UNITED SAFETY AGENTS

FSVP

COMPLIANCE PLAN

HILLSIDE FARMS CORP. | DBA/IOR: SHANGHI ADAMS

Name of FSVP Importer

WENZHOU YUANFEI PET TOY PRODUCTS CO., LTD.

Name of Foreign Supplier

HILLSIDE FARMS' PORKHIDE TWISTS

Name of Product

JULY 19, 2019 / JULY 10, 2022

Date of Initial Verification / Reverification

JULY 20, 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.

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FOREIGN SUPPLIER VERIFICATION PROCEDURES

Continued from previous page.

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.

Continued onto next page.

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd.

Product: Hillside Farms' Porkhide Twists

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

Review Start: June 24, 2022 Review End: July 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd.

Product: Hillside Farms' Porkhide Twists

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

Review Start: June 24, 2022 Review End: July 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. FDA FFR: 14883771552

Manufacturing Address: No. 01 Chongle Road, Zhangjiang Industrial Park FDA FEI: 3009807829

City: Wenzhou City, Pingyang County Province/Territory: Zhejiang Province Country: China

Office Address: No. 01 Chongle Road, Zhangjiang Industrial Park

City: Wenzhou City, Pingyang County Province/Territory: Zhejiang Province Country: China

Phone Number: +8657763873286 Email Address: lichang@wzyuanfei.com

Name *of* Representative*(s)*: Mr. Chang Li Title: QI / Technical Rep.

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

Agent/QI Name: Claudio Innocenti Signature: Claudio Innocenti

Title: Partner & Preventive Controls Qualified Individual. Date: July 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**	
Hillside Farms' Porkhide Twists. 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd.

Product: Hillside Farms' Porkhide Twists

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Review Start: June 24, 2022 Review End: July 10, 2022

REGISTER *of* SUBSTANTIATING DOCUMENTS

HAZARD ANALYSIS

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

NOTES Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s HACCP Plan received.
Dated: June 01, 2017.
Plan Entitled: "Food Safety Plan" and contains information about the following: 1) Facility Information; 2) Food Safety Team; 3) Product Descriptions and Characters; 4) Process Flow Chart; 5) Process Steps; 6) Hazard Analysis; 7) Process Preventive Controls; 8) Allergen Preventive Controls; 9) Sanitation Preventive Controls; 10) Supply-Chain Preventive Controls; and 11) Recall.
Note: We respectfully request that an unabridged copy of the supplier's HACCP/HARPC Plan be provided for evaluation.

ON-SITE AUDIT

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

NOTES Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s BRC Audit Report received.
Dated: May 11, 2019.
Re-audit Due Date: June 07, 2020.
Audit Grade: B.
Number of Major Non-conformities: 1. Number of Minor Non-conformities: 5.
Previous Audit Grade: B.
Previous Audit Date: April 13, 2018.
Note: We respectfully request that FSVP Importer provide USA with supplier's updated audit report.

SAMPLING OR TESTING RESULTS

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

NOTES 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s FSMA Certificate received.
Dated: May 11, 2017 and June 10, 2019.
FSMA Preventive Controls Preparedness Module Assessment Report received.
U.S. Food and Drug Administration's Establishment Inspection Report received.
Dated: September 12, 2014.
Conclusion: There was no Form FDA-483, lnspectional Observations, issued during the current inspection and it was classified as NAI. FEI: 3004273276.

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd.

Product: Hillside Farms' Porkhide Twists

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

Review Start: June 24, 2022 Review End: July 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

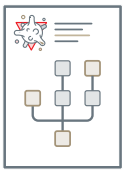
- ☑ if positive results are returned
- ☑ if recall or import refusal occurs
- ☑ if inspection occurs
- ☑ on an annual basis
- ☐ on a per-batch/shipment basis
- ☑ Chemical ☑ Biological
- ☐ *other:*_____

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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 Munchy Bones. (Sizes: 5, 4-inch and 1, 8-inch dog chews) (“product” or “imported product”), supplied by Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s on-site audit report. Per (e)(1)(i)(B) Wenzhou Yuanfei Pet Toy Products 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.

FOREIGN SUPPLIER FSVP QUESTIONNAIRE, including a review and assessment of the Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s reported critical/process/supply-chain controls for biological, chemical, environmental, allergenic, and physical hazards; facility cleaning information; staff hygiene details; pest control procedures; HACCP, TACCP, and VACCP; traceability procedures; release procedures; packaging format; customer complaint handling procedures; and plans/information relating to a recall and/or food safety issue. 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 qualified individual (“QI”) were completed.

OTHER APPROPRIATE SUPPLIER VERIFICATION ACTIVITIES, including a review of Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s compliance history, including whether Wenzhou Yuanfei Pet Toy Products 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

ONGOING VERIFICATION ACTIVITIES

To confirm that all relevant or identified food safety hazards requiring a control, for Munchy Bones. (Sizes: 5, 4-inch and 1, 8-inch dog chews) ("product" or "imported product"), supplied by Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s FOOD SAFETY PLAN will be required if any change or update occurs. Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s most up-to-date copy.

An updated version of Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s HACCP PLAN will be required if any change or update occurs. Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s most up-to-date copy.

An updated version of Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s ON-SITE AUDIT REPORT will be requested annually, or if any change or update occurs prior to year's end. Wenzhou Yuanfei Pet Toy Products 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 Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s FOOD FACILITY REGISTRATION remains active with FDA will be made annually by USA.

An updated version of Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s RECALL PLAN/OTHER RELEVANT FOOD SAFETY RECORDS listed under the Initial Verification Activities will be required if any change or update occurs. Wenzhou Yuanfei Pet Toy Products Co., Ltd. has been informed of this ongoing requirement and USA will confirm annually that the documents on file remain current and faithfully illustrates all process and procedures, or acquire and review Wenzhou Yuanfei Pet Toy Products Co., Ltd.'s most up-to-date copy or copies.

An updated copy of USA's FSVP SUPPLIER QUESTIONNAIRE will be required if any change or update occurs. Wenzhou Yuanfei Pet Toy Products Co., Ltd. has been informed of this ongoing requirement and USA will confirm annually that the details relayed via the questionnaire on file remain current or acquire a newly completed version.

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. Wenzhou Yuanfei Pet Toy Products 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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
N/A	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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. FEI: 3009807829 Date: July 10, 2022

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

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

REVISION LOG *for* FSVP PLAN

Version No.	Date *of* Change	Description *of* Revision
No. 01	July 19, 2019.	Foreign Supplier and product underwent initial verification.
No. 02	July 17, 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	July 16, 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	July 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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 Supply-chain control procedures to ensure that raw materials have been irradiated. Details: All raw materials are purchased from approved suppliers with quarantine certificate and qualifications. The raw materials should have high quality and no off-smell. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Raw Material Inspection Procedure, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product. 02. Supplier utilizes Supply-chain control procedures to ensure that raw materials have been checked by their QI prior to receipt. See above. 03. Supplier utilizes a Sterilization process to kill any living biological organism that may be present. Details: Sterilized by high temperature (75°C-90°C) for at least 2 hours or by the temperature and time that required by destination country. ——————NOTE—————— 01. We respectfully request recent copies of laboratory testing conducted to determine the presence of all biological hazards (preferably from an ISO 17025-accredited laboratory)	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. Product has low moisture level. The risk posed by biological hazards is very low. * So long as low Aw is maintained. ——————— ----- 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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 to help control for chemical hazards. Details: Supplier utilizes Supply-chain control procedures to ensure that raw materials do not contain the identified hazards. 02. The purchasing department require the suppliers providing the samples and the supplier document and the third party test report. Details: Testing program established. The testing methods, limits and frequencies are defined. Trend analysis for testing results of size, appearance is conducted monthly. One batch of each product is selected annually for shelf life study. ——————NOTE—————— 01. Product is derived from natural sources and consists of a single main component. The risk profile for chemical hazards is very low. 02. If FSVP Importer is aware of a specific Drug Residue and/or Industrial Chemical that supplier has failed to control in the past – or is of particular concern based on past knowledge – then FSVP Importer should confirm its absence via independent laboratory testing. 03. We respectfully request recent copies of laboratory testing conducted to determine the presence of all chemical hazards (preferably from an ISO 17025-accredited laboratory)	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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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**** ----- HAZARD PROFILE ----- ---------- SOURCE ---------- Appendix E: Food for Animals Category: Animal Protein Prod Subcategory: Pet Treats. Ex.: Chews; Jerky. Storage: Ambient	-	-	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.

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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. Hazards posed by recontamination with environmental pathogens are controlled through a documented facility cleaning and sanitation program. 02. Supplier utilizes Supply-chain control procedures to ensure that raw materials have been irradiated. Details: All raw materials are purchased from approved suppliers with quarantine certificate and qualifications. The raw materials should have high quality and no off-smell. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Raw Material Inspection Procedure, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product. 03. Supplier utilizes Supply-chain control procedures to ensure that raw materials have been checked by their QI prior to receipt. See above. 04. Supplier utilizes a Sterilization process to kill any living biological organism that may be present. Details: Sterilized by high temperature (75°C-90°C) for at least 2 hours or by the temperature and time that required by destination country. ———————NOTE——————— 01. We respectfully request recent copies of laboratory testing conducted to determine the presence of all biological hazards (preferably from an ISO 17025-accredited laboratory)	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. Product has low moisture level. The risk posed by biological hazards is very low. * So long as low Aw is maintained. Please see the Addendum section of this FSVP Plan and pages 44 - 46 of FDA's Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, Guidance for Industry (affixed) for additional information. ——————————— ----- 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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: 2.0 mm. Non Ferrous: 2.5 mm. Stainless Steel: 2.5 mm. 02. Glass and Breakable Plastic Program in use.	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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

ASSESSMENT *of* FOREIGN SUPPLIER

1.0 FOREIGN SUPPLIER INFORMATION

1.1. Supplier name: Wenzhou Yuanfei Pet Toy Products Co., Ltd. 1.2. Supplier country: China

1.3. Products manufactured/supplied: Dried pet and animal food and ingredients.

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

Standard: BRC, ISO 9001, ISO 22000 and ISO 14001.

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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

Wringing, cutting, enzymology, molding, dyeing, heating sterilization, flavoring and packing into plastic bag of expanded rawhide and pork hide dog chews. Sorting, grading, cutting, soaking, molding, drying, smoking, heating sterilization, flavoring and packing into plastic bag of dry dog chews. Hide milling, rice cooking, mixing, molding, heating sterilization, flavoring and packing into plastic bag of munchy dog chews. The company was established in 1990. The facility has been used since 2011. There are 400 employees including 30 QA & QC employees in the company. There are four building in the factory. 1st building is office building. 2nd building is the pet food workshop. 3rd building is the warehouse. 4th building is the pet toy workshop. There are 160 operators in the pet food workshop. There is one shift (8 hours per shift) every day. There are 7 working days every week. It is a private company. The company has been ISO 9001, ISO 22000 and ISO 14001 certificated. The sales volume was 200 million CNY in 2018. 100% volume is exported.

Testing Program & Accreditation

Testing program established. The testing methods, limits and frequencies are defined. Trend analysis for testing results of size, appearance is conducted monthly. One batch of each kind of product was selected for shelf life study every year. The retained samples are tested monthly for appearance, odor, color, moisture, coliform and salmonella.

Pathogen testing lab is located in the office building. The labs are located outside of the production zone. The GLP program has been established. The 3rd party labs are CNAS certificated. All testing methods are copied from the official standards. The official analyst licenses are filed. The internal sample check program is established. Internal sample checking is conducted annually for all analysts.

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.

Packaging Type & Shipping / Handling Requirements

Supplier certifies that packaging is accredited for food use. Packaging type: polyethylene bags that contains the 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. Product Characteristics: Ambient, long shelf life=18-36 months, heating sterilization (75-90C for 2 hours), irradiation treatment for finished products, moisture<14%. NOTE: per the Food Allergen Labeling and Consumer Protection Act, we recommend that label include FSVP Importers full business address.

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd.

Product: Hillside Farms' Porkhide Twists

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

Review Start: June 24, 2022 Review End: July 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.

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 copies of laboratory testing conducted to determine the presence of all biological and chemical hazards (preferably from an ISO 17025-accredited laboratory).

that FSVP Importer provide USA with supplier's updated audit report.

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.

END

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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).

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

ADDENDUM

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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

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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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

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Bob Bauer

completed on

09/14/2018

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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

Produce Safety ALLIANCE

AFDO | CONNECT · SHARE · IMPACT · PROTECT | 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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

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Bob Bauer

completed on

05/31/2018

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Institute for Food Safety and Health

Gerald Wojtala, Executive Director
International Food Protection Training Institute

Joseph Corby, Executive Director
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Bob Bauer

completed on

09/14/2017

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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
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Certificate # d2e9c287

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 10, 2022

CERTIFICATIONS & QUALIFICATIONS *of* FSVP AGENT

FSPCA
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CERTIFICATE OF TRAINING

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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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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

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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
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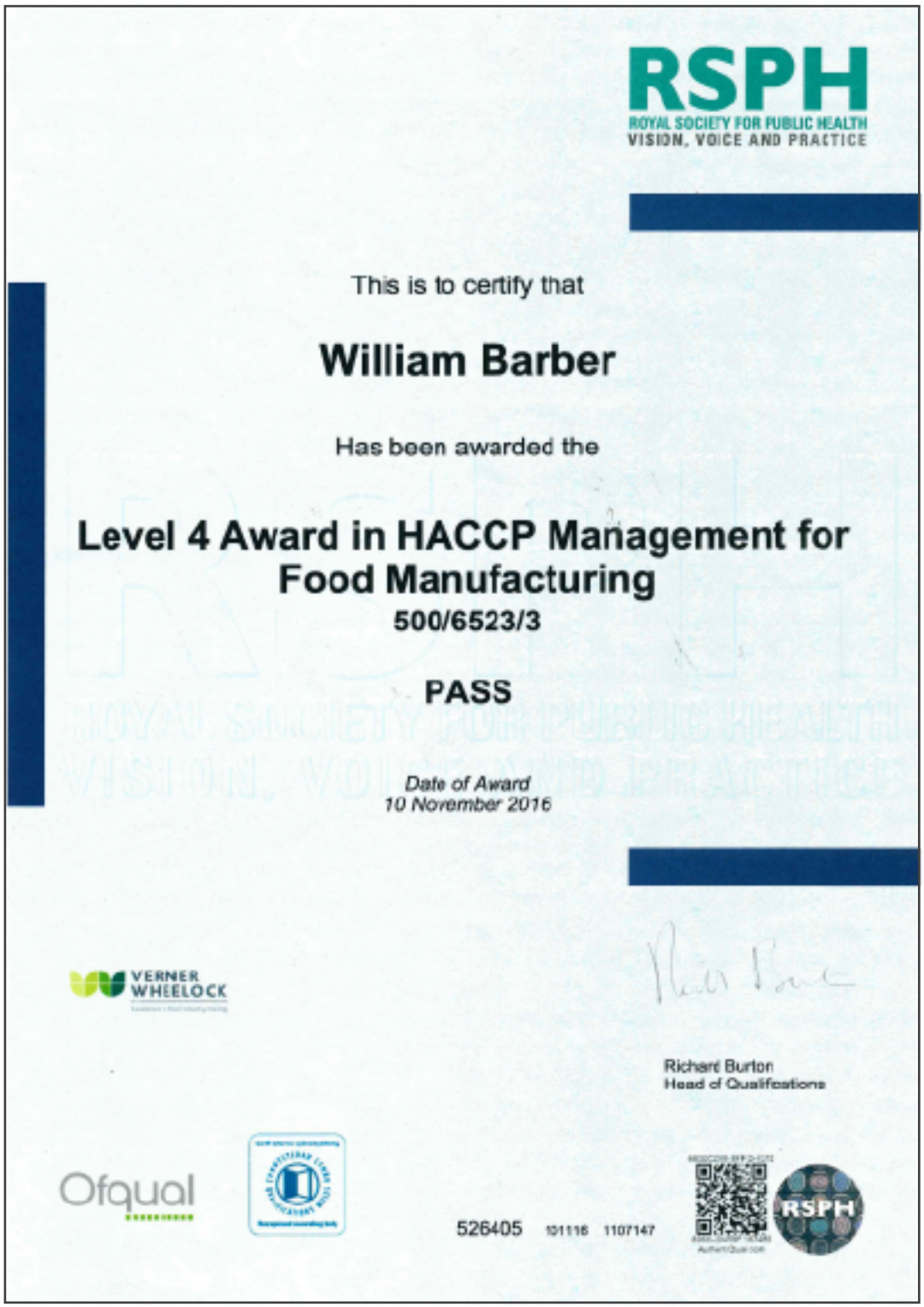
Certificate # 917b0241

