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| PLANT NAME: FSPCA Exercise Version                           | ISSUE DATE | 2/25/2016    |
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Selected Sections of a

# Food Safety Plan for Fettuccini Marinara with Broccoli Ready to Cook

## **Teaching Example**

| Reviewed by: | Plant Manager | Date:    |
|--------------|---------------|----------|
|              | <br>          | <u> </u> |

The information in this example is for training purposes only and does not represent any specific operation. Many processing steps were omitted or combined to facilitate its use for class exercises. It is not complete and contains both required and optional information.

Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.





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## **Company Overview**

This example company is a small firm that makes a variety of frozen entrees that are intended to be cooked prior to consumption. Products include:

- · Fettuccini Marinara with Broccoli,
- Shrimp and Angel Hair Pasta
- and Pasta Primavera.

Product is made 5 days a week in one 8 hour production shift, followed by 4 hours for sanitation. An integrated pest control program is also in place.

This Food Safety Plan covers production of Fettuccini Marinara with Broccoli, but parts of it (e.g., pasta cooking) apply to other products as well.

**Product Description** 

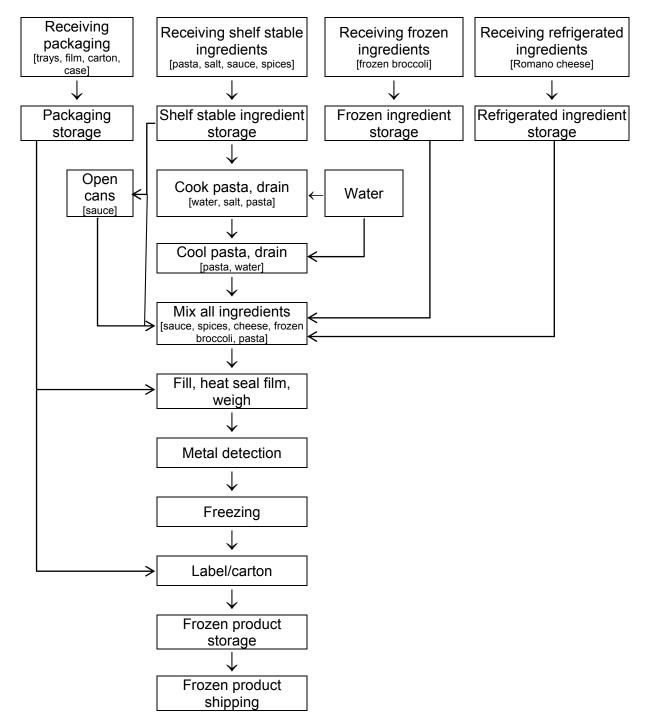
| 1 Toduct Description   |   |  |  |  |
|--|---|--|--|--|
| Product Name(s)  | Fettuccini Marinara with Broccoli Meal  |  |  |  |
| Product Description, including Important Food Safety Characteristics | Fettuccini Marinara with Broccoli is a frozen, ready-to-cook meal packed in a plastic tray and sealed with a transparent film. The frozen product is placed in a box and warehoused, distributed and retailed frozen. |  |  |  |
| Ingredients  | Cooked enriched pasta (wheat), Marinara sauce (tomato sauce, spices), Romano cheese, salt, spices and broccoli.   |  |  |  |
| Packaging Used   | 8" plastic tray with clear film overwrap inside pre-printed carton. 10 ounces serving size.   |  |  |  |
| Intended Use   | Fully cook before serving (NRTE- not ready to eat)  |  |  |  |
| Intended Consumers   | General public  |  |  |  |
| Shelf Life   | 1 to 2 years frozen   |  |  |  |
| Labeling Instructions  | Keep frozen. Microwave cooking instructions. Allergen labeling.   |  |  |  |
| Storage and Distribution   | Frozen storage and retail distribution  |  |  |  |
| Approved:  | Date:   |  |  |  |
| Signature: 7. S. Leader  | 23 February 2016  |  |  |  |
| Print name: F.S. Leader  |   |  |  |  |





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## **Flow Diagram**





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### **Process Narrative**

### Receiving Ingredients and Packaging:

Ingredients and raw materials are purchased from a broker that offers products only from suppliers complying with internationally recognized food safety and quality schemes. Ingredients are stored appropriately according to manufacturers' requirements.

Receiving packaging: Pre-labeled cartons, 10oz. plastic trays, heat sealable film, and
cases are received in bulk. Labeled cartons are reviewed for conformance with product
allergen requirements and ingredients. Specifications require food grade material
compatible for frozen food and microwavable products.

### Receiving shelf stable ingredients:

- Wheat pasta: Received dry from sole source broker.
- Salt: Received in bags from sole source broker. Specifications require food grade salt
- Tomato sauce: Received as a shelf stable product in metal #10 cans from sole source broker.
- Spices (pepper and garlic powder): Received from sole source broker. Specifications require the garlic powder and pepper to undergo microbial reduction treatments for vegetative pathogens.
- Receiving refrigerated ingredients: Shredded, aged Romano cheese received from sole source broker in bags.

