農林水産省補助事業

米国食品安全強化法

# 「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（麺）

## ＜英語原文＞

2018 年 3 月

日本貿易振興機構（ジェトロ）

農林水産・食品部　農林水産・食品課

シカゴ事務所

本資料は、2015 年 9 月 17 日に公表された米国食品安全強化法「ヒトが摂取する食品に関する予防管理についての最終規則」に関して、米国の弁護士事務所 Olsson Frank Weeda Terman Matz PC(OFW)に委託をして食品安全計画の雛形（麺）を作成したものです。

＜Olsson Frank Weeda Terman Matz PC(OFW)＞

ウェブサイト： http://www.ofwlaw.com

# お役立ち度アンケートへのご協力のお願い

ジェトロでは、米国食品安全強化法（FSMA）への対応の参考とすることを目的に本調査報告書を実施しました。ぜひお役立ち度アンケートにご協力をお願いいたします。

◆本報告書のお役立ち度　（必須）

□役に立った　□まあ役に立った　□あまり役に立たなかった　□役に立たなかった

その理由をご記入ください。

◆本報告書をご覧になり、実際にビジネスにつながった例がありましたらご記入ください。（任意）

◆今後のジェトロの調査テーマについてご希望等がございましたら、ご記入願います。（任意）

◆貴社・団体名（任意）

◆お名前（任意）

◆メールアドレス（任意）

◆企業規模　（必須）　□大企業　□中小企業　□その他

**FAX 送信先：03-3582-7378　ジェトロ農林水産・食品課宛**

**本アンケートはインターネットでもご回答頂けます**

**（ https://www.jetro.go.jp/form5/pub/afa/fsma ）**

※お客様の個人情報につきましては、ジェトロ個人情報保護方針に基づき、適正に管理運用させていただきます。また、上記のアンケートにご記載いただいた内容については、ジェトロの事業活動の評価および業務改善、事業フォローアップ、今後の調査テーマ選定などの参考のために利用いたします。

【報告書名：米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（麺）＜英語原文＞】

# はじめに

本調査報告書は、2015 年 9 月 17 日に公表された米国食品安全強化法「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」（PCHF）規則に関して、食品安全計画の策定のための参考資料として「麺」を例に作成した雛形である。

食品安全計画の様式は PCHF 規則では規定されていない。またそれぞれの施設によって設備や製品、製造工程などは個々に異なるため、本報告書に記載された内容はあくまで一例である。実際の事業者の食品安全計画は、この雛形に、施設固有の管理すべき危害や予防管理手順を修正・追加することによって、適切なものとなる点に留意いただきたい。

なお、ジェトロは他にも「冷凍チャーハン」「味噌」「まんじゅう」「ドレッシング」「清涼飲料水」「醤油」「ごま油」「緑茶」の雛形を作成しているので、参考にしていただきたい。

本調査報告書が米国食品安全強化法（FSMA）への対応の参考となれば幸いである。

2018 年 3 月
日本貿易振興機構（ジェトロ）
農林水産・食品部　農林水産・食品課
シカゴ事務所

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# 1． Preventive Controls Plan Overview

# Preventive Controls Plan Overview

The United States Food and Drug Administration's (FDA) Preventive Controls for Human Food regulation provides a proactive and systematic approach to food safety. It is similar to other risk-based food safety programs such as the FDA low-acid canned food regulations, FDA Seafood HACCP regulations and the United States Department of Agriculture's (USDA) Food Safety and Inspection Service's (FSIS) HACCP regulations.

- Preventive control programs are structured to work in conjunction with, and be supported by, other relevant programs such as Good Manufacturing Practices (GMP), good agriculture practices and good transportation practices.
- A preventive controls plan incorporates controls that go beyond those that would be managed as Critical Control Points (CCP) in the traditional Hazard Analysis Critical Control Points (HACCP) framework. While CCPs may be included (most commonly for process steps that are critical for the safety of the food), the preventive controls plan also includes controls for hazards related to food allergens, sanitation, suppliers and any other hazards requiring a preventive control. While CCPs are associated with a maximum and/or minimum value, other preventive controls will use parameters and values that will not have a precise critical limit.
- Also, a deviation of some preventive controls may only require an immediate correction (such as re-cleaning a production line prior to start-up of production) rather than a formal corrective action that includes product risk evaluations and development of preventive measures. Moreover, the validation activities (demonstrating the controls actually work) may be less rigorous for some preventive controls than others such as those that would qualify as a CCP under a HACCP approach.
- The FDA regulation requires that the original records or true copies be retained for at least two (2) years after the date they were prepared. Records supporting the process and its adequacy, such as validation studies, must be retained as long as necessary to support the operation and then at least two (2) years after their use is discontinued. Other details may be found in the regulation.
- All records and documents must include information adequate to identify the plant or facility (*e.g.*, name, and when necessary, the address of the plant or facility).
- If a facility identifies the need for a preventive control when it completes its hazard analysis, it must then also have a written **recall plan** (***see* Supp. #36** for an example of a recall plan).
- Good Manufacturing Practices (GMPs) are addressed in 21 C.F.R. Part 117, Subpart B. Areas addressed by the GMP regulations include personnel, plant and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, holding and

distribution of human food by-products for use as animal food, and defect action levels. When doing a hazard analysis, it may be determined that some GMPs may need to rise to the level of a preventive control as it is determined that it is controlling a hazard. For example, if you run product containing wheat flour on a production line and then must change to run a product without wheat flour, you would need to clean the production line to ensure that no allergen cross-contact occurred and wheat was not still present on the line. In this case, the sanitation process would rise to the level of a preventive control.

- For example, in the Boiled Noodles Preventive Controls Plan, some GMPS you would monitor during steps 1 – 9 are as follows:
  - Receiving dock and warehouse to ensure that doors are kept closed when not in use and that all dock brushes and seals prevent access by pests or rodents.
  - Ensure that there are no uncovered or damaged containers of ingredients, products or product packaging.
  - Ensure that all ingredients are stored correctly if they contain various types of allergens.
  - Ensure there are no uncovered glass bulbs or broken glass in the area.
  - Ensure that all containers are properly labeled with ingredient statements and no unapproved items are stored in the same area as product (e.g., cleaning chemicals).
- During steps 10, 11, 18, 19, 20 and 21, also may monitor the following:
  - Ensure that product containers are properly covered to prevent accidental contamination from occurring.
  - Ensure that containers are properly labeled and also have the times the containers were generated if important to the process.
  - If containers of product must be left uncovered, ensure that the overheads are clean and free from anything that may fall onto the product.
  - Ensure that there is limited access to stored product so that it does not become accidentally contaminated.
  - Ensure the product is used in the proper order to prevent out-of-date product.
- During steps 12, 13, 14, 15, 16, 17, and 19 where product may be open to the environment, the following GMPs may be monitored:
  - Ensure the overheads are monitored on a routine basis to ensure that there is no condensation that could drip into exposed product.
  - Ensure there is no loose paint or debris that could fall into product.
  - Ensure there are no loose nuts or bolts or other pieces of equipment.

        - Ensure that there is not product or ingredients left on the floor for extended times.
        - Ensure that trash is in proper containers and they are not overflowing.
        - Ensure that product does not remain in production areas for too long if the ingredients are temperature-sensitive and the production area is not refrigerated.
        - Ensure that personnel who are handling the product have on frocks and are wearing disposal gloves to prevent direct contact with the product.
        - Ensure that personnel do not wear jewelry in the production are and that all have hair restraints and beard nets if needed.
        - Ensure that all entries are kept closed and there is no ability for pests or insects to enter the area.
    - During steps 21 – 24, the following may be monitored:
        - Ensure that labels are correct on all boxes and shipping containers.
        - Ensure that boxes are not damaged and wooden shipping pallets are in adequate condition to prevent product damage.
        - Ensure that trucks are clean, not damaged, and free of debris, pests, and evidence of rodents prior to loading with product.
    - All individuals working in a facility or warehouse are required by regulation to have documentation on file that they have been training in the necessary GMPs appropriate to the job they are performing, in addition to any additional food safety training, to ensure compliance with a facility's food safety plan (*see* 21 C.F.R. § 117.4).
- Supply Chain Preventive Controls – This is one type of a preventive control. When in a hazard analysis, it is determined that a supplier controls the identified hazard; a company must implement a supply chain preventive control. For example, if you are purchasing processed cheese for to put on top of a cooked omelet, the supplier is ensuring that the cheese has been processed using a lethality step to control pathogens. Since the supplier is controlling this hazard as you are not cooking the cheese, you must put in place a supply chain program to verify that the supplier is performing the lethality process acceptably. Supply chain preventive controls are identified at the receiving steps in a hazard analysis.