AFDO

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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

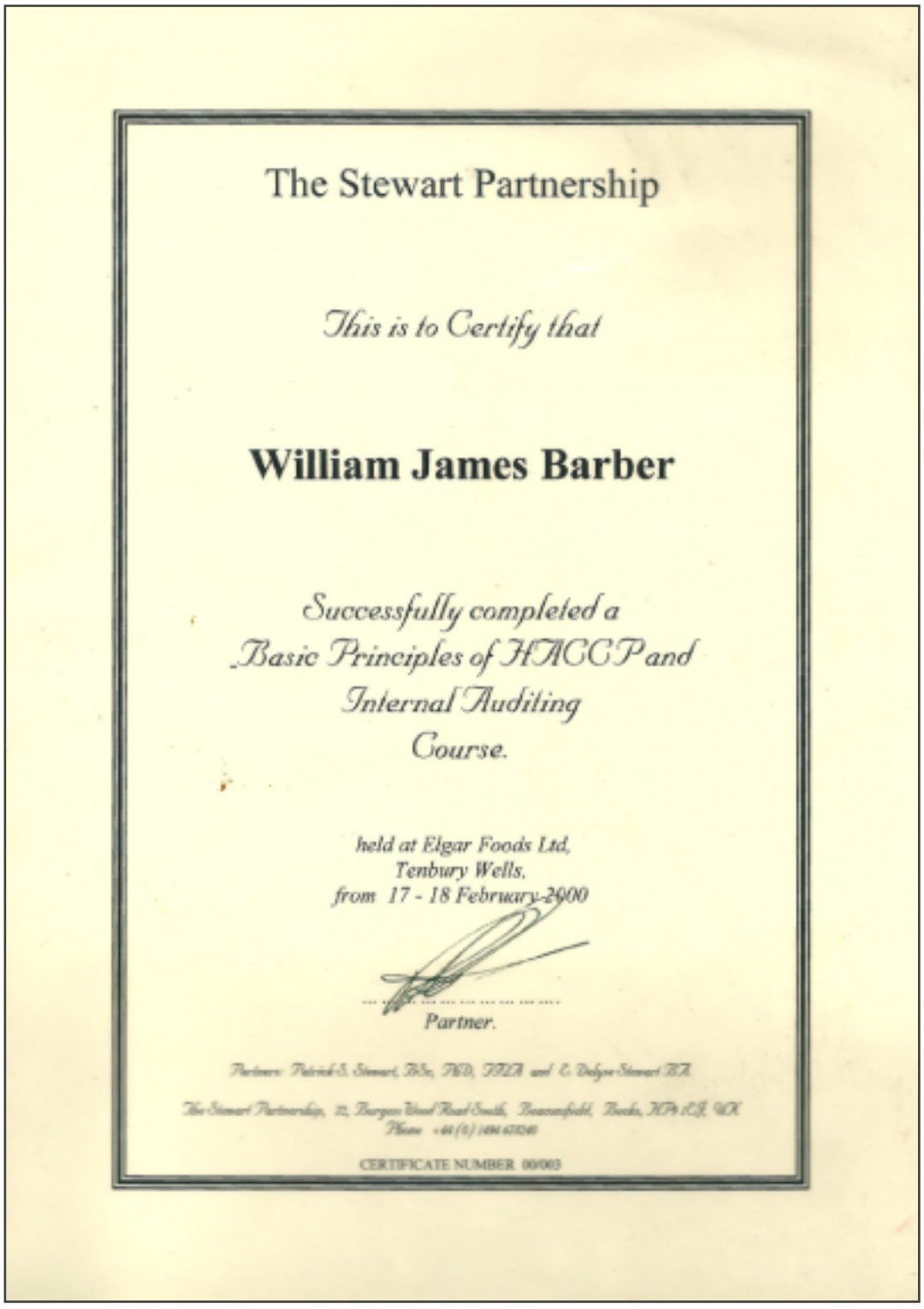
526405 101116 1107147

RSPH

Supplier: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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. Dafyn Stewart BA

The Stewart Partnership, 22, Burgess Wood Road South, Beaconsfield, Bucks, HP9 1EJ, UK
Phone +44 (0) 1494 672040

CERTIFICATE NUMBER 00003

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 0739/024907A/124203/PXC4025/1/13/03/64

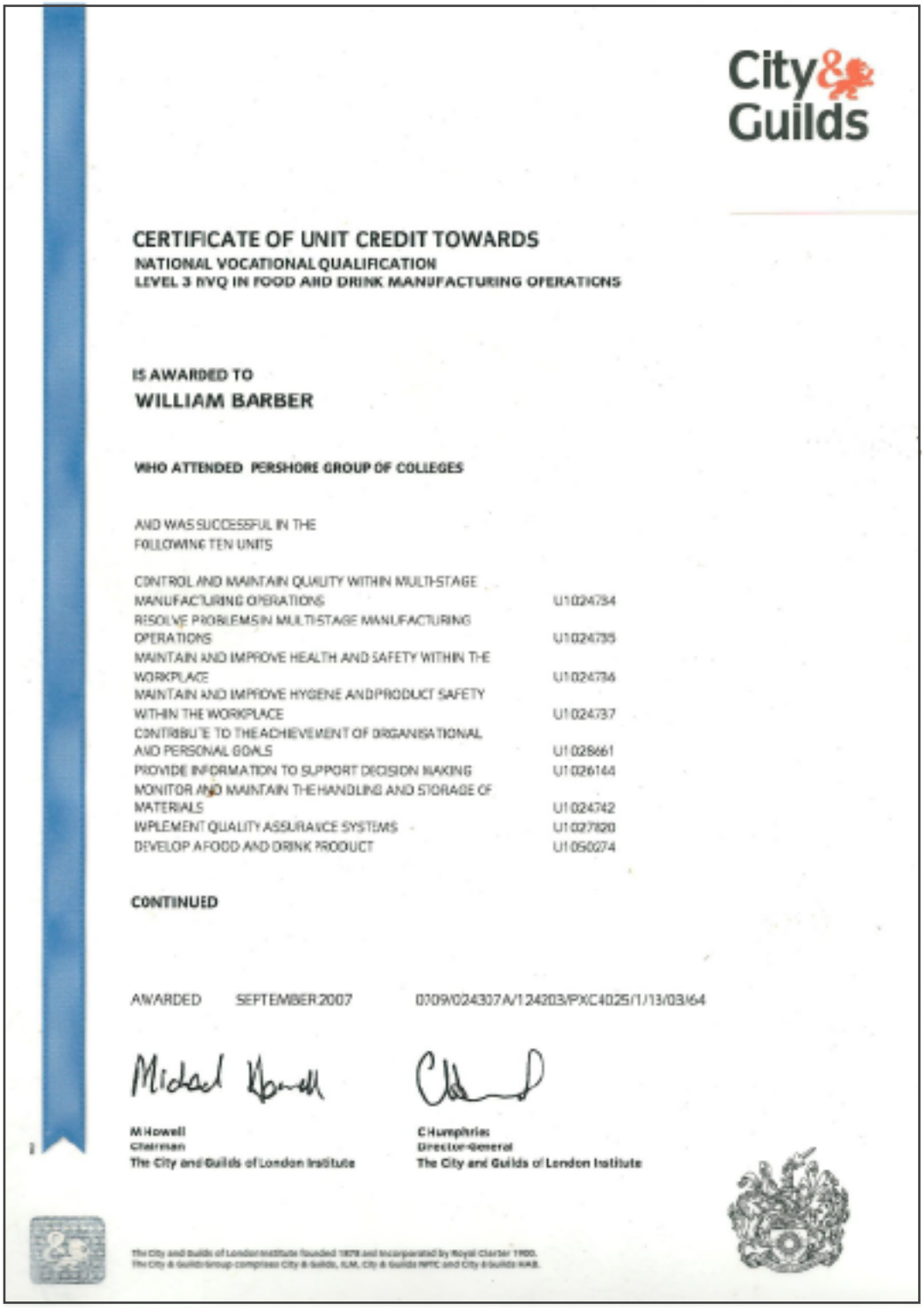
M Howell
Chairman
The City and Guilds of London Institute

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: Wenzhou Yuanfei Pet Toy Products Co., Ltd. Product: Hillside Farms' Porkhide Twists

Agent(s): Claudio Innocenti (PCQI. Member, USA LLC) Review Start: June 24, 2022 Review End: July 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.

Food Safety Plan

Reviewer: *Zhuang Mingyun*

Date: 2017.6.1

Table of Contents

Facility Information

Wenzhou Yuanfei Pet Toy Products Co., Ltd. is one of the leading manufacturers as well as exporter of pet products in China. With more than 27 years experience in pet industry, Yuanfei can provide one-stop professional services, from product design, development, production to marketing. Dog chews are made from premium rawhide with unique designs; all products are manufactured under strict food safety guidelines.

Food Safety Team

Name	Position	Training（on the record）
Zhuang Mingyun	General Manager	In Plant Training
*Li Chang	QC Manager	FSPCA class
Feng Mingchao	Production Supervisor	In Plant Training
Yang Xiaochun	Sanitation Supervisor	In Plant Training

* Preventive Controls Qualified Individual (PCQI)

Product Descriptions and Characters

1 Raw Material

1.1 Beefhide or Porkhide (split leather)

Characters (Physical, Biological, Chemical)	The color of processed split leather which is purchased from approved suppliers is white or golden yellow. The leather easily gets mildewed or spoiled. The pesticides and veterinary drugs residues, heavy metal, chemicals residues and others should meet GB standard or destination country's requirements. The raw material should have no infectious diseases and pollution, and without spoiling.
Origin	Zhejiang, Shandong, Henan, Hebei and etc.
Production Methods	Washing, Degreasing, Soaking, Unhairing, Splitting, Washing, Deliming, Bleaching or Drying
Delivery, Packing and Storing	Yuanfei；Tied up with rope；Stored in qualified warehouse at room temperature with label.
Pre-process	Not Required
Acceptance Criteria	Raw Material Inspection Procedure
Guarantee Period	24 Months (Room Temperature)

1.2 Artificial Food Coloring and Artificial Food Flavor

Name	Artificial Food Coloring	Artificial Food Flavor
Characters (Physical, Biological, Chemical)	Solid texture, uniform color and luster, free of hard lumps, no visible foreign body	No foreign body, free of hard lumps with a flavor and odor as claim.
Composition	As per GB2760	As per GB2760
Origin	Qualified Supplier	Qualified Supplier
Production Methods	Process permitted by the State	Process permitted by the State
Packing and Delivery	Non-toxic harmless packaging with standard label. Purchased from approved suppliers.	Non-toxic harmless packaging with standard label. Purchased from approved suppliers.
Pre-process	Not Required	Not Required

Storing and Guarantee Period	Stored in a dry, clean, hygienic and airy environment. Shouldn't be stored with virulent, harmful, smelly, volatile, or perishable articles. Guarantee Period: As per instructions	Stored in a dry, clean, hygienic and airy environment. Shouldn't be stored with virulent, harmful, smelly, volatile, or perishable articles. Guarantee Period: As per instructions
Acceptance Criteria	Coloring Acceptance Criteria	Flavor Acceptance Criteria

2 Packaging Materials

2.1 PE Bag, PVC Bag, EVA Bag, PE and PVC Shrink Film and etc.

Characters (Physical, Biological, Chemical)	Correct pattern and contents，standard color and luster, no off-smell and foreign matter. Health Indicators: GB9687
Origin	Qualified Supplier
Delivery, Packing and Storing	Purchased from approved suppliers with proper outer packing. Stored in a dry, airy, dustproof and anti-pest warehouse.
Pre-process	Disinfected by ultraviolet ray or ozone for more than 30 minutes.
Acceptance Criteria	Hygienic Standard: GB9687

