedure for implementing as: Vehicle control and inspection; Mails, packaging, material proper control; Physical security coverage to facilities; Defensive posture of security personnel; Security advisory dissemination; plant security; CCTV system; Control of access device;
Factory site has been registered with government authority as below:
And export registration number is 3700PF013, US FDA no. is 12149111738.

4.3 Layout, product flow and segregation

There was effective segregation to minimize the risk of product contamination.
The plan of the site which designates areas including low risk areas and enclosed areas; the raw material and finished product storages and chemical storage were defined as enclosed areas; the other areas were defined as low risk areas.
Working space and storage was sufficient to enable operations to be carried out properly under safe hygienic conditions.
The process flow from intake to dispatch was arranged well to minimize the risk of product contamination.
Physical barriers were in place to minimize the risk of the contamination of raw materials, packaging, finished products and different processes.

Segregation considered the flow of product, nature of materials, equipment.
Facilities for tray and utensil washing are segregated from production activities. There was no contamination finding during the audit on site.
For its products, not high risk/ high care / ambient care product.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The fabrication of the site, buildings and facilities were suitable for its products process.
Walls were designed, constructed, finished and maintained could be accepted.
Floors were in normal acceptable condition. Drainage was sited, designed and maintained to minimise risk of product contamination.
The ceilings were designed, constructed, finished and maintained well. Adequate access to the ceiling was provided. Cleaning and maintenance of false ceiling were scheduled.
Windows were designed can be accepted. The windows in process and warehouse were shielded with film to avoid the contamination with the food when the windows are broken.
The lightings were adequate in the areas. All bulbs and strip lights, including those on electric fly-killer devices were adequately protected.
Fans were used in processing area, they were maintained well.
For its products, not high risk/high care product;
Positive air was needless for its products.

MINOR CAR is raised here under against clause 4.4.8,

One door in the raw work area was not enclosed well.

4.5 Utilities – water, ice, air and other gases

Utilities are properly designed and maintained in normal condition.
The processing used water used on site is from main water.
The quality of water that is incorporated into products as ingredients and comes in direct or indirect contact with food or packing is monitored as bellows:
By contracted Lab once a year.
By internal Lab, Sensory: color, appearance, odor, TPC, coliform, weekly checking.
Water distribution plan is in place. Records that related to treatment activity were maintained.
Annually testing of in-process water that covering chemical, microbiological is in place as test report (report no. No. QDF20-002620-01) done on 2020-02-21 by external laboratory Qingdao SGS Test Co., Ltd. (ISO17025, CNAS L0604). The results meet GB5749-2006.
The own lab tested the water microorganisms every week. Tested odour and chlorine residue daily. E.g. testing record for microorganisms items on 2020.03.13.
Steaming produced from its potable water and can contact its product and has monitored its quality monthly.
Workshop air: plate count survey and coliform is once per week in the company.
Ice is not used for processing.

4.6 Equipment

The equipment was suitably designed for the intended purpose.
The machines, such as cutting machine, tumbling machines, drying rooms, MD were made from stainless steel and plastic.
Certificate indicated food safety compliance with legal requirements.
The specification of machine would be specified in purchasing order. The machine would be tested and commissioned prior used. Commissioning reports would be performed effectiveness of implementation.
If new equipment purchased, the commissioning report will be in place done by equipment producer.

MINOR CAR is raised here under against clause 4.6.1,

Some burr edge was found on the SUS container on site.

4.7 Maintenance

Preventive maintenance, breakdown maintenance procedure and new machine commissioning procedure are established and implemented.
The machine and equipment used for production process and utilities are determined in preventive maintenance plan (2020, HS04-02-37).
Maintenance was done by engineer as preventive maintenance plan. Maintenance records were maintained.
Documented hygiene inspection on start-up completed by production supervisors, however, the records of cleaning activity after a small number of equipment maintenance were not kept.
The equipment inventory was established and the maintenance was carried out if the equipment cannot work normally and the maintenance records were maintained on file. The maintenance staffs were available in the facility and the special certificates were kept on files.
On site checked no found temporary repair in the production areas.
Hygiene clearance procedure is established to prevent contamination due to maintenance, e.g. personal hygiene policy for maintenance staff and subcontractor, line cleaning and clearance after maintenance.
Food grade lubricant (NSF H1, 142327) used, no allergen.
No major breakdowns in last 12 months.
Engineering workshops was located on outside production area to prevent contamination risks to the product and maintained well.

4.8 Staff facilities

Adequate working space, rest room, toilet and single large changing facility were provided at the entry of the workshop which maintained in clean condition by hygiene pilot.
The hand washing station was provided and monitored and equipped with sufficient and temper water where posted the hand washing advisory signs.
The hand washing and protective clothes cleaning effectiveness were verified by visual check.
No smoking in the factory.
The toilet was isolated from the workshop and necessary facilities were provided and controlled by hygiene pilot.
The worker's working and outdoor clothes were separated fully in the changing room and not allow worker with working clothes go out of the working area.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

A chemical control procedure was in place managing the using, storage and handling of non-food chemicals.
And the chemicals were stored in separated room, relevant MSDSs, testing reports and approved chemicals list was in place.
The designated staffs are responsible for storage, mixed, and use. Records were kept and specified the responsible staffs as well as the date and the concentration.
Approved chemical list was available for review, main included soap liquid, food grade alcohol, food grade NaClO, Na2CO3 and lab chemicals.
All COAs were in place.

4.9.2 Metal control
Metal control policy was defined in the procedure in place for implementing, and there was daily inspection record for damage and the investigation of any lost items. Staple and snap off blade are not allowed to use and take into production area and on packaging materials in its procedure. Company has used the knives and others metal tools at processing step which control number and status as before and end using. The metal control records were verified, such as 2020-03-16 and 2020-02-10.
4.9.3 Glass, brittle plastic, ceramics and similar materials
Glass and brittle materials control procedure was established and implemented throughout the processing, packing and storage area. List and lay out of glass and hard plastic equipment are detailed in place. Weekly inspection was in place for all areas. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily. Glass and hard plastic record was maintained and verified, such as 2020-02. Glass windows in production area, and bulbs and strip lights, including those on electric fly-killer devices were protected. Documented procedures are in place detailing the actions to be taken in case of breakage of glass are in place. The measures include the following: identifying the scope of goods to be isolated; Authorized personnel clearing the production area and releasing the production line for the continued production. Interviewed staff, they showed competency of handling process. Handling records were kept on files. **MINOR CAR is raised here under against clause 4.9.3.2,** **The walkie-talkies, plastic brushes, air condition and scales were not recognized as brittle material.**
4.9.4 Products packed into glass or other brittle containers
NA (4.9.4.1-4.9.4.3) No glass or brittle final product containers.
4.9.5 Wood
The wooden tools were prohibited to use in the production area and if happened, they will be removed and the status will be checked, evaluated and recorded. The wood control procedure was established and included in the foreign bodies control system.
4.9.6 Other physical contaminants
The site put off the raw material packaging in the buffer room to prevent contamination. All pens were used in site were without small parts and could be detected by MD machine.
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
Documented foreign body control procedure was established and implemented. Risk assessment was conducted during the hazard analysis process on 2020-03-01. The metal fragment was identified as risk during the production. The metal detector was used in packing line.
4.10.2 Filters and sieves
N/A. No filters and sieves were used in the site.

4.10.3 Metal detectors and X-ray equipment
Metal detector is determining as CCP in HACCP plan. Operation procedure of metal detector is operated according to procedure respectively. Metal detector with stop and alarm system was used for its products. Maintenance team is responsible for retesting of sensitivity program of detection of metal detection incorporated with detection performance and speed belt. 3 standard testing pieces (Fe $\phi \leqslant$1.5mm, Sus $\phi \leqslant$1.5mm, Non-Fe $\phi \leqslant$1.5mm) are used to verify detection performance as defined in HACCP plans and operation procedures. Records of verification are maintained. Records were signed by responsible person and maintained. Production staff demonstrated their competency and understanding of operation procedures.
4.10.4 Magnets
N/A. No magnets used.
4.10.5 Optical sorting equipment
N/A. Not used optical sorting equipment.
4.10.6 Container cleanliness – glass jars, cans and other rigid containers
PET bottle is used, it's flexible, it's not east to break. PET bottle is cleaned and checked before using. It was disinfection with ozone.
4.11 Housekeeping and hygiene
Housekeeping and cleaning control procedure was in place and cleaning and disinfection plan was established and implemented. The cleaning procedure details the following requirements: arrangement of cleaning, responsibility for cleaning, item/area to be cleaned, frequency of cleaning, method of cleaning, cleaning materials to be used, retaining for cleaning records and methods /responsibility for verification. Cleaning record retained. Cleaning schedules were in place for all processing equipment. The cleaning frequency is every day after finishing work. The cleaning item: tools, equipment, surface contact food and environment; Frequency before and after production shift, during processing, tools with 100-150 ppm sodium hypochlorite hand with 50-100 ppm sodium hypochlorite and 75% alcohol; Verification by swabbing or visible checking. Records reviewed. Cleaning and housekeeping is carried out by trained personnel. Company set the monitoring process in case of the checking result was out of specification included issuing of the non-conformity record for investigate and root cause solving. Cleaning chemicals are fit for its purpose. The testing reports are in place to demonstrate food grade requirements are met. Alcohol and soap labelling demonstrate it is suitable for its intended use. The swabbing testing for contact surface was conducted once per week, and the testing items TPC, Coli form and E. coli were included. Records were remained on files. Cleaning and disinfection procedures are validated when necessary. Cleaning equipment are fit for purpose. Onsite evaluation, MD machine, tumbling machine and chop mixing machine was checked the inside hygiene condition. **MINOR CAR is raised here under against clause 4.11.1,**

The hygiene of the bottom and on the top of the SUS cover for steaming was not cleaned well.

4.11.7 Cleaning in place (CIP)

No CIP.

4.11.8 Environmental monitoring

The environmental monitoring programme established based on risk.
Based on risk assessment, the environmental monitoring programme details the following requirements: typical sampling areas, organisms being assessed, frequency and methods of testing, handling for out of specification results;
Lab staff is responsible for Environmental monitoring (TPC, coliform, E.coli, salmonella, staphylococcus aureus, Listeria) such as testing the TPC for workshop (processing areas, packing area) every month, related monitoring records, such as 2019-12-31 were reviewed, the results are satisfied.
No pathogenic bacteria detected, then the monitoring plan will be adjusted.

4.12 Waste

Waste disposal procedure was established and implemented.
Some waste of raw materials is sold to use for feed and they were segregated from other waste. Others disposed by local authorities. External waste collection containers are managed well to minimise risk.
External waste collection containers are managed well to minimise risk. The wastes were removed by approved service supplier and the contract was maintained.
No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal.
Its waste package materials were sold, the packing with trademark of customer will be destroyed before the sale.

4.13 Management of surplus food and products for animal feed

For manage the surplus food with trademark of client, procedure was in place.
The production follows the orders, so the surplus food was few, for the few surplus foods, the factory would communicate with its client, the general measures were put into next order, or downgrading after removing packaging.
No customer-branded products which did not meet the specification would be sold to others.
The final product was used as pet food.

4.14 Pest management

The company was responsible for minimising the risk of pest infestation on the site. The pest control procedure was established and implemented.
The company was responsible for minimising the risk of pest infestation on the site.
The pest control procedure was established and implemented.
The pest control work was conducted by service supplier-Yantai Aojie Biological Technical Co., Ltd. (contact until 2021-03-03), the certificate of the PCO can be available, weekly inspection, related work records in place; and treatment of the site to deter and eradicate infestation. there was a training cert of pest control staffs named Shang KX and Peng J.
There was a pest control procedure covering all area of the site and a map of pest control facilities which identified the location of pest control facilities in place.

Fly killers and glue boards were used for in house treating; Traps and bait station were used in external environment.
Fly killer light bulbs were changed every year.
Suitable measures were in place to prevent birds from entering buildings or roosting above loading or unloading areas, and no roosting in factory area during site tour.
Check records of pest control were in place, e.g. 2019-11-07, 2019-08-02 and 2019-05-08. However, there is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory.
Bird control measures were in place. There was no bird activity onsite.
The in-depth, documented pest control survey was undertaken quarterly by experienced PCO. Considered the layout of workshops, pest control devices, idle equipment, activity of pests and others. The result of survey was as input of next pest control plan. The last survey was conducted on 2020-03-11.
Results of pest control inspections were assessed and analysed for trends. Frequency quarterly. Record was in place. The “hot spot” identified. The reports were in place, the last analysis was conducted on 2019-12-29.
No evidence of infestation was found or had recently been reported. No issues highlighted through trending reports.
Employees had been trained to understand the signs of pest activity and were aware of the need to report any evidence of pest activity to their supervisor.

4.15 Storage facilities

The products were stored on the pallets and away from the wall in warehouses.
Raw materials should be kept in cold storage, temperature should below -18℃, for its cold storage, QC test and recorded the storage temperature by handheld thermometer at least every 4 hours, and records were in place, such as 2020-03 and 2019-12.
Temperature Intervention system was in place to prevent temperature to exceed defined limits.
Final products and ingredients and packaging materials were stored in ambient condition and its warehouses was found most areas in normal condition.
Humidity checking for finisher product warehouse was conducted daily, records kept, such as 2020-03.
No outside storage for products of this company.

4.16 Dispatch and transport

Procedure to maintain product safety and quality during loading and transportation developed on the basis of risk assessment and implemented accordingly.
Transport requirements with the logistics company were clearly defined in the contract.
The batch number of products was records during dispatching.
Documented maintenance and hygiene procedures were maintained for all vehicles and equipment used for loading/unloading. The vehicle inspection before loading and unloading was conducted by storage person. The inspection item: cleanness, foreign bodies, odour and other. Products deliver check records can be available.
The service transport supplier was approved, and contract is valid.
The products are ambient. Finished products were shipped in dry container. The loading record can be available. E.g. 2019-12-27 （dried chicken jerkies）.
The container and vehicle control procedure were in place.
The truck driver or storage employee will inform responsibility personnel at once and the responsibility personnel will assess the product. The decision was based on result of the assessment.
There was no loading process during the evaluation, the supervisor could answer the loading requirement well.

5. Product control

5.1 Product design/development

Product design and development procedures have been established and implemented, including clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards (e.g. drug residues) which would be unacceptable to the company or customers; and the HACCP study was a part of the product design and development process.
HACCP team fully monitor all the new products and changes to product formulation, packaging or methods of processing. The changes need to be approved by HACCP team leader.
For its product, shelf life test procedure has been established and implemented. Shelf life trial records for its products were retained on files. The test items: Micro, sensory, moisture and others.
MINOR CAR is raised here under against clause 5.1.4,

The procedure of acceleration life test required the salmon slices test at least 20 weeks, but the record showed the site only tested 16 weeks.
And the samples of every batch pet food were preserved till at least shelf life plus 6 months, and the samples have been evaluated too.

5.2 Product labelling

The foreign clients provided the design of the label and carton. The marking of label and carton has been confirmed before printing. The safety and legal issue was confirmed by clients, legal requirements and CIQ requirements.
Ready to eat for pets as snacks.
No claims made to satisfy a consumer group (e.g. no nutritional claims).

5.3 Management of allergens

Allergen procedure based on risk assessment was established and implemented. The products were used for pet eating only.
The allergen training was provided for all staffs, records kept.

5.4 Product authenticity, claims and chain of custody

The procedure was in place, necessary measures for identified risk have been developed, documented and implemented, such as supplier evaluation, traceability test, survey and others.
Documented vulnerability assessment for all materials was planned to be conducted every year, the last assessment was conducted on 2020-03-13, and report was kept. For raw materials and ingredients, no obvious risk was identified for adulteration or substitution.
For its products, no IP materials, no GMO materials.
MSC Certificate (no.: MSC-C-55562, valid until 2022-11-07, issued by SGS).
Traceability test carried out every batch （at least 2 times annually）to cover both directions (raw material to finished product and vice versa).
And the company would check its incoming materials batch when receiving.
The production records were maintained for every time reworks such as label problems, and the batch numbers were clearly marked and recorded to ensure complete traceability, at present, no rework occurred.

5.5 Product packaging

The plastic bag and carton with COA of each lot provided by the supplier.

The assay report was in place including sensory appraisal which refers to specification.

The packaging was released by QA. The plastic bag was tested by local lab about physical & chemical items. Product package is suitable for its intended use.

Desoxidant supplier named Jiangsu Oukai Packing Technical Co., Ltd. Business licenses, COC (No.: OK2000786-1, 2020-02-12).
inner supplier named Dalian Rongguan Packing Co., Ltd., Business licenses, COC (No.: W2019045310310340, 2019-04-08). Questionnaire dated on 2019-06-28.
The colour blue of product contact liners was different between its products.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Documented inspection and analysis standard and sampling plan were in place.
Testing and inspection schedules have been established to ensure specified product requirement were met.
The company had an in-house laboratory to undertake analyses or mandatory inspection by SGS - Qingdao Branch(or other CNAS lab, ISO17025) to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.
The schedules included inspection method, standard, test items, frequency. Incoming raw materials, semi-processing products, finished products, food-contact surface, packaging material had been defined in it.
Inspection result trend analysis was done at least once per month. Reports kept, such as 2018-12-10 dried chicken fillet, 2019-01-09 dried chicken/ minced cowhide.
The system of ongoing shelf life assessment is in place.

5.6.2 Laboratory testing

The lab was designed normally and separated with product areas and storages. No risk to products.
Pathogen (Salmonella, Staphylococcus aureus) testing was carried out internally and also subcontracted to an external laboratory such as SGS (CNAS accreditation lab based on ISO17025).
The test items main include Sensory, TPC, Coli form, pathogenic bacterium, Pb, As and pesticide residue.
CNAS lab and internal lab used for finished product testing, raw materials testing.
E.g.:
Chicken chips, 2020-02-10, dexamethasone, tilmicosin, trimethoprim, enrofloxacin, sulfamethoxazole, result is OK, SGS lab.
Chicken chips,2020-01-16, salmonella, result is OK, SGS lab.
Chicken chips, 2020-01-16, melamine and others, results are OK, SGS lab.
Total 9 lab technicians were in its lab.
All of them are suitable trained, and training certificates are maintained on files. The plant conduct contrast test annually, records kept. The last time was conducted on 2019-09 for TPC and salmonella items with local official lab, all the results are satisfied.

5.7 Product release

Product quality control procedure was established and in place.
All finished products must be followed this procedure before release.
QA manager Yu LF was the authorized person to release product by consideration of result of product analysis such as process control, physical &chemical items, and sensory.

5.8 Pet Food

The site ensure pet food is formulated/designed for the intended use is pet snacks (such as dog and cat).
The site have specific procedures for the management of any ingredients, raw materials, products or rework that could be harmful to unintended recipients.
No pet food contained medicinal substances.

6. Process control

6.1 Control of operations

The company established process control parameters related to food safety and quality.
Operating procedure was established and implemented in order to control all parameters.
Process control parameters were defined for each step, e.g. receiving, process control, weight control, packing and storage.
All critical control points and quality control points were regularly monitored as defined plan. Production and QA supervisors were assigned to verify. Staff who responsible for monitoring process parameters demonstrated their competence from interviewing during on-site assessment, and the equipment settings was only completed by trained and authorised staff. Training records were maintained.
Temperature distribution records were in place such as 1# drying room dated on 2019-05-22 by China national centre for HACCP application research. And the coolest point of the whole drying room had been recognized by own staff dated on 2019-04-01 and 02.

The procedure to ensure product safety prior to release covering equipment failure and process deviation was established. Details were defined in HACCP Plan. Corrective action records were maintained in case of process deviations.

6.2 Labelling and pack control

Documented checks were carried out at start-up, product changes to ensure all products and packaging from the previous production have been removed from the line before changing to the next production.

There was a system to verify packaging type and labelling before use.

Verified labelling and packaging materials check records were well within specification. According to its production plan, the company verify packaging type and labelling before use, end of production, during production and changing production and check record was in place.
Record retained in place. E.g. 2019-11 and 2019-12.
During the audit of 2020-03-16, all previous chicken products wrapped with cowhide had been cleaned well before chicken products wrapped with biscuit products.

6.3 Quantity, weight, volume and number control

Quantity control system was in place with 100% check by production staff for each package and verified by QC team. Production and QC record of all products were reflected conformity.
The acceptance range of all products was established to ensure compliance with legal, company specification and customer requirement.
Net weight checking, 10 samples are checked at start and end of production and every hour on line QC, records kept, such as 2020-03-16 and 2020-02-10.
Finished products were sampling check as defined frequency in sampling plan for quantity checking compare with the weight declaration on the label.
At present, not used online check scale.