### • Receiving frozen ingredients:

Individually quick frozen, blanched broccoli is received from sole source broker. For this ingredient, the broker's letter of guarantee states that the supplier complies with 21 CFR part 117, that is subpart B, GMPs; subpart C, Hazard Analysis and Riskbased Preventive controls; and subpart G, Supply-chain program were followed. The supplier also obtained an audit to verify that the farm followed the requirements outlined in 21 CFR part 112 (Produce Rule) for growing and harvesting the broccoli.

### Storing Ingredients and Packaging:

- Packaging storage: Cartons, trays, film and cases are stored in the dry storage room in the packaging area, arranged by product code to avoid mixing of packaging. Packaging is used First-In-First-Out and partially used carton cases are closed during storage.
- **Dry ingredient storage**: Tomato sauce, pasta, salt, and spices are stored in the dry storage room in the ingredient area, arranged by ingredient code number. All containers are sealed to avoid food allergen cross-contact and cross-contamination during storage. Ingredients containing food allergens are identified and stored in specific locations with like allergenic ingredients, unless allergen cross-contact is not foreseeable.
- Frozen ingredient storage: After receipt, frozen broccoli and ice are taken to the frozen storage area (≤0°F) and used on a First-In-First-Out basis. Broccoli in not thawed before use.
- **Refrigerated ingredient storage**: Cheese is stored in a cooler that is kept at ≤40°F and used on a First-In-First-Out basis.

**Open cans**: Sauce cans are opened using a mechanical can opener. Periodically, metal shavings have been observed. Preventive maintenance is used to examine and adjust the can openers on a periodic basis.

Water: Water is treated and tested per EPA requirements by the city and used as needed.





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**Cook pasta, drain:** Salt is added to water in a steam jacketed kettle and is brought to boiling. The pasta is added to boiling water and cooked for at least 15 minutes to achieve acceptable product quality. Product temperature exceeds 165°F in this processing time. Only pasta is processed in the pasta cook area. The kettle is drained; cooked pasta is retained in the kettle.

**Cool pasta, drain**: Potable cold water is used to cool the drained pasta. Cold water temperatures are 50-55°F depending on the season. Pasta is cooled by running cold water through it. Generally the pasta is cooled to the cold water temperature in <30 minutes from the time the boiling water was drained, but this depends on the cooling water temperature and the time it takes for staff to begin the cooling process. Cooled pasta is drained and transferred to the area where it is mixed with other ingredients.

**Mix all ingredients**: Dry ingredients are blended with tomato sauce and cheese to distribute spices just prior to adding cooked pasta and frozen broccoli using a blender to gently blend to a uniform mixture. A batch of cooled, drained pasta is mixed with other ingredients in <30 minutes after delivery to the mixing area or sticking will occur. The blended ingredient temperature is typically below ambient after mixing.

**Fill**, **heat seal film**, **weigh**: 10 oz. trays are filled, a film is heat sealed to close the tray and trays are weighed.

**Metal detection:** Sealed trays are passed through a metal detector.

**Freezing:** Packaged product passes through a freezer tunnel. Product temperature is ≤0°F in 20 minutes.

**Label/Carton:** Frozen, sealed trays are placed in labeled cardboard cartons and are boxed in cases – 12 per case. Carton has ingredient and allergen information that declare the wheat and milk allergens. Labels on cartons are matched to the specific description and product number as listed on the Daily Production Schedule.

Frozen product storage: Finished product is transferred to frozen storage (≤0°F).

**Frozen product shipping**: Product is shipped in freezer trucks to customers (convenience stores, office cafeterias, quick serve restaurants and grocery stores) under frozen conditions ( $\leq$ 0°F).