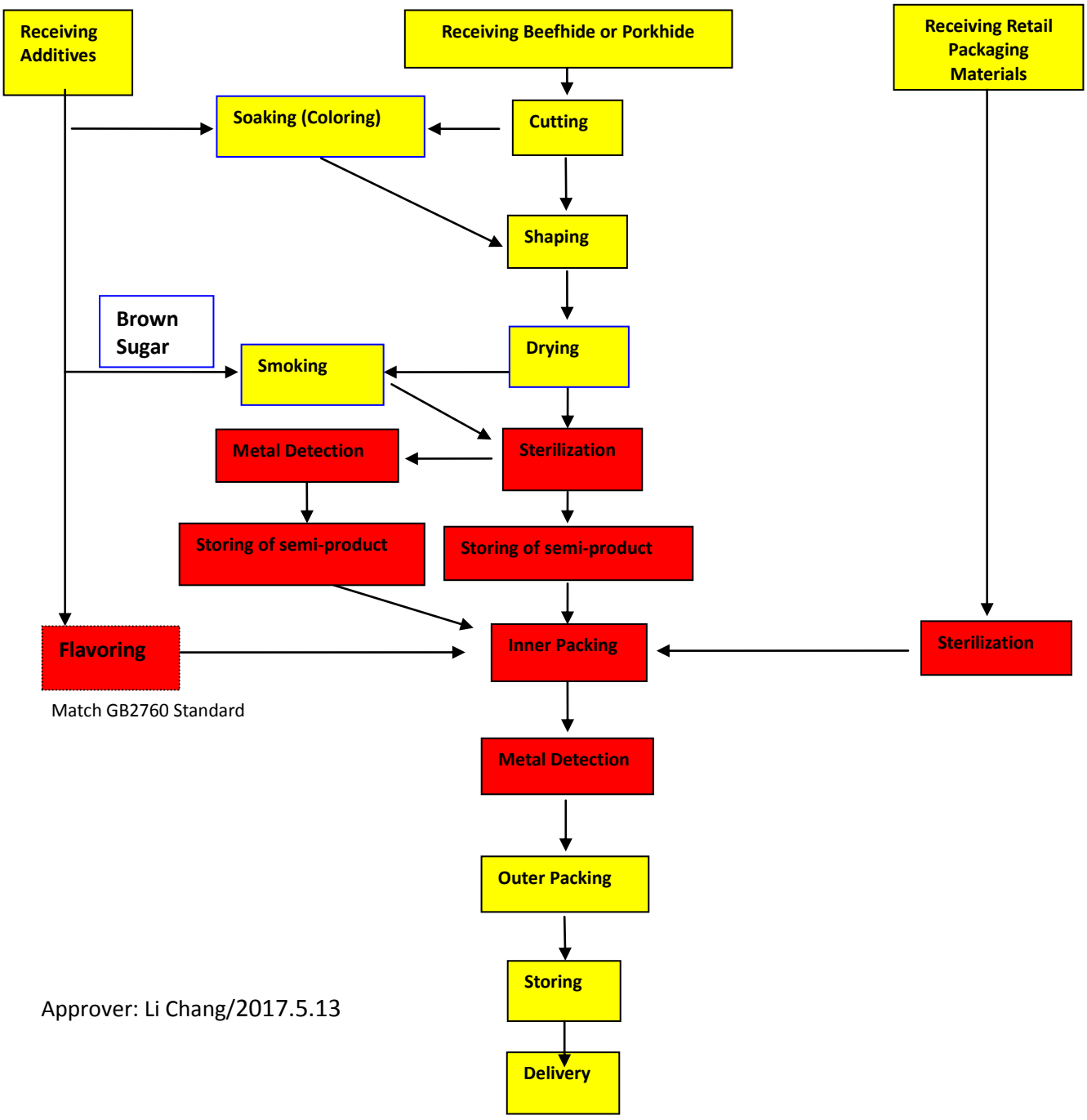
2.2 Outer Carton

Characters (Physical, Biological, Chemical)	Correct pattern and contents，standard color and luster, clean, no off-smell and foreign matter.
Origin	Qualified Supplier
Delivery, Packing and Storing	Purchased from approved suppliers with proper outer packing. Stored in a dry, airy, dustproof and anti-pest warehouse.
Pre-process	Not Required
Acceptance Criteria	Packaging Materials Acceptance Criteria

3 Product Characters

Product Name	Dog Chews (Rawhide Items)
Ingredients	Beefhide or Porkhide, Artificial Coloring, Artificial Flavor
Processing Methods	Sterilized by high temperature (75℃-90℃) for at least 2 hours or by the temperature and time that required by destination country.
Characters (Physical, Biological, Chemical)	Pesticides and veterinary drugs residues, heavy metal, chemicals residues, feed additives and others meet GB standard or destination country's requirements. No infectious diseases and foreign matter. Moisture≤14% Salmonella None Detected/25g, n=5, c=0, m=0, M=1；Enterobacteriaceae n=5, c=2, m=10, M=300
Packaging	Inner: Plastic Bag, Outer: Carton
Guarantee Period	18-36 Months (According to specific products' characters and customers' request)
Claim and Instructions	According to GBT7718 and customers' requirements
Sales, Transportation and Storage	At room temperature
Intended use and consumers	Tear packaging and feed dog directly. Dogs
Approver/Date	Li Chang/2017.5.13

Process Flow Chart



Approver: Li Chang/2017.5.13

Process Steps-Rawhide Items

1 Receiving Ingredients and Packaging:

1.1 Beefhide or Porkhide (CCP1)

All raw materials should be purchased from approved suppliers with quarantine certificate and qualifications. The raw materials should have high quality and no off-smell. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Raw Material Inspection Procedure, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product.

1.2 Auxiliary Materials and Additives

Auxiliary Materials and Additives should be purchased from approved suppliers with qualifications. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Raw Material Inspection Procedure, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product.

1.3 Retail Packaging (Inner Packaging)

Retail Packaging (Inner Packaging) should be purchased from approved suppliers with qualifications. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Packaging Materials Acceptance Criteria, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product.

1.4 Outer Packaging

Outer Packaging should be purchased from approved suppliers with qualifications. The origin and qualifications should be checked by QC department, and QC would inspect the raw materials as per Packaging Materials Acceptance Criteria, only qualified materials can be put in storage, unqualified materials should be operated as per Management of Nonconforming Product.

2 Grading

As per customers' requirements, grading the Beefhide or Porkhide base on color, size and etc.

3 Cutting

Cut the Beefhide or Porkhide to required size as per procedure.

4 Preparation of Coloring

Mix the colorings with hot water in definite proportions. The recipe should meet the requirements of GBT2760-2003.

5 Coloring

After drying, soak or spray the products with pigment solution, then drying again.

6 Shaping

Make the shape, weight and size as per customers' requirements.

7 Drying

Send the products to drying room, all products should be heated and dried as per procedure.

8 Smoking (Only for Smoked Items)

Send the products to smoking oven and smoke them by brown sugar for about 1 hour.

9 Sterilization (CCP2)

Sterilized by high temperature (75℃-90℃) for at least 2 hours or by the temperature and time that required by destination country.

10 Metal Detection (CCP3)

After drying and sterilization, to ensure the safety and reduce the waste of packaging materials and risk, conduct metal detection for products which are unable to conduct metal detection after inner packing. Only qualified products can be sent to semi-product warehouse.

11 Storing of semi-product

After cooling, the products should be stored in semi-product warehouse. And the products are stored and removed in according with the FIFO principle. The warehouse should be kept clean and tidy.

12 Acceptance of Packaging Materials

Inspect the packaging materials as per Packaging Materials Acceptance Criteria. All inner packaging materials should be disinfected by ultraviolet ray or ozone for more than 30 minutes.

13 Adding Flavoring

Add flavorings to products by spraying as per procedure.

14 Inner Packing

Check the weight, length and shape of the products, add flavoring if needed, pack and seal the qualified products as per procedure.

15 Metal Detection (CCP3)

To ensure the safety, conduct metal detection again for packed products.

16 Outer Packing

Transmit the packed products to outer packing workshop by conveyor belts, and then conduct outer packing as per procedure.

17 Storing in Warehouse

The finished products should be stored by item no. and batch no., the warehouse administrator shall tag the labels and make records as per procedure.

18 Delivery

Transport facility must be kept clean. The products should not be mixed with polluted goods during transportation. In transit, take necessary precautions to protect goods from sun, rain, insects, and mice.

Hazard Analysis

Hazard identification (column2) considers those that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B= Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C= Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P= Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

(1) Ingredient/ Processing Step	(2) Indentify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) *What preventive control measure(s) can be applied to significantly minimize or prevent the 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
Receiving Raw Materials - Beefhide or Porkhide	B	Pathogens, Parasites, Virus and Infectious Diseases	X		The raw materials may carry pathogens, or raw materials may be exposed during processing or transportation. Animals that fail to undergo quarantine inspection may be sick or carry parasites and virus.	Process Control-Sterilized by high temperature at a subsequent step		X
	C	The exceeding standard rate of heavy metal, feed additives, pesticides and veterinary drugs residues, chemicals residues	X		Chemicals accumulate in the animals. Chemicals residues from tanning.	Supplier Control-Third Party's Testing Report	X	
	P	Metal impurities	X		The raw materials may contain metal impurities.	Process Control –Metal Detection at a subsequent step		X
Receiving Brown Sugar, Flavoring, Coloring or other Additives	B	Pathogen Contamination	X		Infected during processing, storing or transportation of additives	Sanitation Control-To prevent contamination		X
	C	The exceeding standard rate of heavy metal, pesticide residues and other noxious substances. Banned additives.	X		Polluted during the usage of materials or processing. Banned additives may be used during processing.	Supplier Control-Third Party's Testing Report	X	
	P	N/A						
Receiving Retail Packaging Materials	B	Pathogen Contamination	X		The outer packing of retail packaging materials may be broken, and then the materials will be	Process Control - Disinfected by ultraviolet ray or ozone at a subsequent step		X

					infected by pathogens.			
	C	The exceeding standard rate of migration substances and dissolution substances	X		The production and processing of retail packaging materials is not controlled properly. The raw materials of retail packaging materials don't meet the standard.	Supplier Control-Third Party's Testing Report	X	
	P	N/A						
Receiving Outer Packaging Materials	B	N/A						
	C	N/A						
	P	N/A						
Cutting	B	Pathogen Contamination	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination		
	C	N/A						
	P	Plastic string	X		Mixing of plastic string during processing.	Sanitation Control-To prevent mixing of foreign matter	X	
Coloring	B	Pathogens contamination and growth	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination	X	
	C	The exceeding standard rate of additives	X		The recipe doesn't meet the requirements of GBT2760. Add too much additives during weighting and preparation.	Process Control-Measurement equipment calibration, verification of recipe and preparation.	X	
	P	N/A						
Shaping	B	Pathogens contamination and growth	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination	X	
	P	N/A						
	C	N/A						
Drying	B	Pathogens residue and multiply	X		Improper control of products' moisture may cause pathogens multiply during storing.	Process Control-Strictly follow the operation procedure, control the temperature and time properly.	X	
	C	N/A						
	P	N/A						
Smoking	B	Pathogens contamination and growth	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination	X	

	C	The exceeding standard rate of smoked hazardous substances	X		The exceeding standard rate of smoked hazardous substances	Process Control-Make sure the smoking temperature is less than 80℃.	X	
	P	N/A						
Sterilization	B	Pathogens residue and multiply	X		Improper control of temperature and time may cause pathogens residue and multiply.	Process Control-Strictly follow the operation procedure, control the temperature and time properly.	X	
	C	N/A						
	P	N/A						
Metal Detection	B	N/A						
	C	N/A						
	P	Metal impurities	X		Metal matter which is introduced during the contact with metals in processing.	Process Control-Metal Detection	X	
Storing of semi-product	B	Pathogens residue and multiply	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent cross infections	X	
	C	N/A						
	P	N/A						
Flavoring	B	Pathogens secondary pollution	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination	X	
	C	The exceeding standard rate of additives			Add too much additives during processing.	Process Control-Measurement equipment calibration, verification of recipe and preparation.	X	
	P	N/A						
Inner Packing	B	Pathogens secondary pollution	X		If there is no sanitation control, pathogen contamination may happen during processing.	Sanitation Control-To prevent contamination	X	
	C	N/A						
	P	N/A						
Metal Detection	B	N/A						
	C	N/A						
	P	Metal impurities	X		Improper control of the sensitivity of metal detector.	Process Control-Metal Detection	X	
Outer Packing	B	N/A						
	C	N/A						
	P	N/A						
Storing	B	N/A						

	C	N/A						
	P	N/A						
Delivery	B	N/A						
	C	N/A						
	P	N/A						

Process Preventive Controls

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Raw Materials (Receiving Beefhide or Porkhide)	Parasites, Virus, Heavy metal and Veterinary drug residue	All raw materials should be purchased from approved suppliers with qualifications. Pb≤20mg/kg Cr≤10mg/kg As≤10mg/kg Chloramphenicol and nitrofurans must not be detected	Parasites, Virus	For each lot, check the qualifications of raw materials	Each Lot	Acceptance staffs of raw materials	If the raw materials from infected areas are used, the products must be quarantined. Assess the situation of outbreaks and quarantine, if the sources are confirmed safe, and then continue processing. If there is potential risk, all affected products should be scrapped. And the affected areas should be thoroughly disinfected.	Review the acceptance records of raw materials everyday.	Acceptance records of raw materials, Qualifications from supplier, Third party's testing reports
			Heavy Metal	Third party's testing reports	Yearly		Quaranitne and return	Arrange testing yearly	Acceptance records of raw materials, Third party's testing reports
			Veterinary drug residue	Third party's testing reports	Yearly		Quaranitne and return	Arrange testing yearly	Acceptance records of raw materials, Third party's testing reports

Claudio Innocenti

Product Description: Dog Chews (Rawhide Items)	Pubdate: 2017.06.01
Facility: Wenzhou Yuanfei Pet Toy Products Co.,Ltd.	FDA Registration No.: 14883771552

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Sterilization by high temperature	Pathogens	Temperature: 75-90℃ Time≥2 Hours	Temperature and time of sterilization	Verify drying rooms' temperature, continue to monitor temperature and time by temperature recorder.	1. Each Hour 2. Continuous	Sterilization Personnel	When the sterilization temperature and time don't meet the standard, the whole lot should be quarantined. Review sterilization records and determine the temperature and time of re-sterilization.	Review the sterilization records everyday. Calibrate the thermometer yearly.	Sterilization Records, Corrective Action Records
Metal Detection	Metal impurities	Fe: dia≤2.0mm Sus: dia≤2.5mm Non-Fe: dia≤2.5mm	Metal impurities in products	Operate the metal detector properly, detect products one by one.	Continuous	Operator of metal detector	If the products are not detected, the redetection is required. If the sensitivity of metal detector doesn’t meet the standard, stop the detection and calibrate the detector. Then arrange the detection for all affected products again.	Verify the sensitivity of metal detector by standard metals every two hours.	Metal Detection Records, Corrective Action Records, Calibration Records

Claudio Innocenti

Research of Sterilization by high temperature

Confirmation of the time and temperature of Salmonella and Enterobacteriaceae inactivation in products

FDA 2011.Fish and Fishery Products Hazards and Controls Guidance Fourth Edition

INTERNAL PRODUCT TEMPERATURE (°F)	INTERNAL PRODUCT TEMPERATURE (°F)	LETHAL RATE	TIME FOR 6D PROCESS (MINUTES)
•158	70	1.000	2.0
•167	75	4.642	0.4
•185	85	100.0	0.02

Lethal rate, as used in this table, is the relative lethality of 1 minute at the designated internal product temperature as compared with the lethality of 1 minute at the reference internal product temperature of 158°F (70°C). The times provided are the length of time at the designated internal product temperature necessary to deliver a 6D process for L. monocytogenes. The length of time at a particular internal product temperature needed to accomplish a six logarithm reduction in the number of L. monocytogenes (6D) is, in part, dependent upon the food in which it is being heated. The values in the table are generally conservative and apply to all foods. So the sterilization for rawhide items is Temperature: 75-90℃ Time≥2 Hours.

