# Appendix A

## AAFCO Standard for "Human Grade" Pet Food

AAFCO developed the following standard for making "human grade" pet food claims on pet food and specialty pet food labeling. This standard must be met when applying under the USDA Agriculture Marketing Service (AMS) Process Verified Program (PVP).

(1) In the AAFCO defined feed term "human grade", the use of the term "human grade" is only acceptable in reference to the product as a whole. The feed term specifies that every ingredient and the resulting product must be stored, handled, processed, and transported in a manner that is consistent and compliant with 21 CFR part 117 and all other applicable federal human food law as required by ingredient, process and/or facility type.

a. A claim regarding "human grade ingredients" is only acceptable if the product as a whole is "human grade."

b. Every use of the term "human grade" must be coupled with the statement of intended use (e.g. human grade dog food or human grade cat treats).

(2) It shall be the manufacturing firm's responsibility to ensure it is able to manufacture in a human food facility and be licensed and inspected by the authorized agency for human food production. Human Grade Pet Food claims are voluntary, and as such, no feed control official, neither state nor federal, can mandate that a human food authority license a facility that is only manufacturing a pet food product.

a. All facilities that process or package a final "human grade" pet food product that is considered ready-to-eat must be registered as both an FDA animal food facility and an FDA human food facility.

(3) A 21 CFR part 117 GMP equivalency audit shall be conducted annually by Agriculture Marketing Service through the Process Verified Program unless the facility has been inspected for compliance by an agency with enforcement authority with applicable food safety regulations within the last year.

(4) The firm must maintain written procedures to ensure "human grade" products are stored, transported, and handled throughout the distribution channel in a manner that maintains the product's "human grade" status.

(5) In order to substantiate that a "human grade" pet food claim is truthful and not misleading on products manufactured in an FDA Human Food Facility subject to 21 CFR Part 117, the firm must maintain and make available upon request, documentation sufficient to show that:

a. All individual ingredients supplied to the manufacturer that are further utilized in the manufacture of human grade pet food, are fit for human consumption.
b. Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with 21 CFR part 117 and the final product is considered ready-to-eat;
c. The manufacturing facility is licensed to produce human food by all appropriate/required authorities; and

(6) In order to substantiate that a “human grade” pet food claim is truthful and not misleading, on products that are/contain ingredients traditionally under the federal authority of an agency other than FDA (e.g., USDA FSIS), where final processing or packing occurs in:

a. A registered FDA Human Food Facility subject to 21 CFR Part 117, the firm must maintain and make available upon request, documentation sufficient to verify that:

i. All included ingredients were processed, packed, held and shipped in compliance with the applicable federal regulations for the manufacture of human foods and the final product is considered ready-to-eat.

ii. All non-FDA registered facilities utilized in the manufacture of the included ingredients are authorized by the appropriate regulatory authority to produce human food; and

iii. The FDA facility that processes or packs the “Human Grade” Pet Food is licensed to produce human food by all appropriate/required authorities.

or;

b. A non-FDA food facility producing human food (e.g., slaughter plant), the firm must maintain and make available upon request, documentation sufficient to verify that:

i. All included ingredients were processed, packed, held and shipped in compliance with the applicable federal regulations for the manufacture of human foods and the final product is considered ready-to-eat.

ii. All non-FDA registered facilities utilized in the manufacture of the included ingredients are authorized by the appropriate regulatory authority to produce human food;

iii. The processing or packing of the “Human Grade” Pet Food is conducted in an area/room identified within the facilities required HACCP/Food Safety Plan as an area/room dedicated to the blending, packaging, repackaging and/or labeling of a ready-to-eat food; and

iv. The non-FDA facility that processes or packs the “Human Grade” Pet Food is licensed to produce human food by all appropriate/required authorities.

(7) The manufacturer of a pet food or specialty pet food product with “human grade” claims must ensure:

a. It is clearly labeled for its intended use as animal food, and each use of “human grade” must be coupled with the statement of intended use such as “human grade dog food” or “human grade cat treats”.

b. No statements of quality or grade appear in the ingredient statement [PF5(d)(3)];

c. All uses of the words “human grade” pet food on the label are in a type size no larger than that of the statement of intended use, as required by PF2(a)(2);

d. A claim of “human grade ingredients” is only acceptable if the product as a whole meets the requirements of the “human grade pet food” term;

e. Requirements (7) a & c noted above are applied to all forms of labeling (brochures, point of sale materials, websites, etc.) where the term “human grade pet food” is utilized; and

f. The label is in compliance with all applicable labeling rules, including any voluntary labeling allowed under participation in the Agriculture Marketing Service Process Verified Program.

# AAFCO "Human Grade" Pet Food Standard Checklist

AAFCO developed the following standard for making voluntary "human grade" pet food claims on pet food and specialty pet food labeling. This standard must be met when applying under the USDA Agriculture Marketing Service (AMS) Process Verified Program (PVP).

1. **Prepare QAD 1001A PVP Checklist.**
2. **Identify program documents and sections that address each criterion**
3. **Explanations and/or comments must be provided to provide enough evidence of conformance or non-conformance, as applicable.**

***NOTE: When this Addendum is complete, print to ADOBE and add to the audit documentation. Do NOT copy and Paste to a 1001A Checklist.***

☐ **Audit the program using the checklist below:**

| AAFCO Human Grade Pet Food Standard Criteria | Conform (Y/N?) | Objective Evidence/Findings/Remarks |
|---|---|---|
| **1. Ingredients**<br><br>In the AAFCO defined feed term "human grade", the use of the term "human grade" is only acceptable in reference to the product as a **whole**.<br><br>a) The firm has documented that all included ingredients were stored, handled, processed and transported in a manner that is consistent and compliant with 21 CFR part 117 and those applicable federal human food laws as required by ingredient, process and/or facility type.<br><br>b) The firm has documented that all individual ingredients supplied to the manufacturer that are further utilized in the manufacture of human grade pet food are fit for human consumption. | | |
| **2. Facility**<br><br>It shall be the manufacturing firm's responsibility to ensure it is able to manufacture in a human food facility and be licensed and inspected by the authorized | | |

| | | |
|---|---|---|
| agency for human food production. Human Grade Pet Food claims are voluntary.<br>a) The facility is registered and/or licensed to produce human food by all appropriate/required authorities (both federal and state or local).<br>b) The facility is registered as both an FDA animal food facility and human food facility. | | |
| **3. Inspection**<br>A 21 CFR part 117 GMP equivalency audit shall be conducted annually by Agriculture Marketing Service through the Process Verified Program unless the facility has been inspected for compliance by an agency with enforcement authority with applicable food safety regulations within the last year.<br>a) The facility has been inspected for compliance by an agency with enforcement authority with applicable food safety regulations within the last year. Date of Audit? _____<br>b) If no, conduct the 21 CFR part 117 equivalency audit. | | |
| 4. **Written Procedures** (Ref Standards 4-6)<br>a) The firm maintains written procedures to ensure "human grade" products were stored, transported, and handled throughout the distribution channel in a manner that maintains the product's "human grade" status. | | |

| | | |
|---|---|---|
| b) In an **FDA regulated facility**, the firm can demonstrate that every ingredient and the resulting product is stored, handled, processed, and transported in a manner that is consistent and compliant were t with 21 CFR part 117 and the final product is considered ready-to-eat.<br><br>c) In a **non-FDA regulated facility**, the firm can demonstrate that the processing or packing of the "Human Grade" Pet Food is conducted in an area/room identified within the facilities required HACCP/Food Safety Plan as an area/room dedicated to the blending, packaging, repackaging and/or labeling of ready-to-eat food. | | |
| **7. Label**<br><br>The manufacturer of a pet food or specialty pet food product with "human grade' claims must ensure the following:<br><br>a) It is clearly labeled for its intended use as animal food, and each use of "human grade" must be coupled with the statement of intended use such as "human grade dog food" or "human grade cat treats"<br><br>b) The label is in compliance with all applicable labeling rules, including any voluntary labeling allowed under participation in the Agriculture Marketing Service Process Verified Program. | | |

