|  |  |
| --- | --- |
| Facility name: | RFE Permit/License Number: |
| Address: | Person In Charge: |
| Process Reviewed: | Person(s) interviewed: |
| Date of written plan approval: | Amended since approval? Yes No |
| Inspector: | Date of Audit: |
| Inspection type: Pre-approval Routine Verification Follow-up | |

Facility Overview and General HACCP Criteria/Observations

Space in each comment field will expand as needed to accommodate as much data as is required. Additional rows may be added to each section or deleted from each section as needed.

**A. Processes Reviewed** (All regulatory citations are based on the current version of the FDA Food Code.)

|  |  |  |  |
| --- | --- | --- | --- |
| *Must complete the process-specific lettered section of this form (in the following pages) for each applicable process.* | | | |
| Section H: ROP for storage of raw proteins or cheeses  Section I: ROP – Sous Vide cooking  Section J: ROP Cook-Chill  Section K: ROP – Other ROP packaging per 3-502.11(D)  Section L: Curing for preservation 3-502.11(A-C)  Section M: Acidification/Fermentation/Additives | Section N: Sprouting  Section O: Custom Processing  Section P: Molluscan Shellfish Tanks  Section Q: Processing Juice  Section R: Other processing methods per 3-502.11(G) requiring HACCP – specify: | | |
| Practices, products and equipment observed in the kitchen reflect the HACCP plan as approved | |  |  |
| A working copy of each approved HACCP plan is available for daily use. | |  |  |
| Storage and display – shelf life and expiration dates meet requirements of the approved plan | |  |  |
| Monitoring Records required by HACCP plan are current and available | |  |  |
| Other: | |  |  |
| **Comments:** | |  |  |

**B. Establishment has implemented effective Pre-Requisites**

**(Document violations on Food Establishment Inspection Report.) 8-103.12(A)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Yes** | **No** |
| **Training 8-201.14(E)(1)** | The RFE has a training program supporting all aspects of the plan. |  |  |
| The food safety issues of concern are included in training. |  |  |
| Is training provided whenever appropriate, is it documented, and are records available? |  |  |
| Employee correctly demonstrates relevant calibration procedures and pH, temperature, or other CCP measurements for inspector. |  |  |
| **Employee Health and Hygiene Policies**  **2-103.11(P), 2-2, 2-3, 2-4** | The RFE has an Employee Health Policy that includes a written plan for exclusion, restriction and reinstatement. |  |  |
| The RFE has an Employee Hygiene Policy that meets requirements of Food Code 2-2, 2-3. |  |  |
| Bare-hand contact with ready-to-eat (RTE) foods is prohibited, per Food Code 3-301.11(B). |  |  |
| **Sanitation Procedures (SSOP) 2-201.14(E)(3)** | A procedure and schedule or frequency are provided for cleaning and sanitizing equipment used in the approved process. |  |  |
| When applicable to the process, potential physical hazards are prevented by inspection of process equipment as part of sanitation procedures. |  |  |
| **Validation & Verification**  **8-201.14(D)(4,6); (E)(3)** | Appropriate validation is provided for each critical limit (specified by regulation, other authoritative source, or scientific data). |  |  |
| Calibration procedures and frequency are provided for pH meters, thermometers, and/or scales used to monitor Critical Limits. |  |  |
| Responsibility and frequency for management verification of employee compliance with procedures and review of monitoring records is assigned. |  |  |
| Responsibility and frequency for management review and maintenance of the HACCP plan is assigned. |  |  |
| Comments: | |  |  |

**C. List Critical Control Points and Critical Limits identified by the approved HACCP Plan(s). 8-103.12(B)**

|  |  |  |  |
| --- | --- | --- | --- |
| **HACCP Process** | **Critical Control Point #**  **and description** | **Critical Limits** | **Comments/Problems Noted** |
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**D. List monitoring records required by the establishment’s HACCP plan(s). 8-103.12(B)(1)**

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| --- | --- | --- |
| **Process reviewed:** | | |
| **Record Name and document date** | **Monitoring Procedure and Frequency** | **Observations: Compliant with Plan, and consistent with facility operations?** |
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| **Comments:** | | |