Conclusion: According to the temperature, lethal rate and time stated in FDA 2011.Fish and Fishery Products Hazards and Controls Guidance Fourth Edition, 167°F（75°C）-194°F（90°C ≥2Hours will effective control the risk of Salmonella and Enterobacteriaceae in rawhide items.

Signature: Li Chang Date: 2012-01-05

Product Testing for Verification

Purpose: To verify the adequacy of process control (Sterilization) for the hazard of Salmonella and Enterobacteriaceae, and the adequacy of sanitation controls to prevent recontamination.

Sample identification: Rawhide items at the assembly table prior to packaging are sampled. Results from the rawhide items sampled represent one day of production because cleaning and sanitizing occurs daily.

Sampling procedure: Once per lot, five (5) rawhide items are randomly selected throughout the day. Each rawhide item is from a different assembly station. Individual rawhide items are aseptically collected, placed in sterile, plastic sample bags, which are labeled with the date, time, product, type, lot number and operator number. Samples are sealed by sealing worker. Sealed samples are sent to our own lab.

Product from the sampled lot is held until results are received and confirmed to be in compliance with acceptance criteria identified under "Results" below.

Test conducted: The lab samples a portion from each rawhide item and retains the remaining sample under refrigeration for further testing if results are not acceptable. Each portion is tested individually for *Enterobacteriaceae*. Of the 5 samples taken, 2 can have results between 10 and 100/g. No individual sample can have a count greater than 100/g.

Microorganism	Analytical Method	Sampling plan		Limits/g	
		n	c	m	M
Enterobacteriaceae	AOAC 2003.1	5	2	10	100

n =number of sample units
c =number of sample units that can have results between m and M
m =concentration separating good from marginally acceptable results
M =concentration separating marginally acceptable from unacceptable results

Interpretation of results:

Acceptable results – release product if either of the following are observed
1. All results are≤10/ g
2. 1 or 2 results between 10 and 100/g; all others≤10/g

Unacceptable results – Apply corrective action if either of the following is observed
1. More than 2 samples have results between 10 and 100
2. One or more results> 100/g

Corrective action for unacceptable results:

1. Determine the disposition of the lot (day's production) by testing 25g from each of the five (5) retained rawhide items for *Salmonella* and Listeria monocytogenes. Product is on hold and release status until negative results are confirmed.
a. If no pathogen is detected - Release the product and implement other corrective actions below
b. If either pathogen is detected - Divert the product to rendering and implement other corrective actions
2. Determine root cause
a. Increase observation of sterilization time and temperature verification at sterilization step to hourly.
1) Observe the records of packing workshop for signs of unsterilization.
2) If the unsterilized products are observed, arrange the sterilization for all products in mentioned packing workshop.
b. Conduct stringent sanitation efforts in the packing workshop, drying room and hallway between these areas. Increase observation of cleaning procedures at the end of the day and before start up to identify issues. Also observe procedures in the Utensil and Small Equipment wash room and Mixing area.
1) Make improvements if warranted in any of these areas.
c. Review environmental monitoring results for *Listeria spp.* to identify potential issues, regardless of whether or not *Listeria* is found in the product.
1) Direct cleaning and sanitation in areas of potential concern.
d. If *Salmonella* is detected in sampled product, in addition to observation of sterilization time and temperature verification, initiate environmental monitoring for *Salmonella*, focusing on the packing workshop, drying room and hallway between packing workshop and drying room to identify potential environmental sources. Continue weekly until results are negative for 5 consecutive weeks, then reduce to monthly.
e. Increase routine sampling for *Enterobacteriaceae* to at least weekly until 5 consecutive results are acceptable. Then return to the routine schedule.
3. Provide staff training

a. Review the situation with staff to alert them to the issue. Seek input on potential areas of improvement that can help resolve the issue.

Allergen Preventive Controls

Ingredient Allergen Identification

Raw Material Name	Supplier	Allergens in Ingredient Formulation								Allergens in Precautionary Labeling
		Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	Shellfish	
Artificial Flavoring	Sensient China									None
Artificial Flavoring	Ogawa Flavors & Fragrances (Shanghai) Ltd									None
Artificial Coloring	Shanghai Haixiang Food Ingredients Co., Ltd.									None
Caramel, Artificial Smoke Flavor	AIPU Food Industry Co., Ltd.									None
Brown Sugar	Shantou Chenghai Huanfa Food Co.,Ltd.									None

Sanitation Preventive Control

Objective: To address 1) cleanliness of food contact surfaces and 2) prevention of cross-contamination (recontamination)

Scope: Apply to all food manufacturing-related staffs in the factory

Item	Hazards	Dept.	Requirements	Monitoring	Corrective Action	Records	Verification
Raw Materials	B: Pathogens C: Pesticides residues P: Metal impurities	QC Dept.	1. All raw materials must from non-epizootie area. 2. Qualifications Check: Supplier Declaration, Certificate of Disinfection for Vehicle, Testing Report	For every lot, QC inspect raw materials as per procedure	Quarantine and reject materials without qualifications, and arrange the sterilization for related areas.	Raw Material Inspection Records	For every lot, QC manager review Supplier Declaration, Certificate of Disinfection for Vehicle, Testing Report
Ingredient	B: Microorganisms C: The exceeding standard rate of heavy metal	QC Dept.	1. Manage the supplier as per Food Quality and Safety Procedure. 2. For every batch, QC verifies the indexes (Sense, Physical, Chemical, Microbial and etc), warehouse keeper verifies the packaging, specification and quantity, only qualified materials can be sent to warehouse for storing. 3. For new materials, Food Safety Team will conduct Hazard Analysis, only confirmed materials can be used.	QC check materials as per procedure during processing.	Return unqualified materials.	Ingredient Inspection Records	QC manager review inspection records.
Packaging Materials	B: Microorganisms C: The exceeding standard rate of migration substances and dissolution substances	QC Dept.	1. Manage the supplier as per Food Quality and Safety Procedure. 2. For every batch, QC verifies the indexes (Sense, Physical, Chemical, Microbial and etc), warehouse keeper verifies the packaging, specification and quantity, only qualified materials can be sent to warehouse for storing.	QC check materials as per procedure during processing.	Return unqualified materials.	Inspection Sheet, Warehousing Entry	QC manager review inspection records.

Flow	B: Microorganisms P: Foreign Matter	Workshop	1. Worker---From non production areas to production areas 2. Product---Divide by time and space to avoid cross contamination 3. Water---From drains to sewer directly 4. Gas---Control the entry, out by positive pressure exhauster	Food Safety Team verify randomly	Take corrective actions in time for no conformities	Daily Sanitation Inspection Records	Food Safety Team verify randomly
Control of maintenance	B: Microorganisms P: Foreign Matter, Oil	Workshop	1. Maintenance staff pass in the workshop must change clothes, wash the hands, disinfection, and the wind drench the room. 2. Record the tools and accessories taken to the workshop, verify them when pass out. 3. Clear out the maintenance site before recovery of production.	Workshop manager check the condition after maintenance	Take corrective actions in time for no conformities	Maintenance Records	Workshop manager's verification
Tools, Machines	B: Microorganisms P: Foreign Matter	Workshop	1. Dedicated food contact tools, raw materials turnover boxes, leftover materials turnover boxes, semi-finished products turnover boxes and etc. 2. If the surface of food contact tools or machines is polluted by waste water or the surface touch ground or unhygienic article, the tools or machines must be cleaned and sterilized. In order to avoid recontamination, the clean tools or machines must be kept at least 30cm above the earth or sterilized base plate.	Daily Inspection	Take corrective actions in time for no conformities	Daily Sanitation Inspection Records	QC manager review Daily Sanitation Inspection Records
Personnel Practices	B: Microorganisms	Workshop	1. Workers must wear hat or other binds, and shouldn't wear jewelry or necklace which may fall into products, machines or packaging materials. 2. Eating, chewing drinking or smoking is prohibited in workshop. 3. Workers from different clean area can't enter or pass another area at random. 4. Before entering the workshop, workers should sterilize their shoes by disinfecting mat which contains 100-200PPM trichloroisocyanuric acid. 5. The trichloroisocyanuric acid should be changed every four hours during production.	Every two hours before operation or in processing. 5. Every four hours before operation or in processing.	Take corrective actions in time for no conformities	Daily Sanitation Inspection Records, Disinfectant Configuration Record	QC manager review records

Tools	B: Microorganisms	Workshop	After daily production, all turnover boxes and tools should be sterilized by 75% alcohol or Chlorine solution (150-200ppm).	QC staffs conduct inspection before, during and after production. Conduct microbiological testing twice per month (At least 2 tools/time)	Conduct sterilization again if any no conformity is observed.	1. Daily Sanitation Inspection Records 2. Cleaning and Sterilization Records 3. Technical Sanitation Records	1. Production Manager review Sterilization Records everyday. 2. Analysts conduct microbiological testing for tools regularly.
Machines	B: Microorganisms	Workshop	1. Sterilized by 75% alcohol before production. 2. Sterilized by ultraviolet lights after production.	QC staffs conduct inspection before and after production. Conduct microbiological testing twice per month (At least 2 machines/time)	Conduct sterilization again if any no conformity is observed.	1. Daily Sanitation Inspection Records 2. Cleaning and Sterilization Records 3. Technical Sanitation Records	1. Production Manager review Sterilization Records everyday. 2. Analysts conduct microbiological testing for machines regularly.
Work Environment	B: Microorganisms	Workshop	1. Clean and sterilize workshop's wall and ground by 75% alcohol after production everyday. 2. Clean ceiling, doors, windows regularly.	QC staffs conduct inspection before and after production.	Conduct sterilization again if any no conformity is observed.	Daily Sanitation Inspection Records	Production Manager review Sterilization Records everyday.
Air	B: Microorganisms	Workshop	The workshop should be sterilized by 75% alcohol after production.	QC staffs conduct daily inspection. Conduct Settle Plate Test twice per month.	Take corrective actions in time for no conformities	1. Cleaning and Sterilization Records 2. Technical Sanitation Records	1. Production Manager review Sterilization Records everyday. 2. Review Technical Sanitation Records monthly.
Work Clothes	B: Microorganisms	Workshop	1. Workers should make sure the work clothes clean, without stains and foreign matter before entering workshop. 2. The work clothes are concentrated cleaning, disinfection (200ppm chlorine solutions) and drying.	Sanitation supervisor conduct daily inspection. Microbiological testing twice per month.	Change the work clothes if there is any unqualified one.	Daily Sanitation Inspection Records, Microbiological Testing Report.	Verify microbiological every 15 days.

Environmental Monitoring for Sanitation Preventive Control Verification

1. Purpose: Establish the management of food contact articles and water's indexes (Sense, Physical, Chemical, Microbial and etc) to have a better control of production sanitary conditions.
2. Scope: Testing of food contact articles and waters in production lines.
3. Principal: Analysts and QC Manager
4. Procedure:
4.1 Sampling: For microorganisms, the testing item is total bacterial count and coliforms. Analysts conduct sterile sampling, and label the samples properly. At the same time, analysts should check the sensory index of water and summarize the records every 15 days.
4.2 Sampling sites: From site that is difficult to clean, and easy breeding microorganisms.
4.2.1 Contact surface include food contact surfaces, food contact tools, inner packaging, workers' hands and air.
4.2.2 Water from primary piping and water points.
4.3 Frequency: Conduct sampling and testing once per half a month. If any anomaly or no conformity is observed, double it. The official request is to conduct sampling of production water yearly, and test the samples according to government standard.

Interpretation of results:

Action for a negative result---Continue routine operations
Corrective action for a positive result:
1. If a composite is positive, the positive areas are re-sampled within a day of notification and prior to implementing intensive sanitation procedures. Additional samples (number depends on size of area) are taken in other potential problem areas in an attempt to identify a site of contamination. All samples are run individually, without compositing.
2. Intensive sanitation procedures are implemented after sampling is complete.
3. Production can continue after sanitation is complete and product can be shipped.
4. If all re-samples are negative, resume the normal sampling frequency.
5. If one or more re-samples are positive, perform corrective action investigation to resolve the issue. Implement a hold and finished product testing procedure per the Product Testing for Verification corrective action protocol.

Supply-Chain Preventive Controls

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control

Ingredient (requiring supply-chain-applied control)	Approved Supplier	Hazard(s) requiring supply-chain-applied control	Date of Approval	Verification method	Verification records
Beefhide or Porkhide	Yancheng Dafeng Huasheng Leather Company Limited	The exceeding standard rate of heavy metal, feed additives, pesticides and veterinary drugs residues,	04/01/2008	Supplier's certification or Third Party's Testing Report	Third Party's Testing Report
Beefhide or Porkhide	Zhejiang Mingxin Auto Leather Co.,Ltd.	The exceeding standard rate of heavy metal, feed additives, pesticides and veterinary drugs residues,	03/01/2008	Supplier's certification or Third Party's Testing Report	Third Party's Testing Report
Artificial Coloring and Flavoring	Sensient China	The exceeding standard rate of heavy metal, banned coloring	08/10/2007	Supplier's Testing Report or Third Party's Testing Report	Testing Report or Third Party's Testing Report
Artificial Flavoring	Ogawa Flavors & Fragrances (Shanghai) Ltd	The exceeding standard rate of heavy metal	03/01/2009	Supplier's Testing Report or Third Party's Testing Report	Testing Report or Third Party's Testing Report
Artificial Coloring	Shanghai Haixiang Food Ingredients Co., Ltd.	The exceeding standard rate of heavy metal, banned coloring	04/06/2014	Supplier's Testing Report or Third Party's Testing Report	Testing Report or Third Party's Testing Report
Caramel, Artificial Smoke Flavor	AIPU Food Industry Co., Ltd.	The exceeding standard rate of heavy metal	05/02/2015	Supplier's Testing Report or Third Party's Testing Report	Testing Report or Third Party's Testing Report
Brown Sugar	Shantou Chenghai Huanfa Food Co.,Ltd.	The exceeding standard rate of heavy metal	03/01/2016	Supplier's Testing Report or Third Party's Testing Report	Testing Report or Third Party's Testing Report
Inner Packaging	Zhejiang Finder Flexible Packaging Co.,Ltd.	The exceeding standard rate of heavy metal, migration substances and dissolution substances	02/01/2007	Supplier's certification or Third Party's Testing Report	Certification or Third Party's Testing Report

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

Purpose: Ensure that all ingredients requiring a supply-chain-applied preventive control are received from approved suppliers with appropriate preventive controls in place.
Frequency: Each delivery
Who: Receiving clerk
Procedure:
1. Verify that each load of ingredients was produced by approved suppliers by checking the product name and manufacturer name on receiving sheet.
2. Document on receiving sheet
Corrections: If product is not from the approved supplier:
1. Receiving clerk places product on hold, notifies QA
2. QA reviews status and
•Reject load, or
•Attaches to the receiving record documentation of verification activity applied for use of ingredients from temporary supplier, allowing release for use
•Marks the receiving record and sample" Food for research or evaluation use" and attaches a sticker stating "Food for research or evaluation use" and retains the shipping document stating that the food is for research or evaluation purposes and can't be sold or distributed to the public.
Records: Receiving Sheet, Food for Research or Evaluation Use Sticker
Verification: Receiving records review within 7 working days

Determination of Verification Procedures

Raw Material: Beefhide or Porkhide, Brown Sugar, Artificial Flavor, Artificial Coloring
Hazard requiring a supply-chain-applied control: Hazard analysis determined that heavy metal, pesticides and veterinary drugs residues, banned coloring and migration substances and dissolution substances are hazards requiring supply-chain-applied controls in the production of ingredients.
Preventive controls applied by the supplier: The supplier must choose the beefhide or porkhide that pass inspection & quarantine, and avoid the exceeding standard rate of pesticides and veterinary drugs residues. Use food grade chemicals in the processing of beefhide or porkhide. Implement food grade processing standard for the production of brown sugar, artificial flavor and artificial coloring.
Conclusion: Third party's testing of beefhide or porkhide to verify control of the identified hazards.
Verification procedures: Conduct third party's testing of suppliers' products yearly, and add the records to supplier profile. If the result is negative, take the corrective actions immediately and audit the supplier.
Records: QC manager keep all testing reports.