This generic plan was developed to serve as a guide. The document provides the framework for the development of a Preventive Control Plan for Frozen Boiled Noodles. This generic plan is not intended to be used "as is" for your plant specific preventive control plan. It includes the required steps from the regulations as well as recommendations by FDA.

Since each processor of Frozen Boiled Noodles needs to conduct a hazard analysis for their own unique operation, this provides resources to assist in the development of the plant-specific plan. The document includes suggestions (in red) where there are decision points in the process.

Additionally, there are suggested formats for forms included even though there is no specific format required by the regulation.

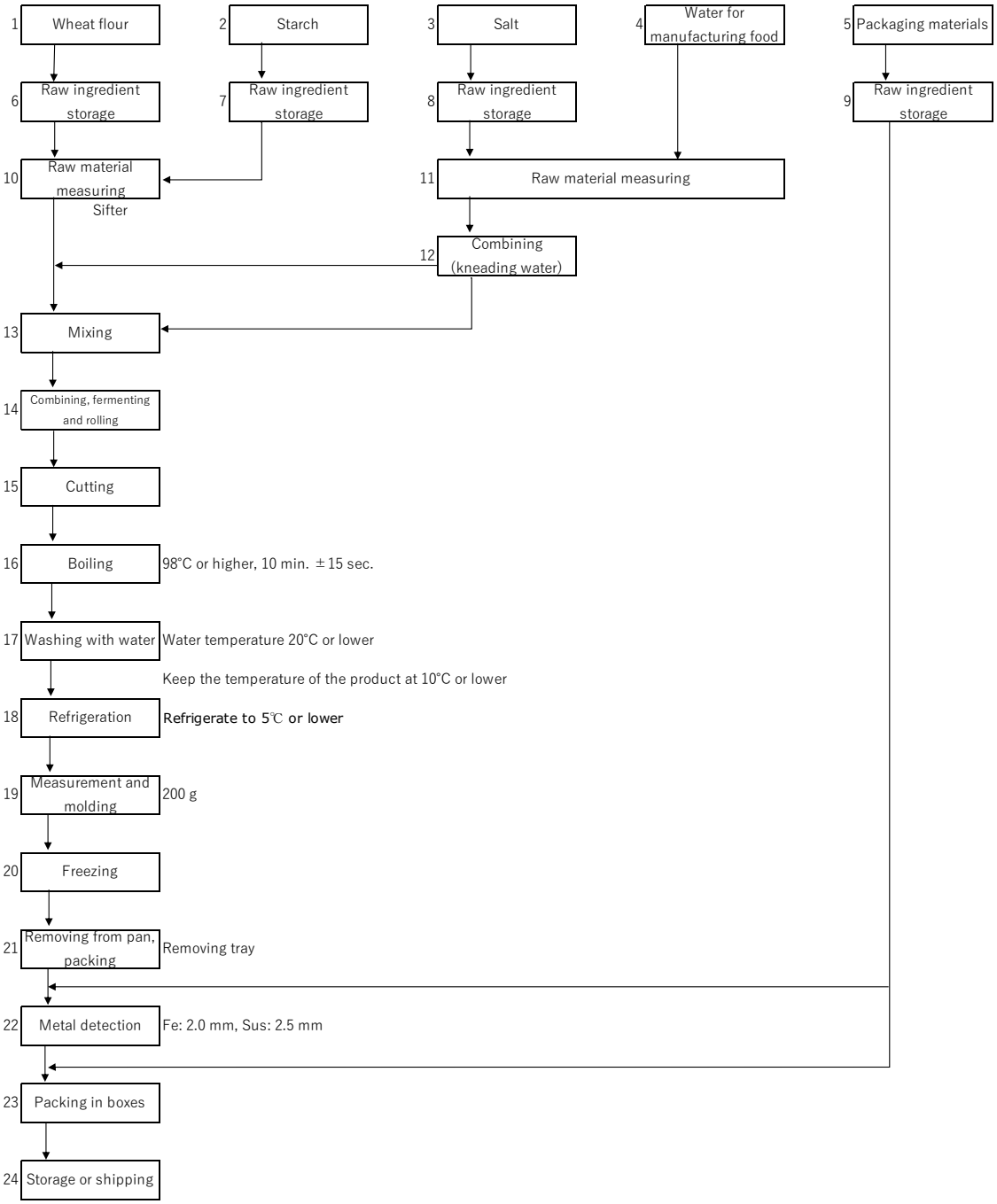
Examples of procedures and records that would be found in implementation of this food safety plan are included for use or modification. There is no regulatory requirement on how procedures or forms must look. Examples include those identified in the list of Supplements as follows:

#9, Example – Sample Letters of Guarantee for Packaging
#19, Example – Employee Training Record
#27, Example – Metal Detection Log
#28, Example – Reanalysis Form
#29, Example – Corrective Action Form
#31, Example – Equipment Calibration Log
#33, University of Wisconsin - Madison Center for Meat Process Validation. 2008. "Example – SOP for Calibration of Thermometer." Accessed November 28, 2017: https://meathaccp.wisc.edu/prerequisite_programs/assets/SOP%20Thermometer.pdf
#36, Example – Generic Recall Plan
#37, Example – SOP Sifter Inspection
#38, Example – Storage Area GMP Audit.
#39, Example – GMP Inspection of Preparation Areas Audit

# ２． Flowchart

# Flowchart

# (Frozen Boiled Noodle)



# ３．Product explanatory document (example)

## Product explanatory document (example)

| Entry | Content |
|---|---|
| Product name and type | Frozen boiled udon<br>(frozen boiled noodles) |
| Entry related to raw materials | Wheat flour, starch, salt, water for manufacturing food (tap water) |
| Additives with usage standards and their usage standards | None |
| Allergens | Wheat (The plant where this product is manufactured also manufactures products containing eggs.) |
| Materials and shapes of containers and packaging | Materials: PP (polypropylene)<br>Form: Packaging bag |
| Product characteristics | <Japan Frozen Noodle Association Hygiene Standards><br>(Frozen boiled noodles produced in Japan must meet the Japan Frozen Noodle Association Hygiene Standards. The USA does not have standards for frozen boiled noodles.*) |
| Storage method<br><br>Use-by date or best-by date | Storage method: Must be kept frozen (-18℃ or colder)<br><br>Best-by date: D+365 (12 months) |
| Method of eating or using | Eat after boiling, or boil, cool with water and then eat |
| Target consumers | General consumers |

*If a company includes a production description with their Preventive Control plan, the company should ensure that only food safety parameters are included. Quality parameters should typically not be included, unless they contribute to the food safety characteristics of the food product.

# ４．Generic Preventive Control Plan

# Generic Preventive Control Plan

# For Frozen Boiled Noodles

Facility Name: Frozen Boiled Noodles Plant 5

Facility Address: 1 xx-cho, xx-shi, 000-0000 XX

**The hazard analysis must match the steps in a facility's flowchart/actual production process. As noted, we have added and made assumptions on some steps in the process. Each facility should ensure that the flowchart and hazard analysis match the steps in its actual process.**

**Owner/Operator/Agent-in-Charge:** **Noodle Goro**

**Owner/Operator/Agent-in-Charge Signature:**

(The preventive control regulation requires in 21 C.F.R. § 117.310 that the owner, operator or agent in charge of the facility must sign and date the food safety plan upon initial completion of the plan and upon any later modification.)