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## **Hazard Analysis**

Hazard identification (column 2) 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 hazards, 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)             | (2)                            | /2\        | (4)                                | (5)                         | 16     | ١             |
|-----------------|--------------------------------|------------|------------------------------------|-----------------------------|--------|---------------|
| (1)             | (2)                            | (3)        | (4)                                | (5)                         | (6     |               |
| Ingredient/     | Identify <u>potential</u> food | Do any     | Justify your decision for column 3 | What preventive control     |        |               |
| Processing Step |                                | potential  |                                    | measure(s) can be applied   |        |               |
|                 | introduced, controlled         |            |                                    | to significantly minimize   | cont   |               |
|                 | or enhanced at this            | hazards    |                                    | · ·                         | applie |               |
|                 | step                           | require a  |                                    | hazard?                     | this s | tep?          |
|                 |                                | preventive |                                    | Process including CCPs,     |        |               |
|                 |                                | control?   |                                    | Allergen, Sanitation,       |        |               |
|                 |                                | Yes No     |                                    | Supply-chain, other         | Yes    | No            |
|                 |                                |            |                                    | preventive control          |        |               |
| Receiving       | B None                         |            |                                    |                             |        |               |
| packaging       | C Undeclared                   | Х          | Labels on cartons must declare     | Allergen Control for        | Χ      |               |
|                 | allergens                      |            | allergens present in the product   | label review by             |        |               |
|                 |                                |            | and print errors have occurred     | qualified individual        |        |               |
|                 | P None                         |            | and print errors have securred     |                             |        |               |
| Dogoising       |                                | V .        | D corous aparagraph ha massart     | Cubooguant cooline          |        | $\overline{}$ |
| Receiving       | B Sporeforming                 | X          | B. cereus spores may be present    |                             |        | Х             |
| shelf stable    | pathogens such                 |            | in dry pasta and outbreaks due     | step prevents B.            |        |               |
| ingredients –   | as B. cereus                   |            | to growth after hydration have     | cereus growth and           |        |               |
| pasta           |                                |            | occurred. Levels present at        | toxin formation in          |        |               |
|                 |                                |            | receiving are not hazardous and    | rehydrated pasta.           |        |               |
|                 |                                |            | will not change as long as the     |                             |        |               |
|                 |                                |            | pasta is dry.                      |                             |        |               |
|                 | Vegetative                     | Х          | Salmonella may be present in       |                             |        |               |
|                 | pathogens such                 |            | pasta at a very low frequency      |                             |        |               |
|                 | as Salmonella                  |            | and subsequent cooking is more     |                             |        |               |
|                 | as Sairioriella                |            |                                    |                             |        |               |
|                 | Otavalanda a a a a a a a       | V          | than adequate to destroy it        | Committee also in Committee |        | V             |
|                 | Staphylococcus                 | X          | S. aureus can form heat stable     | Supply-chain Control        |        | Х             |
|                 | aureus                         |            | toxin during pasta production at   | is essential to prevent     |        |               |
|                 | enterotoxin                    |            | the supplier without preventive    | S. aureus enterotoxin       |        |               |
|                 |                                |            | control.                           | prior to receipt.           |        |               |
|                 | C Allergen – wheat             | X          | Wheat is an allergen and could     | Allergen Control for        |        | Χ             |
|                 |                                |            | contribute to cross-contact for    | cross-contact               |        |               |
|                 |                                |            | other products that do not         | prevention and              |        |               |
|                 |                                |            | contain wheat.                     | allergen labeling at a      |        |               |
|                 |                                |            |                                    | later step                  |        |               |
|                 | P None                         | 1          |                                    | later step                  |        |               |
| Receiving       | B None                         |            |                                    |                             |        |               |
| shelf stable    | C None                         |            |                                    |                             |        |               |
|                 |                                |            |                                    |                             |        |               |
| salt            | PNone                          |            |                                    |                             |        |               |
| Receiving       | B None                         |            | Low pH, shelf-stable product is    |                             |        | ]             |
| shelf stable    |                                |            | not likely to have biological      |                             |        |               |
| ingredients -   |                                |            | hazards                            |                             |        |               |
| tomato          | C None                         |            |                                    |                             |        |               |
| sauce           | P None                         |            |                                    |                             |        |               |
|                 | -  : 1011C                     | 1          | <u>l</u>                           | L                           |        |               |