Wenzhou Yuanfei Pet Toy Products Co.,Ltd.

Recall Plan

Approved by: *Zhuang Mingyun*, President
Date: 2017.6.1

Table of Contents

Recall Team

Recall Team	Person	Position	Contact Information
Team Leader	Zhuang Mingyun	President	535900
FDA Recall Coordinator	Zhu Xiaorong	General Manager	535362
Executive Team Leader	Li Chang	Quality Assurance	683573
Member	Feng Mingchao	Production Manager	530315
Member	Zeng Feifan	R&D Manager	500812
Member	Yan Huihuang	Admin & Hr Manager	530610
Member	Zhuang yan	Purchasing Manager	659111
Member	Yang Xueguo	Financial Manager	661778
Member	Zhou Aixiang	Sales Manager	530071
Member	Xie Zhaodi	Workshop Manager	530039
Member	Long Benyan	Warehouse Supervisor	537509
Member	Tang Jidong	Warehouse Supervisor	530213

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe the product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	**If no recall is needed**: Document why not and action.
News media story on problem with a type of food produce	Assemble recall team, review internal records		**If recall is needed**: • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		
Health Department believes the produce is causing illness	Assemble recall team, contact appropriate regulatory agency		

Information Templates for FDA Communication

PRODUCT INFORMATION:

Modify the “Product Description, Distribution, Consumers and Intended Use” form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

CODES (Lot Identification Numbers):

- UPC code(s) involved: _____
- Lot number(s) involved: _____
- Lot numbers coding system: Describe how to read your product code:

_____
_____

- Expected shelf life of product: _____

RECALLING FIRM Contacts

Manufacturer name:
Wenzhou Yuanfei Pet Toy Products Co.,Ltd.
No.1 Chongle Road, Standard Park, Shuitou, Pingyang, Wenzhou,Zhejiang, China 325405

Position	Name, Title	Contact Information
RECALL coordinator	Zhu Xiaorong/General Manager	Office:86-577-59885710 Mobile: 86-13587955362 Fax: 86-577-63878286 email: info@wzyuanfei.com
Most responsible individual	Zhuang Mingyun/President	Office:86-577-59885710 Mobile: 86-13906665900 Fax: 86-577-63878286 email: info@wzyuanfei.com
Public contact:	Zhu Xiaorong/General Manager	Office:86-577-59885710 Mobile: 86-13587955362 Fax: 86-577-63878286 email: info@wzyuanfei.com

REASON FOR THE RECALL:

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved	
If a State agency is involved in this recall, identify Agency and contact.	

VOLUME OF RECALLED PRODUCT:

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • distributor level	
• customer level	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

DISTRIBUTION PATTERN:

Type	**Number**
wholesalers/distributors	
repackers	
manufacturers	
retail	
consumers (internet or catalog sales)	
federal government consignees	
foreign consignees (specify whether they are wholesale distributors, retailers or users)	
Geographic areas of distribution, including foreign countries	

CONSIGNEE LIST

Name	*Street Address*	*City*	*State*	*Recall contact name*	*Contact phone number*	*Recalled product **was** shipped?*	*Recalled product **was** sold?*	*Recalled product **may have** been shipped or sold*

Was product sold under Government Contract?
Yes _____ No _____
If yes, include contact name and information above AND complete information below.

Contracting Agency	*Contract Number*	*Contract date*	*Implementation date*

RECALL STRATEGY:

Level in the distribution chain

Level	Included		Rationale if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Product destruction/reconditioning

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]
[--No Other Products Affected--]

Contact
Consumer:
1-xxx-xxx-xxx

Media Contact:
xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- **[insert lot codes]**

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	[insert product codes(s)]	[insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

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Page separates individual foreign supplier-provided food safety documents.

1.AUDIT SUMMARY

Company name	Wenzhou Yuanfei Pet Toy Products Co., Ltd.	Site Code	8594252
Site name	Wenzhou Yuanfei Pet Toy Products Co., Ltd.		
Scope of audit	Wringing, cutting, enzymolysis, moulding, dyeing, heating sterilization, flavouring and packing into plastic bag of expanded rawhide and porkhide dog chews. Sorting, grading, cutting, soaking, moulding, drying, smoking, heating sterilization, flavouring and packing into plastic bag of dry dog chews. Hide milling, rice cooking, mixing, moulding, heating sterilization, flavouring and packing into plastic bag of munchy dog chews.		
Exclusions from scope	The manufacturing of pet toy products		
Justification for exclusion	The workshop of pet toy products is located in separated building.		
Audit Finish Date	2019-04-26		
Re-audit due date	2020-04-26		

ADDITIONAL MODULES INCLUDED

Modules	Result	Scope	Exclusions from scope
FSMA Preventative Controls and FSVP Preparedness	Passed	Scope of FSMA selected is same with BRC Food V8	The manufacturing of pet toy products
Choose a module	Choose an item		

Head Office	No

2. AUDIT RESULTS

Audit result	Certificated	Audit grade	B	Audit type	Announced
Previous audit grade	B	Previous audit date	2018-04-13		

Certificate issue date	2018-05-11	Certificate expiry date	2019-06-07

Number of non-conformities	Fundamental	0
	Critical	0
	Major	1
	Minor	5

3.COMPANY DETAILS

Address	No. 1, Chongle Road, Standard Park, Shuitou Town, Pingyang County, Wenzhou City, Zhejiang Province		
Country	P. R. China	Site Telephone Number	+8657763873286
Commercial representative Name	Michael LIN	Email	michael@wzyuangei.com
Technical representative Name	Chang LI	Email	lichang@wzyuanfei.com

4.COMPANY PROFILE

Plant size (metres square)	<10K sq.m	No. of employees	51-500	No. of HACCP plans	1-3
Shift Pattern	Single shift				
Subcontracted processes	Yes				

Other certificates held	ISO 9001, ISO 22000 and ISO 14001
Regions exported to	North America Europe Asia Oceania Choose a region Choose a region
Company registration number	FDA:14883771552
Major changes since last BRC audit	None

Company Description

The company was established in 1990. The facility has been used since 2011. There are 400 employees including 30 QA & QC employees in the company. There are four building in the factory. 1st building is office building. 2nd building is the pet food workshop. 3rd building is the warehouse. 4th building is the pet toy workshop. There are 160 operators in the pet food workshop. There is one shift (8 hours per shift) every day. There are 7 working days every week. It is a private company. The company has been ISO 9001, ISO 22000 and ISO 14001 certificated. The sales volume was 200 million CNY in 2018. 100% volume is exported. Pet toy products are excluded from the BRC audit. BRC logo was not used.

5.Product Characteristics

Product categories	15 - Dried food and ingredients VM - FSMA Preventative Controls and FSVP Preparedness Category Category				
Finished product safety rationale	Ambient, long shelf life=18-36 months, heating sterilization (75-90oC for 2 hours), irradiation treatment for finished products, moisture<14%				
High care	No	High risk	No	Ambient high care	No
Justification for area	The audit products are not microbiological sensitive products because of low				

	moisture.
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
Product claims made e.g. IP, organic	None
Product recalls in last 12 Months	No
Products in production at the time of the audit	5" hide roll and 4.5" hide bone

6.AUDIT DURATION DETAILS			
On-site duration	28 man hours	Duration of production facility inspection	14 man hours
Reasons for deviation from typical or expected audit duration	Half day for FSMA module		
Next audit type selected	Announced		

AUDIT DURATION PER DAY

Audit Days	Audit Dates	Audit Start Time	Audit Finish Time
1 (start date)	2019-04-23	8:30	17:30
2	2019-04-24	8:30	17:30
3	2019-04-25	8:30	17:30
4(finish date)	2019-04-26	8:00	12:00

	Auditor (s) number	Name	Role
Auditor Number	168084	Jackie Lee	Lead Auditor
Second Auditor Number	N/A		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
LI Chang/Quality supervisor	X	X	X	X
FENG Minchao/Production supervisor	X	X	X	X
LIN Min/Sales	X		X	X
WEN Linzhi/HR	X		X	X
LIN Zhenghai/Warehouse	X	X	X	X
ZHUANG Minyuan/General manager	X			X

AUDIT REPORT
GLOBAL STANDARD FOR FOOD SAFETY ISSUE 8: AUGUST 2018

Document #: F834 MASTER Food 8 Release Date: 23-JAN-2019

Non-Conformity Summary Sheet

CRITICAL OR MAJOR NON CONFORMITIES AGAINST FUNDAMENTAL REQUIREMENTS				
No.	**Requirement ref.**	**Details of non-conformity**	**Critical or Major?**	**Anticipated**

CRITICAL			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipated**

MAJOR						
No.	**Requirement ref.**	**Details of non-conformity**	**Correction**	**Proposed preventive action plan (based on root cause analysis)**	**Evidence provided document, photograph, visit/other**	**Da re**
1	3.5.1.3	The procedure for the approval and monitoring of suppliers of services was absent.	Conduct supplier capability assessment and capability survey for service providers, and update the supplier list	Vendor manager contains oversight of service type providers, but no record of failure to enforce it Make supplier evaluation form and capability survey form for each new supplier, and file them uniformly	Procedure, Photo	20

AUDIT REPORT
GLOBAL STANDARD FOR FOOD SAFETY ISSUE 8: AUGUST 2018

Document #: F834 MASTER Food 8 Release Date: 23-JAN-2019

MINOR

No.	Requirement ref.	Details of non-conformity	Correction	Proposed preventive action plan (based on root cause analysis)	Evidence provided document, photograph, visit/other	Da re
1	3.4.1	The internal audit control procedure was issued on 2012-01-10. The frequency is defined as twice per year.	Print the revised internal audit documents, and the quality control department is responsible for revising the internal audit documents twice a year	Internal audit procedure document updated, but not printed.	Procedure, Photo	20
2	3.4.2	The internal audit control procedure was issued on 2012-01-10. The frequency is defined as twice per year. Latest internal audit was performed on Jan.3, 2019. 4 auditors attended this audit. Only one NCR was raised in internal audit. But found that two auditors from quality department audited their own work.	The production department shall re-examine the problems of the quality inspection department and sign for confirmation Stipulate 4 staggered time audits in a year to prevent audit errors.	Due to the shortage of personnel in the internal audit process, the department reviews its personnel	Procedure, Photo	20
3	3.5.1.4	A supplier list was issued in Jan.2019. But a trade supplier (Shanghai Xinrong) was absent in this list.	Update the latest supplier list	There is information on xinrong, but the directory has not been updated. The quality control department is responsible for the registration and update, and check the supplier list once a month to ensure its integrity	Procedure, Photo	20
4	4.9.5.1	On the first audit, the auditor found that wood tool was used in the moulding area of Vegetable Starch chew.	Clean up the existing wood products in the workshop and operate with metal tools instead	The management of workshop is not in accordance with the foreign body control procedures, and the implementation is not in place Train workshop management and staff on wood product control	Photo	20

				procedures		
5	4.14.6	No pest control was found in the primary packaging materials warehouse.	The quality control department shall contact the pest control company to set up the fly light, and make regular control	No pest prevention tools were set up in the packing material warehouse during the pest prevention process	Procedure, Photo	20

COMMENTS ON NON-CONFORMITIES

AUDIT REPORT
GLOBAL STANDARD FOR FOOD SAFETY ISSUE 8: AUGUST 2018

Document #: F834 MASTER Food 8 Release Date: 23-JAN-2019

Additional Modules / Head Office Non-Conformity Summary Sheet

CRITICAL			
No.	**Requirement ref.**	**Details of non-conformity**	**Anticipate**

AUDIT REPORT
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MAJOR						
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Da rev**

MINOR						
No.	**Requirement ref.**	**Details of non-conformity**	**Corrective action taken**	**Root cause analysis and proposed action plan**	**Evidence provided document, photograph, visit/other**	**Da rev**

Detailed Audit Report

1. SENIOR MANAGEMENT COMMITMENT

1.1 SENIOR MANAGEMENT COMMITMENT AND CONTINUAL IMPROVEMENT

The policy: legal abidance, control CCPs hardly, ensure product quality, customer satisfaction, external communication, continuous improvement and increase product quality and management system. The policy is included in the quality manual and the manual was signed by the general manager on May 10, 2017. The policy has been posted in the workshops.. BRC logo was not misused.
A food safety and quality culture was documented. The G.M maintain annually plan for the development and continuing improvement of it.

The objective: customer satisfaction>=85%, staff training rate>=98%, first grading>=90% and food safety/quality incident=0.
The objectives have been posted in the workshops. The review of the objectives is performed monthly.
The management review is conducted annually. Last review was conducted on 2019-02-24. Previous action plans, validation results, changes, emergency information, incident, system modification, customer feedback, audit results, policy, objectives, corrective action, suggestion, HACCP program. Total 4 decisions for understanding of new quality manual against ISO 9001:2015, record filling, SOP training and monitoring for routine activities were issued.
The monthly management meeting is performed. The meeting minutes on Mar 30, 2019 covered the issues of marking and product quality.
Confidential reporting system was established, The G.M. assessing any concerns raised, and handle it.
The company's senior management shall provide the human and financial resources.
1.5 million CNY for maintenance projects in 2018.
The quality department is responsible for external information collection.
The printed BRC book (Issue8) is filed. The list of changes is filed.
The re-audit was performed on time.
The general manager and all department managers attended the opening and closing meeting.
All findings were issued during the last audit were closed completely.

1.2 ORGANISATIONAL STRUCTURE, RESPONSIBILITIES AND MANAGEMENT AUTHORITY

The executive, quality, production, equipment, purchasing, sales and finance department managers report to the general manager directly. The backup list for the key positions is filed.
The training for responsibilities has been conducted for all staff.