6.4 Calibration and control of measuring and monitoring devices

All the measuring equipment used to monitor CCPs, product safety and legality were identified properly, and the company has identified and established the complete registration list. And the records of results of calibration and verification were maintained.

Measuring and monitoring devices were calibrated by 3rd party Shenzhen Xinguanghang using traceable and recognized standards, and the certificates were maintained, such as:
Scales-annual- JJG539-2016 valid date until 2020-05-30; cert No. ZS1971167S,
Water content meter- JJG658-2010 valid date until 2020-12-22; cert No. ZS2010742S,
thermometer-annual- JJG617-1996 valid date until 2020-12-22, cert No. ZS2010742S,
standard- annual– JJG99-2006 - valid date until 2021-02-25 cert No. ZS2020039S

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

HR management and training procedure and training plan of 2019-2020 was established for managing the activity of training program to ensure the competent staff and workers.
Training plan was prepared for all staff and all levels. On the job training was conducted by each area.
Orientation training program was provided for new comers that include factory's rule, management policy, food safety/security/quality, personal hygiene and all quality management systems.
Training evaluation system was conducted after end of course in order to ensure their competency for relevant staff with evaluation of training by observing from actual operation, interview or examination.
Training records contain name of trainer, name of trainee, content, training date with duration. Reviewed on the job training for staff who responsible for metal detection, allergen material, and temperature checking, packaging preparation. Training records were in place and staff demonstrated well awareness.
SSOP Training dated on 2020-02-13, trainer Sui SY, BRCGS training dated on 2020-03-05, trainer Yu LF, CCP training dated on 2019-03-26, trainer Yu LF, allergen training dated on 2020-04-03, trainer Yu LF, Food safety protection training dated on 2019-05-14, trainer Yu XF, chemical training dated on 2019-06-05, trainer Yu XF, Label and packing training dated on 2019-07-10 trainer Yu LF,
Documented training program was scheduled on yearly basis based on training need from each department including refresh training. Specific training or on the job training were provided by admin./General Management based on their description.
Personal performing work affecting product quality, food safety was competent on the basis of appropriate education, training, skill and experience. Routinely reviewing was established and implemented as defined to be training plan.

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

Documented personal hygiene requirement was established and implemented defined in its PRP.
Compliance with the requirement was daily checked and recorded. False nail was not allowed.
Fingernails must be kept short and unvarnished. Jewellery, watches, ring, perfume were not allowed to use in production area. This company regulation was informed to visitor and contractor before entering to production area which checked by production team leader prior to enter.
Smoking, eating, and drinking were allowed in designated areas only.
Hand washing facilities including liquid soap, hand drier, alcohol disinfection and washing instruction with appropriate language was sufficiency provided at every access point.
If wounded, use the plaster. The plasters were suitable, blue and contained a metal detectable strip, and verified by MD. There was a testing record dated on 2020-02-19.
Personal medicines could be kept in locker only.

7.3 Medical screening

Employees would be medically examined, prior to employment and yearly during employment. The healthy certificates named Ms Ma L(Issued date 2019-06-18)and Mr Chang YL（issued date 2019-06-

18） were sampled. The certs were issued by Yantai Qishan hospital.
Visitors and contractors would be required to answer health questions before entering production area and warehouse.
Return to work procedure after illness was in place for review. Medical screening procedure defined communication to staff by training and others such as visitor through questionnaires.
In case of infectious disease, staff was moved to work in low risk area and re-screening was required.

7.4 Protective clothing: employees or visitors to production areas

Completed protective clothing should be put on before entering production zone for staffs, visitors and contractors, detailed as below,
Cap
Mask
Protective clothing
work shoes
gloves for staffs
Protective clothing must be changed in changing room before to toilet and use of canteen and smoking areas outside workshop. Every staffs had 2 sets protecting clothing. Every shift changed one time.
Clothing is cleaned daily by in house laundry in factory. Designated workshop supervisor visual check the effectiveness of the cleaning work before use. The effectiveness of cleaning and disinfecting for clothes and apron was verified by swab test weekly on TPC with records retained. The swabbing record dated on 2019-05-20 was in site.
There was a food grade testing report for gloves used in site, the testing report issued by SGS-CSTC on 2019-05-31.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones

8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones

There was a site plan showed that production areas. no high-risk zones, ambient high-care production risk zones and high-care zones.

8.2 Building fabric in high-risk and high-care zones

no high-risk zones and high-care zones.

8.3 Maintenance in high-risk and high-care zones

no high-risk zones and high-care zones.

8.4 Staff facilities for high-risk and high-care zones

no high-risk zones and high-care zones.

8.5 Housekeeping and hygiene in the high-risk high-care zones

no high-risk zones and high-care zones.

8.6 Waste/Waste disposal in high risk, high care zones
no high-risk zones and high-care zones.
8.7 Protective clothing in the high-risk high-care zones
no high-risk zones and high-care zones.

Details of non-applicable clauses with justification	
Clause/section reference	**Justification**
3.5.2.3	No live animals
3.5.4	No out sourced processing
4.3.5	No temporary structures constructed.
4.4.6	No elevated walkways.
4.9.4.1	No products packed into glass or other brittle containers
4.9.4.2	No products packed into glass or other brittle containers
4.9.4.3	No products packed into glass or other brittle containers
4.10.2	No filters and sieves were used in the site.
4.10.4	No magnets used.
4.10.5	Not used optical sorting equipment.
4.11.7	No CIP was in place.

4.13.1	No customer branded products made
4.15.4	No controlled atmosphere storage.
4.15.5	No outside storage
5.2.3	No claims made to satisfy a consumer group (no nutritional claims)
5.2.4	No customers or nominated third party responsible for label information
5.3	Not applicable for pet
5.4.5-5.4.6	No claims made about the methods of production.
6.1.4	No in-line monitoring devices in place.
6.2.4	No on-line vision equipment used to check product labels and printing
6.3.2	No bulk quantities packed.
8.1.2-8.7	Not high-risk, high-care, ambient high care production risk zones

9 - Traded Products

9.1 Approval and performance monitoring of manufacturers/packers of traded food products

N/A there were no traded products

9.2 Specifications

N/A there were no traded products

9.3 Product inspection and laboratory testing

N/A there were no traded products

9.4 Product legality

N/A there were no traded products

9.5 Traceability

N/A there were no traded products

Module 13 FSMA Preventive Controls Preparedness Module Version 2 July 2018				
Item no.	**Clause**	**Module item**	**Conforms (Y/N) or Not Applicable (NA)**	**Comments**
1	13.1.1	Handwashing areas, dressing and locker rooms, and toilet rooms must have adequate lighting.	Y	On-site audit found the lighting in the handwashing dressing and locker rooms, and toilet rooms are adequate.
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	The piping systems in the facility were clearly marked, no cross-connection found; and base on risk analysis, back-pressure valves were installed.
3	13.1.3	All food contact surfaces of plant equipment and utensils used in manufacturing, processing, packing, or holding food must be corrosion resistant. Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.	Y	Food contact surfaces were stainless steel (304# or 316L) or other appropriate materials (such as PVC), the materials can stand cleaning chemicals, and the materials are corrosion resistant.
4	13.1.4	Ice used in contact with food must be manufactured in accordance with Good Manufacturing Practice (GMP) requirements of 21 CFR 117.	N/A	No ice in contact with food.
5	13.1.5	Where defect action levels (DAL) are established for a food, quality control operations must reduce defects to the lowest level possible. Defect levels rendering the food adulterated may not be reduced by mixing the food with another lot.	Y	DALs have been established in specifications based on FFDCA, FDA AFSS, AAFCO and others (such as 21CFR558), and SOPs have been established and implemented to reduce defects to the lowest level possible. Base on risk assessment, food adulterated risk considered, and prevent measures established and implemented.

6	13.1.6	The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility: • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety	Y	FSP plan was in place. Hazard analysis worksheet has been updated to add economic adulterants which affect food safety, radiological hazards and unintentional adulterants that affect food safety.
7	13.1.7	All identified known or reasonably foreseeable hazards must be evaluated to determine "hazards requiring a preventive control" (i.e., significant hazards).	Y	Hazard analysis has been completed from raw material, processing to final products, including of Biological hazards (e.g. pathogenic bacterium, parasite), chemical hazards (e.g. Heavy metal, drug residue), and physical hazards (e.g. hard bones, metal, glass). Radiation hazards; Food fraud and food defence. Likely occurrence of hazard (A/B/C/D/E) and severity of the effects (I/II/III/IV) considered fully during the hazard analysis, so the risk coefficient is 1-20, if the risk coefficient of any identified hazards is from 1 to 3, the hazard shall be defined as significant hazard, then decision tree would be used to decision CCPs. All hazards which are reasonably likely to occur are considered during hazard analysis and risk analysis. The hazard analysis must identify and evaluate, but which was the significant hazards for pathogenic bacteria not clearly determined in FSP.
8	13.1.8	Establish one or more preventive control(s) for each identified "hazard requiring a preventive control" (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed,	Y	For identified hazards, more preventive control measures have been developed, documented and implemented, such as supplier audit, test, inspection, survey, traceability.

		or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.		
9	13.1.9	Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following: • Notifying consignees of how to return or dispose of recalled product • Conducting effectiveness checks to verify recall is carried out • Appropriate disposal (i.e., destroy, divert, repurpose) of recalled product	Y	Product recall and withdrawal procedure was in place and evaluated and updated at least annually. The procedure defined notifying consignees of how to return or dispose of recalled product, conducting effectiveness checks plan to verify recall is carried out and appropriate disposal of recalled product (i.e., destroy, divert, and repurpose). The last recall test was conducted on 2020-03-05, for dried duck (batch no. F009AG4D45, 720 cartons), mock cause was salmonella problem. Records (including input and issue warehouse record, inventory record, handling records) were remained and mock recall rate was 100%, within 2 hours.
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRCGS section 2.10.	Y	The decision tree was used to assess the hazard controls at each process step and the results were documented. For drying pet food with sterilization: CCP1: raw materials receiving, significant hazards: drug residue; CCP2: sterilization, significant hazards: pathogenic bacteria; CCP3: metal detection, significant hazards: metal foreign body. Monitoring procedures were in place, and monitoring records kept. The procedures for each CCP identify the corrective action to be taken when the limits were exceeded.
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRCGS sections 2.11 and 3.7. Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities	Y	Corrective actions for every CCP were in place. The procedures for each CCP identify the corrective action to be taken when the limits are exceeded. Pathogen as unconventionality item was required as verification method, corrective action procedure was in place, such as recall/ withdraw, sterilization.

		(i.e., product testing and/or environmental monitoring).		
12	13.1.12	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring re-validation or within 90 calendar days of the first food production. Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.	Y	Procedures of validation and verification to confirm that the HACCP system working effectively was in place. The last review was conducted on 2019-04-11. The company operates a formal sign off process for all new products and significant changes and new equipment which includes sign off by the HACCP Team leader to confirm the impact of any changes have been assessed. The company reviews its HACCP system yearly, or when any changed.
13	13.1.13	The PCQI (or authorized designee) reviews monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification. The PCQI (or authorized designee) reviews verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.	Y	The PCQI plan to review monitoring and corrective action records within 7 days. The planned to be reviewed verification records including calibration records, product testing, and supply-chain audits, the timeframe is within 7 days.
14	13.1.14	Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • Sampling procedure to include method, quantity, frequency, and number of samples • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected	Y	Pathogen test was conducted in 3rd party accreditation labs (ISO17025) and own lab(ISO17025) . Sampling procedure to include method, quantity, frequency and number of samples were defined in test procedure, and corrective action procedure was established where a pathogen is detected. The factory declared that no positive pathogen found in previous test results.
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and	Y	Pathogen (Salmonella) testing was carried out internally and subcontracted to an external laboratory such as SGS (CNAS accreditation lab based on ISO17025).

		written testing procedure must identify the following: • Adequate number and location of sample sites • Timing and frequency of sampling • Analytical method • Laboratory conducting analysis • Corrective action procedure where pathogen is detected		The swabbing testing for contact surface was conducted once per week, and the testing items TPC and Coli form were included, reports were in place, such as 2020-03, 2020-02.
16	13.1.16	Devices used to verify preventive controls must be calibrated.	Y	The company has identified the measuring equipment used to verify preventive controls. Measuring and monitoring devices register was in place. All identified measuring devices, including new equipment, have been checked and where necessary adjusted. In-house calibration was conducted regularly, based on national standards; SOP in place. Calibration records kept. Measuring and monitoring devices calibrated by Local Institute of Metrology.
17	13.1.17	Identify a Preventive Controls Qualified Individual (PCQI) responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training and qualification via job experience.	Y	Mrs. Yu, she had more than 15 years' experience in food industry, and better understanding of HACCP principles and their application. She has successfully completed the FSPCA training cause, the Certificate No.: 9ea3ac8c, issue on 2017-09-08. and Ms Sui SY had more than 10 years' experience in food industry.
18	13.1.18	All records required by 21 CFR § 117 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	On-site sampling and reviewing the records found, the necessary information (e.g. date, time, signature, materials information, process) included.

19	13.1.19	The owner, operator or agent in charge of facility must sign and date the written food safety plan initially and then upon any changes following reanalysis.	Y	FS plan was approved by FST Leader (Mr. Jiang YS), and reviewed annually.
20	13.1.20	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.	Y	Records control procedure was established and implemented. The requirement of collation, review, maintenance, storage and retrieval of records were defined in it. Shelf life for its products is 18 months, documents and records relating to the food safety plan kept for at least 3 years.
21	13.1.21	Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities. Where a hazard requiring a supply-chain-applied control is identified AND the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying implementation of the control.	Y	Some hazards (such as heavy metal, drug residue) were controlled by supply-chain, specific supplier approval and verification activities have been established, such as supplier selection, supplier evaluation, sampling, collecting COA/ COC. QA/QC sampling / inspection (or testing) for every batch material.
22	13.1.22	Supplier approval must be documented before receiving and using raw materials and ingredients. Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.	Y	Approved suppliers list was in place, all raw materials and packaging materials shall be from approved suppliers, QC check it for every receiving. QA/QC sampling / inspection (or testing) for every batch material. If QC dose not receive any necessary inspection (or test) result, the materials shall be temporary held in special area.
23	13.1.23	One or more supplier verification activities (defined in § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients AND periodically thereafter at an adequate frequency.	Y	Some supplier verification activities have been established and implemented, such as supplier audit, sampling/ testing, review food safety plan of suppliers, performance assessment, GFSI certs and others.
24	13.2.1	Human food by-products held for distribution as animal food must be	N/A	No human food by-products were used in pet food products.

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

		held under conditions that will protect against contamination, including the following: - During holding, human food by-products for use as animal food must be accurately identified. * Labeling that identifies the product by the common or usual name must be affixed to or accompany the human food by-products for use as animal food when distributed. * Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute human food by-products for use as animal food must be examined prior to use to protect against the contamination of animal food from the container or vehicle when the facility is responsible for transporting the human food by-products for use as animal food itself or arranges with a third party to transport the human food by-products for use as animal food.		All raw materials are food grade.
25	13.3.1	A Qualified Individual (QI) is responsible for developing the site's food defense plan, conducting a vulnerability assessment, identifying mitigation strategies, and conducting a reanalysis of the plan. The QI responsible for developing the food defense plan shall be identified on the site's organizational chart. One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.	Y	Food defense plan (HS-QF-02-37) is in place. Risk assessment has been conducted, for identified risk, control measures have been established and implemented. 6 QI's are nominated for monitoring food defense, Mr. Jiang (FST leader) is leader.
26	13.3.2	The site shall have a written food defense plan, which includes the following: • A vulnerability assessment identifying significant vulnerabilities and actionable process steps	Y	Food defense plan (HS-QF-02-37) is in place. Risk assessment has been conducted, for identified risk, control measures have been established and implemented.

		• Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification		
27	13.3.3	A written vulnerability assessment shall be prepared for each food type manufactured, processed, packed, or held, which evaluates the following key criteria (at a minimum): • Scale and severity of threat if a contaminant is added to product • Degree of physical access to the product • Ability of an attacker to successfully contaminate product—including consideration of an inside attacker A vulnerability assessment shall be documented for each food type regardless of the outcome and provide justification as to why each point, step or procedure in the operation was or was not identified as an actionable process step.	Y	Documented vulnerability assessment for all materials was planned to be conducted every year, the last assessment was conducted on 2020-03-13, and report (HS-QR-04-PG-55) was kept. For raw materials and ingredients, no obvious risk was identified for adulteration or substitution.
28	13.3.4	Written mitigation strategies shall be established and implemented for each actionable process step identified in the vulnerability assessment. Justification shall be documented explaining how the strategy significantly minimizes or prevents the vulnerability.	Y	The Written mitigation strategies were in place, necessary measures for identified risk have been developed, documented and implemented, such as supplier evaluation to reduce fraud, traceability test to verification if fraud exist, survey to search if fraud raised and others.
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies.	Y	Monitoring system is established, the record indicates monitoring date/time/monitoring results, all monitoring is signed by operators and verified by PCQI.

		Procedures shall include recordkeeping requirements for all monitoring activities.		Such as supplier evaluation annually, traceability test every year.
30	13.3.6	Written corrective action procedures shall be established and implemented when mitigation strategies are not properly implemented. The procedure shall include the following criteria: • Method for identifying and correcting a lack of implementation • Method for reducing the likelihood of recurrence • Recordkeeping requirements for corrective actions	Y	It covers all identified steps in assessment and monitoring plan, corrective is established such as product segregated, selecting, investigation and access adding.
31	13.3.7	Written verification procedures shall be established and implemented to ensure that food defense monitoring and corrective action are performed according to procedures. Verification procedures shall describe activities to verify implementation of mitigation strategies. Verification procedures shall include: • A review of monitoring and corrective action records within an appropriate timeframe (e.g., 7 days) • Other verification activities as appropriate (e.g., internal audit) • Method for verifying that reanalysis of the food defense plan was conducted • Frequency for verification activities • Recordkeeping requirements of all verification activities	Y	The verification procedure is established and the last verification is carried out on 2019-04-11 and the verification reports including reanalysis plan are maintained.
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever	Y	Food defence plan reanalysis was conducted annually, no changed from previous audit.

		• A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the food or facility becomes known • Mitigation strategies are not implemented as intended • FDA requires reanalysis based on new threats or scientific evidence		
33	13.3.9	All records required by 21 CFR § 121 must include: • Date and time of activity being documented • Signature/ initials of individual performing activity or conducting record review • Information to identify the facility (e.g., name and location) • Identity of the product and lot code where applicable	Y	Related records are retained on files such as date, time, signature and information to identify the facility.
34	13.3.10	The owner, operator or agent in charge of facility must sign and date the written food defense plan initially and then upon any changes following reanalysis.	Y	Signed by FST Leader (Mr. Jiang YS).
35	13.3.11	All documents and records relating to the food defense plan (i.e., all records required by 21 CFR § 121) must be retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours with the exception of the food defense plan, which must remain onsite.	Y	All documents and records are stored in site, easy to get. Could retrievable within 24 hours
36	13.4.1	Vehicles and transportation equipment must be maintained and stored in a sanitary condition appropriate for the intended use to prevent food from becoming unsafe during transportation. Where inspection reveals that vehicles or	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.

		containers are not in a clean condition, they shall not be used. A documented procedure shall describe cleaning and storage practices of all vehicles and transportation equipment maintained by the site whether leased or owned and as appropriate for the intended use. The procedures shall be fully implemented. Cleaning activities shall be recorded.		
37	13.4.2	The site shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the site acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
38	13.4.3	Where the site arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the site does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.

40	13.4.5	Where the site receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
41	13.4.6	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications (including pre-cooling requirements where applicable) • Recording compliance with operating temperature where critical to food safety • Procedures for the use of bulk vehicles, which includes recording the previous cargo and most recent cleaning for the shipper	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
42	13.4.7	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
43	13.4.8	The site shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.

		records shall be retrievable within 24 hours.		
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite records are retrievable within 24 hours.	N/A	For the factory, no contracted transport practices for food transported by motor or rail within US.
45	13.5.1	Personnel (permanent and temporary) who handle produce or food contact surfaces must receive additional training on the following: • Principles of food hygiene and food safety Produce safety standards applicable to an individual's job	Y	PRPs, HACCP principles, FSMA training had been conducted.
46	13.5.2	Personnel (permanent and temporary) who conduct harvest activities (including washing and cooling) must receive additional training on the following: • Recognizing produce contaminated with known or reasonably foreseeable hazards • Inspecting harvest containers and equipment to ensure that they are clean, maintained and do not contaminate produce with hazards • Correcting problems with harvest containers or equipment	N/A	No personnel who conduct harvest activities in the factory. All raw materials and ingredients are from factory.
47	13.5.3	One or more supervisors or individuals responsible for the operation must have successfully completed food safety training equivalent to standardized curriculum recognized by the FDA.	Y	2 PCQI Ms Yu LF and Ms Sui SY was in site.
48	13.5.4	A supervisor shall be identified with responsibility for the operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.	Y	PCQI certified supervisor Ms Yu LF (QC manager) is responsible for this function of organizational chart.