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| (1)                     | (2)                         | (3          | 3)         | (4)  | (5)   | (6     | 3)    |
|-------------------------|-----------------------------|-------------|------------|--|---|--------|-------|
| Ingredient/             |                             |             | any        | Justify your decision for column 3                               | What preventive control                             | ls t   |       |
| Processing Step         |                             | pote        | •          | , ,  | measure(s) can be applied                           | preve  | ntive |
|                         | introduced, controlled      |             | afety      |  | to significantly minimize                           | cont   |       |
|                         | or enhanced at this         | haza        |            |  | or prevent the food safety                          |        |       |
|                         | step                        | requ        |            |  | hazard?   | this s | tep?  |
|                         |                             | preve       |            |  | Process including CCPs,                             |        |       |
|                         |                             | cont<br>Yes | roi?<br>No |  | Allergen, Sanitation,<br>Supply-chain, other        | Yes    | No    |
|                         |                             | 163         | 140        |  | preventive control                                  | 163    | 140   |
| Receiving               | B Vegetative                | Х           |            | Salmonella has been known to                                     | Supply-chain Control                                |        | Χ     |
| shelf stable            | pathogens                   |             |            | occasionally contaminate spices.                                 | – pathogen reduction                                |        | ,     |
| ingredients –           | (Salmonella)                |             |            |  | treatment for these                                 |        |       |
| spices                  | ,                           |             |            |  | ingredients   |        |       |
| (pepper,                | Pathogenic                  |             | Χ          | C. perfringens and B. cereus                                     |   |        |       |
| garlic)                 | sporeformers (C.            |             |            | spores may be in spices but                                      |   |        |       |
|                         | perfringens, B.             |             |            | cannot grow in the dry spice or in                               |   |        |       |
|                         | cereus)                     |             |            | the sauce during processing                                      |   |        |       |
|                         |                             |             |            | time, especially given the acid                                  |   |        |       |
|                         |                             |             |            | pH of the tomato sauce.  |   |        |       |
|                         | C None                      |             |            |  |   |        |       |
| D                       | P None                      |             |            |  | 0 1 1 0 1 1   |        |       |
| Receiving               | B Vegetative                | X           |            |  | Supply-chain Control                                |        | X     |
| frozen<br>ingredients – | pathogens such as <i>L.</i> |             |            | present in raw produce. Supplier determined that their blanching | <ul> <li>Blanching and<br/>environmental</li> </ul> |        |       |
| broccoli                | monocytogenes,              |             |            |  | sanitation controls                                 |        |       |
| Dioccoil                | Salmonella                  |             |            |  | reduce vegetative                                   |        |       |
|                         | Gairnonella                 |             |            | recontamination can occur if                                     | pathogens and                                       |        |       |
|                         |                             |             |            |  | freezing prevents                                   |        |       |
|                         |                             |             |            |  | pathogen growth.                                    |        |       |
|                         | C Pesticides                |             | Χ          | Ingredient is US-sourced and                                     |   |        |       |
|                         |                             |             |            | FDA data show that unapproved                                    |   |        |       |
|                         |                             |             |            | pesticides or residues above                                     |   |        |       |
|                         |                             |             |            | EPA tolerance levels are rare.                                   |   |        |       |
|                         | P None                      |             |            |  |   |        |       |
| Receiving               | B Vegetative                | Х           |            |  | Supply-chain Control                                |        | X     |
| refrigerated            | pathogens such              |             |            | practices influence the potential                                | processing and                                      |        |       |
| Romano                  | as Salmonella,              |             |            |  | fermentation  |        |       |
| cheese                  | Staphylococcus aureus and   |             |            | growth, which must be controlled by the supplier                 | hazards   |        |       |
|                         | pathogenic <i>E.</i>        |             |            |  | liazaius  |        |       |
|                         | coli                        |             |            |  |   |        |       |
|                         | C Allergens                 | Х           |            | Cheese is a source of milk                                       | Allergen Control for                                |        | Χ     |
|                         |                             |             |            |  | cross-contact                                       |        | , ,   |
|                         |                             |             |            |  | prevention and                                      |        |       |
|                         |                             |             |            |  | allergen labeling at a                              |        |       |
|                         |                             |             |            |  | later step  |        |       |
|                         | P None                      |             |            |  |   |        |       |
| Packaging               | B None                      |             |            |  |   |        |       |
| storage                 | C Allergen cross-           |             |            | Plant- specific GMPs allow only                                  |   |        |       |
|                         | contact during              |             |            | sealed containers of allergenic                                  |   |        |       |
|                         | storage                     |             |            | ingredients in dry storage, thus                                 |   |        |       |
|                         | PNone                       | -           |            | cross-contact unlikely   |   |        |       |
| Continued               | PNone                       |             |            |  |   |        |       |
| Continued               |                             |             |            |  |   |        |       |