ISSUED: August 31, 2017
REVISED:January 23, 2018

## Preventive Controls Food Safety Team

(The team should consist of individuals with different specialties and experience with the facility's processes and procedures. The Food Safety team should include members who are directly involved with the plant's daily operations and may include personnel from maintenance, production (including equipment experts), sanitation, quality assurance, engineering, purchasing, and laboratory, if applicable. These individuals develop the food safety plan under the oversight of a Preventive Controls Qualified Individual, and verify on-going implementation of the food safety system.)

**Examples of Participants on a Food Safety Team:**

- General Manager
- Preventive Controls Qualified Individual (required) (Supp. #19)
- QA/Technical Service Manager
- QA Supervisor/HACCP Coordinator/Food Safety Manager
- Plant Superintendent
- Packaging Supervisors
- Purchasing Manager
- Processing Supervisors
- Kitchen Supervisors
- Logistics Manager
- Plant Engineer
- Plant Change Agent

**PROCESS CATEGORIES AND INGREDIENTS****

(This form is useful to list out ingredients and categories of ingredients and other items used in product production. The ingredients listed below are examples of how a product could be broken into its components.)

| Spices/Flavorings | Food Additives | Preservatives/Acidifiers |
|---|---|---|
| | | |
| **Other** | **Proteins** | **Packaging Materials** |
| Water*<br>Salt<br>Starch | Wheat flour | Polypropylene<br>Paper<br>Cardboard |
| **Allergens** | | |
| Wheat flour | | |

*Water used as an ingredient in product produced as well as any water used for handwashing and sanitation should be potable. The facility should have in its files documentation on at least an annual basis, that the water used in the facility meets regulatory requirements for potable use. This may be in a form of a letter from the local municipal water supplier stating the water being delivered to the facility meets all local and national standards and it details what those standards are and when it was tested.

**All ingredients and suppliers of those ingredients should be evaluated prior to purchase of the respective ingredient to determine whether or not the ingredient and/or supplier has been involved in a food safety event such as a recall or an outbreak. The supplier and ingredient should be researched in databases relevant to the supplier and the source of the ingredient. For example, in the U.S. it would be expected that as part of a product evaluation into its safety, the Centers for Disease Control and Prevention's (CDC) "The Foodborne Outbreak Online Database" (https://wwwn.cdc.gov/foodborneoutbreaks/) would be reviewed as well as the Food and Drug Administration's (FDA) "Recalls, Market Withdrawals, Safety Alerts" (http://www.fda.gov/Safety/Recalls/) for any concerns that might involve the ingredient and/or the supplier of a respective ingredient. This information should be used in determining the likelihood of a particular hazard to occur.

## 4-1. Hazard Analysis

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|---|---|---|
| ADDRESS : 1 xx-cho, xx-shi, 000-0000 XX | SURPERSEDES: January 23, 2018 | PRODUCT CODE |

# Hazard Analysis

| Ingredient/Processing Step | Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step<br>B = Biological; C = Chemical including Radiological; P = Physical | Do any Potential Food Safety Hazards Require a Preventive Control? | | Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.) | What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard?<br>(Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control) | Is the Preventive Control Applied at this Step? | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| #1 Receiving Wheat Flour | B – Shiga toxin-producing *E. coli, Salmonella, B. cereus, L. monocytogenes, Staph aureus* | X | | Pathogens have been known to contaminate flour. If flour was received with ≤ 12% moisture level, pathogen growth will be controlled. However these hazards are addressed in subsequent thermal treatment step.(Supp. #1, 2, 10) | Process control – subsequent thermal treatment step | | X |
| | C – Mycotoxin | X | | Mycotoxin production could occur during growth or primary process of flour. (Supp. #1, 2) | Supply chain control | X | |
| | C – Radiological (Whether this is a hazard depends on where the wheat is grown) | X | | Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster. (Supp. #3) | Supply chain control Preventive Control – Approved supplier and third party supplier audit by qualified auditor | X | |
| | C – Economically motivated hazard (While a rare occurrence, hazards may be introduced for purposes of economic gain. Only adulteration that affects food safety should be addressed in the Food Safety Plan. Examples have included the addition of melamine to dairy products in China. While this may be rare, it must be reviewed for each step in the process. | X | | Economically motivated hazard (Supp. #4, 5, 6) | Supply chain control Preventive Control – Approved supplier and third party supplier audit by qualified audit | X | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | Generally, economically motivated hazards are controlled though a supply-chain program. **You only must focus on economic adulteration that has a history of resulting in a hazard in that particular food**.) | | | | | | |
| | C – Allergens (wheat)<br>(Product must be labeled to address allergens of concern in the country to which product is exported. The U.S. requires that milk, egg, peanut, tree nuts (by species), fish (by species), crustacean shellfish, wheat, and soy be labeled.) | X | | Wheat is an allergen that must be labeled to inform consumers. (Supp. #22, 23, 24) (If non-wheat-containing products are also produced in the same facility, allergen cross-contact with other products must be controlled.) | Allergen control – allergen labeling at later steps in the process<br>Sanitation controls – at a subsequent step if needed to prevent cross-contact | | X |
| | P – None Identified | | X | Flour is not known to contain physical hazards. Flour is also sifted through a 60 mesh screen (250 microns) as a good manufacturing practice (GMP) to ensure no foreign materials are present from transportation and storage. (*See* example in Supp. #35 – page 84 on how a program should be designed for monitoring the sifting operation. May | | | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | | | | need to modify depending on whether your operation is in-line or a batch process.) (Supp. #2, 33, 34, 35) | | | |
| #2 Receiving Starch | B – *Bacillus cereus*, *Salmonella* | X | | Pathogens have been known to contaminate shelf-stable starches.(Supp. #2) | Process control – subsequent thermal treatment step | | X |
| | C – Unapproved Colors & Additives in Starch | X | | Starch has been known to possibly contain unapproved colors and additives<br>(Supp. #2, 7) | Supply chain control – Approved supplier and third party supplier audit by qualified audit | X | |
| | C – Radiological (Whether this is a hazard depends on where the raw material used to produce the starch (i.e., corn) is grown.) | X | | Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster. (Supp. #3) | Supply chain control – Approved supplier and third party supplier audit by qualified auditor. | X | |
| | P – Metal | X | | Starch has been known to contain metal. (Supp. #2) | Metal Detection | | X |
| #3 Receiving of Salt | B – None Identified | | X | Salt is not known to contain biological hazards. (Supp. #2) | | | |
| | C - Unapproved Colors And Additives in Salt | | X | These ingredients are not known to be at risk for containing unapproved colors upon review of current import alerts. (Supp. #2, 7) | | | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | C – Economically motivated hazard (While a rare occurrence, hazards may be introduced for purposes of economic gain. Only adulteration that affects food safety should be addressed in the Food Safety Plan. Examples have included the addition of melamine to dairy products in China. While this may be rare, it must be reviewed for each step in the process. Generally, economically motivated hazards are controlled though a supply-chain program. You only must focus on economic adulteration that has a history of resulting in a hazard in food.) | X | | Economically motivated hazard (Supp. #4, 5, 6) | Supply chain control – Approved supplier and third party supplier audit by qualified audit | X | |
| | P – None Identified | | X | No physical hazards have been identified or enhanced at this step in the process. | | | |
| #4 Receiving of Water (Tap) | B – *Campylobacter, Salmonella, Shigella, Vibrio cholera, Yersinia* | X | | Biological hazards are potential contaminates of water. If well water is sourced, it should be tested at some | Process control – subsequent thermal treatment step | | X |

# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | *entercolitica,* Shiga toxin-producing *E. coli, Cyclospora,* Hepatitis A, SRSV | | | frequency after in-house treatment to ensure it meets acceptable potable water standards. If water is obtained from a municipality, certificates of potability should be on file. (Supp. #8) | | | |
| | C – Radiological (Whether this is a hazard depends on where the water is sourced) | X | | Radiological hazard may result from accidental contamination such as release from a nuclear facility or damage to a nuclear facility during a natural disaster (Supp. #3). | Supply chain control – Approved supplier and third party supplier audit by qualified auditor | X | |
| | P – None Identified | | X | No physical hazards have been identified in potable water. | | | |
| #5 Receiving of Packaging Materials | B – None Identified | | X | No biological hazards have been identified. | | | |
| | C – Chemical Residues | | X | C – Chemical Residues – Purchasing specifications require that all materials have on file a letter of guarantee from the manufacturer that states these products are approved for their intended use. (Supp. #9, 10) | | | |
| | C – Allergens (Wheat) | X | | C – Allergens – Product labels must declare all allergens present in the product. (Supp. #9, 10, 23) | Allergen control – label review for allergen information (Label review may be done at the receiving step, but should also be performed when label is applied to the finished product to ensure the proper label is used.) | X | |

# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | P - None Identified | | X | No physical hazards have been identified with receipt of packaging. | | | |
| #6 Raw Ingredient Storage<br>(Wheat Flour) | C – Mycotoxin | X | | Mycotoxin level can increase during storage of wheat flour if the environment has a high moisture level. Flour stored in tightly sealed containers preventing moisture gain would eliminate the potential hazard. (Having a procedure that ensures flour is received and stored to prevent moisture absorption would eliminate the need for a preventive control at this step.) (Supp. #1, 2, 10, 29) | Process control – Maintain flour at <12% moisture level for mycotoxin control | X | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P –None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #7 Raw Ingredient Storage<br>(Starch) | B – None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P –None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |

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# Hazard Analysis

| Ingredient/Processing Step | Identify Potential Food Safety Hazards Introduced, Controlled, or Enhanced at this Step<br>B = Biological; C = Chemical including Radiological; P = Physical | Do any Potential Food Safety Hazards Require a Preventive Control? | | Justify Your Decision for Column 3 (Each company will need to determine the appropriate decision and scientifically support that decision within their process. Examples are provided.) | What Preventive Control Measure(s) Can Be Applied to Significantly Minimize or Prevent the Food Safety Hazard?<br>(Process including CCP's, Allergen, Sanitation, Supply Chain, or other Preventive Control) | Is the Preventive Control Applied at this Step? | |
|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| #8 Raw Ingredient Storage (Salt) | B – None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P –None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #9 Raw Ingredient Storage (Packaging Materials) | B – None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P –None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #10 Raw Material Measuring (sifter) | B – None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P - Metal | X | | Pieces of metal may be introduced during the process from equipment used. This can be controlled by subjecting the product to metal | Process control – metal detection | | X |

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# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | | | | detection. (Supp. #11, 12) | | | |
| #11 Raw Material Measuring<br>(Salt, Water) | B – None identified | | X | No biological hazards and introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #12 Combining<br>(Kneading water) | B – None identified | | X | No biological hazards and introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P – None identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #13 Mixing | B - None Identified | | X | No biological hazards and introduced or enhanced at this step in the process. | | | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | X | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | P - metal | X | | Pieces of metal may be introduced during the process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #11, 12) | Process control – metal detection | | X |
| #14 Combining, Fermenting and Rolling<br>(This step may need broken into three separate steps. Or at least the "combining and fermenting" may be a separate step as usually product that is "fermenting" is sitting for a period of time. If so, there may be a concern with time and temperature of the holding area and whether or not any biological hazards could be enhanced at this step.) | B - None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | X | |
| | P - None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #15 Cutting | B – None Identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – Allergen Cross-contact | X | |
| | P – Metal | X | | Pieces of metal may be introduced during the process from equipment used. This can be controlled by subjecting the product to metal detection. (Supp. #11, 12) | Process control – metal detection | | X |
| #16 Boiling | B – Shiga toxin-producing *E. coli, Salmonella, B. cereus, L. monocytogenes, Staph aureus, Clostridium botulinum* | X | | Pathogens – cooking the noodles to ≥ 98°C and maintaining that temperature for at least ten (10) minutes ±15 seconds will kill the vegetative pathogens as well as . inactivate Non-Proteolytic C. botulinum Type B. (Supp. #13) | Process control – cooking | X | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | X | |
| | P - None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |

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# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| #17 Washing with Water | B – *Clostridium botulinum*, *B. cereus* | X | | *Clostridium botulinum, B. cereus* – growth of sporeformers can occur if product is not chilled rapidly. (Supp. #2, 14) | Process control – water temperature ≤20°C. & product ≤10°C in ≤2 hours (Use of temperature control usually has a time associated with it. Product must be chilled quickly. Depending on the operation, a time that product must reach ≤10°C should also be included as part of the process control step unless there is information justifying that the low temperature is reached very rapidly.) | X | |
| | B – *Listeria monocytogenes* | X | | B – *L. monocytogenes* – can be introduced to un-packaged product post-lethality by the environment. (Supp. #15, 16, 17, 18, 20,) | Sanitation Control | X | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | X | |
| | P – None identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #18 Refrigeration | B – *Clostridium botulinum*, *B. cereus* | X | | *Clostridium botulinum, B. cereus* – growth of sporeformers can occur if product is not chilled rapidly. (Supp. #2, 14) | Process control – water temperature ≤20°C. & product ≤10°C in ≤2 hours (Use of temperature control usually has a time associated with it. Product must be chilled quickly. Depending on the | X | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | | | | | operation, a time that product must reach ≤10°C should also be included as part of the process control step unless there is information justifying that the low temperature is reached very rapidly.) | | |
| | B – *Listeria monocytogenes* | X | | B – *L. monocytogenes* – can be introduced to un-packaged product post-lethality by the environment. (Supp. #15, 16, 17, 18, 20, 21) | Sanitation control | X | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | X | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #19 Measurement and Molding | B – *Listeria monocytogenes* | X | | B – *L. monocytogenes* – can be introduced to un-packaged product post-lethality by the environment. (Supp. #15, 16, 17, 18, 20) | Sanitation control | X | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in | Sanitation control – allergen cross-contact | | |

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# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | | | | the boiled noodles.) (Supp. #2, 24) | | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #20 Freezing | B – *Listeria monocytogenes* | X | | B – *L. monocytogenes* – can be introduced to un-packaged product post-lethality by the environment. (Supp. #15, 16, 17, 18, 20) | Sanitation control | X | |
| | C – Allergen – cross-contact as facility produces product with eggs | X | | Allergen cross contact can occur if equipment is not adequately cleaned after product containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | Sanitation control – allergen cross-contact | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #21 Removing from Pan, Packing | B – *Listeria monocytogenes* | X | | B – *L. monocytogenes* – can be introduced to un-packaged product post-lethality by the environment. (Supp. #15, 16, 17, 18, 20) | Sanitation control | X | |
| | C – Allergen (wheat) | X | | C – Allergens – Product labels must declare all allergens present in the product. (Supp. #9, 10, 23) | Allergen control – review of final package label | X | |
| | C – Allergen – cross-contact as facility produces product | X | | C – Allergen cross-contact can occur if equipment is not adequately cleaned after product containing eggs | Sanitation control – allergen cross-contact | X | |

# Hazard Analysis

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | with eggs | | | containing eggs is produced. (This only applies if the equipment is used to produce products containing an allergen not present in the boiled noodles.) (Supp. #2, 24) | | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #22 Metal Detection | B – None identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P – Metal | X | | Metal-to-metal contact during processing may introduce metal into product.<br>(Supp.# 11, 12, 26) | Process control – metal detection | X | |
| #23 Packing in Boxes | B – None identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or enhanced at this step in the process. | | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |
| #24 Storage or Shipping | B – None identified | | X | No biological hazards are introduced or enhanced at this step in the process. | | | |
| | C – None Identified | | X | No chemical hazards are introduced or | | | |

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|---|---|---|---|---|---|---|---|
| | | Yes | No | | | Yes | No |
| | | | | enhanced at this step in the process. | | | |
| | P – None Identified | | X | No physical hazards are introduced or enhanced at this step in the process. | | | |