49	13.5.5	Personnel (permanent and temporary) shall avoid contact with animals or take measures such as hand washing and protective clothing to prevent contamination of produce and food contact surfaces following contact with worker animals.	N/A	No animal in the factory.
50	13.5.6	The water distribution system supplying agricultural water used for harvest, packing, holding—and associated equipment—shall be maintained, regularly inspected and equipment properly stored to prevent the system from being a source of contamination to produce and food contact surfaces. The system shall be inspected for conditions, which could introduce known or foreseeable hazards into or onto produce. Where testing of the water source or system inspection reveals contamination, deficiencies shall be corrected such as the repair of well caps or sanitary seals.	N/A	The water is not for agricultural water.
51	13.5.7	Agricultural water treatment must be delivered and monitored at a frequency that ensures water is safe, of adequate sanitary quality, and meets the microbial quality criteria of no detectable generic Escherichia coli (E. coli) in 100mL.	N/A	The water is not for agricultural water.
52	13.5.8	Potable water quality standards used shall ensure the microbial quality criterion is met, which is no detectable generic E. coli in 100 mL.	Y	Utilities are properly designed and maintained in normal condition. The processing used water used on site is from main water. The quality of water that is incorporated into products as ingredients and comes in direct or indirect contact with food or packing is monitored as bellows: By contracted Lab once a year. By internal Lab, Sensory: color, appearance, odor, TPC, coliform, weekly checking. Water distribution plan is in place. Records that related to treatment activity were maintained. Annually testing of in-process water that covering chemical, microbiological is in place as test report (report no. No. QDF20-002620-01) done

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If you would like to feedback comments on the BRC Global Standard or the audit process directly to BRC, please contact tellus@brcglobalstandards.com

Claudio Innocenti

				on 2020-02-21 by external laboratory Qingdao SGS Test Co., Ltd. (ISO17025, CNAS L0604). The results meet GB5749-2006. The own lab tested the water microorganisms every week. Tested odour and chlorine residue daily. E.g. testing record for microorganisms items on 2020.03.13. Steaming produced from its potable water and can contact its product and has monitored its quality monthly. Workshop air: plate count survey and coliform is once per week in the company. Ice is not used for processing.
53	13.5.9	Where agricultural water does not meet microbial quality criteria or is determined to be unsafe and not of adequate sanitary quality, water use must be discontinued along with treatment or other correction that reestablishes sanitary quality and microbial criteria. Where water treatment is not performed, re-inspection of the entire affected agricultural water system shall be conducted followed by the identification of conditions leading to the introduction of hazards into or onto produce or food contact surfaces, correction, and verification of correction to ensure water meets microbial quality criteria.	N/A	The water is not for agricultural water.
54	13.5.10	Agricultural water testing may be performed by the site (or site representative) or by a third party provided representative samples of the site's water source is secured. Aseptic water sampling must be performed. The method of analysis for water testing is U.S. Environmental Protection Agency (EPA), ‘‘Method 1603: Escherichia coli (E. coli) in Water by Membrane Filtration Using Modified membrane-Thermotolerant Escherichia coli Agar (Modified mTEC), EPA–821–R–09–007),’’ December, 2009 or equivalent method.	N/A	The water is not for agricultural water.

55	13.5.11	During harvest, packing and holding operations (e.g., hydrocooling, washing), manage water to maintain its safety and sanitary quality and prevent contamination of produce to include establishing and following a water-change schedule for recirculated water. Visually monitor the water quality of water used for harvest, packing, and holding activities for organic build-up (e.g., soil, plant debris). Maintain and monitor the temperature of water used for harvest, packing, and holding activities as appropriate to the commodity and operation to minimize infiltration of pathogens into produce.	N/A	The water is not for agricultural water.
56	13.5.12	Dropped produce (i.e., produce that comes in contact with the ground prior to harvest) where the produce would not normally touch the ground as a part of growing and harvest (e.g., cantaloupe, almonds, etc.) shall not be distributed.	N/A	It is not for primary production.
57	13.5.13	Sewage disposal and septic systems shall be controlled and appropriate for the site to prevent the contamination of produce and food contact surfaces.	N/A	It is not for primary production.
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	N/A	Back-pressure valves were used on every tap. It is not for primary production.
59	13.5.15	All produce safety related records must be reviewed, dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.	N/A	Records are reviewed, dated, and signed within 7 days. It is not for primary production.
60	13.5.16	All produce safety documents and records must be retained at the site for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours. Records related to equipment or processes used by the site for	N/A	Record is stored in factory and kept for 4 years in factory. It is not for primary production.

		analyses, sampling, or action plans—including the results of scientific studies, tests, and evaluations—shall be retained at the site for at least 2 years after their use is discontinued.		
61	13.5.17	Specific additional requirements for the harvesting, packing, and holding of sprouts. Establish and implement a written Environmental Monitoring plan for the testing of Listeria spp or Listeria monocytogenes. The environmental monitoring plan shall include the following criteria: • Target test (i.e., Listeria spp. or L. mono) • Sample frequency (no less monthly) • Sample timing (i.e., when in the process are samples collected) • Sample sites where the number of samples and location are sufficient to determine the efficacy of controls (includes food contact and non-food contact surfaces) The plan shall describe aseptic methods for sample collection and testing according to FDA's ‘‘Testing Methodology for Listeria species or L. monocytogenes in Environmental Samples,’’ Version 1, October 2015 (or equivalent).	N/A	No sprouts production.
62	13.5.18	Specific additional requirements for the harvesting, packing, and holding of sprouts. The environmental monitoring plan shall include a corrective action plan if any samples are positive for Listeria spp. or L. mono. If Listeria spp. or L mono are identified in the harvesting, packing, holding area, the following activities shall occur as a part of the corrective action process:	N/A	No sprouts production.

		• Resample positive surfaces and the surrounding area to determine the extent of contamination • Clean and sanitize the affected and surrounding areas • Resample and re-test to confirm the elimination of Listeria spp. or L. mono • Conduct finished product testing as appropriate • Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		

Audit Report

Global Standard for Food Safety Issue 8: August 2018

1.Audit Summary			
Company name	Yantai Hao's Pet Food Tech. Co., Ltd.	Site Code	9892347
Site name	Yantai Hao's Pet Food Tech. Co., Ltd.		
Scope of audit	Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.		
Exclusions from scope	None		
Justification for exclusion	N/A		
Audit Finish Date	2019-03-21		
Re-audit due date	2020-03-25		

Additional modules included			
Modules	Result	Scope	Exclusions from scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Head Office	No

2. Audit Results					
Audit result	Certificated	Audit grade	A	Audit type	Announced
Previous audit grade	A	Previous audit date	2018-03-16		
Certificate issue date	2019-04-24	Certificate expiry date	2020-05-06		

Number of non-conformities	Fundamental	0
	Critical	0
	Major	0
	Minor	7

3.Company Details

Address	No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City, Shandong Province 264003		
Country	P.R. China	Site Tel. Number	00865356727937
Commercial representative Name	Zhang Yunnuan	Email	catherine@wanpy.com.cn
Technical representative Name	Yu Lifeng	Email	yulf@wanpy.com.cn

4.Company Profile

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3

Shift Pattern	One shift x 8 hours (08:00~17:30); drying room, 3 shifts, 8 hours per shift.
Subcontracted processes	No
Other certificates held	ISO22000, ISO9001, ISO14001, MSC
Regions exported to	North America Europe Choose a region Choose a region Choose a region Choose a region
Company registration number	12149111738.
Major changes since last BRC audit	No major changes since last BRC audit.

Company Description

Yantai Hao's Pet Food Tech. Co., Ltd. was a joint venture company, which was established in 1999, located at No. 16 Puchang Road, Laishan Economic Development Zone, and Yantai City, Shandong Province, China.

There was one workshop and about 400 contracted staffs in the plant. QCs were 7 persons who take over the quality inspection during the production. There was 1 shift per day, about 8 hours (expect drying room, 3 shifts, 8 hours per shift) and 6 days per week.

The output of a year was about 3000 ton and main products are exported to North America and Europe. At present, the company holds ISO22000, ISO9001, ISO14001 and MSC certificate.

5.Product Characteristics

Product categories	15 - Dried food and ingredients Category Category Category				
Finished product safety rationale	Finished product safety rationale ambient stable, 18-24 months, Sterilization temperature/ time: USA, ⩾80℃/ ⩾30 minutes; Europe, ⩾90℃/ 30 minutes. Ambient (Aw below 0.68).				
High care	No	High risk	No	Ambient high care	No
Justification for area	Because all final products were used as pet food, and Aw was below 0.68, so only low risk and enclosed area were in place.				
Allergens handled on site					
Product claims made e.g. IP, organic	MSC				
Product recalls in last 12 Months	No				
Products in production at the time of the audit	Air-dried chicken wrapped with cowhide, dried duck with bone, packed in plastic bag.				

6.Audit Duration Details

On-site duration	18 man hours	Duration of production facility inspection	9 man hours
Reasons for deviation from typical or expected audit duration	Time as per BRC audit calculator		
Next audit type selected	Announced		

Audit Duration per day

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-03-20	08:30	18:30
2(finished date)	2019-03-21	08:30	18:30

	Auditor (s) number	Name	Role
Auditor Number	176454	Jesse YIN	Lead Auditor
Second Auditor Number			Please select

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings (ref: clause 1.1.11) Name / Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Liu Yan/ Plant manager	x	x		x
Yu Lifeng / QC Manager	x	x	x	x
Liu Chunna / Purchase Manager	x		x	x
Shao Yan / Trade	x	x	x	x
Sui Shaoyuan/ QC	x	x	x	x
Yu Xiaofei / QC	x	x	x	x

Non-Conformity Summary Sheet

Critical or Major Non Conformities Against Fundamental Requirements				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated re-audit date**

Critical			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated re-audit date**

Major							
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided**	**Date reviewed**	**Reviewed by**

Minor							
No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided	Date reviewed	Reviewed by
1	3.4.1	The company planned to conduct internal audit quarterly, however how to define the frequency each activity is not clearly.	According to the requirements of clause 3.4.1, the BRC clauses was conducted risk assessment of importance, legal requirements, clients' requirement and past performance, and the frequency of audit was determined according to the results of risk assessment.	We carry out Internal audit according to the results of risk assessment, and update the risk assessment at least annually. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The risk assessment for BRC clauses dated on 2019-04-01. The training records dated on 2019-03-24 09:00-11:30.	2019-04-11	Jesse YIN
2	3.5.3.2	The transport agreement does not clearly define service expectations of the potential food safety risks associated with the service.	We have added the requirements of food safety during transportation to the contract and sign a supplementary agreement.	We check the other contracts to check if similar questions still exist. We conduct training for relevant person to avoid similar questions raise again.	The supplementary agreement dated on 2019-04-01 The training records dated on 2019-03-24 13:00-15:00.	2019-04-11	Jesse YIN

				Deadline: 2019-04-08			
3	4.7.4	The records of cleaning activity after a small number of equipment maintenance were not kept.	We have communicated with relevant maintenance man to confirm the cleaning activities, and recorded cleaning activity after maintenance.	We review maintenance record more strictly in the future. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The completed maintenance records dated on 2019-03-28. The training records dated on 2019-03-25 13:00-15:30.	2019-04-11	Jesse YIN
4	4.9.3.2	Inspection of glass and breakable materials in open product areas and enclosed areas is conducted weekly. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily.	The inspection frequency has been adjusted. The inspection frequency in the areas without open products (changing rooms, external corridors and toilets), 1 time/week; and the inspection frequency in the areas with open products (all areas of the workshop), 1 time/day.	We use the updated glass checking plan in the future. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The daily checking record (doc. HS04-02-67) dated on 2019-04-01_04) The training records dated on 2019-03-26 09:00-11:50.	2019-04-11	Jesse YIN
5	4.9.6.2	The pen used by the staff in the pre-processing room has small parts, easy to fall off.	Have replaced the pen to new type (no small part).	We check all the other areas to confirm if similar questions still exist. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The photo of the pen (no small part). The training records dated on 2019-03-26 09:00-11:50.	2019-04-11	Jesse YIN

6	4.14.4	There is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory.	We have updated the pesticide use record, the items include pesticide concentration, usage and spraying area in detail.	We use the updated pesticide using record in the future, and we check the other records. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The updated pesticide using record dated on 2019-04-01. The training records dated on 2019-03-25 09:00-11:30.	2019-04-11	Jesse YIN
7	7.1.6	For some internal courses, the records did refer to the material, work instruction or procedure that is used in the training.	We have standardized the filling of training records.	We review all training records based on standard requirements in the future. We conduct training for relevant person to avoid similar questions raise again. Deadline: 2019-04-08	The training records dated on 2019-03-26 13:00-15:30.	2019-04-11	Jesse YIN

Comments on non-conformities
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Detailed Audit Report

1. Senior management commitment

1.1 Senior management commitment and continual improvement

Continual improvement control procedure was documented and implemented. Its GM demonstrated they were fully committed to the implementation of the requirements of the Global Standard for Food Safety including provision of adequate resources, effective communication, food safety culture, systems of review and actions taken to effect continual improvement, and opportunities for improvement was identified, implemented and fully documented.
The policy was stated as the following: Total employee involvement, ensure customer satisfaction, ensure safety and hygiene, and obey regulation, ongoing improvement.
The food safety and quality policy can be available in its food safety and quality manual. The food safety and quality policy signed by its GM and dated on 2019-03-08. It is defined in quality and food safety manual (HS-SFQM-01 9.0) and displayed on site in the company.
A list of the activities on site that have an impact on food safety and quality culture was in place, such as food safety policy, food safety culture team, action plan, and approved by its GM; the effectiveness would be assessed from the next audit to Issue 8.
The quality objects were established as followed:
Pet food safety incident was 0; Customer satisfaction rate above 96%; Import country inspection qualified rate 100%, customer complaint rate less than 7/year.
Policy and objects management control procedure was documented and implemented.
The policy and objects were communicated among all departments and all staffs by training and showing.
The objectives were reviewed by management on basis. Trend analysis conducted, the results reported to top management quarterly, at present, the objectives of 2018 achieved, Last reviewed and reported on 2019-01-13.
A list of the activities on site that have an impact on food safety and quality culture was in place, such as food safety policy, food safety culture team, action plan, and approved by its GM; the effectiveness would be assessed from the next audit to Issue 8.
The quality meeting plan approved by GM was in place and the frequency is at least weekly. The meeting records were remained on files, e.g. 2019-03-18.
A confidential reporting procedure (issued on 2019-03-01) is established, documented and implemented, the relevant telephone number for reporting is open to all staff.
The management review procedure was documented and implemented. The frequency of the management review was planned to be yearly.
Latest annual management review conducted on 2019-01-13. The management review is hosted by GM, and related supervisor, such as QC manager, Production manager, admin. manager, trade manager, purchasing manager participated. The management review report was maintained on files covering necessary inputted materials. The KPI of every department has been covered and the report demonstrate that all KPIs have been achieved.
3 decisions were raised in the management review. The action and responsible of the output has been defined, and will be completed on 2019-03-25.
The main products were sell in domestic and the monitoring system for relevant regulations collection was established and the documents of external origin were in place.
Three approaches to obtain the updated regulation. A: communicate with its suppliers and customers to know its raw materials and finished products standards; B: contact potential customs for obtaining the new regulation; C: from web to obtain the new regulation such as China, FDA and EU regulation.
The company has a Chinese version original copy of Issue 8 of the Standard at the audit.
All previous CARs (8 minor CARs) were followed up and effectively improved;
The most senior production/operations managers on site was GM, QA/QC manager, production Manager available during opening and closing meeting and available for management interview after the opening meeting.
BRC logo using policy is in place, and the company knows how to use BRC logo.

1.2 Organisational structure, responsibilities and management authority

Organisational chart and responsibilities defined, including those with an impact on product safety, legality and quality.
Clear organization structure was established covering all business processes under Global Standard for Food Safety. The organisation chart is defined in Food safety and Quality Manual (doc. HS-SFQM-01 9.0).
Job descriptions, which clearly defined the assigned duty, appropriate arrangement when absent, qualification, reporting and subordinating lines, were in place for all positions of the current organization structure. Designated staff was expected to 'acting' in case of absence, and this was stated in Job description such as production monitor, QC manager, admin and lab staff.
Work instructions are available, are communicated and are in place for staff who are responsible for every key activity related to product safety, legality and quality.

2 The Food Safety Plan – HACCP

HACCP plan established and maintained based on the codex Alimentarius HACCP principles. HACCP plans for its dried pet foods (HS-HA-01_03) approved by GM.
The multi-disciplinary food safety team was established, members 14 staff: such as GM, Production manager, QC manager, Business manager, Engineering manager, Office, Operator and others.
The team leader is GM and the others staffs were identified as members. HACCP team leader had over than 20 years' experience in manufacturing of pet foods and had been trained for HACCP system;
Internal HACCP trainings were held yearly and current conducted on 2018-05-09 for all team members.
Its HACCP plan scope was Air-dried pet foods, from receiving to delivery.
Documented PRPs were in place, including layout, maintenance of equipment and facilities, purchasing, allergen, cleaning, pest control, personnel hygiene, training and others.

HACCP plans are established according to Codex standard, scientific literature for pet foods, and nature of product, hazard analysis, food safety legislation, experimental study and customer requirements.
Relevant information such as scientific literature, historical and known hazard (physical-metal, glass, stone, wood, chemical-Furan, chloramphenicol, radiation, heavy metal and microbiological – TPC, Coliform, E. coli, salmonella), code of practice (Codex Alimentarius standard or guideline), legislation (EU, USA) and customer requirements were reference for HACCP analysis conducting.
Full description of the products developed including: Frozen chicken, duck, beef, pork, fish, salt, sugar, starch, soybean; drying; Packaging system: PE bag, cartons, PET bottles; storage and distribution conditions (ambient); 18-24 months, sterilization.

Such as the calcium bones description: ingredients include corn starch, wheat flour starch, soybean protein, calcium carbonate and coloring matter. Packaging: inner was PE bag and outer was cartons, deoxidizer added ambient, shelf life was 18 months.
The intended use was defined as ready to eat after open for pet snacks.

Incoming raw materials/ ingredients receiving- storing- defrosting-cutting or tumbling- moulding- shaping- drying/ sterilization- cooling- off net- cutting (when needed) - selecting- metal detecting- packing- sterilization (when needed) - inspecting- storing-irradiating-delivery.

The flow diagrams were verified on site by HACCP teams and were signed off on 2019-02-25_28.
No subcontracting.

The relevant information needed to conduct the hazard analysis were collected, maintained, documented and updated. The relevant codes of practice and customer requirements and other information were all available for review.
The method of developing the hazard analysis was using the risk grade which consideration matrix the likelihood and severity and the CCP decision tree.
The drug residue (e.g. chloramphenicol), pathogen and metal fragments were identified as obvious hazards in the production process.

The CCP and CL and monitoring measures were as follows:
The decision tree was used to assess the hazard controls at each process step and the results were documented.
For its air-dried pet foods: CCP1: incoming raw materials receiving; CCP2: sterilization; CCP3: metal detection.
For its air-dried pet foods: CL1: certificate of inspection and quarantine for each batch and residue of veterinary drug test report once a year. CL2: drying room temp≥85℃, time≥ 30 minutes for normal products (to EU: drying room temperature ≥ 90℃, time more than 30 minutes); every 10 minutes. CL3: Fe φ≤1.5mm, Susφ≤1.5mm, Non-Fe φ≤1.5mm. Start and end of production per hour.
For CCP1, reject the materials;
For CCP2, adjust the temperature and duration separated and review the products;
For CCP3, Isolate the potential effected products and assess. Re-detect the product by metal detector.
Samples of CCP monitor records were reviewed:
CCP1: Raw duck incoming date 2019-01-12, COA was issued by Linyi Liuhe Hongchen, report No. 2019011201, drug residues were tested, the result is satisfied; Animal inspection certificate (No. 3753585466).
CCP2: Sterilization, lamb meat rolled on dried fish fillet dated on 2018-12-05, temperature ⩾90℃, duration 30 minutes.
CCP3: Metal detection, dated on 2018-12-06, product name dried chicken, calibration time from 08:10 ~ 10:00, Fe φ 1.5mm, Susφ 1.5mm, Non-Fe 1.5mm.
Documents and records review find that there is no deviation for the CCPs.