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| (1)                | (2)                                   | /2          | ١  | (4)                                    | (E)                            | 16         | :1 |
|--------------------|---------------------------------------|-------------|----|--|--------------------------------|------------|----|
| (1)<br>Ingredient/ | (2)<br>Identify <u>potential</u> food | (3<br>Do a  |    | (4) Justify your decision for column 3 | (5)<br>What preventive control | (6<br>Is t |    |
| Processing Step    |                                       | poter       | -  | Justily your decision for column 3     | measure(s) can be applied      |            |    |
| Trocessing Step    | -                                     | food safety |    |  | to significantly minimize      | cont       |    |
|                    | or enhanced at this                   | haza        |    |  | or prevent the food safety     |            |    |
|                    | step                                  | requi       |    |  | hazard?                        | this s     |    |
|                    | 3334                                  | preve       |    |  | Process including CCPs,        |            |    |
|                    |                                       | conti       |    |  | Allergen, Sanitation,          |            |    |
|                    |                                       | Yes         | No |  | Supply-chain, other            | Yes        | No |
|                    |                                       |             |    |  | preventive control             |            |    |
| Shelf stable       | B None                                |             |    |  |                                |            |    |
| ingredient         | C Allergen cross-                     |             | Χ  | Plant-specific GMPs allow only         |                                |            |    |
| storage            | contact during                        |             |    | sealed containers of allergenic        |                                |            |    |
| [pasta,            | storage                               |             |    | ingredients in dry storage, thus       |                                |            |    |
| sauce, salt,       |                                       |             |    | cross-contact unlikely                 |                                |            |    |
| spices]            | P None                                |             |    |  |                                |            |    |
| Frozen             | B None                                |             |    |  |                                |            |    |
| ingredient         | C None                                |             |    |  |                                |            |    |
| storage            | P None                                |             |    |  |                                |            |    |
| [broccoli]         |                                       |             |    |  |                                |            |    |
| Refrigerated       | B None                                |             |    |  |                                |            |    |
| ingredient         | C Allergen cross-                     |             | Χ  | Only closed containers of              |                                |            |    |
| storage            | contact during                        |             |    | allergenic ingredients are stored      |                                |            |    |
| [cheese]           | storage                               |             |    | in this storage area.                  |                                |            |    |
|                    | P None                                |             |    |  |                                |            |    |
| Open cans          | B None                                |             |    |  |                                |            |    |
| [sauce]            | C None                                |             |    |  |                                |            |    |
| 1                  | P Metal shavings                      | Χ           |    | Preventive maintenance is              | Process control –              |            | Х  |
|                    |                                       |             |    |  | subsequent metal               |            |    |
|                    |                                       |             |    | are observed from time to time         | detection                      |            |    |
| Cook pasta,        | B None                                |             |    | Validation data demonstrated           |                                |            |    |
| drain              |                                       |             |    | that for pasta, temperatures           |                                |            |    |
|                    |                                       |             |    | achieved during the cooking            |                                |            |    |
|                    |                                       |             |    | process (boiling water for ≥15         |                                |            |    |
|                    |                                       |             |    | minutes) to achieve a palatable        |                                |            |    |
|                    |                                       |             |    | texture far exceed those needed        |                                |            |    |
|                    |                                       |             |    | to destroy vegetative pathogens.       |                                |            |    |
|                    | C Allergen – wheat                    |             |    | Kettles used only for cooking          |                                |            |    |
|                    |                                       |             |    | wheat pasta, which prevents            |                                |            |    |
|                    |                                       |             |    | cross-contact to other foods           |                                |            |    |
|                    |                                       |             |    | prepared in facility.                  |                                |            |    |
|                    | PNone                                 |             |    |  |                                |            |    |
| Water              | B None                                |             |    | Water is treated and tested per        |                                |            |    |
|                    | CNone                                 |             |    | EPA requirements by the city           |                                |            |    |
|                    | PNone                                 |             |    |  |                                |            |    |
| Cool pasta,        | B Sporeforming                        | Χ           |    | Spores may survive cooking.            | Process Control –              | Χ          |    |
| drain              | pathogens such                        |             |    | Growth and toxin production            | Time and                       |            |    |
|                    | as B. cereus                          |             |    | could occur during slow cooling.       | temperature control            |            |    |
|                    |                                       |             |    |  | for cooling pasta              |            | L  |
|                    | CAllergen                             |             | Χ  | Kettles used only for cooking          |                                |            |    |
| i .                | I I -                                 |             |    | wheat pasta, which prevents            |                                |            |    |
| 1                  |                                       | l l         |    | provide provide, minimum providence    |                                |            |    |
|                    |                                       |             |    | cross-contact to other foods           |                                |            |    |
|                    | PNone                                 |             |    | cross-contact to other foods           |                                |            |    |