***NOTE: When this Addendum is complete, print to ADOBE and add to the audit documentation. Do NOT copy and Paste to a 1001A Checklist.***

Approved by JW

*The information and examples included in this guidance document are not intended to be a limiting, all-inclusive list for substantiation documents required to support conformance with the Human Grade Pet Food Standard and Audit Checklist. Forms of documentation and content may vary based on facility and product type.*

## FSIS Facility (Process Flow Example 1)

**Facility:**

a) Documentation of FDA Animal Food Facility Registration and FDA Human Food Facility Registration **(see Appendix 1)**
b) The facility is registered and/or licensed to produce human food by all appropriate/required authorities (may vary by jurisdiction and state). Such evidence may include, but is not limited to:
    a. facility licenses or permits for operation of edible food manufacturing facilities; or **(see Appendix 2a, 2b)**
    b. results of most recent inspections issued by local, county, or state public health authorities

**Inspection:**

a) Documentation of current FSIS Grant of Inspection **(see Appendix 3)**
    a. Section 7: Proteins must be indicated on Grant of Inspection
    b. Section 8: Type of Grant is "Final"
    c. Verify establishment and Pack Code indicated on Grant of Inspection are listed on FSIS Meat, Poultry, and Egg Product Inspection Directory https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpi-directory
b) 21 CFR part 117 GMP equivalency audit shall be conducted for area/room identified within the facilities' required HACCP/Food Safety Plan as an area/room dedicated to the blending, packaging, repackaging, and/or labeling of ready-to-eat food.

**Ingredients:**

a) Such evidence may include, but is not limited to:
    a. If ingredient is or contains a combination of 3% or greater beef, pork, lamb, poultry, or rabbit - Verify ingredient Pack Code ("Passed and Inspected" FSIS stamp of inspection) **(see Appendix 5)**
    b. Affidavit from manufacturer *and/or* guarantor of product **(see Appendix 6)**
    c. Affidavit from ingredient suppliers
b) Such evidence may include, but is not limited to:
    a. Affidavit from manufacturer *and/or* guarantor of product **(see Appendix 6)**
    b. Affidavit from ingredient suppliers
    c. If ingredient is or contains a combination of 3% or greater beef, pork, lamb, poultry, or rabbit - Verify ingredient Pack Code ("Passed and Inspected" FSIS stamp of inspection)
    d. Ingredient specification sheets

**Written Procedures:**

a) Not applicable for this facility type

b) Firm has documented procedures and SOPs for processing or packing of the "human grade" pet food in the area/room dedicated to the blending, packaging, repackaging, and/or labeling of ready-to-eat food indicated in the facility's HACCP/Food Safety Plan.
c) Firm has written documentation outlining the process and procedures to be followed in order to ensure products, labeled as "Human Grade" pet food, are stored and transported throughout the distribution channel in a manner compliant with applicable human food regulations. Such documentation must also include an identified section that indicates measures/steps taken to ensure that all parties involved in the distribution channel are aware of the product's "Human Grade" status. **(see Appendix 7)**

**Label:**
(a – e) AAFCO Labeling Requirements as indicated in the AAFCO Model Bill and Regulations and Official Feed Term "Human Grade"
(f) If using the PVP shield, the firm follows all applicable labeling rules, including any voluntary labeling allowed under participation in the Agriculture Marketing Service Process Verified Program

## FDA Facility (Process Flow Example 2)

**Facility:**

a) Documentation of FDA Animal Food Facility Registration and FDA Human Food Facility Registration **(see Appendix 1)**
b) The facility is registered and/or licensed to produce human food by all appropriate/required authorities (may vary by jurisdiction and state). Such evidence may include, but is not limited to:
    a. facility licenses or permits for operation of edible food manufacturing facilities; or **(see Appendix 2a, 2b)**
    b. results of most recent inspections issued by local, county, or state public health authorities

**Inspection:**
a) Documentation of notarized Certificate of Inspection by an agency with enforcement authority to conduct 21 CFR 117 GMP inspections **(see Appendix 4)**
b) Verify inspection date

**Ingredients:**
c) Such evidence may include, but is not limited to:
    a. If ingredient is or contains a combination of 3% or greater beef, pork, lamb, poultry, or rabbit - Verify ingredient Pack Code ("Passed and Inspected" FSIS stamp of inspection) **(see Appendix 5)**
    b. Affidavit from manufacturer *and/or* guarantor of product **(see Appendix 6)**
    c. Affidavit from ingredient suppliers
d) Such evidence may include, but is not limited to:
    a. Affidavit from manufacturer *and/or* guarantor of product
    b. Affidavit from ingredient suppliers
    c. If ingredient is or contains a combination of 3% or greater beef, pork, lamb, poultry, or rabbit - Verify ingredient Pack Code ("Passed and Inspected" FSIS stamp of inspection)
    d. Ingredient specification sheets

**Written Procedures:**

a) Procedures and SOP to ensure that every ingredient and final product are stored, handled, processed, and transported in a manner that is consistent and compliant with 21 CFR part 117.
    a. Verify final product contains no more than 3% beef, pork, poultry, or rabbit and meets the definition of ready-to-eat as defined by 21 CFR 117.3