Critical limit had been agreed and signed off by team. The CCP CIs were based on published data or industry best practice and FDA. CCPs are monitored and recorded regularly. Non-conforming product would be degraded, rework or rejected and kept in hold before releasing by QA. The corrective action was taken by competent person trained fully.
Procedures of validation and verification to confirm that the HACCP system working effectively is in place. And the last verifications were carried out on 2019-03-19, and the verification reports were maintained.
The HACCP records were maintained at least 3 years.

The company operates a formal sign off process for all new products and significant changes and new equipment which includes sign off by the HACCP Team leader to confirm the impact of any changes have been assessed.
The company should be reviewed its HACCP system yearly. latest reviewed on 2019-03-16_18, considered all related items.

3. Food safety and quality management system

3.1 Food safety and quality manual

The food safety and quality manual (Chinese) was established (Doc. HS-SFQM-01 9.0), valid on 2019-03-08.
Quality manual contained outline of work method, practice reference of BRC Food Issue 8 requirements related their processes.
Quality manual was distributed under document control process to main office and each department.

3.2 Document Control

Document control procedures (Doc. HS-CX-01) was established.
Documents have been approved by designed authorized person and distribute to relevant department to ensure the correct version available in place.
All controlled documents were controlled by document controller and share in electronic system; therefore, all documents are readily accessible to relevant staff at all times.
During audit, document observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.
The obsolete documents were recalled back to document control department, stamp cancelled and disposed.
At present, the documents are not stored in electronic form.

3.3 Record completion and maintenance

Record control procedure (Doc. HS-CX-02) was established.

The requirement of collation, review, maintenance, storage and retrieval of records were defined in it. Records were kept at least 3 years (shelf life 18-24 months). And the list of quality record was in place. During audit, record observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.

3.4 Internal audits

Documented internal audit procedure was established with reference document (Doc. HS-CX-11).
The auditee has established an internal audit plan at least quarterly, however, how to define the frequency each activity is not clearly. The audit standard is BRC Food V8.0 standard. The internal audits are "scheduled throughout the year.

One minor CAR (against 3.4.1) has been raised in this section, details as "Non-Conformity Summary Sheet".

The last internal audit for BRC was carried out on 2019-02-14_15, audit scope was whole company. And internal audit results were maintained on files.
The internal auditors included Mrs. Yu LF (team leader) and the members (Wu Du YL, Guo JD, Yu XF) who were competent (HACCP training, BRC food issue 8.0 training, food experiences), and they were all independent from the audited department.
Internal audit records included attendance record of open/close meeting, non-conformities record; summary report, corrective action report and internal audit checklist were in place.
4 CARs was raised in the latest internal audit, audit findings will confirm with the auditee, and the corrective actions and timescales were also confirmed.
Internal audit team leader was responsible for verify the corrective action taken by the auditee, and the corrective action had been taken and verified.

The frequency of GMP inspection is once per day in open product areas. The frequency of GMP inspection is once per month in plant yard and storage areas. And check records were kept on files.

3.5 Supplier and raw material approval and performance monitoring

3.5.1 Management of suppliers of raw material and packaging

The documented purchasing control procedure (Doc. HS-CX-12, HS-CX-25) based on risk assessment was in place. The supplier review was carried out by purchasing Dept. and QC Dept. effectively. The grades of suppliers were defined according to the risk of affecting products and onsite audit or questionnaire investigation methods were defined.
The documented risk assessment of each raw materials including foreign body risks, microbiological and chemical contamination, variety or species cross-contamination, legislative control and substitution were in place in the facility and it was updated and reviewed annually. The last assessment was conducted 2019-03-01 and the records were maintained.
Supplier monitoring and evaluation included in purchasing control procedure; For high risk suppliers, on site audit or GFSI certificate. Supplier performance/ monitoring is evaluated on every 12 months and summarized for supplier communication. Primary production control is appropriately controlled based on risk assessment such as on site verification, or questionnaire updating that reissued at least three years.
Approved suppliers were registered in approved supplier list.
The frequency of supplier evaluation was conducted once a year, the supplier audit is not completed by a second or third party.
Evaluation records were in place. Sample:
Frozen chicken supplier named Dacheng Food (Dalian) Co., Ltd., Business licenses, COC (No.: GMAAK2HX66208501, 2018-04-02).
Frozen chicken supplier named Fuxin A&F Development Co., Ltd. Business licenses, COC (No.: A2180147475101001CAR2, 2018-09-21).
Garlic powder supplier named Beijing Weitenong Biological Technical Development Co., Ltd. Business licenses, COC (No.: GMAZIOJK46377505).
Frozen carrot supplier named Laiyang Huatai Food Co., Ltd. Business licenses, COC (No.: 19022-W2, 2019-02-24).
Desoxidant supplier named Jiangsu Oukai Packing Technical Co., Ltd. Business licenses, COC (No.: HG180913-35, 2018-09-13).

Packaging supplier named Dalian Rongguan Packing Co., Ltd., Business licenses, COC (No.: W2018045310310620, 2018-05-21).
For all suppliers, the relevant certificates or licenses required by authorization were collected and reviewed once a year.
Traceability system of all suppliers was checked by GFSI certificates, on-site audit, questionnaires. Evidences kept.
At present, raw materials and other materials are not purchased from agents or brokers
The trail will be done when they cooperate with new supplier or purchase new material. If there are changes or amendments to the documents, the reasons will be recorded.
Some exceptions (such as any supplier was prescribed by client) have been described in procedure.
The original supplier label and product received were verified through the warehouse storage area for onsite evidence check and records of receiving and dispatch were also verified. COCs were available.

3.5.2 Raw material and packaging acceptance, monitoring and management procedures

Product inspection and test procedure is established and implemented. The parameters for acceptance, approved changes to raw materials and frequency of testing are clearly defined in it.
The received materials are verified by authorized person such as QC and store staff prior to receive. The status of passed test material is identified in tag identification for each material for communication with related functions.
And intake records inspected during audit.
Verified incoming materials receiving on 2019-01-25(frozen chicken), 2018-08-18 (duck), 2019-03-04 (garlic powder), 2019-01-16 (mycose), 2019-03-14 (desoxidant).

3.5.3 Management of suppliers of services

Management service provider was documented as defined in procedure, for implementing.
Evaluation of services providers' performance is also done for every service activities.
Approved service suppliers were registered in approved supplier list.
Those include pest control, waste service, transportation service and lab service.
The related contracts were kept on files, such as pest control service (Yantai Aojie, valid until 2021-03-03).
Evaluation records were kept.
Most contract that detailed sufficient requirements to ensure product safety were maintained and reviewed. However, the transport agreement does not clearly define service expectations of the potential food safety risks associated with the service.

One minor CAR (against 3.5.3.2) has been raised in this section, details as "Non-Conformity Summary Sheet".

3.5.4 Management of Out sourced processing

No processes are outsourced.

3.6 Specifications

All materials specifications were in place taking into account relevant CN, GB or other regulars and customer requirements, such as:
The specification for raw materials, ingredients and packaging were in place, such as Raw materials (HS-QW-01-23) –chicken, duck, beef, lamb, pork. Ingredients (HS-QW-01-24) –salt, potato starch, corn starch, garlic powder, vitamin E, wheat powder, glycerine, carmine, pet biscuit, cheese, oxygen absorber.
Packaging (HS-QW-01-25) – PE bag, carton.
In-process product –net weight, moisture, temperature and time;
Final specifications (dried pet foods, Q/HS009) were in place.
Specifications cover details of safety parameters (physical, chemical and biological hazard) such as raw materials, ingredients and packaging, finished product.
Formally agreed specification was established, and reviewed up to date to supplier, customer of raw materials and finished product specification.
Specification was reviewed every 3 years.

At present, no head office.

3.7 Corrective and preventive actions

Corrective actions procedure (Doc. HS-CX-14) is established and implemented.
QA department is responsible for this issue.

Records review finds that the company takes corrective actions in a timely manner for non-conformities, and consider the analysis (root cause) of non-conformities for trends, a non-conformity places the safety, legality or quality of a product at risk.

3.8 Control of non-conforming product

Documented non-conformity control procedure (Doc. HS-CX-20) was established, and the responsibility for decision making on the use or disposal of products was defined, and QA manager was responsible for it and GM could make final decision.
The designated separated storage room for non-conforming products were identified and marked with labels, and the clear process was understood by staff interviewed during the audit. The non-conforming product records were maintained. Non-conforming disposing product records were kept on files.
Corrective actions are implemented to avoid recurrence of non-conformance. No major trends.

3.9 Traceability

The traceability control procedure was established (Doc. HS-CX-20) to ensure the complete traceability for tracing materials from raw material to finished product and vice versa. The traceability testing was conducted at least every year to cover both directions.
The company ensured the traceability of all materials used for its raw materials, ingredients, packaging and finished products could also be included. The batch number coding system was established.
Mock traceability exercise procedure was established and implemented.
Traceability test carried out once every year to cover both directions (raw material to finished product and vice versa).
The most recent traceability (from raw materials to final products, and vice versa) testing for dried duck fillet on 2019-01-18, and the traceability testing records were maintained on file.
Frozen chicken batch number was aAL2C14, quantity: 30000 kg, finished product batch number was K315AL2C14, K323AL2C14, A323AL2C14, quantity:14627.96 kg, plastic bag batch was also traced in it.
Quantity check and mass balance considered in its traceability testing. The duration was within 2 hours.
For supplier approved based on a questionnaire, considered the product safety, traceability, HACCP review and GMPs; such as packing materials supplier, traceability done on 2018-06-02.
And the company would check its incoming materials batch when receiving.
A test (raw frozen duck, production date 2018-05-27_06-09), initiated by the auditor on the day of the audit involved the following: from raw material to finished products (including package) and vice versa, which was completed within 2 hours and mass balance, quantities were accurate, related raw material, frozen duck, batch no. aG4C15, 27000kg received on 2018-06-11; finished products (dried duck products), 6 batches (K309/ K310/ K315/ K317/K319/ K321 aG4C15, production date are 2018-11-05, 2018-11-06, 2018-11-11, 2018-11-13, 2018-11-15 and 2018-11-17), total quantity is 21.857 ton, mass balance.
The production records were maintained for every time reworks such as label problems, and the batch numbers were clearly marked and recorded to ensure complete traceability, at present, no rework occurred.

3.10 Complaint-handling

The customer complaint handling procedure was established (Doc. HS-CX-07). Trade Department was responsible for complaints collecting and then discussed with production manager and QC manager. After discussing and analysis, QC department and/or production department will find the cause and make a decision how to take the corrective action. QC manager will verify the corrective actions and preventive actions taken and business department will reply customer.
The complaints are recorded and investigated, take corrective action via root cause to avoid recurrence, and the results of the customer complaint are recorded.
At present, the company declared that 6 complaint were raised from 2018 to now, and no food safety complaints.
Trend analysis was conducted every year, the last time was dated on 2019-01-02.

3.11 Management of incidents, product withdrawal and product recall

The recall and withdrawal procedure (Doc. HS-CX-22) is in place that contained handing method and responsible person of each stage.
Classifications of product recall:
Class I Recall: This is an emergency involving the removal from marketing and distribution channels those products that, because of a deficiency, pose an immediate or long-term serious threat to health or life. In a

Class I Recall, top priority must be given to the complete and immediate removal of the recalled products from all levels in the distribution chain all the way down to the consumer level.
Class II Recall: This is a priority situation in which a product deficiency may cause temporary or medically reversible adverse health consequences and where the probability of serious adverse health consequence is remote. An example of such a product is a food product containing Salmonella enteritis. In a Class II Recall, products must be removed from all levels in the distribution chain.
Class III Recall: This is a routine situation in which adverse health consequences of a product deficiency are highly improbable or non-existent. Products are recalled because of adulteration or misbranding not involving a health hazard. Examples of Class III Recalls are situations involving improperly labelled products or products with filth contamination. In a Class III Recall, products must be removed from the wholesale levels of the distribution chain.
The list of key contacts, e.g. suppliers, client, certification body is in place.
Communication plan was defined in the procedure.
The product recall and withdrawal procedures are tested once annually.
The last withdraw test was conducted on 2018-10-16, for dried duck (batch no. K289AG4C11, 7402.984 kg), mock cause was foreign body problem. Records (including input and issue warehouse record, inventory record, handling records) were remained and mock recall rate was 100%,within 2 hours.
In the event of a product recall, the company will be informed within three working days of the decision to issue a recall to CB.
No recalls to date.
The emergency preparedness and response procedure (Doc. HS-CX-19) is established and implemented.
The items cover: the equipment broken, water, energy, fire, malicious contamination or sabotage and disease. The company carried out mock powder off on 2018-06-21.

4. Site standards

4.1 External standards

The company was established on 1999-07-21.
In normal repair and well maintained with investments regularly planned. Located in an industrial park.
No local activities that would risk product contamination.
No pest harborages found nearly.
Adequate drainage system was in place and no standing water hazard happen.
The additional building (e.g. restaurant, dormitory, power room) were checked, and in normal condition.
Adequate drainage system was in place and no standing water hazard happen.

4.2 Site security and food defence

Food defence procedure (doc. HS-QW-01-11 6.0) and site boundaries have established and clearly defined to prevent access of unauthorised persons to factory.
Access to site of contractors, suppliers and visitor has implemented by registered at main factory gate that defined in its procedure. Visitor cards will be declared and this card must be returned when exit. Identify card must be tagged at all times in factory. In terms of production and storage areas, the staff's uniforms are the system to identify authorized staff who work in that area.
There are security guards 24 hours at every gate of entrance.
Storage procedure, delivery procedure and transportation contract have been defined instruction for product security.
Production, warehouse areas were defined as strictly control areas. They were locked when no activities performed.
The latest annual review for a documented threat assessment plan was conducted on 2018-10-10 and the staffs had been trained for security plan on 2018-07-02.
Based on analysis results, the raw materials and products are not particular risk found.
The information that detailed in procedure for implementing as: Vehicle control and inspection; Mails, packaging, material proper control; Physical security coverage to facilities; Defensive posture of security personnel; Security advisory dissemination; plant security; CCTV system; Control of access device;
Factory site has been registered with government authority as below:
And export registration number is 3700PF013, US FDA no. is 12149111738.

4.3 Layout, product flow and segregation

There was effective segregation to minimise the risk of product contamination.
The plan of the site which designates areas including low risk areas and enclosed areas; the raw material and finished product storages and chemical storage were defined as enclosed areas; the other areas were defined as low risk areas.
Working space and storage was sufficient to enable operations to be carried out properly under safe hygienic conditions.
The process flow from intake to dispatch was arranged well to minimise the risk of product contamination.
Physical barriers were in place to minimise the risk of the contamination of raw materials, packaging, finished products and different processes.
Segregation considered the flow of product, nature of materials, equipment.
Facilities for tray and utensil washing are segregated from production activities. There was no contamination finding during the audit on site.
For its products, not high risk/ high care / ambient care product.

4.4 Building fabric, raw material handling, preparation, processing, packing and storage areas

The fabrication of the site, buildings and facilities were suitable for its products process.
Walls were designed, constructed, finished and maintained could be accepted.
Floors were in normal acceptable condition. Drainage was sited, designed and maintained to minimise risk of product contamination.
The ceilings were designed, constructed, finished and maintained well. Adequate access to the ceiling was provided. Cleaning and maintenance of false ceiling were scheduled.
Windows were designed can be accepted. The windows in process and warehouse were shielded with film to avoid the contamination with the food when the windows are broken.
The doors and dock levellers in these areas were close fitting or adequately proofed. Doors were in acceptable condition and easy to clean.
The lightings were adequate in the areas. All bulbs and strip lights, including those on electric fly-killer devices were adequately protected.
Fans were used in processing area, they were maintained well.
For its products, not high risk/high care product;
Positive air was needless for its products.

4.5 Utilities – water, ice, air and other gases

Utilities are properly designed and maintained in normal condition.
The processing used water used on site is from main water.
The quality of water that is incorporated into products as ingredients and comes in direct or indirect contact with food or packing is monitored as bellows:

- By contracted Lab once a year.
- By internal Lab, Sensory: color, appearance, odor, TPC, coliform, weekly checking.

Water distribution plan is in place. Records that related to treatment activity were maintained.
Annually testing of in-process water that covering chemical, microbiological is in place as test report (report no. No. QDF19-003765-01) done on 2019-02-20 by external laboratory Qingdao SGS Test Co., Ltd. (ISO17025, CNAS L0604) . The results meet GB5749-2006.
Steaming produced from its potable water and can contact its product, and has monitored its quality monthly.
Workshop air: plate count survey and coliform is once per week in the company.
Ice is not used for processing.

4.6 Equipment

The equipment was suitably designed for the intended purpose.
The machines, such as cutting machine, tumbling machines, drying rooms, MD were made from stainless steel and plastic.
Certificate indicated food safety compliance with legal requirements.

The specification of machine would be specified in purchasing order. The machine would be tested and commissioned prior used. Commissioning reports would be performed effectiveness of implementation.
If new equipment purchased, the commissioning report will be in place done by equipment producer.

4.7 Maintenance

Preventive maintenance, breakdown maintenance procedure and new machine commissioning procedure are established and implemented.
The machine and equipment used for production process and utilities are determined in preventive maintenance plan (2019, HS04-02-37).
Maintenance was done by engineer as preventive maintenance plan. Maintenance records were maintained, such as sealing machine 2019-03-01, tumbler 2019-03-01.
Documented hygiene inspection on start-up completed by production supervisors, however, the records of cleaning activity after a small number of equipment maintenance were not kept.
The equipment inventory was established and the maintenance was carried out if the equipment cannot work normally and the maintenance records were maintained on file. The maintenance staffs were available in the facility and the special certificates were kept on files.
On site checked no found temporary repair in the production areas.
Hygiene clearance procedure is established to prevent contamination due to maintenance, e.g. personal hygiene policy for maintenance staff and subcontractor, line cleaning and clearance after maintenance.
Food grade lubricant (NSF H1, 111102) used, no allergen.
No major breakdowns in last 12 months.
Engineering workshops was located on outside production area to prevent contamination risks to the product and maintained well.
One minor CAR (against 4.7.4) h**as been raised in this section, details as "Non-Conformity Summary Sheet".**

4.8 Staff facilities

Adequate working space, rest room, toilet and single large changing facility were provided at the entry of the workshop which maintained in clean condition by hygiene pilot.
The hand washing station was provided and monitored and equipped with sufficient and temper water where posted the hand washing advisory signs.
The hand washing and protective clothes cleaning effectiveness were verified by visual check.
No smoking in the factory.
The toilet was isolated from the workshop and necessary facilities were provided and controlled by hygiene pilot.
The worker's working and outdoor clothes were separated fully in the changing room and not allow worker with working clothes go out of the working area.

4.9 Chemical and physical product contamination control: raw material handling, preparation, processing, packing and storage areas

4.9.1 Chemical control

A chemical control procedure was in place managing the using, storage and handling of non-food chemicals.
And the chemicals were stored in separated room, relevant MSDSs, testing reports and approved chemicals list was in place.
The designated staffs are responsible for storage, mixed, and use. Records were kept and specified the responsible staffs as well as the date and the concentration.
Approved chemical list was available for review, main included soap liquid, food grade alcohol (COC, 2018-06-29 based on GB 10343-2008), food grade NaClO (COC, 2018-04-03 based on GBT19106-2013 A) and lab chemicals.
Washing liquid, alcohol COA was in place.