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| (1)             | (2)                           | (3           |    | (4)  | (5)  | (6     |      |
|-----------------|-------------------------------|--------------|----|--|--|--------|------|
| Ingredient/     | Identify <u>potential</u> foo |              | -  | Justify your decision for column 3                 | What preventive control                      | ls t   |      |
| Processing Step |                               | poter        |    |  | measure(s) can be applied                    |        |      |
|                 | introduced, controlle         |              |    |  | to significantly minimize                    | con    |      |
|                 | or enhanced at this           |              |    |  | or prevent the food safety                   |        |      |
|                 | step                          | requi        |    |  | hazard?                                      | this s | tep? |
|                 |                               | preve        |    |  | Process including CCPs,                      |        |      |
|                 |                               | conti<br>Yes | No |  | Allergen, Sanitation,<br>Supply-chain, other | Yes    | No   |
|                 |                               | 163          | NO |  | preventive control                           | 163    | INO  |
| Mix all         | BEnvironmental                | X            |    | Recontamination may occur if                       | Sanitation controls                          | Х      |      |
| ingredients     | pathogens such                |              |    | environmental control is not in                    | verified by                                  | ^      |      |
| ingredients     | as L. mono.                   | '            |    | place  | environmental                                |        |      |
|                 | as L. mono.                   |              |    | piace  | monitoring <sup>1, 2</sup>                   |        |      |
|                 | CNone                         |              |    |  | monitoring                                   |        |      |
|                 | P Metal                       | X            |    | Mixing metal on metal contact                      | Process Control –                            |        | Χ    |
|                 | I Wictai                      | ^            |    | may periodically produce metal                     | metal detection at a                         |        | ^    |
|                 |                               |              |    | hazards.   | later step                                   |        |      |
| Fill heat seal  | B Environmental               | Х            |    | Recontamination may occur if                       | Sanitation Controls                          | Χ      |      |
| film, weigh     | pathogens such                |              |    | environmental control is not in                    | verified by                                  | ^      |      |
| illiii, weigii  | as L. mono.                   | '            |    | place  | environmental                                |        |      |
|                 | as L. mono.                   |              |    | piace  | monitoring                                   |        |      |
|                 | CNone                         |              |    |  | monitoring                                   |        |      |
|                 | PNone                         |              |    |  |  |        |      |
| Metal           | B None                        |              |    |  |  |        |      |
| detection       | CNone                         |              |    |  |  |        |      |
| detection       | P Metal                       | Х            |    | Opening cope and mixing metal                      | Process Control –                            | Χ      |      |
|                 | Pivietai                      | ^            |    | Opening cans and mixing metal on metal contact may | metal detection                              | ^      |      |
|                 |                               |              |    | periodically produce metal                         | inetal detection                             |        |      |
|                 |                               |              |    | hazards.   |  |        |      |
| Freezing        | B Growth of                   |              |    | Product is frozen in under 1 hour                  |  |        |      |
| i reezing       | environmental                 |              |    | and pathogens won't grow in                        |  |        |      |
|                 | pathogens and                 |              |    | frozen product. As per SOPs,                       |  |        |      |
|                 | pathogenic                    |              |    | freezer is cleaned and                             |  |        |      |
|                 | sporeformers                  |              |    | maintained to be in sanitary                       |  |        |      |
|                 | Sporcionners                  |              |    | condition.   |  |        |      |
|                 | CNone                         |              |    |  |  |        |      |
|                 | PNone                         |              |    |  |  |        |      |
| Label/carton    |                               |              |    |  |  |        |      |
| Label/carton    | C Undeclared                  | X            |    | Product contains wheat and milk                    | Allergen Control -                           | Χ      |      |
|                 | Allergens –                   | ^            |    | allergens  | declaration on label                         |        |      |
|                 | wheat, milk                   |              |    |  |  |        |      |
|                 | P None                        |              |    |  |  |        |      |
| Frozen          | B None                        |              |    |  |  |        |      |
| product         | CNone                         |              |    |  |  |        |      |
| storage         | PNone                         |              |    |  |  |        |      |
| Frozen          | B None                        |              |    |  |  |        |      |
| product         | C None                        |              |    |  |  |        |      |
| shipping        |                               |              |    |  |  |        |      |
| ariippiriy      | PNone                         |              |    |  |  |        |      |

<sup>&</sup>lt;sup>1</sup> Sanitation Controls to include equipment cleaning, zoning and employee practices to prevent cross

contamination. <sup>2</sup> Some facilities may conclude that a preventive control is not needed because the product is not readyto-eat





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## **Process Controls**

| Process                 | Hazard(s)  | Critical   |  | Monitori  | ng          |                     | Corrective Action  | Verification  | Records  |
|-------------------------|--|--|--|---|-------------|---------------------|--|---|--|
| Control(s)              |  | Limits   | What   | How   | Frequency   | Who                 |  |   |  |
| Cool<br>pasta,<br>drain | Growth of spore-formers such as <i>B. cereus</i> | Chill pasta<br>to 50°F or<br>less within 4<br>hours or<br>less | Pasta<br>temperature<br>and time                                       | Recording<br>thermometer<br>that is<br>placed<br>directly in<br>pasta | Every       | Cook or<br>designee | If temperature is not achieved in the specified time, then 1) add more cold water or ice to achieve temperature; 2) segregate product, evaluate product, rework or discard as appropriate, 2) identify root cause; 3) conduct training to prevent recurrence | Daily review of Pasta Cooling log by Supervisor.  Accuracy of thermometer checked weekly by QA Tech.  Quarterly thermometer calibration | Pasta cooling log  Thermometer calibration records  Verification records  Validation report for determining critical limit cooling parameters  Corrective action log |
| Metal<br>detection      |  | of pote can va   | pood Safety Plar<br>ential wording for<br>try depending consystem, etc | or metal detec<br>on the product                                      | tion. Parar | neters              |  |   |  |





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## **Allergen Preventive Controls**

| Allergen   | Hazard(s)                                     | Criteria  | Monitoring        |   | Corrective Action                                  | Verification         | Records   |  |  |
|--|---|---|-------------------|---|--|----------------------|---|--|--|
| Controls   |   |   | What              | How   | Frequency  | Who                  |   |  |  |
| Receiving packaging                              | allergen -                                    | Presence of<br>allergens in<br>formulation on<br>labels received                | product           | Visual<br>inspection to<br>product<br>specification | Each receipt<br>before<br>release to<br>production | Label<br>coordinator | If allergen statement is incorrect:  1) segregate and block packaging stock;  2) Contact supplier for return, identification of root cause, and delivery of new labels  | QA manager reviews and initials records weekly and compares results with past information to determine any trends. | Allergen label receiving inspection log Corrective action records Verification records |
| Label/<br>carton<br>step<br>allergen<br>labeling | Undeclared<br>Allergens –<br>Wheat or<br>milk | Correct labels<br>applied to<br>finished<br>product using<br>labeled<br>cartons | product<br>number | of one<br>finished<br>product                       |  | line worker          | If label is incorrect:  1) segregate product, inspect back to the last good check, re-package in cartons with correct label, or discard product;  2) identify root cause;  3) conduct training as appropriate | and initials records<br>weekly and<br>compares results   | Allergen Label<br>Check log<br>Verification<br>records<br>Corrective<br>action records |