    21 CFR 117.3 *Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

b) Not applicable for this facility type

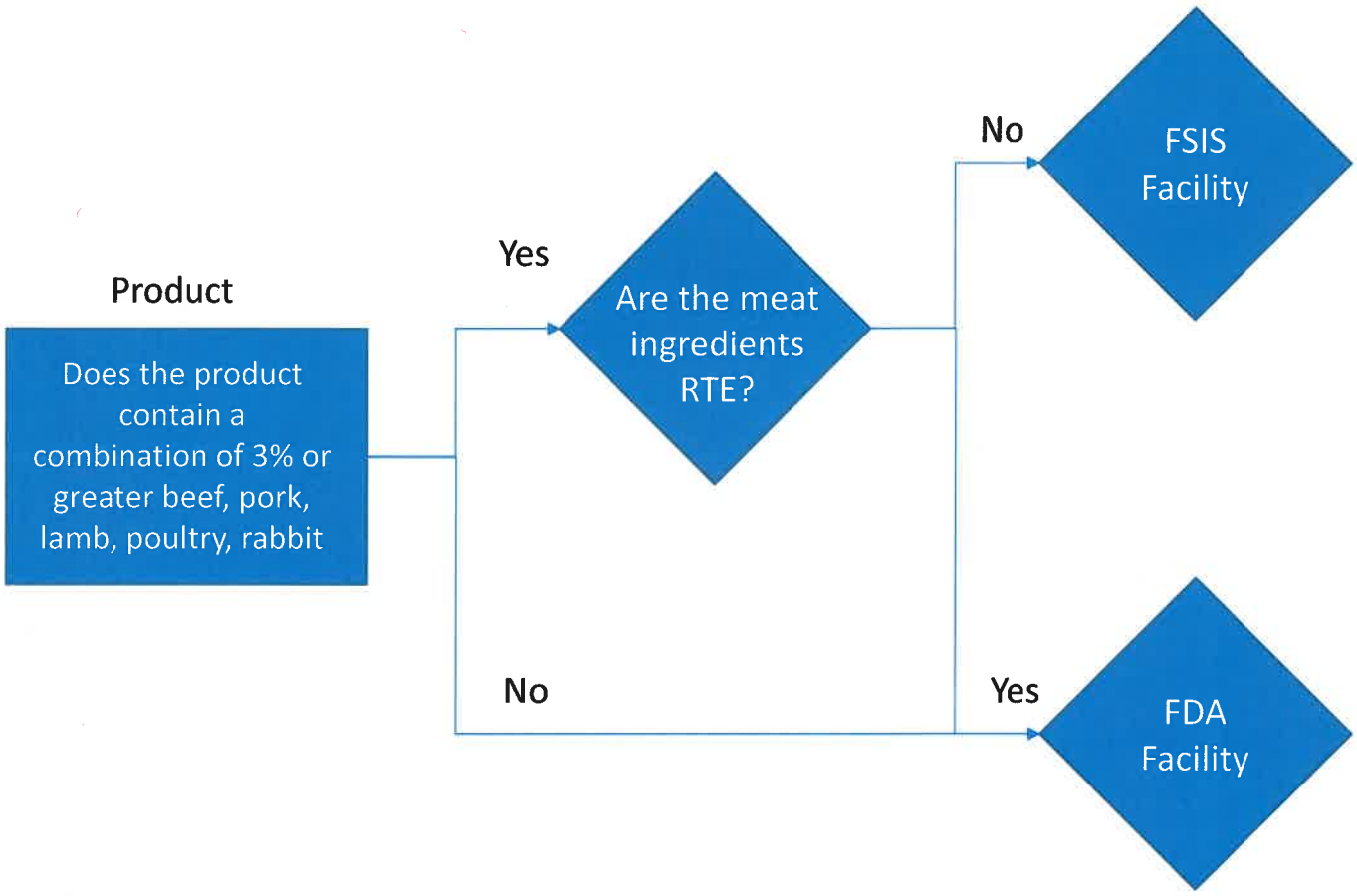
c) Firm has written documentation outlining the process and procedures to be followed in order to ensure products, labeled as "Human Grade" pet food, are stored and transported throughout the distribution channel in a manner compliant with applicable human food regulations. Such documentation must also include an identified section that indicates measures/steps taken to ensure that all parties involved in the distribution channel are aware of the product's "Human Grade" status. **(see Appendix 7)**

**Label:**

(a – e) AAFCO Labeling Requirements as indicated in the AAFCO Model Bill and Regulations and Official Feed Term "Human Grade"

(f) If using the PVP shield, the firm follows all applicable labeling rules, including any voluntary labeling allowed under participation in the Agriculture Marketing Service Process Verified Program

# Production Facility Checklist



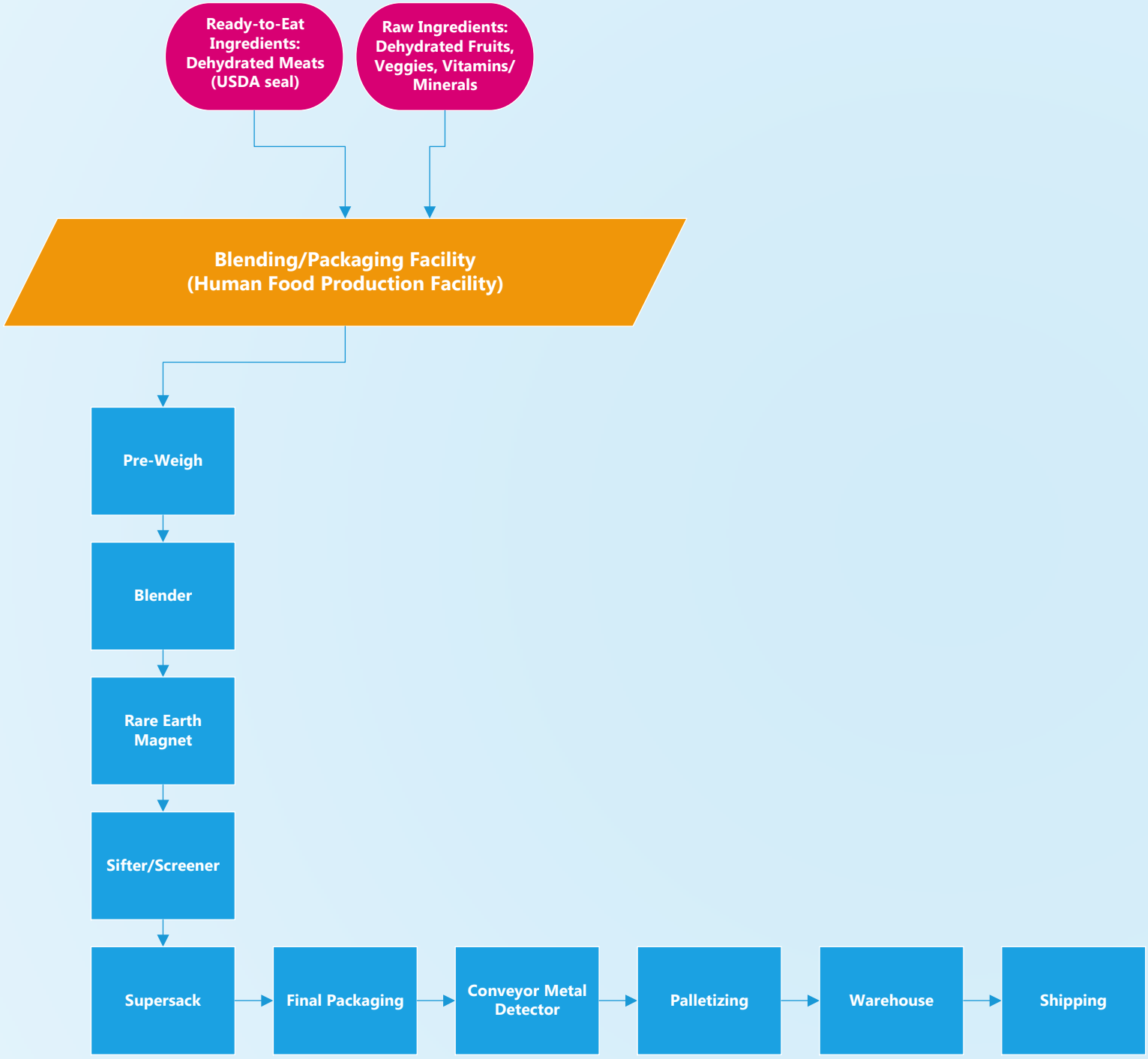

## FSIS Facility Inspection

- FSIS Grant of Inspection
  - Proteins need to be listed on inspection
  - Plant listed on FSIS approved facility website
- Ingredient Verification
- Pack-off Area Inspection
- Product Label Review

## FDA Facility Inspection

- Registered FDA Human Food Facility
- Ingredient Verification
- CFR Part 117 GMP equivalency Audit
- Product Label Review

# Process Flow Example 2 - FDA Facility



# Appendix 1

Date: [redacted]

## Section 1 Type of Registration

1a. DOMESTIC REGISTRATION

1b. INITIAL REGISTRATION: [redacted] PIN NUMBER: [redacted]