## 4-2. Preventive Control Plan

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# Preventive Control Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Supplier Control – Mycotoxin in Wheat Flour | Mycotoxin | Received from an Approved Supplier approved on XX (date supplier(s) was approved, Supplier must be approved prior to receiving ingredients) | (Monitoring not required for supply-chain applied preventive controls.)<br><br>(While monitoring is not required, there should be a procedure that identifies a qualified individual to review and document that each incoming shipment is received from an approved supplier.) | | | | The Qualified Individual will determine the root cause and implement corrective actions to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.<br><br>The PCQI can make a determination to temporarily approve the supplier if adequate documentation is provided.<br><br>(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly affect product safety.)<br><br>The Qualified Individual can reject shipments received from an unapproved supplier. Alternatively, the ingredient can be used in food for research only or other non-sales. | Incoming Receiving Record<br><br>Bill of Lading<br><br>Copy of audit report by a qualified auditor obtained from the supplier<br><br>Record showing use for research or non-sale item if applicable<br><br>Correction/Corrective Action Records (Supp. #28)<br><br>Reanalysis Form (Supp. #27) | PCQI ensures the reviews of the initial and annual audit of the supplier by the qualified auditor.<br><br>PCQI ensures the reviews of the receiving record log within 7 days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>PCQI ensures the review of the corrections record within 7 days.<br>(Considerations for appropriate verification can include:<br>• What does the hazard analysis suggest about the nature of the hazard?<br>• Are preventive controls applied by the supplier or the supplier's supplier?<br>• What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material?<br>• Has FDA issued warning letters or import alerts related to the supplier's compliance?<br>• Do your historical test or audit results for the supplier indicate a trend – positive or negative?<br>• Have the supplier's corrective actions to past issues been appropriate and timely?<br>• Are the supplier's storage or transportation practices appropriate?) |

# Preventive Control Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Supplier Control – unapproved colors and additives in starch | Unapproved colors and additives | Received from an Approved Supplier approved on XX (date supplier(s) was approved, Supplier must be approved prior to receiving ingredients) | (Monitoring not required for supply-chain applied preventive controls.)<br><br>(While monitoring is not required, there should be a procedure that identifies a qualified individual to review and document that each incoming shipment is received from an approved supplier.) | | | | The Qualified Individual will determine the root cause and implement corrective actions to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met.<br><br>The PCQI could make a determination to temporarily approve the supplier if adequate documentation is provided.<br><br>(The below are considered "corrections" as corrections may be used for minor and isolated problems that do not directly impact product safety.)<br><br>The Qualified Individual can reject shipments received from an unapproved supplier. Alternatively, the ingredient can be used in food for research only or other non-sales. | Incoming Receiving Record<br><br>Bill of Lading<br><br>Copy of audit report by a qualified auditor obtained from the supplier<br><br>Record showing use for research or non-sale item if applicable<br><br>Correction/Corrective Action Forms (Supp. #28)<br><br>Reanalysis Form (Supp. #27) | PCQI ensures the reviews of the initial and annual audit of the supplier by the qualified auditor.<br><br>PCQI ensures the reviews of the receiving record log within 7 days. (While the regulation requires records review within 7 working days of completion; it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>PCQI ensures the review of the corrections record within 7 days.<br>(Considerations for appropriate verification can include:<br>• What does the hazard analysis suggest about the nature of the hazard?<br>• Are preventive controls applied by the supplier or the supplier's supplier?<br>• What are the supplier's procedures, processes and practices related to safety for the ingredient or raw material?<br>• Has FDA issued warning letters or import alerts related to the supplier's compliance?<br>• Do your historical test or audit results for the supplier indicate a trend – positive or negative?<br>• Have the supplier's corrective actions to past issues been appropriate and timely?<br>• Are the supplier's storage or transportation practices appropriate?) |

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# Preventive Control Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Labeling of Allergens | Allergens: wheat | All finished product labels declare allergens present in the product. | Ingredients in the product produced (as per product mixing record) matches the ingredient statement on the finished product label. | Visual review of product mixing records to confirm accuracy of product produced.<br><br>Visual review of finished product labels for correct allergen declaration. (Review of the finished product labels can be done at receiving of the product labels as well as when applied to the finished product – especially important if other types of similar products are also produced in the same facility) | Every batch of product produced. | Qualified Individual or designee | If the mixing record does not reflect the product being produced, the Qualified Individual will retain product to identify whether the product was formulated correctly and can be labeled and released.<br><br>If the finished product label does not contain the correct allergen declarations, the labels will be corrected or destroyed, Product will not be released without proper labeling.<br>The Qualified Individual will determine the root cause and implement corrective actions to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met. | Product Mixing Record<br><br>Finished Product Labels Check Form<br><br>Corrections/Corrective Action Form (Supp. #28)<br>Reanalysis Form (Supp. #27) | PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>PCQI will ensure there is a direct observation of the product being made and ensure that it matches the description on the mixing record. |

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| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Storage Of Wheat Flour (If wheat is received in containers that prevent moisture absorption, the concern would only apply to open containers that can not be tightly closed to prevent moisture adsorption.) | Increase in mycotoxin and pathogen growth | Maintaining moisture level in product at ≤ 12%<br><br>OR<br><br>Store wheat to ensure that moisture level in product does not increase above 12%. (This can be achieved by storing product in tightly sealed containers to prevent moisture absorption or by controlling the environmental conditions in the storage area that ensures the product moisture level stays ≤12% moisture.) | Measure moisture level in product<br><br>OR<br><br>Ensure that storage area environment is maintained to prevent increase of product moisture levels. | Heat samples of flour in oven and determine moisture level. (Supp. #30)<br><br>OR<br><br>Monitor environmental parameters such as temperature and humidity of the storage area. | Frequency of testing will depend on the product storage container and the length of time product remains in storage.<br><br>Environmental monitoring frequency is contingent on how well the environmental parameters can be controlled. | Qualified Individual or designee | If product moisture levels increase above 12%, product should be retained and management notified.<br><br>The Qualified Individual will determine the root cause and implement corrective actions to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met. | Product Moisture Level Form<br><br>Storage Area Condition Log<br><br>Correction/Corrective Action Form (Supp. #29)<br><br>Reanalysis Form (Supp. #28) | PCQI will ensure review of records within 7 working days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) |

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| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Boiling Noodles | *Salmonella, Listeria monocytogenes,* Shiga toxin-producing *E. coli, Bacillus cereus, Clostridium botulinum Type B* | Cooking the noodles in water with a temperature of ≥ 98°C and maintaining that temperature for at least ten (10) minutes ±15 sec. will kill the vegetative pathogens as well as inactivate Non-Proteolytic C. botulinum Type B. | Water temperature is ≥ 98°C. and maintained at that temperature for at least 10 minutes ±15 sec.. | Calibrated and accurate thermometer | Each batch of product | Qualified Individual or designee | If the water temperature is not ≥ 98°C. and maintained at that temperature for at least 10 minutes ±15 sec., the Qualified Individual will ensure product continues to cook until the water temperatures meets the cook requirements.<br><br>The Qualified Individual will determine the root cause and implement corrective actions to prevent reoccurrence. If finished product water did not meet the minimum temperature and time requirements, the product will be reworked or destroyed.<br><br>All parts of 21 CFR § 117.150(a)(2) will be met. | Cooking Record<br><br>Equipment Calibration Log (Supp. #30)<br><br>Correction/Corrective Action Forms (Supp. #28)<br><br>Reanalysis Form (Supp. #27) | The PCQI will ensure the review of all records within 7 days. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>(Accuracy of thermometers are typically done on a daily basis using ice slurry and/or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #31, 32) )<br><br>(Accuracy checks and calibration of equipment are typically done based on the frequency recommended by the manufacturer. Additional considerations for frequency include the conditions of use and the known "drift" of the equipment.)<br><br>(Accuracy checks are done routinely to ensure the equipment continues to function as intended under plant conditions. Calibration is done periodically to ensure the equipment remains accurate and reliable.) |

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|---|---|---|
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# Preventive Control Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Washing with water | Growth of vegetative and spore-forming pathogens | Noodles are washed in water that is maintained at ≤20°C and product reaches ≤10°C in ≤2 hours | Water temperature maintained at ≤20°C and product reaches ≤10°C in ≤2 hours. | Use a calibrated temperature to determine that water is maintained at ≤20°C and then time the process to ensure temperature of product reaches ≤10°C in ≤2 hours. | Every batch of product. | Qualified individual or designee | If water is not ≤20°C, continue to recirculate and add chilled water until temperature is reached. If product does not reach temperature required in ≤2 hours, place product on hold and take corrective measures.<br><br>All steps in 21 CFR 117.150 (a)(2) will be met. | Cooking Time And Temperature Log<br><br>Equipment Calibration Log (Supp. #30)<br><br>Correction/Corrective Action Form (Supp. #28)<br><br>Reanalysis Form (Supp. #27) | PCQI will ensure review of records within 7 working days. . (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>(Accuracy of thermometers are typically done on a daily basis using ice slurry and/or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #31, 32) )<br><br>(Accuracy checks and calibration of equipment are typically done based on the frequency recommended by the manufacturer. Additional considerations for frequency include the conditions of use and the known “drift” of the equipment.)<br><br>(Accuracy checks are done routinely to ensure the equipment continues to function as intended under plant conditions. Calibration is done periodically to ensure the equipment remains accurate and reliable.) |