4.9.2 Metal control
Metal control policy was defined in the procedure in place for implementing, and there was daily inspection record for damage and the investigation of any lost items. Staple and snap off blade are not allowed to use and take into production area and on packaging materials in its procedure. Company has used the knives and others metal tools at processing step which control number and status as before and end using. The metal control records were verified, such as 2018-12-01, 2018-12-02 and 2018-12-03.
4.9.3 Glass, brittle plastic, ceramics and similar materials
Glass and brittle materials control procedure was established and implemented throughout the processing, packing and storage area. List and lay out of glass and hard plastic equipment are detailed in place. Weekly inspection was in place for all areas. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily. Glass and hard plastic record was maintained and verified, such as 2019-02. Glass windows in production area, and bulbs and strip lights, including those on electric fly-killer devices were protected. Documented procedures are in place detailing the actions to be taken in case of breakage of glass are in place. The measures include the following: identifying the scope of goods to be isolated; Authorized personnel clearing the production area and releasing the production line for the continued production. Interviewed staff, they showed competency of handling process. Handling records were kept on files. **One minor CAR (against 4.9.3.2) has been raised in this section, details as "Non-Conformity Summary Sheet".**
4.9.4 Products packed into glass or other brittle containers
At present, no products packed into glass or other brittle containers. PET bottle is used, it's flexible, it's not east to break.
4.9.5 Wood
The wood control policy was developed that no wooden tools permitted using in workshop and warehouse. No wooden tools were found when site checking. The plastic pallets were used in warehouse and workshop.
4.9.6 Other physical contaminants
Raw material packaging and pen control procedure was in place, defined the requirements on debagging and deboxing and pens; However, the pen used by the staff in the pre-processing room has small parts, easy to fall off. **One minor CAR (against 4.9.6.2) has been raised in this section, details as "Non-Conformity Summary Sheet".**
4.10 Foreign-body detection and removal equipment
4.10.1 Selection and operation of foreign-body detection and removal equipment
Documented foreign body control procedure was established and implemented. Risk assessment was conducted during the hazard analysis process on 2019-03-01. The metal fragment was identified as risk during the production. The metal detector was used in packing line.
4.10.2 Filters and sieves
N/A. No filters and sieves were used in the site.
4.10.3 Metal detectors and X-ray equipment
Metal detector is determining as CCP in HACCP plan. Operation procedure of metal detector is operated according to procedure respectively. Metal detector with stop and alarm system was used for its products. Maintenance team is responsible for retesting of sensitivity program of detection of metal detection incorporated with detection performance and speed belt. 3 standard testing pieces (Fe $\Phi \leqslant 1.5$mm, Sus $\Phi \leqslant 1.5$mm, Non-Fe $\Phi \leqslant 1.5$mm) are used to verify detection performance as defined in HACCP plans and operation procedures.

Records of verification are maintained. Records were signed by responsible person and maintained.
Production staff demonstrated their competency and understanding of operation procedures.

4.10.4 Magnets

N/A. No magnets used.

4.10.5 Optical sorting equipment

N/A. Not used optical sorting equipment.

4.10.6 Container cleanliness – glass jars, cans and other rigid containers

PET bottle is used, it's flexible, it's not east to break.
PET bottle is cleaned and checked before using.

4.11 Housekeeping and hygiene

Documented cleaning procedure SSOP/ cleaning plan were established.
The cleaning plan detail the following requirements: the relevant responsibilities- operator or staff dedicated on the cleaning tasks; Frequency-before and after production shift; Verification by swabbing or visible checking.
The cleanliness of equipment was checked before equipment released back into full production, and cleaning and housekeeping was carried out by trained personnel.
Cleaning chemicals were fit for its purpose. The chemical sodium hypochlorite was food grade and the testing report was in place for review.

50ppm chlorine disinfector for hand disinfecting; 100 ppm chlorine concentration and/or 75% alcohol for equipment disinfecting; 200 ppm chlorine pool for the shoes.
Cleaning records were in place, such as 2019-02-10 and 2019-02-11.

The swabbing testing for contact surface was conducted once per week, and the testing items TPC, coliform, E.coli, salmonella, staphylococcus aureus and Listeria were included, reports were in place, such as 2019-02-18_22.
Air of production area was also tested every week and the items TPC were conducted.

4.11.7 Cleaning in place (CIP)

N/A. No CIP cleaning system was in place.

4.11.8 Environmental monitoring

The environmental monitoring programme established based on risk.
Based on risk assessment, the environmental monitoring programme details the following requirements: typical sampling areas, organisms being assessed, frequency and methods of testing, handling for out of specification results;
Lab staff is responsible for Environmental monitoring (TPC, coliform, E.coli, salmonella, staphylococcus aureus, Listeria) such as testing the TPC for workshop (processing areas, packing area) every month, related monitoring records, such as 2019-02 were reviewed, the results are satisfied.
No pathogenic bacteria detected, then the monitoring plan will be adjusted.

4.12 Waste

Waste disposal procedure was established and implemented.
Some waste of raw materials is sold to use for feed and they were segregated from other waste. Others disposed by local authorities. External waste collection containers are managed well to minimise risk.
External waste collection containers are managed well to minimise risk. The wastes were removed by approved service supplier and the contract was maintained.
No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal.
Its waste package materials were sold, the packing with trademark of customer will be destroyed before the sale.

4.13 Management of surplus food and products for animal feed

For manage the surplus food with trademark of client, procedure was in place.
The production follows the orders, so the surplus food was few, for the few surplus foods, the factory would communicate with its client, the general measures were put into next order, or downgrading after removing packaging.
No customer-branded products which did not meet the specification would sold to others.
The final product was used as pet food.

4.14 Pest management

The company was responsible for minimising the risk of pest infestation on the site. The pest control procedure was established and implemented.
The company was responsible for minimising the risk of pest infestation on the site.
The pest control procedure was established and implemented.
The pest control work was conducted by service supplier-Yantai Aojie Biological Technical Co., Ltd. (contact until 2021-03-03), the certificate of the PCO can be available, weekly inspection, related work records in place; and treatment of the site to deter and eradicate infestation.
There was a pest control procedure covering all area of the site and a map of pest control facilities which identified the location of pest control facilities in place.
Fly killers and glue boards were used for in house treating; Traps and bait station were used in external environment.
Fly killer light bulbs were changed every year.
Suitable measures were in place to prevent birds from entering buildings or roosting above loading or unloading areas, and no roosting in factory area during site tour.
Check records of pest control were in place, e.g. 2018-08-21, 2019-02-21 and 2019-03-07. However, there is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory.
Bird control measures were in place.
The in-depth, documented pest control survey was undertaken quarterly by experienced PCO. Considered the layout of workshops, pest control devices, idle equipment, activity of pests and others. The result of survey was as input of next pest control plan. The last survey was conducted on 2018-12-26.
Results of pest control inspections were assessed and analysed for trends. Frequency quarterly. Record was in place. The “hot spot” identified. The reports were in place, the last analysis was conducted on 2018-12-29.
No evidence of infestation was found or had recently been reported. No issues highlighted through trending reports.
Employees had been trained to understand the signs of pest activity and were aware of the need to report any evidence of pest activity to their supervisor.
One minor CAR (against 4.14.4) has been raised in this section, details as “Non-Conformity Summary Sheet”.

4.15 Storage facilities

The products were stored on the pallets and away from the wall in warehouses.
Raw materials should be kept in cold storage, temperature should below -18℃, for its cold storage, QC test and recorded the storage temperature by handheld thermometer at least every 4 hours, and records were in place, such as 2018-10.
Temperature Intervention system was in place to prevent temperature to exceed defined limits.
Final products and ingredients and packaging materials were stored in ambient condition and its warehouses was found most areas in normal condition.
Humidity checking for finisher product warehouse was conducted daily, records kept, such as 2019-02.
No outside storage for products of this company.

4.16 Dispatch and transport

Procedure to maintain product safety and quality during loading and transportation developed on the basis of risk assessment and implemented accordingly.
Transport requirements with the logistics company were clearly defined in the contract.
The batch number of products was records during dispatching.
Documented maintenance and hygiene procedures were maintained for all vehicles and equipment used for loading/unloading. The vehicle inspection before loading and unloading was conducted by storage person. The inspection item: cleanness, foreign bodies, odour and other. Products deliver check records can be available.
The service transport supplier was approved, and contract is valid.
The products are ambient. Finished products were shipped in dry container. The loading record can be available. E.g. 2018-12-18.
The container and vehicle control procedure were in place.
The truck driver or storage employee will inform responsibility personnel at once and the responsibility personnel will assess the product. The decision was based on result of the assessment.
During audit, the loading was in normal condition.

5. Product control

5.1 Product design/development

Product design and development procedures have been established and implemented, including clear guidelines on any restrictions to the scope of new product developments to control the introduction of hazards (e.g. drug residues) which would be unacceptable to the company or customers; and the HACCP study was a part of the product design and development process.
HACCP team fully monitor all the new products and changes to product formulation, packaging or methods of processing. The changes need to be approved by HACCP team leader.
For its product, shelf life test procedure has been established and implemented. Shelf life trial records for its products were retained on files. The test items: Micro, sensory, moisture and others. Shelf life trial (Acceleration life test) records for its AD chicken/ pigskin (production date: 2018-08-21) from 2018-10-21 to 2018-02-22 (continued) were maintained on files, all results were OK.
And the samples of every batch pet food were preserved till at least shelf life plus 6 months, and the samples have been evaluated too.

5.2 Product labelling

The foreign clients provided the design of the label and carton. The marking of label and carton has been confirmed before printing. The safety and legal issue was confirmed by clients, legal requirements and CIQ requirements.
Ready to eat for pets as snacks.
No claims made to satisfy a consumer group (e.g. no nutritional claims).

5.3 Management of allergens

Allergen procedure based on risk assessment was established and implemented. The products were used for pet eating only.
The allergen training was provided for all staffs, records kept.

5.4 Product authenticity, claims and chain of custody

The procedure was in place, necessary measures for identified risk have been developed, documented and implemented, such as supplier evaluation, traceability test, survey and others.
Documented vulnerability assessment for all materials was planned to be conducted every year, the last assessment was conducted on 2019-03-01, and report was kept. For raw materials and ingredients, no obvious risk was identified for adulteration or substitution.
For its products, no IP materials, no GMO materials.
MSC Certificate (no.: MSC-C-55562, valid until 2019-11-07, issued by SGS).

Traceability test carried out once every year to cover both directions (raw material to finished product and vice versa).
The most recent traceability (from raw materials to final products, and vice versa) testing for dried duck fillet on 2019-01-18, and the traceability testing records were maintained on file.
Frozen chicken batch number was aAL2C14, quantity: 30000 kg, finished product batch number was K315AL2C14, K323AL2C14, A323AL2C14, quantity:14627.96 kg, plastic bag batch was also traced in it.
Quantity check and mass balance considered in its traceability testing. The duration was within 2 hours.
For supplier approved based on a questionnaire, considered the product safety, traceability, HACCP review and GMPs; such as packing materials supplier, traceability done on 2018-06-02.
And the company would check its incoming materials batch when receiving.
A test (raw frozen duck, production date 2018-05-27_06-09), initiated by the auditor on the day of the audit involved the following: from raw material to finished products (including package) and vice versa, which was completed within 2 hours and mass balance, quantities were accurate, related raw material, frozen duck, batch no. aG4C15, 27000kg received on 2018-06-11; finished products (dried duck products), 6 batches (K309/ K310/ K315/ K317/K319/ K321 aG4C15, production date are 2018-11-05, 2018-11-06, 2018-11-11, 2018-11-13, 2018-11-15 and 2018-11-17), total quantity is 21.857 ton, mass balance.
The production records were maintained for every time reworks such as label problems, and the batch numbers were clearly marked and recorded to ensure complete traceability, at present, no rework occurred.

5.5 Product packaging

The plastic bag and carton with COA of each lot provided by the supplier.
The assay report was in place including sensory appraisal which refers to specification.
The packaging was released by QC. The plastic film was tested by authority lab about physical & chemical items. Product package is suitable for its intended use.
For obsolete packaging (including labels), control and handling rule was in place, stored obsolete packaging in isolated area and marked clearly, and handling according to control and handling rule.
The COA of plastic bag, No.: W2018045310310620, 2018-05-21, for physical & chemical parameter was well with specification. COC from supplier was available.
At present, not used product contact liners.

5.6 Product inspection and laboratory testing

5.6.1 Product inspection and testing

Documented inspection and analysis standard and sampling plan were in place.
Testing and inspection schedules have been established to ensure specified product requirement were met.
The company had an in-house laboratory to undertake analyses or mandatory inspection by SGS (or other CNAS lab, ISO17025) to confirm product safety, legality and quality, using appropriate procedures, facilities and standards.
The schedules included inspection method, standard, test items, frequency. Incoming raw materials, semi-processing products, finished products, food-contact surface, packaging material had been defined in it.
Inspection result trend analysis was done at least once per month. Reports kept, such as 2018-12-10 dried chicken fillet, 2019-01-09 dried chicken/ minced cowhide.
The system of ongoing shelf life assessment is in place.

5.6.2 Laboratory testing

The lab was designed normally, and separated with product areas and storages. No risk to products.
Pathogen (Salmonella, Staphylococcus aureus) testing was carried out internally and also subcontracted to an external laboratory such as SGS (CNAS accreditation lab based on ISO17025).
The test items main include Sensory, TPC, Coli form, pathogenic bacterium, Pb, As and pesticide residue.
CNAS lab and internal lab used for finished product testing, raw materials testing.
E.g.:
Duck jerky, 2018-08-14, melamine, result is OK, SGS lab.
Duck jerky 2018-08-14, salmonella, result is OK, SGS lab.

Duck jerky, 2018-08-14, Tilmicosin, Trimethoprim, Enrofloxacin, Sulfaclozine and others, results are OK, SGS lab.
Duck jerky, 2018-08-14, As, Pb, Cd, Cr, Hg, AMOZ, SEM, AHD, AOZ, results are OK, SGS lab.
Pet food, 2019-02-03, Drug residue, E.Coli, Salmonella, AFT B1/B2/G1/G2 and others, results are OK, Sino Silliker lab.
Total 8 lab technicians were in its lab.
All of them are suitable trained, and training certificates are maintained on files. The plant conduct contrast test annually, records kept. The last time was conducted on 2018-11-15 for staphylococcus aureus with Liaoning CIQ; on 2018-11-13 for salmonella, TPC, Coliform and E.Coli, with Shandong CIQ, all the results are satisfied.

5.7 Product release

Product quality control procedure was established and in place.
All finished products must be followed this procedure before release.
QA was the authorized person to release product by consideration of result of product analysis such as process control, physical &chemical items, and sensory.

5.8 Pet Food

The site ensure pet food is formulated/designed for the intended use is pet snacks (such as dog and cat).
The site have specific procedures for the management of any ingredients, raw materials, products or rework that could be harmful to unintended recipients.
No pet food contain medicinal substances.

6. Process control

6.1 Control of operations

The company established process control parameters related to food safety and quality.
Operating procedure was established and implemented in order to control all parameters.
Process control parameters were defined for each step, e.g. receiving, process control, weight control, packing and storage.
All critical control points and quality control points were regularly monitored as defined plan. Production and QA supervisors were assigned to verify. Staff who responsible for monitoring process parameters demonstrated their competence from interviewing during on-site assessment, and the equipment settings was only completed by trained and authorised staff. Training records were maintained.
Temperature distribution records were in place such as 1# drying room dated on 2019-03-08.
The procedure to ensure product safety prior to release covering equipment failure and process deviation was established. Details were defined in HACCP Plan. Corrective action records were maintained in case of process deviations.

6.2 Labelling and pack control

Documented checks were carried out at start-up, product changes to ensure all products and packaging from the previous production have been removed from the line before changing to the next production.
There was a system to verify packaging type and labelling before use.
Verified labelling and packaging materials check records were well within specification. According to its production plan, the company verify packaging type and labelling before use, end of production, during production and changing production and check record was in place.
Record retained in place. E.g. 2019-03.

6.3 Quantity, weight, volume and number control

Quantity control system was in place with 100% check by production staff for each package and verified by QC team. Production and QC record of all products were reflected conformity.
The acceptance range of all products was established to ensure compliance with legal, company specification and customer requirement.

Net weight checking, 10 samples are checked at start and end of production and every hour on line QC, records kept, such as 2019-02-13.
Finished products were sampling check as defined frequency in sampling plan for quantity checking compare with the weight declaration on the label.
At present, not used online check scale.

6.4 Calibration and control of measuring and monitoring devices

The calibration control rule was in place and followed.
Thermometers and scale used in process and instrument in lab were calibrated to traceable standards.
All the measuring equipment were calibrated by regulatory agency once a year.
Such as:
Thermometer, XMZ-101, 200602137, valid till 2020-01-01;
Electronic balance, ACS-3/20-3KG, valid till 2019-06-27;
Pressure meter, Hangzhou, (0-1)MPa, 50526653, valid until 2019-06-23.
The internal calibration was taken during operation.
The internal calibration frequency is once a shift and the records were in place, such as 2019-01-31.

7. Personnel

7.1 Training: raw material handling, preparation, processing, packing and storage areas

HR management and training procedure and training plan of 2018-2019 was established for managing the activity of training program to ensure the competent staff and workers.
Training plan was prepared for all staff and all levels. On the job training was conducted by each area.
Orientation training program was provided for new comers that include factory's rule, management policy, food safety/security/quality, personal hygiene and all quality management systems.
Training evaluation system was conducted after end of course in order to ensure their competency for relevant staff with evaluation of training by observing from actual operation, interview or examination.
Training records contain name of trainer, name of trainee, content, training date with duration. Reviewed on the job training for staff who responsible for metal detection, allergen material, and temperature checking, packaging preparation. Training records were in place and staff demonstrated well awareness.
The latest training records were seen for HACCP, CCP training yearly for operators who carry out CCP checks against monitoring procedure HACCP plan on 2018-11-22, and paper exam and operation to verify the effectiveness.
Legal requirements(FSMA) training dated on 2018-09-19; Cleaning training dated on 2018-04-03; Food defence plan training dated on 2019-02-13; Pest control training dated on 2018-08-15; BRC V8 training dated on 2019-02-20; Allergen training dated on 2018-04-02.
However, for some internal courses, the records did refer to the material, work instruction or procedure that is used in the training.
Site's labelling and packing processes training provided for its staffs on 2018-09-26, the training records were in place
Documented training program was scheduled on yearly basis based on training need from each department including refresh training. Specific training or on the job training were provided by admin./General Management based on their description.
Personal performing work affecting product quality, food safety was competent on the basis of appropriate education, training, skill and experience. Routinely reviewing was established and implemented as defined to be training plan.
One minor CAR (against 7.1.6) has been raised in this section, details as "Non-Conformity Summary Sheet".

7.2 Personal hygiene: raw material handling, preparation, processing, packing and storage areas

Documented personal hygiene requirement was established and implemented defined in its PRP.
Compliance with the requirement was daily checked and recorded. False nail was not allowed.

Fingernails must be kept short and unvarnished. Jewellery, watches, ring, perfume were not allowed to use in production area. This company regulation was informed to visitor and contractor before entering to production area which checked by production team leader prior to enter.
Smoking, eating, and drinking were allowed in designated areas only.
Hand washing facilities including liquid soap, hand drier, alcohol disinfection and washing instruction with appropriate language was sufficiency provided at every access point.
If wounded, use the plaster. The plasters were suitable, blue and contained a metal detectable strip, and verified by MD.
Personal medicines could be kept in locker only.

7.3 Medical screening

Medical screening procedure was defined and implemented for all staff and visitors.
Medical checking including stool examination was provided once a year for existing staff and health questionnaire was provided for visitors and subcontractors. Refer to procedure. Medical checking cards were kept, such as 0041596/ 0047842/ 0049132, all in valid condition.
A system for the notification by employees, including temporary employees, of any relevant infection or disease was established and maintained. Employees must notify their supervisor about illness.
Questionnaire for medical screening was provided for all visitors. During the audit, auditors have been questioned for medical screening and monitored. Reviewed medical checking program including physical check and stool culture of staff, found effectiveness of implementation.
Medical screening procedure defined communication to staff by training and others such as visitor through questionnaires.
In case of infectious disease, staff was moved to work in low risk area and re-screening was required.

7.4 Protective clothing: employees or visitors to production areas

The rules regarding the wearing of protective clothing in specified work areas were document and communicate to all employees, contractors or visitors.
Suitable protective clothing provided for all workers/ visitors/ contractors. Normally, every worker has 2 suits. Laundering of protective clothing taken place by in-house washing room; the frequency of cleaning was defined as daily. Protective clothing washing and disinfecting records were kept on files.
Swab test for the protective clothing was conducted every week.
Gloves procedure were in place, the glove is disposable, changed every shift or when broken.
For the personal protective clothing that are not suitable for laundering are provided (such as shoes), special person will brush them and will disinfect them with NaClO.