**ARE YOU THE NEW OWNER OF A PREVIOUSLY REGISTERED FACILITY?** (•) **Yes** ( ) **No**

1c. PREVIOUS OWNER'S TITLE : [redacted] PREVIOUS OWNER'S NAME : [redacted] PREVIOUS OWNER'S REGISTRATION NUMBER :

## Section 2 Facility Name/Address Information

FACILITY NAME: [redacted]

FACILITY NAME SUFFIX: [redacted]

FACILITY STREET ADDRESS, Line1: [redacted]

FACILITY STREET ADDRESS, Line2:

CITY: [redacted] STATE/PROVINCE/TERRITORY: [redacted]

ZIP CODE (POSTAL CODE): [redacted]

COUNTRY/AREA: UNITED STATES

PHONE NUMBER (Include Area/Country Code): [redacted]

FAX NUMBER (Include Area/Country Code): [redacted]

E-MAIL ADDRESS: [redacted]

## Section 3 Preferred Mailing Address Information

(Complete this section only if different from Section 2, Facility Name/Address Information)

**If information is the same as section 2, check the box:** [✓]

NAME: [redacted]

ADDRESS, Line1: [redacted]

ADDRESS, Line2:

CITY: [redacted] STATE/PROVINCE/TERRITORY: [redacted]

ZIP CODE (POSTAL CODE): [redacted]

COUNTRY/AREA: UNITED STATES

PHONE NUMBER (Include Area/Country Code): [redacted]

FAX NUMBER (Include Area/Country Code): [redacted]

E-MAIL ADDRESS: [redacted]

## Section 4 Parent Company Name/Address Information

(If applicable and If different from sections 2 and 3). If information is the same as another section, check which section:

(•) Section 2 - Facility Address Information

( ) Section 3 - Preferred Mailing Address Information

( ) None of the above

NAME OF PARENT COMPANY: [redacted]

PARENT COMPANY SUFFIX: [redacted]

STREET ADDRESS OF PARENT COMPANY, Line 1: [redacted]

STREET ADDRESS OF PARENT COMPANY, Line2:

CITY: [redacted] STATE/PROVINCE/TERRITORY: [redacted]

ZIP CODE (POSTAL CODE): [redacted]

COUNTRY/AREA: UNITED STATES

PHONE OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): [redacted]

FAX # OF INDIVIDUAL AT PARENT COMPANY (Include Area/Country Code): [redacted]

E-MAIL ADDRESS OF INDIVIDUAL AT PARENT COMPANY: [redacted]

## Section 5 Emergency Contact Information

For foreign facilities, FDA will use your U.S. agent as your emergency contact unless you choose to designate a different contact here.
If information is the same as another section, check which section:

(•) Same as Facility Address (Section 2)

( ) Same as U.S. Agent Information (Section 7)

( ) None of the above

INDIVIDUAL's TITLE: INDIVIDUAL's TITLE OTHER:

INDIVIDUAL'S NAME:

INDIVIDUAL'S MIDDLE NAME:

INDIVIDUAL'S LAST NAME:

TITLE:

EMERGENCY CONTACT PHONE (Include Area/Country Code): [redacted]

E-MAIL ADDRESS: [redacted]

## Section 6 Trade Names

(If this facility uses trade names other than that listed in section 2 above, list them below (E.G.,"also doing business as," "facility also known as"):

ALTERNATE TRADE NAME # 1: [redacted]

## Section 7 United States Agent

(To be completed by facilities located outside any state or territory of the United States, District Of Columbia, or The Commenwealth of Puerto Rico)

FIRST NAME OF U.S. AGENT: -N/A-

MIDDLE NAME OF U.S. AGENT: -N/A-

LAST NAME OF U.S. AGENT: -N/A-

TITLE: -N/A-

ADDRESS, Line 1: -N/A-

ADDRESS,Line 2: -N/A-

CITY: -N/A-

STATE: -N/A-

ZIP CODE (POSTAL CODE): -N/A-

COUNTRY/AREA: -N/A-

PHONE NUMBER (Include Area/Country Code): -N/A-

EMERGENCY CONTACT PHONE NUMBER (Include Area Code): -N/A-

FAX NUMBER (Include Area/Country Code): -N/A-

EMAIL ADDRESS: -N/A-

## Section 8 Seasonal Facility Dates of Operation

Optional - Give the approximate dates that your facility is open for business, if its operations are on a seasonal basis.

**For Harvest 1**

Start Month:

End Month:

**For Harvest 2**

Start Month:

End Month:

## Section 9 General Product Categories - HUMAN/ANIMAL/BOTH

☑ Food for Human Consumption ☑ Food for Animal Consumption

## Section 9a Food for Human Consumption

| | To be completed by all food facilities. Please see instructions for further examples. | **TYPE OF ACTIVITY CONDUCTED AT THE FACILITY ( Optional )<br>Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food.** | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Ambient Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators) | Refrigerated Food Storage Warehouse / Holding Facility (e.g., storage facilities, including storage tanks) | Frozen Food Storage Warehouse / Holding Facility (e.g., storage facilities) | Acidified Food Processor | Low Acid Food Processor | Interstate Conveyance Caterer / Catering Point | Contract Sterilizer | Labeler / Relabeler | Manufacturer / Processor | Repacker / Packer | Salvage Operator (Reconditioner) | Farm Mixed-Type Facility | Other Activity Conducted (Please Specify Below Row 37) |
| ☐ | 1. ALCOHOLIC BEVERAGES [21 CFR 170.3 (n) (2)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 2. BABY (INFANT AND JUNIOR) FOOD PRODUCTS Including Infant Formula | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 3. BAKERY PRODUCTS, DOUGH MIXES, OR ICINGS [21 CFR 170.3 (n) (1), (9)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 4. BEVERAGE BASES [21 CFR 170.3 (n) (3), (35)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 5. CANDY WITHOUT CHOCOLATE, CANDY SPECIALTIES AND CHEWING GUM [21 CFR | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 170.3 (n) (6), (9), (25), (38)] | | | | | | | | | | | | | |
| ☐ | 6. CEREAL PREPARATIONS, BREAKFAST FOODS, QUICK COOKING / INSTANT CEREALS [21 CFR 170.3 (n) (4)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 7. CHEESE AND CHEESE PRODUCT CATEGORIES [21 CFR 170.3 (n) (5)] | | | | | | | | | | | | | |
| ☐ | a. Soft, Ripened Cheese | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | b. Semi-Soft Cheese | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | c. Hard Cheese | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | d. Other Cheeses and Cheese Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 8. CHOCOLATE AND COCOA PRODUCTS [21 CFR 170.3 (n) (3), (9), (38), (43)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 9. COFFEE AND TEA [21 CFR 170.3 (n) (3), (7)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 10. COLOR ADDITIVES FOR FOODS [21 CFR 170.3 (o) (4)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 11. DIETARY CONVENTIONAL FOODS OR MEAL REPLACEMENTS (Includes Medical Foods) [21 CFR 170.3 (n) (31)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 12. DIETARY SUPPLEMENT CATEGORIES | | | | | | | | | | | | | |
| ☐ | a. Proteins, Amino Acids, Fats and Lipid Substances [21 CFR 170.3(o) (20)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | b. Vitamins and Minerals | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | c. Animal By-Products and Extracts | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | d. Herbals and Botanicals | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 13. DRESSING AND CONDIMENTS [21 CFR 170.3 (n) (8), (12)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 14. FISHERY / SEAFOOD PRODUCT CATEGORIES [21 CFR 170.3 (n) (13), (15), (39), (40)] | | | | | | | | | | | | | |
| ☐ | a. Fin Fish, Whole or Filet | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | b. Molluscan Shellfish | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | c. Other Shellfish | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | d. Ready to Eat (RTE) Fishery Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | e. Processed and Other Fishery Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 15. FOOD ADDITIVES, GENERALLY RECOGNIZED | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | AS SAFE (GRAS) INGREDIENTS, OR OTHER INGREDIENTS USED FOR PROCESSING [21 CFR 170.3 (n) (42); 21 CFR 170.3 (o) (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32)] | | | | | | | | | | | | | |
| ☐ | 16. FOOD SWEETENERS (NUTRITIVE) [21 CFR 170.3 (n) (9) (41), 21 CFR 170.3 (o) (21)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 17. FRUIT AND FRUIT PRODUCTS [21 CFR 170.3 (n) (16), (27), (28), (35), (43)] | | | | | | | | | | | | | |
| ☐ | a. Fresh Cut Produce | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | b. Raw Agricultural Commodities | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | c. Other Fruit and Fruit Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 18. FRUIT OR VEGETABLE JUICE, PULP OR CONCENTRATE PRODUCTS [21 CFR 170.3 (n) (3), (16), (35)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 19. GELATIN, RENNET, PUDDING MIXES, OR PIE FILLINGS [21 CFR 170.3 (n) (22)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 20. ICE CREAM AND RELATED PRODUCTS [21 CFR 170.3 (n) (20), (21)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 21. IMITATION MILK PRODUCTS [21 CFR 170.3 (n) (10)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 22. MACARONI OR NOODLE PRODUCTS [21 CFR 170.3 (n) (23)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 23. MEAT, MEAT PRODUCTS AND POULTRY (FDA REGULATED) [21 CFR 170.3 (n) (17), (18), (29), (34), (39), (40)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 24. MILK, BUTTER, OR DRIED MILK PRODUCTS [21 CFR 170.3 (n) (12), (30), (31)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 25. MULTIPLE FOOD DINNERS, GRAVIES, SAUCES AND SPECIALTIES [21 CFR 170.3 (n) (11) (14), (17), (18), (23), (24), (29), (34), (40)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 26. NUTS AND EDIBLE SEED PRODUCT CATEGORIES [21 CFR 170.3 (n) (26), (32)] | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | [illegible] | | | | | | | | | | | | | | |
| ☐ | a. Nut and Nut Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | b. Edible Seed and Edible Seed Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☑ | 27. PREPARED SALAD PRODUCTS [21 CFR 170.3 (n) (11), (17), (18), (22), (29), (34), (35)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 28. SHELL EGG AND EGG PRODUCT CATEGORIES [21 CFR 170.3 (n) (11), (14)] | | | | | | | | | | | | | | |
| ☐ | a. Chicken Egg and Egg Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | b. Other Eggs and Egg Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 29. SNACK FOOD ITEMS (FLOUR, MEAL OR VEGETABLE BASE) [21 CFR 170.3 (n) (37)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 30. SPICES, FLAVORS, AND SALTS [21 CFR 170.3 (n) (26)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☑ | 31. SOUPS [21 CFR 170.3 (n) (39), (40)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☑ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 32. SOFT DRINKS AND WATERS [21 CFR 170.3 (n) (3), (35)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 33. VEGETABLE AND VEGETABLE PRODUCT CATEGORIES [21 CFR 170.3 (n) (19), (36)] | | | | | | | | | | | | | | |
| ☐ | a. Fresh Cut Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | b. Raw Agricultural Commodities | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | c. Other Vegetable and Vegetable Products | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 34. VEGETABLE OILS (INCLUDES OLIVE OIL) [21 CFR 170.3 (n) (12)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 35. VEGETABLE PROTEIN PRODUCTS (SIMULATED MEATS) [21 CFR 170.3 (n) (33)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 36. WHOLE GRAINS, MILLER GRAIN PRODUCTS (FLOURS), OR STARCH [21 CFR 170.3 (n) (1), (23)] | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |
| ☐ | 37. NONE OF THE ABOVE FOOD CATEGORIES | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | |

**If the food categories listed above do not apply, then print the applicable food category or categories.**

**Other Activity Conducted**

## Section 9b Food for Animal Consumption

| To be completed by all animal food facilities. Please see instructions for further examples. IF NONE OF THE MANDATORY CATEGORIES BELOW APPLY, SELECT BOX 28 . | | TYPE OF ACTIVITY CONDUCTED AT THE FACILITY ( Optional ) Check all types of operations that are performed at this facility regarding the manufacturing/processing, packing or holding of food. | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Animal food manufacturer / Processor | Animal Food Warehouse / Holding Facility (e.g., storage facilities, including storage tanks, grain elevators) | Acidified Food Processor | Low Acid Food Processor | Contract Sterilizer | Repacker / Packer | Labeler / Relabeler | Salvage Operator (Reconditioner) | Farm Mixed-Type Facility | Other Activity (Please Specify Below Row 33 |
| ☐ | 1. GRAIN OR GRAIN PRODUCTS (I.E., BARLEY, GRAIN SORGHUMS, MAIZE, OAT, RICE, RYE, WHEAT, OTHER GRAINS OR GRAIN PRODUCTS) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 2. OILSEED OR OILSEED PRODUCTS (I.E., COTTONSEED, SOYBEANS, OTHER OILSEEDS OR OILSEED PRODUCTS) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 3. ALFALFA PRODUCTS OR LESPEDEZA PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 4. AMINO ACIDS OR RELATED PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 5. ANIMAL PROTEIN PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 6. BOTANICALS AND HERBS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 7. BREWER PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 8. CHEMICAL PRESERVATIVES | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 9. CITRUS PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 10. DIRECT FED MICROBIALS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 11. DISTILLERY PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 12. ENZYMES | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 13. FATS OR OILS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 14. FERMENTATION PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 15. FORAGE PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 16. HUMAN FOOD BY-PRODUCTS NOT OTHERWISE LISTED | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 17. MARINE PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 18. MILK PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 19. MINERALS OR MINERAL PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 20. MISCELLANEOUS OR SPECIAL PURPOSE PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 21. MOLASSES OR MOLASSESS PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 22. NON-PROTEIN NITROGEN PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 23. PEANUT PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 24. PROCESSED ANIMAL WASTE PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 25. SCREENINGS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 26. TECHNICAL ADDITIVES | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 27. VITAMINS OR VITAMIN PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 28. YEAST PRODUCTS | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 29. MIXED FEED (E.G., POULTRY, LIVESTOCK, EQUINE) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 30. PET FOOD | ☑ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☑ | 31. PET TREATS OR PET CHEWS | ☑ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 32. PET NUTRITIONAL SUPPLEMENTS (E.G., VITAMINS, MINERALS) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| ☐ | 33. NONE OF THE ABOVE FOOD CATEGORIES | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

**If the food categories listed above do not apply, then print the applicable food category or categories.**

**Other Activity Conducted**

## Section 10 - Owner, Operator or Agent in Charge Information

Provide the following information, If different from all other sections on the form. If information is the same as another section of the form, Check which section:

- ◉ Section 2 - Facility Address Information
- ○ Section 3 - Preferred Mailing Address Information

Section 4 - Parent Company Address Information

Section 7 - US Agent Address Information

NAME OF ENTITY OR INDIVIDUAL WHO IS THE OWNER, OPERATOR, OR AGENT IN CHARGE: Forbes Fisher

STREET ADDRESS, Line 1: [redacted]

STREET ADDRESS, Line 2:

CITY: [redacted] STATE/PROVINCE/TERRITORY: [redacted]

ZIP CODE (POSTAL CODE): [redacted]

COUNTRY/AREA: UNITED STATES

PHONE NUMBER (Include Area/Country Code): [redacted]

FAX NUMBER (OPTIONAL; Include Area/Country Code): [redacted]

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): [redacted]

## Section 11 Inspection Statement

FDA will be permitted to inspect the facility at the time and in the manner permitted by the Federal Food, Drug, and Cosmetic Act.