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| --- | --- | --- |
| **E. Accurate Description of Product, Process and Intended Uses. 8-201.14(A)** | **Yes** | **No** |
| Accurate description or list of products produced is included in each HACCP Plan or procedure |  |  |
| Food flow, menu, packaging, and formulation consistent with flow chart and approved HACCP plans |  |  |
| Plan has been updated to reflect any changes; significant changes have regulatory approval. |  |  |
| Product is used as intended – in-house, sale for consumer use, or both. |  |  |
| Product is labeled according to Food Code and process-specific labeling requirements, including allergen declarations (3-404.11, 3-502.12, 3-602.11). |  |  |
| **Comments:** |  |  |
| **F. Hazards 8-201.14(C)(2)** | **Yes** | **No** |
| HACCP records observed today are accurate for the observed situation in the facility. |  |  |
| Employee(s) demonstrate knowledge of CCPs, monitoring, critical limits, and process risk factors. |  |  |
| Employee demonstrates understanding of importance of critical limits when asked. |  |  |
| All Critical Control Points and Critical Limits are followed per HACCP plan – including temperatures, times, pH values, and others depending on the process. |  |  |
| Routine instrument calibrations (pH, thermometer) performed & documented on appropriate form. |  |  |
| Are there specific strengths or weaknesses in monitoring or record keeping? Note in comments. |  |  |
| **Comments:** |  |  |
| **G. Employee Shows knowledge of corrective actions required if critical limit exceeded/not met.**  **8-103.12(B)(3)** | **Yes** | **No** |
| When critical limits established by plan are not met, are immediate corrective actions taken, recorded? |  |  |
| Employee knows who to contact when taking corrective action, and documents actions on appropriate log form. |  |  |
| PIC demonstrates knowledge of corrective action, proper disposal of food unfit for consumption. |  |  |
| Written procedures and plans, where specified by this regulation and as developed by the retail food establishment, are maintained and implemented as required by the PIC: 2-103.11(P) |  |  |
| Corrective actions taken reflect the same actions prescribed in the RFE’s HACCP plan. |  |  |
| **Comments:** |  |  |

**Process-Specific Observations**

**Review records for three random process dates for each process audited. 1 2 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **H. Reduced Oxygen Packaging 3-502.12(B, C, or E) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| ROP products not requiring a variance are packaged and labeled as required by relevant section of Food Code 3-502.12. |  |  |  |
| ROP products not requiring a HACCP plan are packaged, labeled, stored, and removed from package within 48 hours under an approved variance as required by Food Code 3-502.12(F). |  |  |  |
| Packaging (Seal is complete, appropriate film used, no debris in seal; labels; no evidence of cross-contamination) |  |  |  |
| Fish products of all types, frozen before, during, and after ROP packaging per Food Code 3-502.12(C) and removed from packaging when taken out of freezer. |  |  |  |
| Use-by dates are properly assigned, monitored, and followed. |  |  |  |
| If held under refrigeration, fish products held using 10K OTR under an approved variance; this package not used for sous vide or ROP cook-chill. |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **I. ROP Sous Vide Cooking 3-502.12(D) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Products are cooked, cooled, cold held, and reheated as required by plan. |  |  |  |
| Cold held products held at proper temperature according to plan, with continuous electronic monitoring inspected 2x/day for operation. |  |  |  |
| Cook chill products are bagged at 135oF or higher temperature. |  |  |  |
| Packaging (Seal is complete, appropriate film used, no debris in seal; labeled as required; no evidence of cross-contamination) |  |  |  |
| Use-by dates are properly assigned, monitored, and followed. |  |  |  |
| Sous vide and cook chill products are only for in-house use – not sold to customers for take-out. |  |  |  |
| **Comments:** |  |  |  |

**Review records for three random process dates for each process audited.** **1 2 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **J. ROP Cook Chill Processes 3-502.12(D) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Products are cooked, cooled, cold held, and reheated as required by plan. |  |  |  |
| Cold held products held at proper temperature according to plan, with continuous electronic monitoring inspected 2x/day for operation. |  |  |  |
| Cook chill products are bagged at 135oF or higher temperature. |  |  |  |
| Packaging (Seal is complete, appropriate film used, no debris in seal; labeled as required; no evidence of cross-contamination) |  |  |  |
| Use-by dates are properly assigned, monitored, and followed. |  |  |  |
| ROP Cook chill products are only for in-house use – not sold to customers for take-out. |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **K. Reduced Oxygen Packaging (other methods) or use of 10K OTR 3-502.11(D) N/A**  **(variance required for either method)** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| ROP products not requiring a variance are packaged and labeled as required by relevant section of Food Code 3-502.12. |  |  |  |
| ROP products not requiring a HACCP plan are packaged, labeled, stored, and removed from package within 48 hours under an approved variance as required by Food Code 3-502.12(F). |  |  |  |
| Packaging (Seal is complete, appropriate film used, no debris in seal; labels; no evidence of cross-contamination) |  |  |  |
| Fish products of all types, frozen before, during, and after ROP packaging per Food Code 3-502.12(C) and removed from packaging when taken out of freezer. |  |  |  |
| Use-by dates are properly assigned, monitored, and followed. |  |  |  |
| If held under refrigeration, fish products held using 10K OTR under an approved variance; this package not used for sous vide or ROP cook-chill. |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- | --- |
| **L. Curing and Smoking Processes 3-502.11(A-C) Process Type (describe) N/A** | **Yes/No** | **Yes/No** | **Yes/No** | |
| Batch Dates reviewed |  |  |  | |
| Approved recipes are followed, including proper cure/protein ratio; no unapproved recipes used. |  |  |  | |
| Calibrated scale is used for weighing cure salt and for monitoring drying processes. |  |  |  | |
| Temperatures (and humidity, where specified in the HACCP Plan) are monitored correctly for each CCP. (cooking/smoking; cooling; cold holding) |  |  |  | |
| Unique batch identifier is assigned for traceability on product and batch records. |  |  |  | |
| When required, pH measurements made from properly prepared, representative sample using calibrated, maintained pH meter. |  |  | |  |
| Date marks, when required, are properly assigned and followed. |  |  | |  |
| **Comments:** |  |  | |  |