2 THE FOOD SAFETY PLAN – HACCP

The HACCP team leader is the vice president. He has 13-year experience for the pet products. The team members are from the production, quality, equipment, sales, and executive departments.
For expanded rawhide and porkhide dog chews:
Hide receiving, wringing, cutting, molding, dyeing, heating sterilization, flavoring, inner packing, metal detecting, outer packing, storage and shipping
For dry rawhide and porkhide dog chews:
Hide receiving, sorting, grading, cutting, soaking, molding, drying, smoking, heating sterilization, flavoring, inner packing, metal detection, outer packing, storage and shipping.
For munchy dog chews:
Hide milling, rice cooking, mixing, molding, heating sterilization, flavoring, inner packing, metal detection, outer packing, storage and shipping.
All process steps are in included in the HACCP programs.
The prerequisite programs have been established.
The raw materials, properties, key processing, packing style, storage condition, transportation condition, intended using, target consumer, labelling and shelf life are included in the product descriptions.
The official standards (EC 1069-2009, EN 71, GB/T 23185-2008), customers' requirements and current scientific literature are used for hazard analysis.

Intended using is included in the product description. No vulnerable group is applicable.
The flow chart includes the raw materials, utilities, processing steps, recycling, waste. Some products are brand card packed with staple. So the loose products are metal detected before brand card packing.
The verification for the flow charts was conducted on 2019-04-01.
All potential hazards were identified during the hazard analysis.
Both likely occurrence and severity are considered.
SSOP, SOP and OPRP are considered as the control measures for hazard prevention.
For dry porkhide or rawhide dog chews:
CCP1: hide receiving for disease, medicine residue control. The limit is that hide is provided from the approved vendor, Pb<=20mg/kg, Cr<10mg/kg. As<10mg/kg and medicine residue=not detectable. The monitoring frequency is annually.
CCP2: sterilization for microbiological hazard control. The limits are temperature=75-90oC and time>=2 hours. The monitoring frequency is per hour.
CCP3: metal detection for physical hazard control. The limits are Fe=2.0mm, Cu=2.5mm and SUS=2.5mm. The monitoring frequency is per 2 hours.
For munchy dog chew:
CCP1: hide and rice receiving for disease, melamine, medicine residue, pesticide residue, heavy metal, aflatoxin control. The limit is that hide is provided from the approved vendor, DDT<=0.05mg/kg, benzex<=0.05mg/kg, medicine=not detectable, melamine<=0.25mg/kg, Pb<=20mg/kg, Cr<=10mg/kg, As<=10mg/kg, aflatoxin<=10ug/kg.. The monitoring frequency is annually.
CCP2: sterilization for microbiological hazard control. The limits are temperature=75-90oC and time>=2 hours. The monitoring frequency is per hour.
CCP3: metal detection for physical hazard control. The limits are Fe=2.0mm, Cu=2.5mm and SUS=2.5mm. The monitoring frequency is per 2 hours.
For expanded porkhide and rawhide dog chews:
CCP1: hide receiving for diseas
The CCP monitoring records in Mar, 2019 were reviewed. Date, time, results, signature by operators and signature by reviewers were included.
The corrective action plan is included in the HACCP plan.
The verification for HACCP plan included internal audit results, deviation records, complaints and incidents.
The product shelf life is 18-36 months. The CCP monitoring records are kept for 5 years.
The review of HACCP plans was conducted on 2019-04-01.e, medicine residue control. The limit is that hide is provided from the approved vendor, Pb<=20mg/kg, Cr<10mg/kg. As<10mg/kg and medicine residue=not detectable. The monitoring frequency is annually.
CCP2: sterilization for microbiological hazard control. The limits are temperature=75-90oC and time>=2 hours. The monitoring frequency is per hour.
CCP3: metal detection for physical hazard control. The limits are Fe=2.0mm, Cu=2.5mm and SUS=2.5mm. The monitoring frequency is per 2 hours.
CLs are established against the official standards and customer requirements.
On-line measurement is used.

3. FOOD SAFETY AND QUALITY MANAGEMENT SYSTEM

3.1 FOOD SAFETY AND QUALITY MANUAL

The printed manual (YF/M01:2012) is available.
The manual has been released to each department.
All documents are legible in Chinese.

3.2 DOCUMENT CONTROL

The document control procedure (YF/R-P01:2012) is available. The control document lists are available. The document changing history is filed.

3.3 RECORD COMPLETION AND MAINTENANCE

The record control procedure (YF/P02:2012) is available. The monitoring record for oven sterilization is electronic form. The electronic record is printed every day.
The production and testing records are kept for 5 years. The product shelf life is 18-36 months.

3.4 INTERNAL AUDITS

The internal audit procedure (YF/P14:2012) is available. Internal audit is conducted annually against BRC standard. The activities throughout whole year are covered in the internal audit.

The official internal audit certificates are filed. The certifications were issued form Intertek and their numbers are F15-061005 and F15-061004. Last internal audit was conducted on 2019-01-20~21. Total 2 audit teams performed the internal audit. Auditors were independent.

The audit notification, audit plan, checklist, audit notes, NC reports and audit summary report are filed. Total 2 NCs were issued during the last internal audit. One NC report stated that the floor in the workshop was broken. The corrective actions were repair and daily inspection. The verification was conducted on 2019-01-27.

The hygiene inspection is conducted daily by the executive department.

3.4.1 Minor NC1: The internal audit control procedure was issued on 2012-01-10. The frequency is defined as twice per year.

3.4.2 Minor NC2: The internal audit control procedure was issued on 2012-01-10. The frequency is defined as twice per year. Latest internal audit was performed on Jan.3, 2019. 4 auditors attended this audit. Only one NCR was raised in internal audit. But found that two auditors from quality department audited their own work.

3.5 SUPPLIER AND RAW MATERIAL APPROVAL AND PERFORMANCE MONITORING

3.5.1 MANAGEMENT OF SUPPLIERS OF RAW MATERIAL AND PACKAGING

The risk assessment for raw materials and packaging materials are included in the hazard analysis. Hazard analysis includes the risks for microbiological, chemical, physical, fraud.
The vendor evaluation and selection control procedure (YF/P07:2012) is available. The approved vendor list is

filed. The suppliers of main raw materials hide and packaging materials are onsite audited annually.
No trading company is used.
No exception purchasing is applicable.

3.5.1.3 Major NC1: The procedure for the approval and monitoring of suppliers of services was absent.

3.5.1.4 Minor NC3: A supplier list was issued in Jan.2019. But a trade supplier (Shanghai Xinrong) was absent in this list.

3.5.2 RAW MATERIAL AND PACKAGING ACCEPTANCE, MONITORING AND MANAGEMENT PROCEDURES

The material acceptance standard (YF/WJY1:2012) is available. It includes the material list, acceptance items, acceptance limits, testing frequency, sampling plan, COA checking and visual inspection requirements. The acceptance report of the batch (202018122528) of raw hide was reviewed. The material was tested and released according to the procedures.

3.5.3 MANAGEMENT OF SUPPLIERS OF SERVICES

The control procedure for service companies is available. The transportation, irradiation, pest control, waste management and 3rd party testing are covered by the procedure.
The requirements for safety and quality are included in the contracts.

3.5.4 MANAGEMENT OF OUT SOURCED PROCESSING

The outsourced process, irradiation is required by the customers. Irradiation is refused by the Japanese customers. Other products are irradiation treated by shipping.
One irradiation company is used. It is audited every year. The traceability system is included in the supplier audit program.
The irradiation time and irradiation volume are defined by the contracts.
The microbiological tests are used for the irradiation effectiveness verification.

3.6 SPECIFICATIONS

The specifications (YF/W01-01) for raw materials and packaging materials are available.
The specifications (YF/W01-17) of all products are available.
The specification is copied from GB/T 23185-2008.
Specifications are reviewed annually.

3.7 CORRECTIVE AND PREVENTIVE ACTIONS

The corrective action procedure (YF/P09:2012) is available.
The procedure covers the non-conforming raw materials, non-conforming finished products, out-of-control process, customer complaints and audit/inspection findings. The corrective report for LOT No. 189283 was

reviewed. The report stated that the product was labelled with wrong brand cards. The root cause was brand card issue was not checked. The corrective action was double check for the brand cards. The verification was conducted by QA on 2018-11-23.

3.8 CONTROL OF NON-CONFORMING PRODUCT

The non-conforming product control procedure (YF/P11:2012) is available. The procedure describes that the quality department is responsible for decision making on the treatment of products. One non-conforming product treatment record on 2019-01-22 was reviewed. The root cause was that labels were not checked by the supervisor before issue. The corrective actions were that the training for label control was conducted, communication for quality issue report was conducted for operators and re-checking program for the packed products was established. The verification was conducted on 2019-02-13.

3.9 TRACEABILITY

During the audit all materials were coded for traceability control.
During the audit the batch (202018101223) of raw hide was traceability tested to the finished products and the batch of dog chew was tracked to all raw materials. The traceability rate was 100%. The test was finished within half an hour. Last traceability test from raw material to finished product was conducted on 2019-02-22 and test from finished product to raw materials was conducted on 2019-03-03. The tests were finished within 2 hours. The traceable rate was 100%. Traceability test including mass balance is conducted annually.
Verification of the supplier's traceability system was included in the onsite audit program.
The batch number of rework material is recorded for traceability control.

3.10 COMPLAINT-HANDLING

The customer information control procedure (YF/P19:2012) is available. Complaint data was trend analysed monthly. No complaint for food safety was received. Only one complaint was received in last 12 months. 70% reduction against last year.

3.11 MANAGEMENT OF INCIDENTS, PRODUCT WITHDRAWAL AND PRODUCT RECALL

The crisis management procedure (YF/P10:2012) covers the management for fire occurrence, explosion, natural disaster, chemical leakage, utility (power, water) supplying shortage, equipment breakdown and incident.
The recall management procedure (YF/P12:2012) is available. The recall management team list and related contact information are filed.
During the audit the batch (3301600100190023) was selected for mock recall testing. It could be finished within half an hour. The last mock recall was conducted on 2019-03-22.
Inform BRC CB within 3 working days is defined.

4. SITE STANDARDS

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4.1 EXTERNAL STANDARDS

No risk for site environment was found.

The external ground is made of concrete and maintained cleaning. The vegetation was maintained well.

The buildings were maintained well.

4.2 SITE SECURITY AND FOOD DEFENCE

The food defence plan (YF/FDPW-01) has been established. The water supplying system, production and storage areas are identified as controlled areas. The inspection for security risks is conducted annually. Last review was conducted on 2019-02-22. Total 126 cameras are used for storage and production areas. Employees are trained and encouraged to report signs of possible product tampering or breaks in the food security system.
No outdoor silo tank is used.
FDA: 14883771552

CIQ: 3300PF046

4.3 LAYOUT, PRODUCT FLOW AND SEGREGATION

The map of the factory is filed. The products are low risk products.
The flows of personnel, material, waste, finished products are identified.
The general GMP training is conducted for every visitor.
The cross contamination risk for process flows was not found.
No high risk area.
No high care area.
No ambient high care area.
Sufficient working space and storage capacity are kept.
No temporary structure was found.

4.4 BUILDING FABRIC, RAW MATERIAL HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

Walls were covered with coated iron boards in the workshops.
The walls are painted in the warehouse.
Floors are made of concrete.
The drainage system was in available in each workshop.
Neither high risk nor high care area is applicable.
The ceilings are covered with plastic boards. Risk from the ceilings was not found.
The suspended ceiling was sealed.
All windows in the material open areas are closed.
The window glass is filmed.
All doors were kept close fitting.
Sufficient lighting is provided.

All light fixtures are covered or LED light fixtures are used..
No condensation or excessive dust was found.

4.5 UTILITIES – WATER, ICE, AIR AND OTHER GASES

Tap water is used directly. Full tests for water quality are conducted by the government bureau annually against GB5749. 2-weekly monitoring items are TPC and coliform.
The water pipe map is filed
No initial product cleaning is applicable
No compressed air is used. Steam does not contact the products. Room air in the packing room is tested monthly. Its limit is 30cfu/dish.

4.6 EQUIPMENT

The equipment are suitable designed. Suitable placement of equipment is available for cleaning and maintenance.
The equipment are made of SUS.

4.7 MAINTENANCE

The annual maintenance plan was updated and approved by the equipment manager.
The weekly inspection was conducted by the repairers.
Temporary repair was not found.
The maintained equipment are cleaned before production.
Neither high-risk nor high-care area is applicable.
Food grade lubricant is used. Its NSF number is 145841.
The engineering workshop is located in the isolated building and maintained tidy.

4.8 STAFF FACILITIES

The changing rooms for the pre-treatment workshop and dried product (RTE) ware separated.
Personal items are stored in the designated points.
The outdoor clothing is stored in the cabinets and clean uniforms are stored on the shelf.
No high-risk area is applicable.
No high-care area is applicable.
Liquid soap, foot-control taps with hot water, disinfection pool, hand washing sign, air driers and disinfection pool are available in the hand washing stations.
Toilets are not located in any production buildings.
Smoking is forbidden in the production zone.
Food consuming is forbidden. The designated points for drinking are available.
No canteen is provided in the factory.

4.9 CHEMICAL AND PHYSICAL PRODUCT CONTAMINATION CONTROL: RAW MATERIAL HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

4.9.1 CHEMICAL CONTROL

The chemical control procedure (YF/P22:2012) is available. The controlled chemical list covers the sanitation chemical, engineering chemical, lab chemical. The chemicals are stored in the locked cabinets. MSDS sheets are available in the workshops.
No strongly scented material is used,

4.9.2 METAL CONTROL

The foreign matter control procedure (YF/P21:2012) is available. The scissors are inspected daily.
No clip is used. Staples are used as the packaging for mark card fixing according the customer requirements. Staples are used in the outer packing room.
The metal plates are used for product heating and made of SUS wire.

4.9.3 GLASS, BRITTLE PLASTIC, CERAMICS AND SIMILAR MATERIALS

No mobile glass item is used in the workshops. All windows are filmed.
The glass management procedure (YF/W GL22:2012) is available. All glass items are numbered. The glass inspection is conducted daily.
The above procedure describes that the affected products should be quarantined, the affected areas should be cleaned, the line should be stopped, the uniforms and shoes should be changed, the cleaned area should be inspected by the quality department after the broken glass is found and the broken glass should be replaced immediately.

4.9.4 PRODUCTS PACKED INTO GLASS OR OTHER BRITTLE CONTAINERS

No brittle container is used. The products are packed into soft PE bag.

4.9.5 WOOD

4.9.5.1 Minor NC4: On the first audit, the auditor found that wood tool was used in the moulding area of Vegetable Starch chew.

4.9.6 OTHER PHYSICAL CONTAMINANTS

Physical contaminants control procedure was in place, including depacking and deboxing requirements.

4.10 FOREIGN-BODY DETECTION AND REMOVAL EQUIPMENT

4.10.1 SELECTION AND OPERATION OF FOREIGN-BODY DETECTION AND REMOVAL EQUIPMENT

Metal detection is used for all products. Magnet is used for munchy products.
The HACCP process description includes the type, location and sensitivity of each device.
The verification for the metal detector is conducted per 2 hours.
The metal control procedure describes that the investigation should be conducted when the unexpected material is found.