Details of non-applicable clauses with justification

Clause/section reference	Justification
3.5.1.5	No agents or brokers used.
3.5.2.3	No live animal received.
3.5.4.1~3.5.4.4	No outsourced processing and packing.
4.2.2	The raw materials and products are not particular risk via analysed.
4.3.5	No temporary structures constructed
4.9.1.2	No strongly scented or taint-forming materials used
4.9.4.1~4.9.4.3	No products packed into glass or other brittle containers.
4.10.2	No filters and sieves were used in the site.

4.10.4	No magnets used.
4.10.5	Not used optical sorting equipment.
4.11.7	No CIP cleaning system was in place.
4.12.1	Licensing for the removal of waste isn't required by law
4.12.3	No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal.
4.13.1	At present, No surplus customer-branded products.
4.13.2	At present, No customer-branded products.
4.15.3	No controlled temperature is required.
4.15.4	No controlled atmosphere is required.
4.15.5	No outside storage.
5.2.3	No claims made to satisfy a consumer group.
5.3.6	No allergen cross contamination risks.
5.4.4	No claims made on finished products which are dependent on a status of the raw material.
5.4.5	No claims made about the methods of production.
6.1.4	No in-line monitoring devices in place.
6.2.4	No online verification equipment.
6.3.2	No bulk quantities packed.
8	For its products, not high risk/high care/ ambient care requirements.
9	No Traded Products.

8. High-Risk, High-Care and Ambient High-Care Production Risk Zones
8.1 Layout product flow and segregation in high-risk, high-care and ambient high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.
8.2 Building fabric in high-risk and high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.
8.3 Maintenance in high-risk and high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.

8.4 Staff facilities for high-risk and high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.
8.5 Housekeeping and hygiene in the high-risk high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.
8.6 Waste/Waste disposal in high risk, high care zones
N/A, For its products, not high risk/high care/ ambient care requirements.
8.7 Protective clothing in the high-risk high-care zones
N/A, For its products, not high risk/high care/ ambient care requirements.

9 - Traded Products
9.1 Approval and performance monitoring of manufacturers/packers of traded food products
N/A. No Traded Products.
9.2 Specifications
N/A. No Traded Products.
9.3 Product inspection and laboratory testing
N/A. No Traded Products.
9.4 Product legality
N/A. No Traded Products.
9.5 Traceability
N/A. No Traded Products.

CONFIDENTIAL

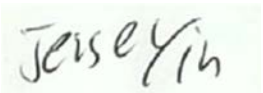
Gap Assessment Audit

Food Safety Modernization Act (FSMA)

Report Date: 23/03/2019

Facility Name	**Yantai Hao's Pet Food Tech. Co., Ltd.**
Facility identifier (if designated by FDA)	N/A
FDA registration number (if applicable)	12149111738.
Address	No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City, Shandong Province
City	Yantai
Postcode	264003
Country	China
Key Contact Name	Zhang Yunnuan
Key Contact E-mail	catherine@wanpy.com.cn
Key Contact Phone number	0086 535 6727937
Auditor acknowledgement (Required for Certification audits Stage 1 and Stage 2)	I hereby acknowledge that I have signed the mandatory conflict of interest & notification statement before being assigned to audit this

	facility. Name: N/A, this is Gap Assessment. Sign: N/A, this is Gap Assessment.

Scheme Reference:	☒ **FSMA PREVENTIVE CONTROLS FOR ANIMAL FOOD (21 CFR 507)**		
Client Representative:	Mrs. Lifeng YU	**Site Preventive Controls Qualify Individual (PCQI):**	Mrs. Shaoyuan Sui (SGS/CN/TAO/PT-18023/014)
Date(s) of audit:	2019-03-22_23	**Total Days on-site**	2
No. of Employees:	FTE:400 Other:/	**No. of Shifts:**	1
Lead auditor:	Jesse YIN 	**Additional audit team member(s):**	/
Scope of audit:	Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.		
Which subparts are covered in this audit?	☐ **Certification Audit: (For FSMA certification audits, all applicable rules, subparts & regulations should be covered)** **Other audit:** ☒ Subpart B (Good Manufacturing Practices) ☒ Subpart C (Hazard Analysis & Preventive Controls) ☒ Subpart E (Supply chain program) ☒ Subpart F (Requirements applying to Records) ☒ Other applicable FDA regulation(s) (if covered by the audit)		
Exclusions from Scope / Exemptions	None		
Description of Organisation	Yantai Hao's Pet Food Tech. Co., Ltd. was a joint venture company, which was established in 1999, located at No. 16 Puchang Road, Laishan Economic Development Zone, and Yantai City, Shandong Province, China. There was one workshop and about 400 contracted staffs in the plant. QCs were 7 persons who take over the quality inspection during the production. There was 1 shift per day, about 8 hours (expect drying room, 3 shifts, 8 hours per shift) and 6 days per week. The output of a year was about 3000 ton and main products are exported to North America and Europe. At present, the company holds ISO22000, ISO9001, ISO14001 and MSC certificate.		

Is the facility registered with FDA?	☒ Yes	☐No

Is the facility a US importer under FSVP?	☒ Yes ☐No
Any sampling and laboratory analysis (e.g., under a microbiological sampling plan) used in the facility?	☒ Yes ☐No
Within the past 2 years, has the facility issued a food safety recall? If yes, explain in section 507.38 of the report.	☐ Yes ☒No
Are there any pending/recent FDA compliance actions?	☐ Yes ☒No
Does the facility hold a valid existing GFSI or ISO 22000 Certification(s)?	☒ Yes BRC Food Certificate, No.: CN14/21490, scope: Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles. ☐No

1. AUDIT OBJECTIVES

- The following report contains a summary and results of the FSMA Gap assessment as carried out by SGS.
- The following report contains a summary and results of the FSMA PC Human Food Gap Assessment as carried out by SGS.
- Details of all findings / nonconformities are documented in the following pages. Due to the sampling nature of auditing, the absence of a finding / nonconformity in any given area does not imply that no deficiency exists.
-

2. AUDIT ATTENDANCE RECORD – (OPENING, SITE AUDIT, CLOSING)

Name	Position	Opening	Site Audit	Closing
Liu Yan	Plant manager	Y	Y	Y
Yu Lifeng	QC Manager	Y	Y	Y
Liu Chunna	Purchase Manager	Y	Y	Y
Shao Yan	Trade	Y	Y	Y
Sui Shaoyuan	QC	Y	Y	Y
Yu Xiaofei	QC	Y	Y	Y

3. AUDIT FINDINGS

• The food safety system documentation and records demonstrated conformity with the requirements of the regulation(s) and provided sufficient structure to support implementation and maintenance of the food safety system.	YES
• The organization has demonstrated effective implementation and maintenance / improvement of its food safety system.	YES
• Preventive Controls have been established and managed adequately.	YES
• Qualifications and training requirements have been implemented effectively.	YES
• Recall processes have been established and are adequate.	YES
• Throughout the audit process, the food safety system demonstrated overall compliance with the requirements of the regulation(s).	YES

4. SIGNIFICANT AUDIT TRAILS FOLLOWED

The specific processes, activities and functions reviewed are detailed in the Audit Planning Matrix and the Audit Plan. In performing the audit, various audit trails and linkages were developed, including the following primary audit trails that were followed throughout the audit:

Drying rooms were improved in 2018, no other major changes in the past 2 years.

Process overview:

There was effective segregation to minimise the risk of product contamination.
The plan of the site which designates areas including low risk areas and enclosed areas; the raw material and finished product storages and chemical storage were defined as enclosed areas; the other areas were defined as low risk areas.
Working space and storage was sufficient to enable operations to be carried out properly under safe hygienic conditions.
The process flow from intake to dispatch was arranged well to minimise the risk of product contamination.
Physical barriers were in place to minimise the risk of the contamination of raw materials, packaging, finished products and different processes.
Segregation considered the flow of product, nature of materials, equipment.
Facilities for tray and utensil washing are segregated from production activities. There was no contamination finding during the audit on site.
One minor CAR raised in this section:
Inspection of glass and breakable materials in open product areas and enclosed areas is conducted weekly. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily

The equipment was suitably designed for the intended purpose.
The machines, such as cutting machine, tumbling machines, drying rooms, MD were made from stainless steel and plastic.
Certificate indicated food safety compliance with legal requirements.
The specification of machine would be specified in purchasing order. The machine would be tested and commissioned prior used. Commissioning reports would be performed effectiveness of implementation.
If new equipment purchased, the commissioning report will be in place done by equipment producer.

Toxic Substances were stored in the chemical warehouse properly and locked in the workshop.
Chemicals MSDS(s) in place.

The company was responsible for minimising the risk of pest infestation on the site. The pest control procedure was established and implemented.
The company was responsible for minimising the risk of pest infestation on the site.
The pest control work was conducted by service supplier-Yantai Aojie Biological Technical Co., Ltd. (contact until 2021-03-03), the certificate of the PCO can be available, weekly inspection, related work records in place; and treatment of the site to deter and eradicate infestation.
Fly killers and glue boards were used for in house treating; Traps and bait station were used in external environment.
Fly killer light bulbs were changed every year.
Suitable measures were in place to prevent birds from entering buildings or roosting above loading or unloading areas, and no roosting in factory area during site tour.
Check records of pest control were in place, e.g. 2018-08-21, 2019-02-21 and 2019-03-07.
One minor CAR raised in this section:
There is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory.

Utilities are properly designed and maintained in normal condition.
The processing used water used on site is from main water.
The quality of water that is incorporated into products as ingredients and comes in direct or indirect contact with food or packing is monitored as bellows:
By contracted Lab once a year.
By internal Lab, Sensory: colour, appearance, odor, TPC, coliform, weekly checking.
Water distribution plan is in place. Records that related to treatment activity were maintained.
Annually testing of in-process water that covering chemical, microbiological is in place as test report (report no. No. QDF19-003765-01) done on 2019-02-20 by external laboratory Qingdao SGS Test Co., Ltd. (ISO17025, CNAS L0604) . The results meet GB5749-2006.

Waste management system was in place.
The sewage system is discharged into municipal wastewater treatment network system, and the water shall be handled by the local water treatment company.

The calibration control rule was in place and followed.
Thermometers and scale used in process and instrument in lab were calibrated to traceable standards.
All the measuring equipment were calibrated by regulatory agency once a year.
Such as:
Thermometer, XMZ-101, 200602137, valid till 2020-01-01;
Electronic balance, ACS-3/20-3KG, valid till 2019-06-27;
Pressure meter, Hangzhou, (0-1)MPa, 50526653, valid until 2019-06-23.
The internal calibration was taken during operation.
The internal calibration frequency is once a shift and the records were in place, such as 2019-01-31.

The company established process control parameters related to food safety and quality.
Operating procedure was established and implemented in order to control all parameters.
Process control parameters were defined for each step, e.g. receiving, process control, weight control, packing and storage.
All critical control points and quality control points were regularly monitored as defined plan. Production and QA supervisors were assigned to verify. Staff who responsible for monitoring process parameters demonstrated their competence from interviewing during on-site assessment, and the equipment settings was only completed by trained and authorised staff. Training records were maintained.
Temperature distribution records were in place such as 1# drying room dated on 2019-03-08.
The procedure to ensure product safety prior to release covering equipment failure and process deviation was established. Details were defined in HACCP Plan. Corrective action records were maintained in case of process deviations.

Procedure to maintain product safety and quality during loading and transportation developed on the basis of risk assessment and implemented accordingly.
Transport requirements with the logistics company were clearly defined in the contract.
The batch number of products was records during dispatching.
Documented maintenance and hygiene procedures were maintained for all vehicles and equipment used for loading/unloading. The vehicle inspection before loading and unloading was conducted by storage person. The inspection item: cleanness, foreign bodies, odour and other. Products deliver check records can be available.
The service transport supplier was approved, and contract is valid.
The products are ambient. Finished products were shipped in dry container. The loading record can be available. E.g. 2018-12-18.
The container and vehicle control procedure were in place.
The truck driver or storage employee will inform responsibility personnel at once and the responsibility personnel will assess the product. The decision was based on result of the assessment.
During audit, the loading was in normal condition.

2 PCQI Certificates (Mrs. Lifeng Yu, Shaoyuan Sui) are in place.
Food safety plan (HS-FSP-01 3.0) for dried pet food includes process preventive control measures, sanitation preventive control measures, Supplier preventive control plan, recall plan, record-keeping procedure etc.
Incoming raw materials/ ingredients receiving- storing- defrosting-cutting or tumbling- moulding- shaping- drying/ sterilization- cooling- off net- cutting (when needed) - selecting- metal detecting- packing- sterilization (when needed) - inspecting- storing-irradiating-delivery.
The flow diagrams were verified on site by HACCP teams and were signed off on 2019-02-25_28.
No subcontracting
Hazard analysis was conducted.
5 PCs were defined.
Monitoring
PC1: raw materials receiving, Raw duck incoming date 2019-01-12, COA was issued by Linyi Liuhe Hongchen, report No. 2019011201, drug residues were tested, the result is satisfied; Animal inspection certificate (No. 3753585466).
PC2: Sterilization, lamb meat rolled on dried fish fillet dated on 2018-12-05, temperature ≥90℃, duration 30 minutes.
PC3: Metal detection, dated on 2018-12-06, product name dried chicken, calibration time from 08:10 ~ 10:00, Fe φ 1.5mm, Susφ 1.5mm, Non-Fe 1.5mm.
"PC4: Sanitation control in 6 processes - cooling, shelf removal, selection, gold detection, weighing, packaging. 2019-02, 2018-10."
"PC5: Supply chain management in 2 processes - raw materials supplier supervision, irradiation

2018-12, 2019-03."
However, one minor CAR raised in this section:
The transport agreement does not clearly define service expectations of the potential food safety risks associated with the service.

Corrective action and corrections defined.

The verification activities were documented in the validation and verification control procedure.

Validation and verification control procedure was established.
"Control measure combination (e.g. FSP, PRP, and OPRP) was reviewed by PCQI Ms. Lifeng Yu.
Validation date 2019-03-19."

Recall and withdrawal control procedure (HS-CX-22) was in place.
"The recall and withdrawal procedure (Doc. HS-CX-22) is in place that contained handing method and responsible person of each stage.
Classifications of product recall.
The list of key contacts, e.g. suppliers, client, certification body is in place.
Communication plan was defined in the procedure.
The product recall and withdrawal procedures are tested once annually."
No food recalled within the past 2 years.
"The product recall and withdrawal procedures are tested once annually.
The last withdraw test was conducted on 2018-10-16, for dried duck (batch no. K289AG4C11, 7402.984 kg), mock cause was foreign body problem. Records (including input and issue warehouse record, inventory record, handling records) were remained and mock recall rate was 100%,within 2 hours.
"
Purchase Control procedure (HS-CX-12) and Supplier select and assessment procedure (HS-CX-25) in place.
"Purchase Control procedure (HS-CX-12) and Supplier select and assessment procedure (HS-CX-25) in place.

"Supplier control measures were defined in procedure.
Only qualified suppliers can be used for purchase, such as for duck, chicken."
Every batch raw materials and other ingredients were sampled and tested as a supplier verification activity. COA and other food safety certification materials were received by QC. Sample: Refer to the audit trails.

"On-site verification found all raw materials and other ingredients including service were purchased only from approved suppliers.
The qualified supplier list was in place."
Raw materials safety control procedure (HS-CX-17) for raw material and other ingredients, which defined the details about the monitoring items based on risk assessment.

"Supplier select and assessment procedure (HS-CX-25) was in place and implemented well.
Supplier performance evaluation was conducted once yearly and the records were maintained.
Every batch raw materials and other ingredients were sampled and tested as a supplier verification activity. COA and other food safety certification materials were received by QC."
"The type test report for raw material or other ingredient was required at least once every year.
The qualified test lab was selected by organization."
When a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans , onsite audits as verification activity was required at least once every year. Such as corn, soybean supplier.

"Mrs. Lifeng YU is the QC manager of company and attended the FSPCA FSMA training course. She also attended the ISO22000/BRC/ ISO9001/HACCP etc. food safety course.
Purchase manager or account staff also attend this assessment with the QC manager."
Annual assessment report for supplier in 2018 was checked.
Supplier select and assessment procedure (HS-CX-25) was in place and implemented well.

"Record control procedure (HS-CX-02) was established.

All applicable records could be established and maintained well."
"Auditor onsite sampled the production and quality records and confirmed the records include all the required information.
Batch No. of audited products were sampled to test the traceability effectiveness and the related process PC and monitoring records were verified as per FSP."

FSP was approved by Vice GM-Mr. Jiang Yishan (江移山) and dated 2018-11-15.

"Record control procedure (Doc. HS-CX-02) was established.
The requirement of collation, review, maintenance, storage and retrieval of records were defined in it. Records were kept at least 3 years (shelf life 18-24 months). And the list of quality record was in place.
During audit, record observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.

5. OTHER FDA REGULATIONS COVERED

No.	Title
21CFR…	n/a
…	

6. AUDIT FINDINGS & OPPORTUNITIES FOR IMPROVEMENT

No.	Clause	Commentary
1	507.19(e)	There is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory. 厂区杀虫剂使用记录中没有记录杀虫剂浓度、使用量、喷洒面积等信息。
2	507.25(b)	Inspection of glass and breakable materials in open product areas and enclosed areas is conducted weekly. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily. 工厂对开放产品区域和封闭区域的玻璃和易碎品材料检查频率均为每周，基于风险分析，对于开放区域内物料/产品上方的玻璃和易碎品检查是不够的，应该为每天。
3	507.34(b)	The transport agreement does not clearly define service expectations of the potential food safety risks associated with the service. 运输协议中没有清晰定义服务过程中潜在的食品安全风险的期望。

Reviewed and Accepted by:	Jesse YIN	**Date:**	2019-03-23

7. TRAINING NEEDS

Competency gaps identified during the audit
/

8. AUDIT RESULTS & CONCLUSIONS

SUBPART B: CURRENT GOOD MANUFACTURING PRACTICES (CGMP) Choose an item.

Provide a response for each requirement below		
507.14	**Personnel**	
(a)	Disease control includes employees and visitors.	Conformance **Yes**
	Notes: Disease control includes employees and visitors policy is in place. Medical screening procedure was defined and implemented for all staff and visitors. Medical checking including stool examination was provided once a year for existing staff and health questionnaire was provided for visitors and subcontractors. Refer to procedure. Medical checking cards were kept, such as 0041596/ 0047842/ 0049132, all in valid condition. A system for the notification by employees, including temporary employees, of any relevant infection or disease was established and maintained. Employees must notify their supervisor about illness. Questionnaire for medical screening was provided for all visitors. During the audit, auditors have been questioned for medical screening and monitored. Reviewed medical checking program including physical check and stool culture of staff, found effectiveness of implementation. Medical screening procedure defined communication to staff by training and others such as visitor through questionnaires. In case of infectious disease, staff was moved to work in low risk area and re-screening was required.	
(b)	Methods of maintaining personal cleanliness	Conformance **Yes**
	Notes: Documented personal hygiene requirement was established and implemented defined in its PRP. Compliance with the requirement was daily checked and recorded. False nail was not allowed. Fingernails must be kept short and unvarnished. Jewellery, watches, ring, perfume were not allowed to use in production area. This company regulation was informed to visitor and contractor before entering to production area which checked by production team leader prior to enter. Smoking, eating, and drinking were allowed in designated areas only. Hand washing facilities including liquid soap, hand drier, alcohol disinfection and washing instruction with appropriate language was sufficiency provided at every access point. If wounded, use the plaster. The plasters were suitable, blue and contained a metal detectable strip, and verified by MD. Personal medicines could be kept in locker only.	
507.17	**Plant and Ground**	
(a)	Maintenance of grounds	Conformance **Yes**
	Notes: Grounds is maintained well.	
(b)	Plant construction and design	Conformance **Yes**
	Notes: There was effective segregation to minimise the risk of product contamination. The plan of the site which designates areas including low risk areas and enclosed areas; the raw material and finished product storages and chemical storage were defined as enclosed areas; the other areas were defined as low risk areas.	