| Allergen Label Verification Listing | )                       |
|-------------------------------------|-------------------------|
| Products                            | Allergen Statement      |
| Fettuccini Marinara with Broccoli   | Contains: Wheat, milk   |
| Shrimp and Angel Hair Pasta         | Contains: Wheat, shrimp |
| Pasta Primavera                     | Contains: Wheat         |





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**Production Line Allergen Assessment** 

|                                   |                    | Intentional Allergens |      |     |       |                              |        |                                 |                               |  |
|-----------------------------------|--------------------|-----------------------|------|-----|-------|------------------------------|--------|---------------------------------|-------------------------------|--|
| Product Name                      | Production<br>Line | Egg                   | Milk | Soy | Wheat | Tree Nut<br>(market<br>name) | Peanut | <b>Fish</b><br>(market<br>name) | Shellfish<br>(market<br>name) |  |
| Fettuccini Marinara with Broccoli | 1                  |                       | X    |     | Х     |                              |        |                                 |                               |  |
| Shrimp and Angel Hair Pasta       | 1                  |                       |      |     | Х     |                              |        |                                 | Shrimp<br>Unique<br>allergen  |  |
| Pasta Primavera                   | 1                  |                       | Х    |     | Х     |                              |        |                                 | -                             |  |

**Scheduling Implications:** Shrimp and Angel Hair Pasta contains a unique allergen (shrimp) and does not contain the milk allergen present in other products.

**Allergen Cleaning Implications:** Fettuccini Marinara with Broccoli and Pasta Primavera can be run in any order. <u>An allergen cleaning is required before and after any Shrimp and Angel Hair Pasta run.</u>





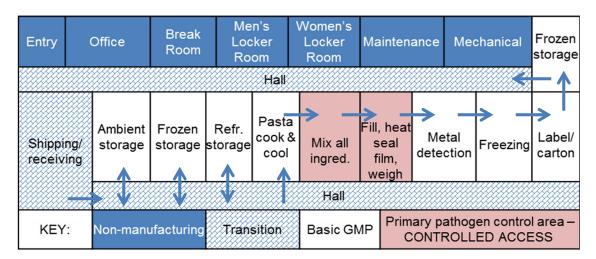
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## **Sanitation Preventive Controls**

NOTE: See Food Safety Plan in curriculum for an example of potential wording for cleaning and sanitation procedures to prevent allergen cross-contact from seafood containing product. Parameters can vary depending on the product, equipment, etc.

### **Hygienic Zoning/ Environmental Monitoring**

**Purpose:** Hygienic zoning in is important to minimize the potential of re-contamination with environmental pathogens. Verification is by environmental monitoring. (See Environmental Monitoring for Sanitation Preventive Control Verification)



**Frequency**: During production

Who: Employees and other individuals entering the Mixing and Fill areas (in pink above)

**Procedure:** Employees entering the Mixing and Fill areas must (in the order listed):

- 1. Take a clean, blue smock from the rack outside the production area and put them on. Smocks must cover outer clothing that would be above the processing line.
- 2. Take blue shoe covers from the box by the entry and put them on over shoes.
- 3. Take a blue hairnet from the box by the entry and put it on. Ensure that all loose hair is captured. Men with facial hair should also apply beard nets.
- 4. Wash hands just before entering the area following the procedures posted by the sink. Apply a clean pair of gloves.
- 5. When exiting the room deposit smocks, shoe covers and hair nets in the receptacles provided. DO NOT reuse disposable items after entering uncontrolled areas.

Maintenance workers and visitors must use follow the above procedures but use white foot covers and clean white smocks when entering this area. Traffic in this area is minimized during production.

**Monitoring:** The sanitation supervisor visually observes the presence of the properly smocked employees, before start up and after lunch break, and every 2 hours.

**Corrections:** Employee is instructed to gown properly.

Records: Daily Hygienic Zoning Record, Environmental Monitoring Sampling Record and lab results

**Verification:** Environmental monitoring for verification of sanitation control and records review within one week





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### **Environmental Monitoring for Sanitation Preventive Control Verification**

**Purpose**: Environmental monitoring is conducted to verify the effectiveness of sanitation and hygienic zoning procedures in the "Mixing" and "Fill" areas to control environmental pathogens such as *L. monocytogenes*.

**Sample identification:** Based on observation when sampling, "worst case" areas are sampled; e.g., standing water or product residue, around table legs, crevasses major traffic areas. Record the specific location sampled.