4.10.2 FILTERS AND SIEVES

No sieve is used.

4.10.3 METAL DETECTORS AND X-RAY EQUIPMENT

Metal detection is used for the audit products.
The belt stop system is used for each metal detector. The locked box is used for detected product storage.
The documented SOP for metal detection is available.
The testing pieces, Fe=2.0mm, SUS=2.5mm and Cu=2.5mm are used.
The corrective action plan is included in the HACCP plan.

4.10.4 MAGNETS

Magnets are used for munchy products. They are tested when munchy products are produced. The limit is 200mT.

4.10.5 OPTICAL SORTING EQUIPMENT

No Optical sorting equipment is available.

4.10.6 CONTAINER CLEANLINESS – GLASS JARS, CANS AND OTHER RIGID CONTAINERS

No rigid container is used.

4.11 HOUSEKEEPING AND HYGIENE

During the audit the building and equipment were maintained cleaning generally.
The sanitation plan (YF/W H08:2012) is available. The production environment is disinfected with ozone every night. The equipment and tool are disinfected with 75% alcohol.
Neither high-risk area nor high-care is applicable.
The maintenance plan includes the requirements for cutting machine for cleaning.
Visual inspection is conducted daily. Swab test is conducted monthly. The limits are TPC<=10cfu/cm2 and coliform=Neg.
The food contact surfaces are cleaned with disposable paper.

4.11.7 CLEANING IN PLACE (CIP)

No CIP is used.

4.11.8 ENVIRONMENTAL MONITORING

Environmental monitoring procedure is implemented.
Record review did not find out-of-specification case.

4.12 WASTE

The license of the waste treatment company is filed.
During the audit the waste containers were maintained clean.
The waste treatment records include the waste volume.

4.13 MANAGEMENT OF SURPLUS FOOD AND PRODUCTS FOR ANIMAL FEED

The packaging materials are removed before disposal.
Rejected products are not sold for human consumption.
Rejected products are not downgraded for animal feed.

4.14 PEST MANAGEMENT

The pest control management requirements are included in the PRP (YF/W H03:2012).
Wenzhou Greenland Pest Control Co., Ltd. is contracted. The PCO licenses were issued from Zhejiang pest prevention control centre.
Contracted pest control company is used.
The map is filed.
The bait stations (No 9, 18, 27, 32) were checked and they are located per 10M.
During the audit all fly insect traps (No 11, 22, 6, 12) were checked and they were located in the suitable points.
The pest control procedure describes that the affected products should be re-evaluated when the infestation is found. No infestation has been found.
Pest inspection is conducted thrice from May to Oct and twice in other months.
The pest control survey is conducted quarterly.
Trend analysis is conducted monthly.
The pest control training for all staff has been conducted.
4.14.6 Minor NC5: No pest control was found in the primary packaging materials warehouse.

4.15 STORAGE FACILITIES

The warehouse management procedure (YF/P29:2012) is available.
The dedicated storage room for packaging materials is available.
Temperature control is not applicable.
Atmosphere storage is not required,
No outside storage is available.

The loading/uploading records are filed for FIFO policy control.

4.16 DISPATCH AND TRANSPORT

The transportation and release management procedure (YF/W GL14:2012) is available.
The carrier inspection is conducted for hygiene and license.
Temperature is not control.
The cleaning record for the lift is filed.
The crisis control plan for transportation, GMP and security requirements are included in the procedure.
The food safety and quality control requirements are included in the contracts.

5. PRODUCT CONTROL

5.1 PRODUCT DESIGN/DEVELOPMENT

The product design and process development procedure (YF/P18:2012) is available.

All changes are approved by the HACCP team.

Trial results are approved the HACCP team before the new equipment is used for formal production.

The products are long shelf life products (1.5-3years). The justification report stated that the main risk is microbiological contamination and the shelf-life is decided against the sterilization parameters.

5.2 PRODUCT LABELLING

Labels are provided by the customers. The information on the labels are verified by the sales and quality department during the contractor review.
The procedure describes that the label design should be reviewed by the quality when the formulation, origin of raw material, raw material and legal are changed.
No special claim.
Any changes are notified to the customers.

5.3 MANAGEMENT OF ALLERGENS

Allergen control is not applicable for pet foods.

5.4 PRODUCT AUTHENTICITY, CLAIMS AND CHAIN OF CUSTODY

The adulteration control procedure (YF/W GL51) was available.
The vulnerability assessment for the risk of adulteration was performed against the requirements from Entry-Exit Inspection and Quarantine Bureau. Last assessment was conducted on 2019-01-10.

Origin certificates of porkhide and rawhide are filed. Melamine test and restricted dye test are conducted.
No special identify preserving claim is applicable.
No special claim for methods of production.

5.5 PRODUCT PACKAGING

The safety characteristics of packaging are tested by the government bureau.
The thickness and tear resistance are included in the specification of plastic bag.

5.6 PRODUCT INSPECTION AND LABORATORY TESTING

5.6.1 PRODUCT INSPECTION AND TESTING

The testing program (YF/W JY03:2012) has been established. The testing methods, limits and frequencies are defined.
Trend analysis for testing results of size, appearance is conducted monthly.
One batch of each kind of product was selected for shelf life study every year. The retained samples are tested monthly for appearance, odor, color, moisture, coliform and salmonella.

5.6.2 LABORATORY TESTING

Pathogen testing lab is located in the office building.
The labs are located outside of the production zone. The GLP program (YF/W GL06:2012) has been established.
The 3rd party labs are CNAS certificated.
All testing methods are copied from the official standards. The official analyst licences are filed. The internal sample check program is established. Internal sample checking is conducted annually for all analysts.

5.7 PRODUCT RELEASE

The product release procedure (YF/W GL14:2012) describes that product release is approved by the quality manager after the related the testing reports for finished product, the production, packing, mass balance calculation, deviation and on-site QC inspection records are reviewed by the QA.

5.8 PET FOOD

The formulated of the product was suitable for the pets.
Products from different animals are thoroughly cleaned during conversion
The product didn't contain medicinal substances.

6. PROCESS CONTROL

6.1 CONTROL OF OPERATIONS

The SOPs for metal detection, packing, pressure moulding, oven sterilization, cutting, soaking and so on are available.
The alarm systems are used for metal detection.
The alarm of the metal detector is tested regularly.
The process validation is conducted per 3 years or when changes.
The procedure described that the affected product should be re-evaluated when the equipment is non-operational.

6.2 LABELLING AND PACK CONTROL

The line clearance procedure is available. The procedure describes that all labels, packaging materials are returned to the warehouse where changeover.
The line clearance is conducted and verified by the supervisor.
The inspection for label, volume, size, weight and printing information is conducted by QA. The inspection rate is established against AQL2.5.
No on-line vision equipment is used.

6.3 QUANTITY, WEIGHT, VOLUME AND NUMBER CONTROL

Double weight checking rate is established against AQL1.5 or customers' requirement.
No bulk material is applicable.

6.4 CALIBRATION AND CONTROL OF MEASURING AND MONITORING DEVICES

The measuring device list including equipment code numbers and their due dates is available. All devices are coded. The calibration management procedure (YF/P13:2012) is available.
The certificates of below devices were checked. They were current.
All devices are calibrated by the government bureau, Pingyang Institute of Measurement for Verification and Testing.
The above procedure describes that the affected products should be re-evaluated when the out-of-calibration equipment is found.

7. PERSONNEL

7.1 TRAINING: RAW MATERIAL HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

The training program for GMP, SSOP, hygiene, SOPs, HACCP, food safety, internal audit, ISO 9001, ISO 22000, EHS, testing, maintenance, supply control, chemical control, logistic, line clearance, security, pest control and so on
The training records for 3 operators for CCP monitoring were reviewed. Their training records for CCP control

were filed.
Training needs are included in the job descriptions. In-house training and on-line training methods are used.
Allergen control is not applicable for animal foods.
The CCP control, sanitation, GMP and chemical control training records are reviewed. The trainee's names, date, duration of the training, title, the trainer's name were included.
Annual performance evaluation is conducted for all staff.

7.2 PERSONAL HYGIENE: RAW MATERIAL HANDLING, PREPARATION, PROCESSING, PACKING AND STORAGE AREAS

The GMP management procedure (YF/W GL07:2012) is available.
Hand washing is required for everyone before entering the product open areas.
Blue plaster with metal wire is used.
The detection testing record of blue plaster is available.
Personnel medicines are stored outside of the workshops.

7.3 MEDICAL SCREENING

The GMP procedure includes the requirements for disease control.
Health questionnaire is filled by every visitor.
The health certificates for 10 employees were reviewed.

7.4 PROTECTIVE CLOTHING: EMPLOYEES OR VISITORS TO PRODUCTION AREAS

The instruction for uniform changing is posted in the changing room.

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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. No High-risk, High-care and Ambient High-care production zone.

8.2 BUILDING FABRIC IN HIGH-RISK AND HIGH-CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

8.3 MAINTENANCE IN HIGH-RISK AND HIGH-CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

8.4 STAFF FACILITIES FOR HIGH-RISK AND HIGH-CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

8.5 HOUSEKEEPING AND HYGIENE IN THE HIGH-RISK HIGH-CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

8.6 WASTE/WASTE DISPOSAL IN HIGH RISK, HIGH CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

8.7 PROTECTIVE CLOTHING IN THE HIGH-RISK HIGH-CARE ZONES

N/A. No High-risk, High-care and Ambient High-care production zone.

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DETAILS OF NON-APPLICABLE CLAUSES WITH JUSTIFICATION	
CLAUSE/SECTION REFERENCE	**JUSTIFICATION**
3.5.1.5	No trading company is used.
3.5.1.7	No exception purchasing is applicable.
4.2.3	No outdoor silo tank is used.
4.3.5	No temporary structure was found.
4.7.3	Temporary repair was not found.
4.8.8	No canteen is provided in the factory.
4.9.1.2	No strongly scented material is used,
4.9.4	No brittle container is used. The products are packed into soft PE bag.
4.10.2	No sieve is used.
4.10.5	No Optical sorting equipment is available.
4.10.6	No rigid container is used.
4.11.7	No CIP is used.
4.13.2	Rejected products are not sold for human consumption.
4.13.3	Rejected products are not downgraded for animal feed.
4.14.3	Contracted pest control company is used.

4.15.3	Temperature control is not applicable.
4.15.4	Atmosphere storage is not required,
4.15.5	No outside storage is available.
4.16.3	Temperature is not control.
5.2.3	No special claim.
5.3	Allergen control is not applicable for pet foods.
5.4.4	No special identify preserving claim is applicable.
5.4.5,5.4.6	No special claim for methods of production.
5.8.3	The product didn't contain medicinal substances.
6.2.4	No on-line vision equipment is used.
6.3.3	No bulk material is applicable.
7.4.6	No glove is use.

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9 - TRADED PRODUCTS

9.1 APPROVAL AND PERFORMANCE MONITORING OF MANUFACTURERS/PACKERS OF TRADED FOOD PRODUCTS

9.2 SPECIFICATIONS

9.3 PRODUCT INSPECTION AND LABORATORY TESTING

9.4 PRODUCT LEGALITY

9.5 TRACEABILITY

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MODULE 11: MEAT SUPPLY CHAIN ASSURANCE	
SCOPE	
11.1 TRACEABILITY	
11.2 APPROVAL OF MEAT SUPPLY CHAIN	
11.3 RAW MATERIAL RECEIPT AND INSPECTION	
11.4 MANAGEMENT OF CROSS-CONTAMINATION BETWEEN SPECIES	
11.5 PRODUCT TESTING	

11.6 TRAINING

MODULE 12: AOECS GLUTEN-FREE FOODS	
SCOPE	
12.1 SENIOR MANAGEMENT	
12.2 MANAGEMENT OF SUPPLIERS OF RAW MATERIALS AND PACKAGING	
12.3 OUTSOURCED PRODUCTION	

12.4 SPECIFICATIONS

12.5 MANAGEMENT OF GLUTEN CROSS-CONTAMINATION

12.6 MANAGEMENT OF INCIDENTS, PRODUCT WITHDRAWAL AND PRODUCT RECALL

12.7 LABELLING

12.8 PRODUCT INSPECTION AND LABORATORY TESTING

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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	The adequate lighting is provided in the hand washing areas, dressing and locker rooms. No bathroom is used.
2	13.1.2	Water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Total three water supplying inlets. The prevent backflow devices are installed for all inlets.
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	Y	The equipment are made of SUS. Seams are smooth.

		growth of microorganisms and allergen cross-contact.		
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 is used at the facility.
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	Dilution with other batches is forbidden. The DALs are established against EC No. 1069/2009, GB/T 23185-2008 and FDA requirements. Coliform<10cfu/g, Salmonella=ND, dye (amaranth & carmine)=ND, Pb<20mg/kg, Cr<10mg/kg, As<10mg/kg, veterinary drug residue=ND and melamine<0.25mg/kg, aflatoxin<1ug/kg..
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	Y	Some products are irradiation treated after packing. Irradiation dose is defined in the contract. The assessment for adulterants has been conducted. Risks from environment pathogens were included in the OPRP program (YF/W H03.2012).

		adulterants which 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	SSOP, GMP, CP, OPRP and CCPs are used for hazard control.
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, 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.	Y	The preventive controls are evaluated for effectiveness.
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	Y	The effectiveness is evaluated every year when mock recall. The methods for recalled product disposal are defined.

		product		
10	13.1.10	Establish monitoring activities and a written procedure for each preventive control consistent with the requirements of BRC section 2.10.	Y	The control plans have been established.
11	13.1.11	Establish corrective action procedures when preventive controls are not implemented consistent with the requirements of BRC 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 (i.e., product testing and/or environmental monitoring).	Y	The HACCP program and OPRP programs require to evaluate the effected products when the negative results of environment monitoring are found.
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	Validation for HACCP program is conducted annually or prior to implementation. Revalidation is conducted before changes are approved.
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	Y	All corrective actions are reviewed by the QA manager who is PCQI certificated. The record control procedure describes that the key records are checked immediately.

		records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record is created.		
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	The sampling plan, testing methods, corrective action plans are included in the OPRP program.
15	13.1.15	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and 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	Y	The environment monitoring program is in place.

		pathogen is detected		
16	13.1.16	Devices used to verify preventive controls must be calibrated.	Y	All devices are included in the calibration plan.
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	The training and job experience of PCQIs are listed. The training certificate number is 09642e75.
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	The records in Mar, 2019 were reviewed. The date, time, signature of operators, location, batch number and product name were included in most records.
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	The food safety plan has been signed by the owner and operators.
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	Y	The records are kept for 5 years. The product shelf life is 18-36 months. All records are kept by the quality department at the facility.

		records are stored offsite, they must be retrievable within 24 hours with the exception of the food safety plan, which must remain onsite.		
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	The suppliers of hide are identified as high risk. They are audited annually. The alarm information is provided from the Pet Food association and CIQ.
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	Emergency purchasing is forbidden. Suppliers are approved before material supplying.
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	The audit for the key suppliers is conducted annually.
24	13.2.1	Human food by-products held for distribution as animal food must be held under conditions that will protect against	N/A	No by-product in factory.