	Working space and storage was sufficient to enable operations to be carried out properly under safe hygienic conditions. The process flow from intake to dispatch was arranged well to minimise the risk of product contamination. Physical barriers were in place to minimise the risk of the contamination of raw materials, packaging, finished products and different processes. Segregation considered the flow of product, nature of materials, equipment. Facilities for tray and utensil washing are segregated from production activities. There was no contamination finding during the audit on site.	
507.19	**Sanitary Operations**	
(a)	Buildings, fixtures, and other physical facilities of the plant maintained in a clean and sanitary condition and kept in adequate repair; cleaning and sanitizing of utensils and equipment is conducted properly	Conformance **Yes**
	Notes: The fabrication of the site, buildings and facilities were suitable for its products process. Walls were designed, constructed, finished and maintained could be accepted. Floors were in normal acceptable condition. Drainage was sited, designed and maintained to minimise risk of product contamination. The ceilings were designed, constructed, finished and maintained well. Adequate access to the ceiling was provided. Cleaning and maintenance of false ceiling were scheduled. Windows were designed can be accepted. The windows in process and warehouse were shielded with film to avoid the contamination with the food when the windows are broken. The doors and dock levellers in these areas were close fitting or adequately proofed. Doors were in acceptable condition and easy to clean. The lightings were adequate in the areas. All bulbs and strip lights, including those on electric fly-killer devices were adequately protected. Fans were used in processing area, they were maintained well. Positive air was needless for its products.	
(b)	Animal food-contact and non-contact surfaces of utensils and equipment cleanable and maintained. Utensils and equipment stored as necessary to protect against the contamination of animal food, animal food-contact surfaces, or animal food-packaging materials. PET FOOD Only: Pathogen Free Cleaning: PRODUCTION ANIMAL: Flushing or Sequencing Method:	Conformance **Yes**
	Notes: The equipment was suitably designed for the intended purpose. The machines, such as cutting machine, tumbling machines, drying rooms, MD were made from stainless steel and plastic. Certificate indicated food safety compliance with legal requirements. The specification of machine would be specified in purchasing order. The machine would be tested and commissioned prior used. Commissioning reports would be performed effectiveness of implementation. If new equipment purchased, the commissioning report will be in place done by equipment producer.	
(c)	Cleaning Compounds must be safe and adequate under conditions of use	Conformance **Yes**
	Notes: A chemical control procedure was in place managing the using, storage and handling of non-food chemicals. And the chemicals were stored in separated room, relevant MSDSs, testing reports and approved chemicals list was in place. The designated staffs are responsible for storage, mixed, and use. Records were kept and specified the	

	responsible staffs as well as the date and the concentration. Approved chemical list was available for review, main included soap liquid, food grade alcohol (COC, 2018-06-29 based on GB 10343-2008), food grade NaClO (COC, 2018-04-03 based on GBT19106-2013 A) and lab chemicals. Washing liquid, alcohol COA was in place.	
(d)	Toxic Substances stored properly	Conformance **Yes**
	Notes: Toxic Substances were stored in the chemical warehouse properly and locked in the workshop. Chemicals MSDS(s) in place.	
(e)	Pest Control	Conformance **No**
	Notes: The company was responsible for minimising the risk of pest infestation on the site. The pest control procedure was established and implemented. The company was responsible for minimising the risk of pest infestation on the site. The pest control work was conducted by service supplier-Yantai Aojie Biological Technical Co., Ltd. (contact until 2021-03-03), the certificate of the PCO can be available, weekly inspection, related work records in place; and treatment of the site to deter and eradicate infestation. Fly killers and glue boards were used for in house treating; Traps and bait station were used in external environment. Fly killer light bulbs were changed every year. Suitable measures were in place to prevent birds from entering buildings or roosting above loading or unloading areas, and no roosting in factory area during site tour. Check records of pest control were in place, e.g. 2018-08-21, 2019-02-21 and 2019-03-07. **One minor CAR raised in this section:** **There is no information about pesticide concentration, usage and spraying area in the pesticide application record of the factory.** 厂区杀虫剂使用记录中没有记录杀虫剂浓度、使用量、喷洒面积等信息。	
507.20	**Sanitary facilities and controls**	
(a)	Water supply	Conformance **Yes**
	Notes: Utilities are properly designed and maintained in normal condition. The processing used water used on site is from main water. The quality of water that is incorporated into products as ingredients and comes in direct or indirect contact with food or packing is monitored as bellows: By contracted Lab once a year. By internal Lab, Sensory: color, appearance, odor, TPC, coliform, weekly checking. Water distribution plan is in place. Records that related to treatment activity were maintained. Annually testing of in-process water that covering chemical, microbiological is in place as test report (report no. No. QDF19-003765-01) done on 2019-02-20 by external laboratory Qingdao SGS Test Co., Ltd. (ISO17025, CNAS L0604) . The results meet GB5749-2006.	
(b)	Plumbing	Conformance **Yes**
	Notes: Well designed, and clear marked.	
(c)	Adequate sewerage system	Conformance **Yes**

	Notes: Waste management system was in place. The sewage system is discharged into municipal wastewater treatment network system, and the water shall be handled by the local water treatment company.	
(d)	Adequate, readily accessible toilet facilities and kept cleaned	Conformance **Yes**
	Notes: The toilet was isolated from the workshop and necessary facilities were provided and controlled by hygiene pilot.	
(e)	Hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature	Conformance **Yes**
	Notes: The hand washing station was provided and monitored and equipped with sufficient and temper water where posted the hand washing advisory signs. The hand washing and protective clothes cleaning effectiveness were verified by visual check.	
(f)	Rubbish and offal conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests	Conformance **Yes**
	Notes: Waste disposal procedure was established and implemented. Some waste of raw materials is sold to use for feed and they were segregated from other waste. Others disposed by local authorities. External waste collection containers are managed well to minimise risk. External waste collection containers are managed well to minimise risk. The wastes were removed by approved service supplier and the contract was maintained. No unsafe products or substandard trademarked materials are transferred to a third party for destruction or disposal. Its waste package materials were sold, the packing with trademark of customer will be destroyed before the sale.	
507.22	**Equipment and utensils**	
(a)	Equipment and utensils	Conformance **Yes**
	Notes: The equipment was suitably designed for the intended purpose. The machines, such as cutting machine, tumbling machines, drying rooms, MD were made from stainless steel and plastic. Certificate indicated food safety compliance with legal requirements. The specification of machine would be specified in purchasing order. The machine would be tested and commissioned prior used. Commissioning reports would be performed effectiveness of implementation. If new equipment purchased, the commissioning report will be in place done by equipment producer.	
(b)	Holding, conveying, manufacturing, and processing systems, including gravimetric, pneumatic, closed, and automated systems, must be designed, constructed, and maintained in away to protect against the contamination of animal food.	Conformance **Yes**
	Notes: Preventive maintenance, breakdown maintenance procedure and new machine commissioning procedure are established and implemented. The machine and equipment used for production process and utilities are determined in preventive maintenance plan (2019, HS04-02-37). Maintenance was done by engineer as preventive maintenance plan. Maintenance records were maintained, such as sealing machine 2019-03-01, tumbler 2019-03-01.	

	Documented hygiene inspection on start-up completed by production supervisors. The equipment inventory was established and the maintenance was carried out if the equipment cannot work normally and the maintenance records were maintained on file. The maintenance staffs were available in the facility and the special certificates were kept on files. On site checked no found temporary repair in the production areas. Hygiene clearance procedure is established to prevent contamination due to maintenance, e.g. personal hygiene policy for maintenance staff and subcontractor, line cleaning and clearance after maintenance. Food grade lubricant (NSF H1, 111102) used, no allergen. No major breakdowns in last 12 months. Engineering workshops was located on outside production area to prevent contamination risks to the product and maintained well.	
(c)	Freezer and cold storage compartment fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device.	Conformance **Yes**
	Notes: Raw materials should be kept in cold storage, temperature should below -18℃, for its cold storage, QC test and recorded the storage temperature by handheld thermometer at least every 4 hours, and records were in place, such as 2018-10.	
(d)	Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity etc. are accurate, precise, adequately maintained, adequate in number	Conformance **Yes**
	Notes: The calibration control rule was in place and followed. Thermometers and scale used in process and instrument in lab were calibrated to traceable standards. All the measuring equipment were calibrated by regulatory agency once a year. Such as: Thermometer, XMZ-101, 200602137, valid till 2020-01-01; Electronic balance, ACS-3/20-3KG, valid till 2019-06-27; Pressure meter, Hangzhou, (0-1)MPa, 50526653, valid until 2019-06-23. The internal calibration was taken during operation. The internal calibration frequency is once a shift and the records were in place, such as 2019-01-31.	
507.25	**Plant operations**	
(a)	General	Conformance **No**
	Notes: The company established process control parameters related to food safety and quality. Operating procedure was established and implemented in order to control all parameters. **One minor CAR raised in this section:** **Inspection of glass and breakable materials in open product areas and enclosed areas is conducted weekly. Based on risk analysis, the inspection frequency of glass and breakable materials above materials/products in open areas is not sufficient, it shall be carried out daily.** 工厂对开放产品区域和封闭区域的玻璃和易碎品材料检查频率均为每周，基于风险分析，对于开放区域内物料/产品上方的玻璃和易碎品检查是不够的，应该为每天。	
(b)	Raw materials and other ingredients	Conformance **Yes**
	Notes: The documented purchasing control procedure (Doc. HS-CX-12, HS-CX-25) based on risk assessment was in place. The supplier review was carried out by purchasing Dept. and QC Dept. effectively. The	

	grades of suppliers were defined according to the risk of affecting products and onsite audit or questionnaire investigation methods were defined. The documented risk assessment of each raw materials including foreign body risks, microbiological and chemical contamination, variety or species cross-contamination, legislative control and substitution were in place in the facility and it was updated and reviewed annually. The last assessment was conducted 2019-03-01 and the records were maintained. Supplier monitoring and evaluation included in purchasing control procedure. Supplier performance/ monitoring is evaluated on every 12 months and summarized for supplier communication. Primary production control is appropriately controlled based on risk assessment such as on site verification, or questionnaire updating that reissued at least three years. Approved suppliers were registered in approved supplier list. The frequency of supplier evaluation was conducted once a year, the supplier audit is not completed by a second or third party. Evaluation records were in place. Sample: Frozen chicken supplier named Dacheng Food (Dalian) Co., Ltd., Business licenses, COC (No.: GMAAK2HX66208501, 2018-04-02). Frozen chicken supplier named Fuxin A&F Development Co., Ltd. Business licenses, COC (No.: A2180147475101001CAR2, 2018-09-21). Garlic powder supplier named Beijing Weitenong Biological Technical Development Co., Ltd. Business licenses, COC (No.: GMAZIOJK46377505). Frozen carrot supplier named Laiyang Huatai Food Co., Ltd. Business licenses, COC (No.: 19022-W2, 2019-02-24). Desoxidant supplier named Jiangsu Oukai Packing Technical Co., Ltd. Business licenses, COC (No.: HG180913-35, 2018-09-13). Packaging supplier named Dalian Rongguan Packing Co., Ltd., Business licenses, COC (No.: W2018045310310620, 2018-05-21). For all suppliers, the relevant certificates or licenses required by authorization were collected and reviewed once a year. At present, raw materials and other materials are not purchased from agents or brokers The trail will be done when they cooperate with new supplier or purchase new material. If there are changes or amendments to the documents, the reasons will be recorded. Some exceptions (such as any supplier was prescribed by client) have been described in procedure. The original supplier label and product received were verified through the warehouse storage area for onsite evidence check and records of receiving and dispatch were also verified. COCs were available. Product inspection and test procedure is established and implemented. The parameters for acceptance, approved changes to raw materials and frequency of testing are clearly defined in it. The received materials are verified by authorized person such as QC and store staff prior to receive. The status of passed test material is identified in tag identification for each material for communication with related functions. And intake records inspected during audit. Verified incoming materials receiving on 2019-01-25(frozen chicken), 2018-08-18 (duck), 2019-03-04 (garlic powder), 2019-01-16 (mycose), 2019-03-14 (desoxidant).	
(c)	Manufacturing operations	Conformance **Yes**
	Notes: Process control parameters were defined for each step, e.g. receiving, process control, weight control, packing and storage. All critical control points and quality control points were regularly monitored as defined plan. Production and QA supervisors were assigned to verify. Staff who responsible for monitoring process parameters demonstrated their competence from interviewing during on-site assessment, and the equipment settings was only completed by trained and authorised staff. Training records were maintained. Temperature distribution records were in place such as 1# drying room dated on 2019-03-08.	

	The procedure to ensure product safety prior to release covering equipment failure and process deviation was established. Details were defined in HACCP Plan. Corrective action records were maintained in case of process deviations.	
507.27	**Holding and distribution**	
	Holding and transportation	Conformance **Yes**
	Notes: Procedure to maintain product safety and quality during loading and transportation developed on the basis of risk assessment and implemented accordingly. Transport requirements with the logistics company were clearly defined in the contract. The batch number of products was records during dispatching. Documented maintenance and hygiene procedures were maintained for all vehicles and equipment used for loading/unloading. The vehicle inspection before loading and unloading was conducted by storage person. The inspection item: cleanness, foreign bodies, odour and other. Products deliver check records can be available. The service transport supplier was approved, and contract is valid. The products are ambient. Finished products were shipped in dry container. The loading record can be available. E.g. 2018-12-18. The container and vehicle control procedure were in place. The truck driver or storage employee will inform responsibility personnel at once and the responsibility personnel will assess the product. The decision was based on result of the assessment. During audit, the loading was in normal condition.	
507.28	**Holding and distribution of human food by-products for use as animal food**	
	Condition of **Holding and distribution of human food by-products for use as animal food**	Conformance **Not Applicable**
	Notes: No human food by-products for use as animal food.	
	Labelling and identification	Conformance **Not Applicable**
	Notes: No human food by-products for use as animal food.	
	Shipping containers and bulk vehicles	Conformance **Not Applicable**
	Notes: No human food by-products for use as animal food.	

SUBPART C—HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS Choose an item.

507.31	**Food Safety Plan [FSP]**	
(a)	Requirement for a food safety plan met? • Written FSP and implemented	Conformance **Yes**
	Notes: Food safety plan (HS-FSP-01 3.0) for dried pet food includes process preventive control measures, sanitation preventive control measures, Supplier preventive control plan, recall plan, record-keeping procedure etc.	
(b)	One or more preventive controls qualified individuals must prepare, or oversee the preparation of, the food safety plan.	Conformance **Yes**
	Notes: 2 PCQI Certificates (Mrs. Lifeng Yu, Shaoyuan Sui) are in place.	
507.33	**Hazard analysis**	
(a)	Requirement for a hazard analysis met?	Conformance **Yes**
	Notes: Food safety plan (HS-FSP-01 3.0) for dried pet food	
(b)	Hazard identification consider known or reasonably foreseeable hazards which could occur naturally, unintentionally introduced or intentionally introduced for purposes of economic gain; Hazards include: • Biological hazards • Chemical hazards, including radiological hazards • Physical hazards	Conformance **Yes**
	Notes: Food safety plan (HS-FSP-01 3.0) for dried pet foods Hazard Analysis is to consider the effect of the following: • Formulation • Facility and Equipment Design • Raw Materials • Transportation • Manufacturing • Packaging & Labeling • Storage & Distribution • Intended Use • Sanitation/ Employee Hygiene	
(c)	Hazard evaluation adequate?	Conformance **Yes**
	Notes: Hazard Evaluation must consider the effect of the following on the safety of the animal food for the intended animal. For Production Animals-Hazard Evaluation is to be on the applicable animal that is intended to be fed	

	and the transfer of risks through. For Pet Animals- Hazard Evaluation is to be on the applicable animal that is intended to be fed and the transfer of risks through Humans feeding animals particularly Salmonella.	
507.34	**Preventive Controls**	
(a)	**Is the facility required to have Preventive Controls?**	Conformance **No**
	Notes: 5 PCs were defined. PC1: raw materials receiving, Raw duck incoming date 2019-01-12, COA was issued by Linyi Liuhe Hongchen, report No. 2019011201, drug residues were tested, the result is satisfied; Animal inspection certificate (No. 3753585466). PC2: Sterilization, lamb meat rolled on dried fish fillet dated on 2018-12-05, temperature ≥90℃, duration 30 minutes. PC3: Metal detection, dated on 2018-12-06, product name dried chicken, calibration time from 08:10 ~ 10:00, Fe φ 1.5mm, Susφ 1.5mm, Non-Fe 1.5mm. "PC4: Sanitation control in 6 processes - cooling, shelf removal, selection, gold detection, weighing, packaging. 2019-02, 2018-10." "PC5: Supply chain management in 2 processes - raw materials supplier supervision, irradiation 2018-12, 2019-03." **However, one minor CAR raised in this section:** **The transport agreement does not clearly define service expectations of the potential food safety risks associated with the service.** 运输协议中没有清晰定义服务过程中潜在的食品安全风险的期望。	
(b)	**If the facility determines that preventive controls are not required, is the justification adequate? Is there documentation supporting the basis for not establishing a preventive control?**	Conformance **Not Applicable**
	Notes: See (a).	
(d)	Are written assurances required from customers?	Conformance **Yes**
	Notes: Yes, such as Antibiotic was specially focused by customers and controlled by supply chain.	
(e)	**If the facility is not required to have preventive controls,** Are records in place to document the applicable circumstances for not having preventive controls?	Conformance **Not Applicable**
	Notes: See (d)	
(f)	**If the facility is required to have preventive controls,** are preventive controls identified, implemented and documented?	Conformance **Yes**
	Notes: Food safety plan (HS-FSP-01 3.0) for dried pet food includes process preventive control measures, sanitation preventive control measures, Supplier preventive control plan, recall plan, record-keeping procedure etc.	
	What are the Preventive Controls identified at the facility? Describe the Preventive Controls and the category of each preventive control (example: process/allergen/sanitation/supply chain/other)	

	Preventive Controls	Verified by auditor?
	PC1: raw materials receiving	YES
	PC2: Sterilization	YES
	PC3: Metal detection, Fe φ 1.5mm, Susφ 1.5mm, Non-Fe 1.5mm.	YES
	PC4: Sanitation control in 6 processes - cooling, shelf removal, selection, gold detection, weighing, packaging.	YES
	PC5: Supply chain management in 2 processes - raw materials supplier supervision, irradiation	YES
		SELECT
		SELECT
		SELECT
507.40	**Monitoring Preventive Controls**	
(a)	Are written procedures for the monitoring of the preventive controls established and implemented?	Conformance **Yes**
	Notes: PC1: raw materials receiving, Raw duck incoming date 2019-01-12, COA was issued by Linyi Liuhe Hongchen, report No. 2019011201, drug residues were tested, the result is satisfied; Animal inspection certificate (No. 3753585466). PC2: Sterilization, lamb meat rolled on dried fish fillet dated on 2018-12-05, temperature ≥90℃, duration 30 minutes. PC3: Metal detection, dated on 2018-12-06, product name dried chicken, calibration time from 08:10 ~ 10:00, Fe φ 1.5mm, Susφ 1.5mm, Non-Fe 1.5mm. "PC4: Sanitation control in 6 processes - cooling, shelf removal, selection, gold detection, weighing, packaging. 2019-02, 2018-10." "PC5: Supply chain management in 2 processes - raw materials supplier supervision, irradiation 2018-12, 2019-03."	
(b)	Is frequency of monitoring adequate for each preventive control?	Conformance **Yes**
	Notes: Defined in HARPC.	
(c)	Are monitoring records in place?	Conformance **Yes**
	Notes: Records kept.	
507.42	**Corrective actions and corrections**	
(a)	Are there corrective action procedures in place?	Conformance **Yes**
	Notes: Corrective action procedures in place.	
	Do corrective actions consider all possible scenarios?	Conformance **Yes**
	Notes: Yes.	
	For supply chain programs: Do corrective actions and corrections take into account the nature of any supplier non-conformance?	Conformance

		Yes
	Yes.	
	If there are NO corrective actions in place, does the facility meet the exceptional circumstances whereby corrective action is not required?	Conformance **Not Applicable**
	Notes: Have.	
(d)	Are corrective action Records in place?	Conformance **Yes**
	Notes: Kept.	
507.45	**Verification of implementation and effectiveness**	
	Are verification activities documented?	Conformance **Yes**
	Notes: The verification activities were documented in the validation and verification control procedure.	
	Are adequate verification measures in place?	Conformance **Yes**
	Notes: Such as test, audit, review and inspection.	
	Are the proper implementation records adequately reviewed as a part of verification activities?	Conformance **Yes**
	Notes: Yes, reviewed.	
(b)	Are adequate written procedures established?	Conformance **Yes**
	Notes: Yes, established.	
507.47	**Validation (ONLY Required for Process Controls)**	
(a)	Do validation activities cover all process preventive controls to make sure they are adequate to controls hazards?	Conformance **Yes**
	Notes: Validation and verification control procedure was established.	
(b)	Validation of preventive controls overseen by preventive controls qualified individual?	Conformance **Yes**
	Notes: Control measure combination (e.g. FSP, PRP, and OPRP) was reviewed by PCQI Ms. Lifeng Yu. Validation date 2019-03-19.	
	Are validation activities performed within acceptable timelines?	Conformance **Yes**

	Notes: Yes	
	Is validation performed using scientific and technical evidence?	Conformance **Yes**
	Notes: Yes, such as paper, legal requirements, industry codex.	
(c)	When validation is determined not to be required, is it substantiated by written justification from the preventive controls qualified individual that validation is not applicable based on factors such as the nature of the hazard, and the nature of the preventive control and its role in the facility's food safety system?	Conformance **Yes**
	Refer to Food safety plan HS-FSP-01.	
507.50	**Reanalysis**	
(a)	Is the food safety plan reanalyzed as a whole at least once every 3 years?	Conformance **Not Applicable**
	Notes: (NOT APPLICABLE for now)	
(b)	Did any of the following events happen at the facility? If yes, then was the food safety plan reanalyzed (either as a whole or the applicable portion of the food safety plan): • A significant change in the activities creates a reasonable potential for a new hazard or creates a significant increase in a previously identified hazard • Facility has become aware of new information about potential hazards associated with the food • After an unanticipated food safety problem • A preventive control, combination of preventive controls, or the food safety plan as a whole is ineffective	Conformance **Not Applicable**
	Notes: No reanalysis occurred from the FSP established.	
(c)	Have all the elements of reanalysis been considered?	Conformance **Not Applicable**
	Notes: No reanalysis occurred from the FSP established.	
(d)	If a significant change has occurred and the facility has determined that no revision was needed, did the facility document the basis for the conclusion that no revisions are needed?	Conformance **Not Applicable**
	Notes: No reanalysis occurred from the FSP established.	
(e)	Has a preventive controls qualified individual (PCQI) performed (or overseen) the reanalysis?	Conformance **Not Applicable**
	Notes: No reanalysis occurred from the FSP established.	
(f)	If FDA has determined that there are new hazards that should be addressed, has the facility performed a reanalysis in light of this determination by FDA?	Conformance **Yes**
	Notes: Auditor onsite asked organization the same question and it should be a positive answer.	