## Section 12 Certification Statement

**The owner, operator, or agent in charge of the facility, or an individual authorized by the owner, operator, or agent in charge of the facility, must submit this form.** By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the owner, operator, or agent in charge of the facility certifies that the above information is true and accurate. An individual (other than the owner, operator or agent in charge of the facility) who submits the form to the FDA also certifies that the above information submitted is true and accurate and that he/she is authorized to submit the registration on the facility's behalf. An individual authorized by the owner, operator, or agent in charge must below identify by name the individual who authorized submission of the registration. Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Name of the Submitter: [redacted]

CHECK ONE BOX

**A.**OWNER, OPERATOR, OR AGENT IN CHARGE (STOP HERE, FORM IS COMPLETED)

**B.**INDIVIDUAL AUTHORIZED TO SUBMIT THE REGISTRATION

ADDRESS INFORMATION FOR THE AUTHORIZING INDIVIDUAL: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line1: -N/A-

AUTHORIZING INDIVIDUAL STREET ADDRESS, Line2: -N/A-

CITY: -N/A-

STATE/PROVINCE/TERRITORY: -N/A-

ZIP CODE (POSTAL CODE): -N/A-

COUNTRY/AREA: -N/A-

PHONE NUMBER (Include Area/Country Code): -N/A-

FAX NUMBER (Optional; Include Area/Country Code): -N/A-

E-MAIL ADDRESS (Required unless FDA has granted a waiver under 21 CFR 1.245): -N/A-

**Appendix #2a**

Wisconsin Department of Agriculture, Trade and Consumer Protection

2811 Agriculture Drive, PO Box 8911, Madison, WI 53708-8911

**License Number:** [redacted]

**Expires:** [redacted]
**Statute:**

# Food Processing Plant

Legal Name:
[redacted]

Doing Business As:
[redacted]

Large Potentially Hazardous Food Processing Plant

Finished Products:
[redacted]

Processing Operations:
[redacted]

This is your license/permit/certification/registration document. Post or carry as required by law. Non-transferrable - subject to revocation or suspension as provided by law.
DMS-BIT-06S (03/18/10)

bits-16.qxd (rev. 11/17)

Remove this card and carry as identification.

Wisconsin Department of
Agriculture, Trade and Consumer Protection

[redacted]

DATCP Contact: [redacted]

Appendix 2b

State of Wisconsin
Governor Scott Walker

**Department of Agriculture, Trade and Consumer Protection**
Sheila E. Harsdorf, Secretary

[redacted]

To Whom It May Concern:

Re: Certificate of Free Sale, Health, Sanitary, Purity & Origin

Destination Country: United States

Product(S) MFG Country of Origin Vendor Product ID #

STEW – Individual Packs Size Barcode

[redacted]

BLENDS – Individual Packs Size Barcode

[redacted]

The Division of Food Safety of the Wisconsin Department of Agriculture, Trade and Consumer Protection, a governmental agency responsible for the licensing and inspection of all dairy and food operations in the State of Wisconsin, hereby certifies that [redacted] license # [redacted], operates a food manufacturing establishment which is licensed by the Department of Agriculture, Trade and Consumer Protection and inspected by inspectors employed by the State of Wisconsin.

This facility is licensed by the State of Wisconsin. However, the inspection of this facility and the dietary or nutritional supplement products it produces are under the inspectional jurisdiction of the FDA, under a signed Memorandum of Understanding.

We certify that the facilities, equipment and raw material and the processing and packaging procedures meet with all of the sanitary requirements of the State of Wisconsin rules which are based substantially on the federal Good Manufacturing Practice regulations (GMP). We also certify that the operations are in good standing in every respect.

We further certify that their products are freely and without qualification sold and used in the food industry and are fit for human consumption in the State of Wisconsin and the United States.

Sincerely,

[redacted]

Director, Bureau of Food and Recreational Businesses
DIVISION OF FOOD AND RECREATIONAL SAFETY

Subscribed and sworn to before me
This [redacted]

[redacted]

Notary Public, Dane County, Wisconsin
My commission expires [redacted]

Appendix 3

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

# GRANT OF INSPECTION

1. DATE [redacted]

2. ESTABLISHMENT NO. M-[redacted] / P-[redacted]

3. DISTRICT/REGIONAL CODE [redacted]

4. NAME AND MAILING ADDRESS OF APPLICANT *(Use 9 Digit Zip Code if Known)*

[redacted]

5. LOCATION OF ESTABLISHMENT (PHYSICAL STREET ADDRESS)

[redacted]

6. ADDRESS OF DISTRICT/REGIONAL OFFICE

[redacted]

7. TYPE OF INSPECTION *(Check all that apply)*

☑ MEAT * ☑ POULTRY ☐ EGG ☐ IMPORT

8. TYPE OF GRANT

☐ CONDITIONAL (VERIFY HACCP PLAN) ☑ FINAL

9. DATE OF INAUGURATION OF SERVICE
MAY 2014

A survey of your establishment at the location shown above (Item 4 or 5) indicates compliance with the applicable requirements of the regulations under the Federal Meat Inspection Act or the Poultry Products Inspection Act, or both. Accordingly, inspection service is granted.

A copy of your Application for Federal Meat, Poultry or Import Inspection, Form FSIS 5200-2, is enclosed. This application specifies the type of operation conducted at your establishment and contains your agreement and certification that you will conform strictly to applicable Federal law and regulations pertaining to meat inspection, poultry inspection, or the importation of meat and poultry products.

Your establishment is under the supervision of the District/Regional Office. Call the District/Regional Office if you need help in interpreting the provisions of the regulations.

** Catfish is included under the category "Meat", as per the 2008 Food Conservation and Energy Act*

REMARKS:

[redacted]

CC: FLS/TA COORDINATOR
IIC
RMA
FSC
EST. FILE

DISTRICT/REGIONAL MANAGER/IIO-HQ SIGNATURE [redacted]

PRINT NAME [redacted]

FSIS FORM 5200-1 (04/28/2010) PREVIOUS EDITIONS OBSOLETE.

**Appendix 4**

[redacted]
Commissioner

# North Carolina Department of Agriculture and Consumer Services

[redacted]
Chief Deputy Commissioner

## CERTIFICATE OF INSPECTION AND FREE SALE

To Whom It May Concern:

This is to certify that [redacted] products are manufactured and/or distributed from their plant operation located at [redacted]. These products are sold freely in North Carolina and, to the best of my knowledge, throughout the United States of America.

**Product:** [redacted]
**For Country of:** [redacted]

[redacted], located at [redacted] is under routine inspection by The North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division. This Division's most recent inspection conducted on [redacted] found the facility to be operating in satisfactory compliance with the North Carolina Food, Drug, and Cosmetic Act and applicable sections of the North Carolina Administrative Code including but not limited to the following regulations as appropriate to the product: TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION.