# Preventive Control Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Refrigeration | *B. cereus* | Refrigerate product at ≤5°C. | Cooler/refrigerated area is maintained at ≤5° C and product is moved into refrigerated area within ≤2 hours;<br><br>Product temperature remains at ≤10° C | Use of a calibrated thermometer to ensure that refrigerated area is maintained at ≤5° C;<br><br>Product is marked with time exiting wash water and placed into refrigeration ≤ 2hours.<br><br>Use of calibrated thermometer to ensure that product temperature remains ≤ 10° C | Minimum of four (4) times per production day<br><br>Every batch of product.<br><br>Every batch of product | Qualified Individual or designee | If refrigerated area is not ≤5°C; immediately take temperature of product to ensure it is ≤ 10° °. Continue to monitor product temperature and move product to an area that is ≤5°C if product temperature begins to rise.<br><br>Take corrective actions to ensure refrigerated area is at correct temperature.<br><br>If product cannot be removed to another area; place product on hold and take corrective actions.<br><br>All steps in 21 CFR 117.150 (a)(2) will be met. | Cooking Time And Temperature Log<br><br>Refrigeration Area Temperature Log<br><br>Equipment Calibration Log (Supp. #30)<br><br>Correction/Corrective Action Form (Supp. #28)<br><br>Reanalysis Form (Supp. #27) | PCQI will ensure review of records within 7 working days. . (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>(Accuracy of thermometers are typically done on a daily basis using ice slurry and/or boiling water. Calibration of the thermometer is done periodically checking the equipment against an NIST standardized thermometer to ensure accuracy. (Supp. #31, 32) )<br><br>(Accuracy checks and calibration of equipment are typically done based on the frequency recommended by the manufacturer. Additional considerations for frequency include the conditions of use and the known “drift” of the equipment.)<br><br>(Accuracy checks are done routinely to ensure the equipment continues to function as intended under plant conditions. Calibration is done periodically to ensure the equipment remains accurate and reliable.) |

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# Preventive Controls Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Sanitation of the washing with water area, Refrigeration area, Measurement and Molding area, Freezing area, Removing from Pan, Packing area | *Listeria monocytogenes* (*Listeria monocytogenes* can contaminate the product exposed to the environment after it has been cooked. These areas require special product handling, employee hygiene and sanitation. Many food companies have separate colored outer clothing, mops and cleaning supplies to prevent cross contamination with the raw product area. A separate document includes "Best Practices" that may be incorporated into a GMP.) | Prevent post-lethality contamination of product with *Listeria monocytogenes* | The cooking equipment/area, cooling and packaging equipment/areas are evaluated for cleanliness.<br><br>Sanitizer strength is measured prior to application in the area e.g., quaternary ammonium at 200 -400 ppm.<br><br>All employees entering the area are wearing the designated outwear, hairnets and gloves. | Visual observation of the cooking equipment/area, cooling and packaging equipment/areas for cleanliness.<br><br>Test strips are used to measure sanitizer strength.<br><br>Employees entering the area are visually observed to be wearing the designated outwear, hairnets and gloves. | The cooking equipment/area, cooling and packaging equipment/areas are observed for cleanliness before start of operations.<br><br>Sanitizer strength is measured prior to use.<br><br>Employees in the area are visually observed for proper attire at start up, and every two hours during production. | Qualified Individual or designee | If the equipment/areas are observed unclean prior to operations, the operations are not permitted to start until the areas are recleaned and reinspected.<br><br>If the sanitizer strength is not appropriate, it is remade or adjusted prior to using.<br><br>If employees are not wearing appropriate attire for the areas, they are instructed to put on the appropriate attire. (It is important to note that the Qualified Individual will need to assess whether the failure to wear proper attire may have led to potential cross-contamination of product.)<br><br>If no product is involved, corrections will be taken. If product is affected, corrective actions will be taken that meet all requirements in 21 CFR § 117.150(a)(2). | Daily Sanitation Record<br><br>Sanitizer Strength Record<br><br>(Note- many companies include the sanitizer strength on the Daily Sanitation Record)<br><br>Correction/Corrective Action Form (Supp. #28)<br>Reanalysis Form (Supp. #27) | The PCQI will ensure review of all records within 7 days. (While the regulation requires records review within 7 working days of completion; it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.) |

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# Preventive Controls Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Sanitation Control – Allergen Cross-Contact | Contamination with an allergen not present in the product or listed on the product label | Ensure equipment is clean if a product containing an allergen not present in the Frozen Boiled Noodles is produced on the equipment | Ensure sanitation process removes all product residue from equipment used to produce product containing unlisted allergen to prevent cross-contact with the Frozen Boiled Noodles | Visual verification that all equipment is clean | After any production of product containing an unlisted allergen in the Frozen Boiled Noodles | Qualified Individual or designee | If equipment is not visually clean – re-clean the equipment, re-inspect.<br><br>If equipment cannot be made visually clean; place equipment on hold and take appropriate corrective actions to prevent product contamination.<br><br>If product has been run on the equipment; place product on hold and take corrective actions (this includes actions to identify and correct the problem, action to prevent reoccurrence, all affected product is evaluated for safety, and all affected food is prevented from entering commerce if adulterated). The Qualified Individual will determine the root cause and implement corrective action to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met. | Daily Sanitation Log<br><br>Laboratory Results<br><br>Correction/Corrective Action Form (Supp. #28) Reanalysis Form (Supp. #27) | Review of documentation within 7 working days is ensured by the PCQI. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>(Many companies use allergen test kits to verify the effectiveness of sanitation when performing an allergen change-over sanitation procedure. Use of a test kit is not required by the FSMA Preventive Controls regulation but is considered a industry "Best Practice." The regulation only requires that the equipment be "visually clean." If using a test kit – this would be listed as a verification activity.) |

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# Preventive Controls Plan

| Process Control | Hazard | Preventive Control Parameters | Monitoring | | | | Corrective Action / Corrections | Record Keeping | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Freq. | Who | | | |
| Metal Detection (Metal detection may occur at one or more steps in the process.) | *Metal* | Metal detector is present and operating and no metal fragments that would cause injury or choking are in the product that passes through the functioning metal detector. | All product passes through the functioning metal detector | Product passes through a functional metal detector, which detects and rejects ferrous at 2.0 mm, non-ferrous –2.5 mm. (The company will have to support the size of the seeded samples used. The PCQI will oversee the validation and supporting material provided by the company for each step in the process.) | Hourly during production.<br><br>(The company will have to support the frequency used.) | Qualified Individual or designee (A person who has the education, training, or experience (or a combination thereof) necessary to manufactur e, process, pack, or hold, clean and safe food as appropriate to the individual's assigned duties) | A Qualified Individual will take appropriate corrections or corrective actions (this includes actions to identify and correct the problem, action to prevent reoccurrence, all affected product is evaluated for safety, and all affected food is prevented from entering commerce if adulterated).<br><br>(In the event of an unanticipated food safety event, a re-analysis of the food safety plan or the appropriate portion of the plan would be required. Any reanalysis of the food safety plan must be done by a Preventive Controls Qualified Individual (PCQI). A PCQI is a Qualified Individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized by FDA or is otherwise qualified through job experience to develop and apply a food safety system.)<br><br>The Qualified Individual will determine the root cause and implement corrective action to prevent reoccurrence. All steps in 21 CFR 117.150(a)(2) will be met. | Metal Detection Log (Supp. #26)<br><br>Validation records for setting and frequency<br><br>Metal Detector Calibratio n Record<br><br>Corrective Action Form (Supp. #28)<br><br>Reanalysi s Form (Supp. #27) | Review of documentation within 7 working days is ensured by the PCQI. (While the regulation requires records review within 7 working days of completion, it is highly recommended that this be done on a daily basis. When issues are identified during the review, corrective action is required.)<br><br>Verification will include the following: Direct observation of monitoring a minimum of once a week.<br><br>The metal detector will be calibrated annually by the manufacturer to detect standardized metal slugs.<br><br>(Note - The company could also use the recommendations of the manufacturer to have a different qualified individual perform periodic calibration.) |

**List of Supplements for Preventive Control Plan**


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36. Example – Generic Recall Program

37. Example – SOP Sifter Inspection
38. Example – Storage Area GMP Audit
39. Example – GMP Inspection of Preparation Areas Audit

## 4-3. Training Form

## Training

In addition to the Preventive Controls Qualified Individual(s), each facility will be required to have Qualified Individuals. Qualified Individuals are defined as "a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment." The Qualified Individuals should be trained for the job they are expected to perform at the facility and a copy of the training records should be maintained.