		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.		
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.	Y	The QA manager was charge for food defence plan, vulnerability assessment design, and the factory manager was QI for food defence and vulnerability assessment.

		One or more QI's shall be responsible for implementing mitigation strategies at actionable process steps.		
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 • Mitigation strategies appropriate to reduce the vulnerability • Procedures for food defense monitoring, corrective action and verification	Y	The food defence procedure was include all the requirement in left table.
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	Y	The vulnerability assessment procedure was in place, all the raw-material and supplier were carry out vulnerability assess annually, the assessment report was documented.

		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.		
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	All the risks corresponding to vulnerability have corresponding measures, such as on-site audit.
29	13.3.5	Written monitoring procedures shall be established and implemented to include the activity and frequency for monitoring food defense mitigation strategies. Procedures shall include recordkeeping requirements for all monitoring activities.	Y	Food defence procedure was include monitoring requirement.
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	Y	Food defence procedure was include corrective action requirement.

		corrective actions		
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	Food defence procedure was include verification requirement.
32	13.3.8	Reanalysis of the food defense plan shall be documented and performed every three years or whenever • A change in facility operations which creates a new significant vulnerability • Knowledge about a new threat applicable to the	Y	The factory review the food defence plan annually and the review was documented.

		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	All the record in factory was meet the 21 CFR 121 requirement.
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	The food defense plan was sign by factory owner.
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 the food defence record were keep at least 2 years.

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 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.	Y	The factory established documented Vehicles and transportation equipment inspection procedure, all the containers and vehicles must inspect and clean before loading.
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.	Y	Contracts was sign with shipping company with FSMA requirement.

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.	Y	All the vehicles and containers were inspect and clean before loading.
39	13.4.4	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	Y	The responsible for the shipping contracts was specific.
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	Dried pet food, no need temperature controlled
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	Y	The responsible for the shipping contracts was specific.

		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		
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	Y	The training requirement for the shipping contracts was specific.
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 records shall be retrievable within 24 hours.	Y	All the transportation record were keep at least 2 years.
44	13.4.9	The recordkeeping policy shall ensure all sanitary design requirements and cleaning procedures for vehicles are maintained onsite and all offsite	Y	All the transportation record were keep at least 2 years.

		records are retrievable within 24 hours.		
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	The food hygiene and produce safety was given to the relevant staff, record were provided.
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 primary agricultural products, no harvest activities in 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	One Staffs had attended FSMA training course, which she was the QA manager in factory.
48	13.5.4	A supervisor shall be identified with responsibility for the	Y	Organizational chart mark the onsite QA monitor the production

		operation and ensuring compliance with Produce Safety regulation. This individual shall be identified on the site's organizational chart.		site product and active.
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 site.
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	No agricultural water on site.
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	No agricultural water on site.

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	Use Chinese national standard GB5749, the testing report include the generic E. coli item, result: no detectable in 100mL.
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	No agricultural water on site.
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	N/A	No agricultural water on site.

		method.		
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	No agricultural water on site.
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	No primary agricultural products, no harvest activities in factory.
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.	Y	Sewage disposal and septic systems was far from the production site, It belongs to municipal water supply network.
58	13.5.14	Plumbing shall not allow backflow or cross-connection between waste and potable water lines.	Y	No cross-connection between waste and potable water lines in factory.
59	13.5.15	All produce safety related records must be reviewed,	Y	All the related record were review by PCQI or authorized staff in

		dated, and signed within a reasonable timeframe after being made by the supervisor or responsible party.		24h.
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 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.	Y	All the record in factory were keep for at least 2 years.
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	Y	EMP was the same as 4.11.8 of BRC. And no primary agriculture product.

		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).		
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: • 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	Y	EMP was the same as 4.11.8 of BRC. And no primary agriculture product.

		• Take additional action to prevent recurrence and to prevent adulterated food from entering commerce		

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FSMA Preventive Controls Preparedness Module Assessment Report

BRC GLOBAL STANDARD FOR FOOD SAFETY ISSUE 7

Item no.	Clause	Module item	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.	Y	The adequate lighting is provided in the hand washing areas, dressing and locker rooms. No bathroom is used.
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	Y	Total three water supplying inlets. The prevent backflow devices are installed for all inlets.
3	117.40	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	The equipment are made of SUS. Seams are smooth.
4	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.	N/A	No ice is used at the facility.
5	117.110	Where defect action levels (DALs) 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	Dilution with other batches is forbidden. The DALs are established against EC No. 1069/2009, GB/T 23185-2008 and FDA requirements. Coliform<10cfu/g, Salmonella=ND, dye (amaranth & carmine)=ND, Pb<20mg/kg, Cr<10mg/kg, As<10mg/kg, veterinary drug residue=ND and melamine<0.25mg/kg, aflatoxin<1ug/kg..
6	117.130 (a)	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 that affect food safety.	Y	Some products are irradiation treated after packing. Irradiation dose is defined in the contract. The assessment for adulterants has been conducted. Risks from environment pathogens were not included in the OPRP program (YF/W H03.2012).
7	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to	Y	SSOP, GMP, CP, OPRP and CCPs are used for hazard control.

		determine 'hazards that require a preventive control' (i.e., significant hazards).		
8	117.135	Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, 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.	Y	The preventive controls are evaluated for effectiveness.
9	117.139	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 of recalled product (i.e., destroy, divert, repurpose).	Y	The effectiveness is evaluated every year when mock recall. The methods for recalled product disposal are defined.
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.	Y	The control plans have been established.
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC 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 (i.e., product testing and/or environmental monitoring).	N	No procedure requires to evaluate the effected products when the negative results of environment monitoring are found.
12	117.160	Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation 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	Validation for HACCP program is conducted annually or prior to implementation. Revalidation is conducted before changes are approved.
13	117.165 (a)	The PCQI (or authorized designee) reviews the monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.	N	NC: No procedure defines the deadline, review the monitoring and corrective action records within 7 days. The record control procedure describes that

		The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.		the key records are checked immediately.
14	117.165 (b)	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 an analysis • corrective action procedure where a pathogen is detected.	Y	The sampling plan, testing methods, corrective action plans are included in the OPRP program.
15	117.165 (c)	Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following: • adequate number and location of sample sites • timing and frequency of sampling • analytical method • laboratory conducting the analysis • corrective action procedure where a pathogen is detected.	Y	The environment monitoring program is in place.
16	117.165	Devices used to **verify** preventive controls must be calibrated.	Y	All devices are included in the calibration plan.
17	117.180	Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan. Document the PCQI's training or qualifications via job experience.	Y	The training and job experience of PCQIs are listed.
18	117.305	All records required by 21 CFR § 117 must include: • the date and time of the activity being documented • signature/initials of individual performing the activity or conducting the record review • information to identify the facility (e.g., name and location) • the identity of the product and lot code where applicable.	Y	The records in Jan, 2017 were reviewed. The date, time, signature of operators, location, batch number and product name were included.

19	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.	Y	The food safety plan has been signed by the owner and operators.
20	117.315	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	The records are kept for 5 years. The product shelf life is 18-36 months. All records are kept by the quality department at the facility.
21	117.405	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	The suppliers of hide are identified as high risk. They are audited annually. The alarm information is provided from the Pet Food association and CIQ.
22	117.420	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	Emergency purchasing is forbidden. Suppliers are approved before material supplying.
23	117.430	One or more supplier verification activities (as defined in 21 CFR § 117.410(b)) must be conducted for each supplier **before** using raw materials and ingredients **and** periodically thereafter at an adequate frequency.	Y	The audit for the key suppliers is conducted annually.

Voluntary Modules Non-Conformity Summary Sheet

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

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

Claudio Innocenti

1	11	No procedure requires to evaluate the effected products when the negative results of environment monitoring are found.	The verification procedure was updated to describe that the effected products should be held and evaluated when the negative environment monitoring result is found.	Update the verification procedure to require evaluating effected products when the negative environment monitoring result is found.	Procedure	2017-05-09	Tony Chen
2	13	No procedure defines the deadline, review the monitoring and corrective action records within 7 days.	The corrective action procedure has been updated to describe that the production records and corrective action records are verified within 7 days.	Update the corrective action procedure to define the record review deadline.	Procedure and records.	2017-05-09	Tony Chen

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Auditor number: 168086

BRC Site Code: 8594252

Wenzhou Yuanfei Pet Toy Products Co., Ltd.

In conjunction with an audit for

Global Standard Food Safety Issue 7

HAS SUCCESSFULLY COMPLETED THE BRC GLOBAL STANDARDSFSMA Preventative Controls Preparedness Module

Scope: Wringing, cutting, enzymolysis, moulding, dyeing, heating sterilization, flavouring and packing into plastic bag of expanded rawhide and porkhide dog chews. Sorting, grading, cutting, soaking, moulding, drying, smoking, heating sterilization, flavouring and packing into plastic bag of dry dog chews. Hide milling, rice cooking, mixing, moulding, heating sterilization, flavouring and packing into plastic bag of munchy dog chews.

Audit Dates: 26-28 Apr 2017

Issue Date: 11 May 2017

Re-audit Due Date from: 29 Mar 2018 to: 26 Apr 2018

Expiry Date: 07 Jun 2018

Issue Number: 051A1206001-M15

Authorised by

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10a Victory Park, Victory Road, Derby, DE24 8ZF,
United Kingdom

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BRC CERTIFICATION BODY

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

Claudio Innocenti

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Auditor number:

BRC Site Code: 8594252

Wenzhou Yuanfei Pet Toy Products Co., Ltd.

No. 1, Chongle Road, Standard Park, Shuitou Town, Pingyang County, Wenzhou City, Zhejiang Province

In conjunction with an audit for

Global Standard Food Safety Issue 8

HAS SUCCESSFULLY COMPLETED

THE BRC GLOBAL STANDARDS 'FSMA'

Scope: Wringing, cutting, enzymolysis, moulding, dyeing, heating sterilization, flavouring and packing into plastic bag of expanded rawhide and porkhide dog chews. Sorting, grading, cutting, soaking, moulding, drying, smoking, heating sterilization, flavouring and packing into plastic bag of dry dog chews. Hide milling, rice cooking, mixing, moulding, heating sterilization, flavouring and packing into plastic bag of munchy dog chews.

BRC GLOBAL STANDARDS FSMA READY

REVIEWED BY CLAUDIO INNOCENTI (PCQI) REVIEWED ON OR ABOUT July 11 - 19, 2019 Managing Partner & Member

REVIEWED

Audit Dates: 23-26 Apr 2019

Issue Date: 10 Jun 2019

Re-audit Due Date from: 29 Mar 2020 to: 26 Apr 2020

Expiry Date: 07 Jun 2020

Issue Number: 051A1206001-M15

Authorised by

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10A Victory Park, Victory Road,
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BRC CERTIFICATION BODY

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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)

Search

Wenzhou Yuanfei Pet

Showing 0 to 0 of 0 entries (filtered from 3,119 total entries)

Filters

Issuing Office

Letter Issue Date **Letters with Response or Closeout**

Posted Date **Year**

Clear Filters

Show 10 entries Export Excel

Posted Date	Letter Issue Date	Company Name	Issuing Office	Subject	Response Letter	Closeout Letter

No matching records found

Showing 0 to 0 of 0 entries (filtered from 3,119 total entries)

Previous Next

Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number Help

14883771552

No data found

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food); and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food)) require that importers and facilities perform certain risk-based activities to verify that their

suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

Collapse All | Expand All

- **Warning Letters**
- **Import Alerts**
- **Recalls**
- **Import Refusals**
- **Inspection Classifications**
- **Other Compliance Resources**

Contact

Questions and comments pertaining to the FDA Data Dashboard and source data may be directed by email to: **FDADataDashboard@fda.hhs.gov** (mailto:FDADataDashboard@fda.hhs.gov)

Language Assistance Available: Español (https://www.fda.gov/about-fda/about-website/language-assistance-services#spanish) | 繁體中文 (https://www.fda.gov/about-fda/about-website/language-assistance-services#chinese) | Tiếng Việt (https://www.fda.gov/about-fda/about-website/language-assistance-services#vietnamese) | 한국어 (https://www.fda.gov/about-fda/about-website/language-assistance-services#korean) | Tagalog (https://www.fda.gov/about-fda/about-website/language-assistance-services#tagalog) | Русский (https://www.fda.gov/about-fda/about-website/language-assistance-services#russian) | العربية (https://www.fda.gov/about-fda/about-website/language-assistance-services#arabic) | Kreyòl Ayisyen (https://www.fda.gov/about-fda/about-website/language-assistance-services#creole) | Français (https://www.fda.gov/about-fda/about-website/language-assistance-services#french) | Polski (https://www.fda.gov/about-fda/about-website/language-assistance-services#polish) | Português (https://www.fda.gov/about-fda/about-website/language-assistance-services#portuguese) | Italiano (https://www.fda.gov/about-fda/about-website/language-assistance-services#italian) | Deutsch (https://www.fda.gov/about-fda/about-website/language-assistance-services#german) | 日本語 (https://www.fda.gov/about-fda/about-website/language-assistance-services#japanese) | فارسی (https://www.fda.gov/about-fda/about-website/language-assistance-services#farsi) | English (https://www.fda.gov/about-fda/about-website/language-assistance-services#english)

Search Results

FEI Number	Firm Name	Physical Address	Mailing Address
3009807829	Wenzhou Yuanfei Pet Toy Products	Zhangjiang Industrial Park, NO. 1 Chongle Road, Wenzhou, Zhejiang, CN	Zhangjiang Industrial Park, NO. 1 Chongle Road, Wenzhou, Zhejiang, CN

Firm/Supplier Evaluation Resources

The FDA firm and supplier database available on this site includes data associated with inspections classification, inspections citations, compliance actions, recalls, and imports.

Search by Firm Name or FEI Number Help

3009807829

No data found

Three FDA FSMA rules (Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals); Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food); and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food)) require that importers and facilities perform certain risk-based activities to verify that their suppliers are meeting applicable U.S. food safety standards. Under these rules, you must evaluate, among other things, the applicable FDA food safety regulations and information relevant to the supplier's compliance with those regulations, including whether the supplier is the subject of an FDA warning letter, import alert, or other FDA compliance action related to food safety, and document the evaluation.

Below is a list of publicly available resources that can be used to meet the requirement set out in these regulations as well as information on their use:

Collapse All | Expand All

Warning Letters

Import Alerts

Recalls

Import Refusals

Inspection Classifications

Other Compliance Resources

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(../cd/imprefusals.htm)

Imports
Entry
(../cd/impentry.htm)

Language Assistance Available: Español
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