**Review records for three random process dates for each process audited. 1 2 3**

|  |  |  |  |
| --- | --- | --- | --- |
| **M. Acidification/Fermentation/Additives used for Preservation 3-502.11(C) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| In pickled fish proteins such as ceviche, parasite destruction is addressed by approved supplier. |  |  |  |
| Date marking is used properly when required by the approved procedure/recipe. |  |  |  |
| When required, pH measurements made from properly prepared, representative sample using calibrated, maintained pH meter or appropriate test strips. |  |  |  |
| When required by the approved procedure, samples are held at proper temperature. |  |  |  |
| Acidified canned or bottled foods held as shelf-stable are produced under a Better Process Control certification. |  |  |  |
| Only approved additives (GRAS) are used in compliance with FDA regulatory specifications |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **N. Sprouting per 3-502.11(H) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Seed is from an approved source traceable by lot code and is inspected upon receipt for sanitary condition with no damage. |  |  |  |
| Stored in clean, sanitized containers, protected from cross-contamination & rodents. |  |  |  |
| An approved pathogen-reducing seed pretreatment is used as prescribed by FDA. |  |  |  |
| Sprouting containers cleaned and sanitized after each batch, no damaged sprouting containers. |  |  |  |
| Irrigation water is tested pre-harvest for Salmonella, E. coli O157:H7. |  |  |  |
| Harvested sprouts are rinsed with potable water, handled according to regulations as RTE food, labeled with lot code/date and kept refrigerated. |  |  |  |
| If using un-treated seed, an approved heat treatment step is applied to the sprouts before service. |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **O. Custom Processing per 3-502.11(F) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Processing is conducted only when RFE is not in operation. |  |  |  |
| Processing is conducted only in designated space or separated by time and thorough sanitation of the space before return to normal use. |  |  |  |
| Unprocessed animals and custom processed meat are stored and processed separate from retail meat, and are tagged “Not for Sale” |  |  |  |
| Receiving and processing records include carcass tag identification, receiving and processing times for all animals processed. |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **P. Molluscan Shellfish Tanks per 3-502.11(E) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Shellstock or processed shellfish received from licensed harvesters/processors, and tags are retained for at least 90 days in chronological order |  |  |  |
| All product received at proper temperature (verified for each shipment) |  |  |  |
| Commingling protocol allows for required traceability by tag number(s) |  |  |  |
| Product stored in cooler or tank is stored at proper temperature, and temperature checked 2x/daily |  |  |  |
| Plan includes policy/procedure for culling cracked and dead shellfish |  |  |  |
| Plan includes procedures and schedule for maintaining the tank and UV disinfection system |  |  |  |
|  |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| **Q. Processing Juice per 3-404.11(A) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| Juice is pasteurized or treated according to conditions prescribed by a recognized process authority; process letter is on file and available for review. |  |  |  |
| Person overseeing treatment is properly certified under Juice HACCP regulations to manage the process. |  |  |  |
| If surface treatments of citrus fruits are used to achieve 5-log microbial reduction, procedure complies with requirements of 21 CFR Part 120. |  |  |  |
| All fruit is properly inspected for defects, bruising, damage that could harbor pathogens prior to processing. |  |  |  |
| Finished product is properly stored and labeled; if treated using UV irradiation rather than pasteurization, is the required label statement included per [FDA Guidance](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-juice-haccp). |  |  |  |
| **Comments:** |  |  |  |

**1 2 3**

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| --- | --- | --- | --- |
| **R. Other Processing Methods that require a HACCP plan per 3-502.11(G) N/A** | **Yes/No** | **Yes/No** | **Yes/No** |
| Batch Dates reviewed |  |  |  |
| All ingredients and packaging materials are from approved sources. |  |  |  |
| Process requirements for critical temperatures and times are followed (cooking, cooling, cold holding, fermenting, aging, drying or other such function – as relevant. |  |  |  |
| Finished product is labeled as required by the approved HACCP plan. |  |  |  |
| Product shelf life and storage conditions are as required by the approved HACCP plan. |  |  |  |
| Any additives in the product formulation are used as specified in the approved HACCP plan. |  |  |  |
| HACCP plan is operated in compliance with process prescribed by a Processing Authority. |  |  |  |
| HACCP plan is operated in compliance with applicable law. |  |  |  |
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| **Comments:** |  |  |  |

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| --- |
| **S. Other Issues or comments needing attention** |
| **Comments:** |

**Corrective Action Needed:**

None – Establishment is in compliance with Food Code and other regulatory requirements as applicable, and with their approved HACCP Plan.

Corrective Action Required for specific items – see inspection report

Suspension of process. <insert explanation>

Voluntary disposal of food

Employee training < insert what type of training and other relevant details>

Other:

|  |  |  |  |
| --- | --- | --- | --- |
| Inspector: |  | Inspection Date: |  |