As a reminder, the Preventive Controls Qualified Individual (PCQI) is considered a qualified individual that has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system. The certification of the PCQI should also be maintained on file at the facility.

## Example Training form

| | | |
|---|---|---|
| **PRODUCT(S):** Frozen Boiled Noodles | | |
| **PLANT NAME: Frozen Boiled Noodles Plant 5** | **ISSUE DATE:** | |
| **ADDRESS: 1 xx-cho, xx-shi, 000-0000 XX** | **SUPERSEDES:** | |

**Training on Proper Sampling Technique for Environmental Monitoring** – training conducted to ensure quality assurance personnel assigned to collect samples understand that a swab must be 30.5 cm by 30.5 cm and the goal is to identify the high risk part of the equipment for swabbing

| Name | Signature | Date |
|---|---|---|
| | | |
| | | |
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| | | |
| | | |

## 4-4. Metal Detection Log

# Metal Detection Log

**Date:** _____

| Time | Batch | Product | Metal Detector (Yes) | Visual Inspection | Initial | Corrective Action |
|---|---|---|---|---|---|---|
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Metal Detector Specifications: Y mm ferrous, Y mm non-ferrous; and Y mm stainless. Frequency- ?
*Needs to be defined per specification

Supervisor (Name and Date): _____

## 4-5. Reanalysis Report

(The FDA defines "reanalysis" of the food safety plan as "A verification procedure to assure that the Food Safety Plan remains valid and the food safety system is operating according to the plan". FDA requires a reanalysis at least every three (3) years; whenever a significant change in product or process occurs; when there is new information that becomes available about potential hazards associated with the food; when there is an unanticipated problem; and when a preventive control is ineffective.)

# Example Reanalysis Report

| | | |
|---|---|---|
| **PRODUCT(S):** Frozen Boiled Noodles | | |
| **PLANT NAME: Frozen Boiled Noodles Plant 5** | **ISSUE DATE:** | |
| **ADDRESS: 1 xx-cho, xx-shi, 000-0000 XX** | **SUPERSEDES:** | |

***Food Safety Plan Reanalysis Report***

(Add rows as needed if different plans are used for different products)

| **Checklist** | **Date reviewed and initials of reviewer** | **Update needed Yes/No** | **Date Updated Completed:** | **Person (PCQI) Completing the Update** (initial of |
|---|---|---|---|---|
| List of Food Safety Team | | | | |
| List of products and processes in place at facility | | | | |
| Product flow diagrams | | | | |
| Hazard Analysis | | | | |
| Sanitation Preventive Controls | | | | |
| Food Allergen Preventive Controls | | | | |
| Process Preventive Controls | | | | |
| Supply-chain Preventive Control Program | | | | |
| Recall Plan | | | | |

## 4-6. CORRECTIVE ACTION REPORT

# CORRECTIVE ACTION REPORT

Date of Report: _____ Date of Incidence: _____

Preventive Control Deviation: _____

Description of **Deviation** (Include pounds, lot number and all details - ATTACH SEPARATE SHEET IF REQUIRED).

Document Completed By:_____

QA Personnel Notified: _____ Manager Notified: _____

**Corrective Action** Taken (To be completed by QA).

**Prevention**

Final **Disposition** of Affected Product

Signature & Date Required By:

Plant Manager: _____

QA Manager: _____

cc: Plant Manager, Director of Technical & VP Operations.

This corrective action response meets the requirements set forth in FDA Regulation 21 C.F.R. § 117.150(a)(2)

- ❖ Identify and correct the cause of the deviation,
- ❖ Action taken to reduce the likelihood the deviation will occur again,
- ❖ All affected product is evaluated for safety, and
- ❖ Prevent distribution into commerce of product adulterated as a result of the deviation.

## 4-7. EQUIPMENT CALIBRATION LOG

# EQUIPMENT CALIBRATION LOG

Equipment exists in the facility that requires periodic calibration. The frequency of calibration is dependent on the type of equipment used.

**Direct Observation of the equipment being calibrated is indicated by the letters "D.O." and the initials of the person doing the direct observation in the space to the left of the "Date" column.**

* Dispose of the thermometer when adjustment is greater than 2°C.*

| Type of Equipment | Accuracy Check Frequency | Calibration Frequency |
|---|---|---|
| Thermometer | Daily | Daily |
| Portable Scales | (per manufacture recommendations) | (per manufacture recommendations) |

| Date | Time | ID for Equipment Calibrated | Mercury Thermometer Reading (°C) | Thermometer Reading (°C) | Comments* | Operator Initials |
|---|---|---|---|---|---|---|
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Reviewed By: _____ Date:_____

## 4-8. Recall Plan

# Company Name Recall Program

## Recall Plan

**FDA requires a Recall Plan whenever the hazard analysis identifies any hazard that requires a preventive control.**

### The goals of a product recall

A product recall is intended to protect public health. Your first goal is to regain control of all potentially hazardous products. If this goal is met, the recall is successful. Sometimes you'll have to also work toward a second goal: telling the public about the potentially hazardous product and how to dispose of it.

### Basic principles of conducting a product recall

There are basic principles that will make execution of your recall plan effective.

1. Use a lot or date code on all products.
2. Designate (ahead of time!) a person who will be in charge of the recall.
3. Designate (ahead of time!) a person who will talk with the media.
4. Keep good records of your wholesale customers so you can easily contact them.
5. Have a plan for informing the public.
6. Have model press releases and customer-contact scripts ready (ahead of time!).
7. Work with regulators.
8. Act quickly – if in doubt take the safer course of action.
9. Practice your recall plan with a "dry run."

PRODUCT RETRIEVAL POLICY

**Company Name** will maintain an effective warning and retrieval system for products that threaten public health, violate government regulations, or do not meet standards.

A. Introduction

Product recalls involve the removal of product from the market which are adulterated, misbranded, or otherwise in violation of federal/state statute or regulation. Recalls may be firm-initiated or USDA/FDA - requested. The term "recall" is used when there is reason to believe a product in commerce is adulterated or misbranded under the provisions of the Federal Meat Inspection Act, Poultry Products Inspection Act or Food Drug and Cosmetic Act. A Recall does not include a market withdrawal or stock recovery that is completed by the firm.

B. Recall Classifications:

Class I - This is a health hazard situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death.

Class II - This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III - This is a routine situation where the use of the product will not cause adverse health consequences.

Market Withdrawals involve the removal of product from the market which are below quality standards or minor regulatory infraction that would not cause the product to be adulterated or misbranded.

Code Dates/Records

1. All products produced by. will have a legible code date that is produced by a code dating system which identifies the day and year of production.

2. **Company Name** will maintain all such records pertaining to product for no less than two years from production date.

D. Responsibilities

1. The decision to initiate a recall is the responsibility of the President or, in that person's absence, the General Manager. The decision to assume the responsibility for a recall activity previously initiated by a supplier/regulatory agency will be made by the President. The proper execution of a recall depends on the Recall Coordinator and the Recall Team, a standby group of personnel that is vital to the success of the recall action plan.