507.53	Requirements applicable to a preventive controls qualified individual and a qualified auditor	
(a)	Is the preventive controls qualified individual (PCQI) performing the required tasks?	Conformance **Yes**
	Notes: There were 2 PCQI staffs in Group and performed their required tasks well.	
(b)	Whenever onsite audits are conducted, is a Qualified auditor conducting the onsite audit(s)?	Conformance **Yes**
	Notes: Yes. Mrs. Lifeng Yu, Mrs. Shaoyuan Sui.	
(c)	Is the preventive controls qualified individual qualified?	Conformance **Yes**
	Notes: There were 2 PCQI staffs qualified.	
(d)	Has all applicable training in the development and application of risk-based preventive controls been documented in records?	Conformance **Yes**
	Notes: SGS training certificate about FSPCA H/ FSPCA A course	
(e)	Do the training records include the date of training, the type of training, and the person(s) trained?	Conformance **Yes**
	Notes: They attended the FSPCA H/ FSPCA A course hold by SGS ACADEMY China and achieved the SGS training certificate and PCQI certificate.	

507.38	RECALLs	
(a)	Is there a written recall plan for the food? (Applies only to food requiring Preventive Control)	Conformance **Yes**
	Notes: Recall and withdrawal control procedure (HS-CX-22) was in place.	
(b)	Does the written recall plan include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform required actions as appropriate to the facility?	Conformance **Yes**
	Notes: The recall and withdrawal procedure (Doc. HS-CX-22) is in place that contained handing method and responsible person of each stage. Classifications of product recall. The list of key contacts, e.g. suppliers, client, certification body is in place. Communication plan was defined in the procedure. The product recall and withdrawal procedures are tested once annually.	
(c)	Has the facility issued a food safety recall within the past 2 years?	**No**
	Explain: No food recalled within the past 2 years.	
	Does recall notification include: ▪ The date or period during which the incident occurred ▪ The product(s) affected, lots, sizes & regions in which the affected products were distributed ▪ Amount of affected product(s) produced & recovered – justification for any	Conformance **Yes**

	variance ▪ The type of action or recall (e.g. regulatory/voluntary recall or legal action) ▪ The reason for the recall (e.g. undeclared allergen) ▪ The recall classification (e.g. Class 1) ▪ Number of individuals known to have been affected or estimates to that effect ▪ Any regulatory or legal reference numbers associated with the recall/legal action ▪ Corrective action, root cause analysis & preventive actions taken	
	Notes: The product recall and withdrawal procedures are tested once annually. The last withdraw test was conducted on 2018-10-16, for dried duck (batch no. K289AG4C11, 7402.984 kg), mock cause was foreign body problem. Records (including input and issue warehouse record, inventory record, handling records) were remained and mock recall rate was 100%,within 2 hours.	

SUBPART E —SUPPLY CHAIN PROGRAM Covered

507.105	**Supply-chain program**	
	Does the facility have risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring supply-chain-applied controls?	Conformance **Yes**
	Notes: Purchase Control procedure (HS-CX-12) and Supplier select and assessment procedure (HS-CX-25) in place.	
	Is the supply chain program written?	Conformance **Yes**
	Notes: Purchase Control procedure (HS-CX-12) and Supplier select and assessment procedure (HS-CX-25) in place.	
	If the facility has identified that certain supplier controls are applied by an entity different than the supplier (non-supplier), has the facility verified that control or obtained documentation of an appropriate verification activity performed by the non-supplier?	Conformance **Yes**
	Notes: Supplier control measures were defined in procedure. Only qualified suppliers can be used for purchase, such as for duck, chicken.	
	If the supplier conducts sampling and testing of raw materials and other ingredients as a supplier verification activity for a particular lot of product, does the receiving facility review and assesses that documentation?	Conformance **Yes**
	Notes: Every batch raw materials and other ingredients were sampled and tested as a supplier verification activity. COA and other food safety certification materials were received by QC. Sample: Refer to the audit trails.	
507.120	**Approved suppliers**	
	Does the facility use approved suppliers only?	Conformance **Yes**
	Notes: On-site verification found all raw materials and other ingredients including service were purchased only from approved suppliers. The qualified supplier list was in place.	
	Has the entity established and implemented written procedures for receiving raw materials and other ingredients?	Conformance **Yes**
	Notes: Raw materials safety control procedure (HS-CX-17) for raw material and other ingredients, which defined the details about the monitoring items based on risk assessment.	
507.130	**Supplier verification activities**	
	Has the facility established and implemented appropriate supplier verification activities for raw materials and other ingredients?	Conformance **Yes**
	Notes: Supplier select and assessment procedure (HS-CX-25) was in place and implemented well. Supplier performance evaluation was conducted once yearly and the records were maintained. Every batch raw materials and other ingredients were sampled and tested as a supplier verification activity. COA and other food safety certification materials were received by QC.	
	Are proper verification activities in place when a hazard in a raw material or other	Conformance

	ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans?	**Yes**
	Notes: The type test report for raw material or other ingredient was required at least once every year. The qualified test lab was selected by organization.	
	Has the receiving facility determined onsite audits as verification activity when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans?	Conformance **Yes**
	Notes: Onsite audits as verification activity was required at least once every year. Such as corn, soybean supplier.	
	Are audits must be conducted before using the raw material or other ingredient from the supplier and at least annually thereafter.	Conformance **Yes**
	Notes: Yes, reports kept.	
507.135	**Onsite audit**	
	Have the onsite audits of a supplier been performed by a qualified auditor?	Conformance **Yes**
	Notes: (provide evidence) Mrs. Lifeng YU is the QC manager of company and attended the FSPCA FSMA training course. She also attended the ISO22000/BRC/ ISO9001/HACCP etc. food safety course. Purchase manager or account staff also attend this assessment with the QC manager. Evidences refer to trail.	
	If the raw material or other ingredient at the supplier is subject to one or more FDA food safety regulations, has the onsite audit considered such regulations?	Conformance **Yes**
	Notes: Yes. Such as annual assessment report for supplier in 2018 was checked.	
507.175	**Supply-chain program documentation**	
	Are records documenting the supply-chain program adequate?	Conformance **Yes**
	Notes: Supplier select and assessment procedure (HS-CX-25) was in place and implemented well.	

SUBPART F—REQUIREMENTS APPLYING TO RECORDS THAT MUST BE ESTABLISHED AND MAINTAINED **Covered partially**

507.200-202	**Records**	
	Are general requirements applying to records met?	Conformance **Yes**
	Notes Record control procedure (HS-CX-02) was established. All applicable records could be established and maintained well.	
	Do records include all the required information?	Conformance **Yes**

	Notes: Auditor onsite sampled the production and quality records and confirmed the records include all the required information. Batch No. of audited products were sampled to test the traceability effectiveness and the related process PC and monitoring records were verified as per FSP.	
507.206	**Additional requirements**	
	Has the owner, operator, or agent in charge of the facility signed and dated the food safety plan?	Conformance **Yes**
	Notes: FSP was approved by Vice GM-Mr. Jiang Yishan (江移山) and dated 2018-11-15.	
507.208	**Record retention**	
	Are requirements for record retention met?	Conformance **Yes**
	Notes: Record control procedure (Doc. HS-CX-02) was established. The requirement of collation, review, maintenance, storage and retrieval of records were defined in it. Records were kept at least 3 years (shelf life 18-24 months). And the list of quality record was in place. During audit, record observed were legible, unambiguous, and clearly detailed. Reason for changes was recorded in document action request.	
507.215	**Written assurance (if applicable)**	
	Are written assurances used?	Conformance **Not Applicable**
	See 507.215 for details	

Certificate CN14/21490

This is to certify that

Yantai Hao's Pet Food Tech. Co., Ltd.

No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City, Shandong Province, 264003, P.R. China

BRC SITE CODE 9892347

has been assessed and certified as meeting the requirements of

Global Standard for Food Safety

Issue 8: August 2018

Achieved Grade A

Audit Programme: Announced

For the following activities

Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.

Product Categories: 15

Exclusions from scope: None

Date of Evaluation 20 March 2019

Certificate Issue Date 24 April 2019

Re-Evaluation Due Date: From 26 February 2020 to 25 March 2020

Certificate Expiry Date 06 May 2020

AUDITOR NUMBER
176454

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Certificate CN14/21490

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No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City, Shandong Province, 264003, P.R. China

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Global Standard for Food Safety

Issue 8: August 2018

Achieved Grade A

Audit Programme: Announced

For the following activities

Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.

Product Categories: 15

Exclusions from scope: None

Date of Evaluation 16 March 2020

Certificate Issue Date 19 April 2020

Re-Evaluation Due Date: From 25 February 2021 to 25 March 2021

Certificate Expiry Date 06 May 2021

AUDITOR NUMBER 176779

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HC SGS BRC FOOD issue 8 0919

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

Claudio Innocenti

Certificate CN20/10488

This is to certify that

Yantai Hao's Pet Food Tech. Co., Ltd.

No. 16 Puchang Road, Laishan Economic Development Zone, Yantai City,
Shandong Province, 264003, P.R. China

BRC SITE CODE 9892347

has been assessed and certified as meeting the requirements of

FSMA Preventative Controls Preparedness Module

Achieved Grade PASSED

For the following activities

Production of dried pet foods including meat/fish products, meat/fish wrapped with other dried food or calcium bones, which are packed in plastic bags or PET bottles.

Exclusions from scope: None

Date of Evaluation 16 March 2020
Certificate Issue Date 19 April 2020
Re-Evaluation Due Date: From 25 February 2021 to 25 March 2021
Certificate Expiry Date 06 May 2021

AUDITOR NUMBER
176779

This certificate supersedes all other certificates bearing this certificate number with earlier certificate issue dates.
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DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

Verification No: CN17/10193

VERIFICATION OF COMPLIANCE

Applicant: YANTAI HAO'S PET FOOD TECH CO., LTD.
No.16 Puchang Road, Laishan Economic Development Zone, Yantai City,Shandong Province, P.R. China

Audit Scope: Manufacture of dried pet foods including chicken breast sorts, duck breast sorts, pork sorts, beef sorts, lamb sorts, rabbit sorts and fish sorts, packed in plastic bag (or PET bottle) in carton.

The business operator has been audited and found to be in conformity with:

Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application Annex to CAC/RCP-1-1969, Rev. 4-2003

This verification of Compliance has been granted to the applicant based on the results of the audit, performed by SGS-CSTC Standards Technical Services Co., Ltd. on the above-mentioned scope in accordance with the provisions of the relevant specific Directives.

This certificate is valid from 28 February 2020 to 27 February 2023
Remains valid subject to satisfactory surveillance audits
Recertification audit due before 10 January 2023
Issue:2 Certified since 28 February 2017

.....
Authorized Signature

DOCUMENT REVIEWED AND ASSESSED BY CLAUDIO INNOCENTI (PARTNER & PCQI) ON OR ABOUT FSVP PLAN'S NOTED REVIEW START AND END DATES

Claudio Innocenti

Item #	Product name	Pack size (Height*Width*Gusset)	Brand name
ORC20	ONE REWARDS FREEZE DRIED CHICKEN	32*29*11cm	One Rewards
ORCL20	ONE REWARDS FREEZE DRIED CHICKEN LIVER	32*29*11cm	One Rewards
ORCLX07	ONE REWARDS FREEZE DRIED CHICKEN LIVER	20*13cm	One Rewards

Claudio Innocenti

Product label

Claudio Innocenti

Warning Letters

Learn about the types of warning letters on FDA's website. (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters)

- Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the letter recipient that may have changed the regulatory status of issues discussed in the letter.
- To obtain additional available information, contact FDA. Requests to FDA for agency records should be sent to: Food and Drug Administration Division of Freedom of Information (HFI-35), 5630 Fishers Lane, Rockville, MD 20857. Instructions for how to submit an FOI request can be found at How to Make a FOIA Request. (/how-make-foia-request)

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Letter Issue Date **Letters with Response or Closeout**

Posted Date **Year**

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Import Alert 99-08

https://www.accessdata.fda.gov/CMS_IA/importalert_259.html Examination of Processed Human and Animal **Foods** for Pesticides"...Department of Health and Human Services U.S. **Food** and Drug Administration A to Z ...

Import Alert 45-02

https://www.accessdata.fda.gov/CMS_IA/importalert_118.html Department of Health and Human Services U.S. **Food** and Drug Administration A to Z Index...Physical Examination and Guidance of **Foods** Containing Illegal ...

Import Alert 99-29

https://www.accessdata.fda.gov/CMS_IA/importalert_267.html Products From China for Animal or Human **Food** Use Due to the Presence of Melamine...Department of Health and Human Services U.S. **Food** and Drug ...

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Pagination

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3010135110	Yantai Hao's Pet Food Tech Co., Ltd.	Laishan, No 16 Puchang Road; Laishan, Yantai, Shandong, 264003, CN	Laishan, No 16 Puchang Road; Laishan, Yantai, Shandong, 264003, CN

FEI Number
3010135110

Firm Name
Yantai Hao's Pet Food Tech Co., Ltd.

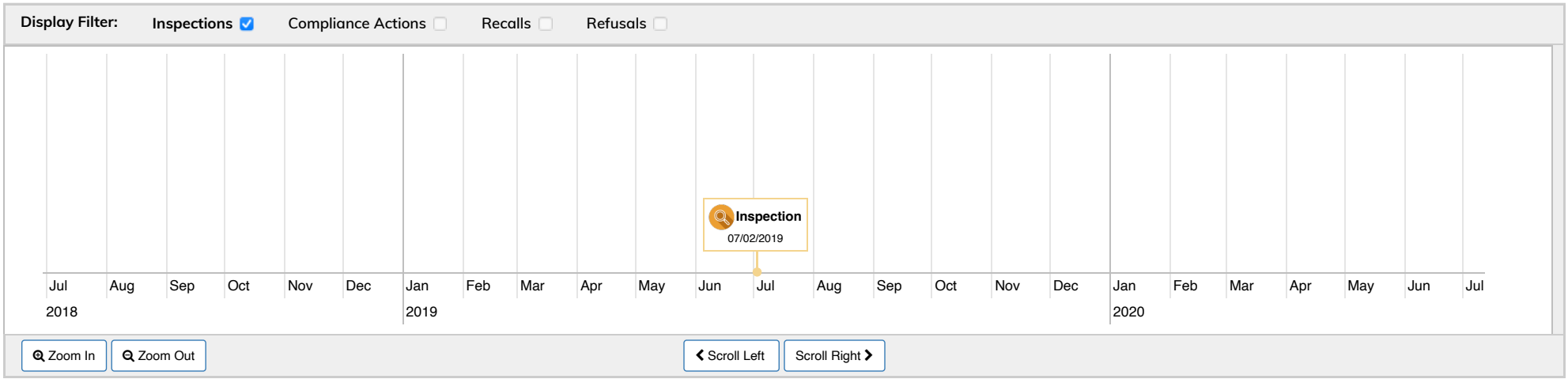
Firm Address

Laishan, No 16 Puchang Road;
Laishan

Yantai, Shandong 264003

China

FDA Actions Timeline



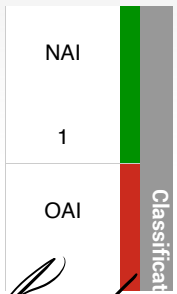
3010135110 – Yantai Hao's Pet Food Tech Co., Ltd.

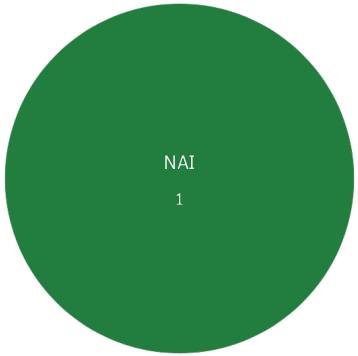
Inspections

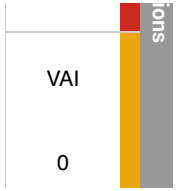
Inspections	Classifications
1	1

Inspection Classifications by Fiscal Year
Fiscal Years: 2019 - 2019

Inspection Classifications by Type
Fiscal Years: 2019 - 2019







Inspections Details Help

Inspection ID	Inspection End Date	Project Area	Product Type	Classification	
1097442	07/02/2019	Monitoring of Marketed Animal Drugs, Feed, and Devices	Veterinary	NAI	

Inspections Citations Details

No data found for the selected firm

*Citations data include Form FDA 483 citations and may not necessarily represent citations on final classification letters.

3010135110 – Yantai Hao's Pet Food Tech Co., Ltd.

Compliance Actions

Warning Letters	Injunctions	Seizures
0	0	0

Actions by Percentage

No data found for the selected firm

Compliance Actions Details

No data found for the selected firm

3010135110 – Yantai Hao's Pet Food Tech Co., Ltd.

Recalls

Recalled Products by Classification

No data found for the selected firm

Recall Events by Status

No data found for the selected firm

Recalls Details

No data found for the selected firm

Import Refusals

Refusals by Product Category

No data found for the selected firm

Import Refusals Details

Download Refusal Charges Reference

No data found for the selected firm

3010135110 – Yantai Hao's Pet Food Tech Co., Ltd.

Import Alerts

- Search results are not returned based on an exact match of the firm name. Users should review the search results to determine whether the firm appears in the Import Alert and that the firm's products are allowed into the country.
- Only current/active Import Alerts are displayed. For more information see Import Alerts.

No Import Alerts data found for the selected firm.

3010135110 – Yantai Hao's Pet Food Tech Co., Ltd.

Warning Letters

- The search results below should be reviewed to determine whether the firm is directly or indirectly referenced in the Warning Letter.
- Only Warning Letters issued in the last 5 years are displayed. For more information see Warning Letters.

No Warning Letters data found for the selected firm.

Caveats:

- Certain information in these datasets may not be presented or may have changed since the posting. The datasets are updated weekly and only include final actions. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.
- Compliance data provide information on a subset of the actions used by the FDA to bring firms into compliance, specifically data pertaining to Warning Letters, Seizures, and Injunctions. The compliance actions disclosed include only finalized and completed actions and are primarily used in the domestic arena.
- More than one establishment may be associated with one compliance action. The counts provided in this section reflect the number of establishments linked to the compliance action.
- For more information regarding the Center for Tobacco Products (CTP) issued warning letters click here.
- FDA has removed Medical Device Single Audit Program (MDSAP) audit reports, which are conducted by certified third-party auditors and may be considered in lieu of an FDA surveillance inspection, from the FDA Data Dashboard. FDA has determined that MDSAP audits do not meet the criteria for posting on the FDA Data Dashboard.