- PART 110 – CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD, or
- PART 111- CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS, or
- PART 114 – ACIDIFIED FOODS

**Certificate #** [redacted]

_____ Date: _____

[redacted]
Chief Deputy Commissioner of Agriculture
North Carolina Department of Agriculture & Consumer Services

North Carolina:

_____ County

I, _____, a Notary Public for said

State, do hereby certify that _____ personally appeared before me this day and acknowledged the due execution of the foregoing instrument. Witness my hand and official seal, this the

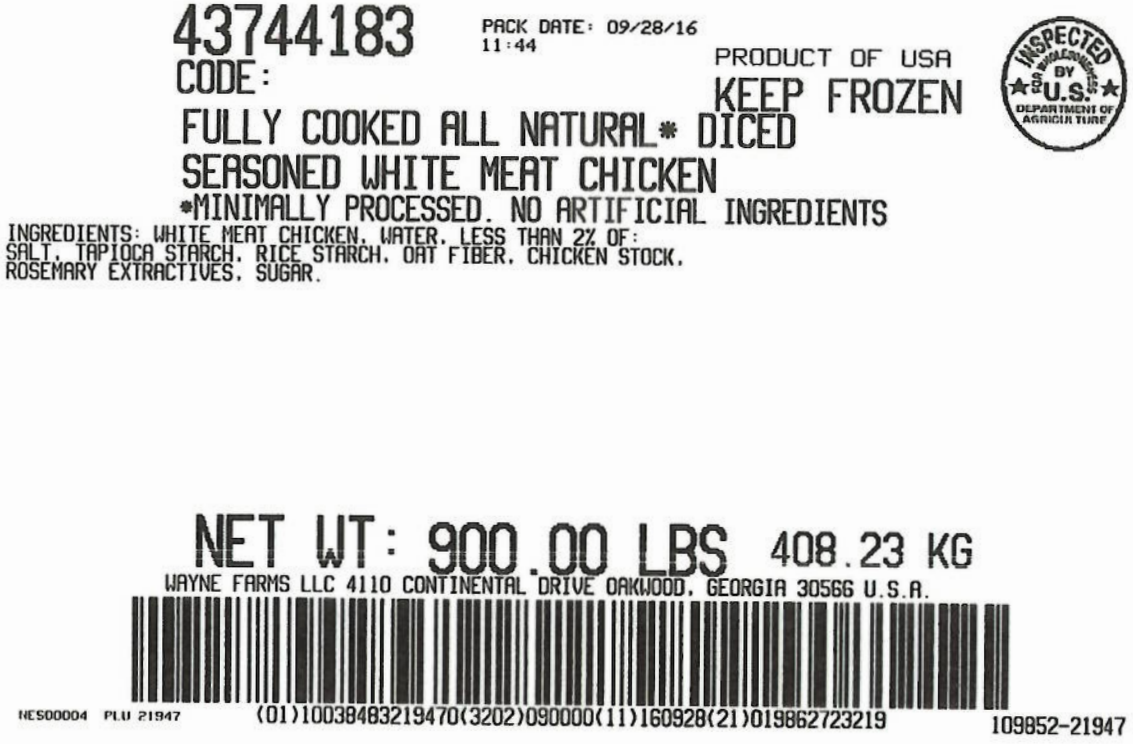
_____ day of _____, 20_____.

My commission expires: _____, 20_____

_____
Notary Public

[redacted], Raleigh, North Carolina, 27699-1001
[redacted] • [redacted] • Email: [redacted]

Appendix 5


43744183
CODE:
PACK DATE: 09/28/16
11:44
PRODUCT OF USA
KEEP FROZEN
INSPECTED BY U.S. DEPARTMENT OF AGRICULTURE
FULLY COOKED ALL NATURAL* DICED
SEASONED WHITE MEAT CHICKEN
*MINIMALLY PROCESSED. NO ARTIFICIAL INGREDIENTS
INGREDIENTS: WHITE MEAT CHICKEN, WATER, LESS THAN 2% OF:
SALT, TAPIOCA STARCH, RICE STARCH, OAT FIBER, CHICKEN STOCK,
ROSEMARY EXTRACTIVES, SUGAR.
SN:01986272321 9
NET WT: 900.00 LBS 408.23 KG
WAYNE FARMS LLC 4110 CONTINENTAL DRIVE OAKWOOD, GEORGIA 30566 U.S.A.
NES00004 PLU 21947
(01)10038483219470(3202)090000(11)160928(21)0198627232 19
109852-21947

## Appendix 6

(COMPANY LETTERHEAD)

**COMPANY NAME Human Food Grade Ingredient Guarantee**

Date: (today's date)

To:
COMPANY NAME
ADDRESS

I, _____ (NAME), _____ (TITLE), am authorized to represent _____ (COMPANY NAME), and am qualified to verify the information provided in this letter.

The following ingredients are supplied to _____ (COMPANY NAME)

| INGREDIENT(S) | Country of Origin |
|---|---|
| | |
| | |
| | |
| | |

This is to certify that the above-named ingredients sold by _____ (SUPPLIER NAME) to _____ (COMPANY NAME), is produced using Good Manufacturing Practices, with no added chemicals or adulterants, and is not produced from genetically modified or engineered recombinant DNA technology.

These ingredients meet the standards set forth by AAFCO in regard to HUMAN GRADE STATUS:

(a) Each individual ingredient supplied to _____ (COMPANY NAME) is fit for human consumption.
(b) Each ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR 117.
(c) The manufacturing facility is licensed to produce human food by the appropriate authority (Attached hereto as "Attachment A") (Such evidence may include, but is not limited to, facility licenses or permits for operation of edible food manufacturing facilities or results of most recent inspections issued by local, county, or state public health authorities.)

I swear/affirm under penalty of perjury that these facts are true according to my best knowledge and belief.

BY: _____ (COMPANY)

_____ _____
Signature of Official Title

_____ _____
Printed Name of Official Date

Appendix 7

# Shipping and Receiving Policy

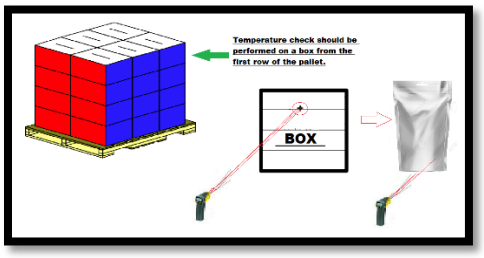
## Cold Chain

1. **Purpose and Scope**: The purpose of this policy is to establish procedures for ensuring food safety throughout the shipping, storage and receiving processes. This policy applies to all frozen food suppliers, and carriers.
2. **Responsibility:**
    a. **Shipping & Receiving Clerks:** Responsible for inspecting and temping all incoming loads and documenting all findings.
3. **Materials:**
    a. Approved and Calibrated Digital Probe Thermometer
4. **Procedure:**
    a. **Vendor Cold Chain**:
        i. Loads coming from Vendor: The Vendor will arrange freight using a list of approved carriers. The Vendor will place Company's approved digital data logger (Quality Blue) into 3 finished product cases on every load. These will be approximately at the beginning, middle and end of the trailer. When it is received, it should be pulled by the Company receiving person, and the minimum, maximum and average temperature recorded on the receiving form to confirm that the cold chain was not broken.
            1. If there is evidence that the cold chain has been broken, the full chart should be downloaded and the load rejected.
        ii. All other loads, please refer to Receiving (Section 3)
    b. **Documentation Requirements:**
        i. Hard copy of Receiving Checklist and BOL must be retained for a minimum of 3 years.
        ii. Facility will upload Frozen Receiving Checklist and BOL to the Supply Chain Damages folder.
            1. Naming Convention for BOL will be PO#XXXXXX
            2. Location: \\HQ Folder\SupplyChainFolder\DamagesFolder
    c. **Receiving:**
        i. When trucks arrive to the Company facility, the seal number shall be reviewed and recorded. If the seal number does not match the seal number listed on the BOL (full trucks only); contact Vendor Compliance, Purchasing and Quality Assurance.
        ii. Record the temperature of the reefer unit on the Receiving Checklist. The set point should be between 0°F and -10°F.
            1. If the reefer unit is not within the above range take pictures, notify the driver and Vendor Compliance, but proceed to open the truck and take product temperatures per below.
        iii. If the seal number matches, open the truck and inspect the interior. Truck must be:

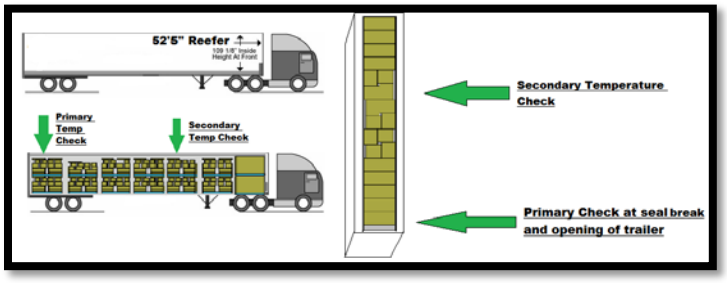
1. Free from pest activity
2. Free from off or unexpected odors
3. Free from damage such as holes in the walls or ceilings (ex: visible light)
4. Clean
    a. If the truck meets all of the above mentioned criteria, proceed to the next step.
    b. If the truck does not meet all above mentioned criteria, record the issue, take pictures as necessary, and contact Vendor Compliance, Purchasing and Quality Assurance.

iv. If the truck meets all required conditions, then the temperature of the load should be verified by Company receiving.

1. Take the first product temperature reading using the thermometer probe per following instructions: Select one box off of the first pallet unloaded, open the box and test the temperature of one internal package. This should be done by using a digital probe thermometer, wrapping the package around the thermometer probe (or holding probe between two packages, making sure the probe is not exposed) and holding it in place until a stable reading is displayed. Record the result on the Receiving Checklist.




    a. The second product temperature should be taken from a pallet located between 4-5 pallet spaces away from the front of the trailer, or mid-way through the load on LTLs. Follow the same steps as listed for product temperature one.




    b. For all product temperature measurements, the reading should be between -10°F to +10°F. Feel the bags and assess formation of large ice crystals. The presence of significant amounts of large ice crystals indicates thawing has occurred with a slow re-

freeze. If the product does not fall within this range or there are visible signs of thawing, contact Vendor Compliance, Purchasing and Quality Assurance and refer to the 'Rejection Procedures'

2. If data loggers are present, locate the digital data loggers, and verify that the cold chain was not broken in transit. Record the following information on the Receiving Checklist: minimum temperature, maximum temperature, average temperature. If cold chain was broken (Greater than 10°F), download the full charts, take pictures and contact Vendor Compliance. If data loggers show product was maintained in acceptable temperature range (-10°F to 10°F), continue to take direct product temperatures below.
3. Receiving Checklists and BOLs shall be scanned daily and retained for three years.

v. If all conditions are acceptable, product will be off-loaded. During the process of off-loading, product should be visually inspected for damage. If any damage is observed, pictures should be taken, product should be segregated and a quantity of damage product determined.

*vi.* *If any of the above requirements are not met, take pictures of all temperature checks and contact Vendor Compliance immediately.*

1. *Additionally, open one container of product and take a direct product temperature with a clean probe. Take a picture of this reading.*
2. *Reference Rejection procedure and provide all information per vendor's requirements. (See Rejection Procedure)*
3. *Reject the load.*

vii. Once product is off-loaded, it should be entered into the High Jump Inventory Management System. The exact quantity received should be recorded. If the quantity received does not match the quantity listed on the BOL, contact Vendor Compliance and Supply Chain Purchasing.

viii. Received pallets shall not sit on the dock longer than 10 minutes before entering the cooler and/or freezer. Any item that exceeds 10 minutes will need to be temperature checked, to ensure the product is still within the acceptable temperature range.

## Inbound Exception Matrix

| Temperature | Damaged | Mislabeled |
|---|---|---|
| • Pass->Product goes to freezer<br>• Fail->If after two temperature fail checks, each pallet much be individually checked and receive only the pallets that pass the temperature test. Pallets that fail should be refused. (Refer to Rejection Procedure) | • Product->(Damaged, mushy, discolored, foul odor) take pictures of damaged product and refer to Damage and Mislabeled Policy. (Receive in, adjust out as damaged)<br>• Pallet damaged-> Record on inbound exception tool and restack to another pallet. | • Cannot Relabel-> take pictures of issue product and refer to Damage and Mislabled Policy.<br>• Relabel-> Relabel product if possible |

d. **Storage:**
   i. Freezers are set to -10°F ± 2°F. If temperature limits are exceeded, an alarm will be triggered if the freezer has been above -10°F for more than 60 minutes.
   ii. If an alarm is received, personnel should investigate the area immediately and determine the cause for the alarm. Corrective actions shall be taken as necessary. A product temperature should be recorded from an item directly next to the alarm area. Document all findings on the Alarm Report.
   iii. Pallets shall be kept in freezer area until they are ready to be picked and processed for shipment.
   iv. The picking/packing area shall be maintained are set to 35°F ± 2°F. If temperature limits are exceeded, an alarm will be triggered. If an alarm is received, follow the same procedure as mentioned above.

e. **Shipping**:
   i. Orders are packed with dry ice based on days in transit. Reference the chart provided by Supply Chain to determine the exact quantity of dry ice needed. The WMS system will reference this chart for every order and systematically determine and print the number of dry ice bricks required for the order. As part of the verification process, the pack tool will require the associate input the number of dry ice that is present.
   ii. An audit process will occur to validate the proper packing of an order and ensure that the required dry ice bricks were used as shipments are sealed. All shipments will be audited and any failures will be documented. Any failure will result in immediate escalation to leadership (Operations and QA) and repeated failures can result in process shut downs, increased audit scrutiny, etc. as appropriate.

iii. Completely packed shipments headed to customers with dry ice, and in insulated containers, will be staged and must depart the same day. Pallets of completed orders shall be maintained in temperature controlled environments until placed onto trucks.
iv. Outbound trucks shall be inspected prior to loading. They shall be:
    1. Free from pest activity
    2. Free from off or unexpected odors
    3. Free from damage such as holes in the walls or ceilings (ex: visible light)
    4. Clean
        a. If the truck meets all of the above mentioned criteria, proceed to load. If it does not, record the issue, take pictures as necessary, and reject the truck. Notify Transportation.

f. **Maintenance**:
    i. A third-party will perform maintenance on a quarterly basis.
g. **Disposal of Product Procedure:**
    i. Before disposing of any product, facility must reach out to Vendor Compliance
    ii. Before product is disposed, facility must make a slice in the bag.
    iii. Product must be disposed of in a secure trash compactor.
    iv. Trash removal must occur at least once a week.

5. **References:**
    a. Receiving Checklist
    b. Damage and Mislabeled Policy
    c. Rejection Procedure
    d. Alarm Report