**Sampling procedure:** Every other week, sponge swabs are collected during production at least 3 hours after production starts. Sampling time is not uniform to avoid bias of results. Samples are shipped to the laboratory using the sampling kit provided by the laboratory. Samples are refrigerated and shipped in an insulated cooler with a gel pack with next day delivery. Samples are NOT frozen.

The following number of samples collected each time.

- 3 in Assembly area
- 3 in Fill, weigh, label area
- 1 in the hallway at the entry of the assembly area
- 3 other samples based on observed conditions

**Laboratory:** Wee Beasties Laboratory (987 Critter Drive, Yourtown, USA) conducts the analysis using XYZ<sup>3</sup> procedures. Analysis is started within 48 hours of sampling.

**Test conducted:** For routine samples, the contract lab composites sponges from the same area to run as one test for *Listeria* species. *Investigation samples must be run individually.* The test result sheet identifies the specific method number used.

### Interpretation of results:

Acton 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.



FSPCA Training Model
For Exercise After Chapter 11: Sanitation Preventive Controls

<sup>&</sup>lt;sup>3</sup> XYZ would be a scientifically valid method, such as AOAC, ISO, FDA, etc.



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## Supply-chain-applied Preventive Controls Program

**Determination of Verification Procedures** 

Spices

**Hazards requiring a supply-chain-applied control:** Hazard analysis determined that vegetative pathogens, such as *Salmonella*, are hazards requiring a preventive control for spices because our process does not have a kill step.

**Preventive controls applied by the supplier**: The spice treatment process should kill the vegetative pathogens.

**Verification activities**: A 3<sup>rd</sup> party supplier audit by a qualified auditor is used to verify control of the identified hazards by the supplier.

**Verification procedures**: A copy of a 3<sup>rd</sup> party audit is requested from the supplier on an annual basis. The audit date, auditor qualifications, audit procedures and audit results are reviewed. Follow up discussion with the supplier takes place, as necessary, to verify that any corrective actions mentioned in the report have been completed, with records maintained for this activity.

**Records**: A copy of the audit report and verification of corrective actions taken by the supplier are maintained in the Supplier Verification file.

#### Pasta

**Hazards requiring a supply-chain-applied control:** Hazard analysis determined that *Staphylococcus aureus* can form heat stable toxin during pasta production at the supplier without preventive control.

**Preventive controls applied by the supplier**: The supplier must be aware of the potential hazard and manage processing conditions to prevent toxin production by *S. aureus*.

**Verification activities**: Same as for Spices.

Verification procedures: Same as for Spices.

**Records**: Same as for Spices.

### Romano cheese

**Hazards requiring a supply-chain-applied control:** Hazard analysis determined that vegetative pathogens such as *Salmonella, Staphylococcus aureus* and pathogenic *E. coli* are hazards requiring a preventive control during cheese manufacture by the supplier.

**Preventive controls applied by the supplier**: The supplier must be aware of the potential hazard and manage processing conditions to prevent toxin production by *S. aureus* and occurrence of *Salmonella* and pathogenic *E. coli*.

**Verification activities**: Same as for Spices. **Verification procedures**: Same as for Spices.

**Records**: Same as for Spices.

#### Frozen broccoli

**Hazards requiring a supply-chain-applied control:** Hazard analysis determined that vegetative pathogens, such as *L. monocytogenes and Salmonella*, are hazards requiring a preventive control for frozen broccoli because our process does not have a kill step.

**Preventive controls applied by the supplier**: Blanching reduces vegetative pathogens, freezing prevents pathogen growth and environmental sanitation minimizes recontamination of the broccoli.

**Verification activities**: Same as for Spices. **Verification procedures**: Same as for Spices.

Records: Same as for Spices.





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

| Ingredient<br>(requiring<br>supply-chain-<br>applied control) | Approved<br>Supplier                     | Hazard(s) requiring supply-chain-applied control                          | Date of<br>Approval | Verification method   | Verification records  |
|---|--|---|---------------------|---|---|
| Spices  | Spicetown<br>Co., Port,<br>USA           | Vegetative pathogens such as Salmonella                                   | 10/08/2010          | Copy of 3 <sup>rd</sup> party audit by a qualified auditor obtained from supplier | Copy of<br>audit kept<br>in Supplier<br>Verification<br>file<br>Incoming<br>goods log |
| Pasta   | MajorCo,<br>Wheaton,<br>USA              | Staphylococcus<br>aureus  | 9/9/2009            |   |   |
| Romano<br>cheese  | Big Cheese<br>Co.,<br>Cheesytown,<br>USA | Vegetative pathogens such as Salmonella, S. aureus and pathogenic E. coli | 1/21/2009           |   |   |
| Frozen<br>broccoli  | USGrown<br>Co.,<br>Farmvalley,<br>USA    | Vegetative pathogens, such as <i>L. monocytogenes</i> and Salmonella      | 2/22/2009           |   |   |

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

For each shipment received, the receiving clerk:

- verifies that the product is from an approved supplier
- documents the above in the incoming goods log.