2. The Recall Officer directs all activities of the Recall Team, which is composed of the Recall Coordinator, and representatives of the following departments: (and hone fax and email for these individuals)

| **Department** | **Representative** | **Alternative** |
|---|---|---|
| Recall Officer/Coordinator | | |
| Marketing | | |
| Legal | | |
| Food Safety Team | | |
| Plant Operations | | |
| Preventive Controls Team/Quality Assurance | | |
| IT/Accounting | | |
| Call Center Operations | | |

The personnel and alternates assigned to the Recall Team are listed above. (**add real names and include only the people you will have on <u>your</u> team)**

.

The major responsibilities of the Recall Team are to:

1. Evaluate pertinent facts, information, and reports to confirm the degree of the hazard, the recall class, recall depth, and appropriate regulatory agency notification.

2. Create the form of written notification of the recall decision to use for all affected customers.

3. Notify distribution with instructions for the recall, including all product information and directives to stop shipments.

4. Develop a recovery force, which will prepare recall forms, conduct supplier notification and customer notification.

5. Establish lines of communication within the company, with the media, the insurance carrier, and with the appropriate regulatory agencies.

6. Prepare recall letters and press releases.

7. Implement effectiveness checks to verify receipt of all recall communications.

8. Maintain a log of all recall events.

9. Evaluate recall facts to assist in correcting errant manufacturing or distribution practices.

10. Identify and implement procedures for terminating the recall.

11. Evaluate the recall process to seek improvement in performing future recalls.

E. The responsibility of individuals and alternates on the Recall Team are as follows: **(*Define for your operations – these are ideas…)***

**Recall Officer Responsibilities**

1. Evaluate preliminary information concerning suspected health hazards, quality defects, or product adulteration, and obtain product samples, if necessary.

2. Coordinate efforts with Quality Assurance staff and food safety personnel to make a preliminary analysis of the suspected hazard.

3. If a health hazard is confirmed and the President decides to recall, call an

immediate Recall Team meeting; coordinate and direct all activities of the recall procedure.

4. Coordinate and direct all activities involved in the disposition of recalled product.

5. Coordinate and direct all activities necessary to correct errant distribution practices.

6. Coordinate and direct internal communications.

7. In the event of regulatory agency involvement, participate in discussions and maintain records.

**Recall Coordinator Responsibilities**

1. Implement effectiveness checks.

2. Maintain a log of all recall events.

**Marketing Responsibilities**

1. In conjunction with the Recall Officer and Recall Team, prepare all external communications and function as media contact.

**Legal Department Responsibilities**

1. Ensure that a recall of product meets all applicable legal requirements.
2. Advise Recall Officer on appropriate actions to be taken to protect the rights of the company and its officials.
3. Review communications with regulatory agencies.
4. Assist in final drafting of information for release to the public.

**Quality Assurance Responsibilities**

1. Receive complaint information and document on Customer Complaint form.
2. Assist Recall Coordinator in making preliminary analysis of potential hazard.
3. Notify plant of initiation of recall action and stop production of suspect product.
4. Obtain all analytical lot information, lot records, product codes, ship dates, code dates, etc., to trace destination of suspect product.
5. Obtain suspect product sample when possible and arrange for shipment to designated laboratory for analysis.
6. Isolate documents and impound product at our facility, warehouse and distribution outlets.
7. Supervise and document the retrieval of suspect product from the customer.
8. Assist in isolating and impounding any raw materials or packaging components responsible for the product deficiency.
9. Confirm and document destruction of returned product if final disposition requires destruction.
10. Retain and provide security for any product samples or materials as requested by the Legal Department.
11. Execute an annual mock recall to assess effectiveness of procedures.

**Sales and Call Center Responsibilities**

***(You may not have a call center- if a large recall and you do not – you may contract with someone to assist with calls… or you may need to increase the volume or your voice mail as you will receive a huge volume of calls and you do not want customers to think you***

***are unavailable!)***

1. Receive complaint information and document.

2. Assist Quality Assurance in obtaining product from customers when available.

3. Assist Quality Assurance in coordinating recall notification.

4. Document the dollar amounts payable to the customer.

5. Coordinate replacement of suspect product.

**Accounting Responsibilities**

1. Ensure that we have assessed and accounted for all costs associated with recall.

2. Ensure a timely recovery of all recall costs.

3. Advise Recall Officer of the status and extent of the supplier's insurance coverage.

4. Notify Company product liability carrier of the recall situation and keep carrier advised as necessary

**ORGANIZATION AND COMMUNICATION GUIDELINES**

A. Complaints: Notification of any physical illness or of any potentially serious product defect or complaint is to be communicated directly to the Recall Officer (or designee) and the Legal Department.

B. Preliminary Analysis of Hazard: If the Recall Officer, with the advice of the Quality Assurance and Legal Departments, determines that the complaint is an isolated instance, invalid, or does not involve any substantial hazard or quality defect, it is to be handled as a normal product quality complaint.

C. Product Recalls and Withdrawals: When there is reasonable evidence that a potential problem that could warrant a recall may exist, the findings are to be communicated by the Recall Officer to the President and the Recall Team. In consultation with legal counsel, the Recall Officer will recommend to the President actions to be taken, including what, if any, additional information needs to be developed and whether the appropriate regulatory agencies should be notified. The Recall Officer will continue to investigate the complaint to confirm the presence or absence of hazards or defects, utilizing all information available.

Decisions not to withdraw or recall a product are to be communicated internally to the Recall Team and to the regulatory agency involved (if such agency was previously informed of the possibility of recall or withdrawal). Subsequent activity would then be the same as in handling a normal product quality complaint.

Decisions to recall will be communicated immediately to the Recall Team and to the appropriate regulatory agency. The Recall Officer will direct all recall activities as described previously. In the event of a recall initiated by a supplier or regulatory agency, the Recall Officer will immediately notify the Recall Team, and will direct all recall activities as specified in Recall Responsibilities of this manual.

D. Communication with Media and Customers:

**(Practice this during mock recalls! Make sure phone lists are up to date. Make sure your employees know not to speak to the media. Have a friend show up in a van, wearing a suit holding a microphone and try to interview them on the way out the door. Will they answer questions????)**

In the event of a recall, external communications with customers and the news media are critical to recalling the product and avoiding damaging publicity. Therefore, all communication with the media will be handled by Director of Marketing. All communications concerning possible recalls, stock recoveries or market withdrawals should follow company confidentiality guidelines. The Recall Team will approve all communications with customers. Where emergency situations exist, telephone,

facsimile transmission, post cards or letters will be used in notifying customers and in locating product for return. To demonstrate that the company is acting in the customer's best interest, and to avoid publication of erroneous information, position statements will be prepared by the Director of Marketing for response to news media inquiries. Such information will be coordinated with the regulatory agency involved and given to the news media voluntarily. Accurate, timely communications with regulatory agencies is important; contact with the agency and release of information to the press will be made only when credible facts are available.

All internal communications regarding a recall and its progress are to be made by the Recall Coordinator and the Director of Marketing. Their statements will describe the situation as it then exists. All calls from the media or the general public must be referred to Director of Marketing.

**RECALL PROCEDURES**

A. Receive Complaint: Customer complaints are normally directed to the Customer Service Representative for handling. If a potentially serious complaint is brought to the attention of the CSR, the Recall Officer and the Legal Department must be notified immediately. Documentation of all pertinent information as required. When available, suspect product will be obtained for shipment to designated laboratories.

B. Assessment of Public Health Significance: Based upon evidence and advice supplied by Quality Assurance and other departments, the President will determine the need to initiate immediate recall. In the event of any recall, the Recall Officer will order that all inventories of the product be impounded. The speed with which a product recall is put into effect is critical. Regulatory agencies require assurance that a recall will be carried out effectively and quickly.

C. Formal Notification of Regulatory Agency: The Recall Officer will notify the

Recall Team when it becomes necessary to initiate a product recall. The Recall Officer will consult with legal counsel to ensure compliance with government regulations, and to determine company liability for seizures, injunctions, and prosecutions. When the decision to recall is made, the Recall Officer will communicate directly with the appropriate regulatory agency. The notice to regulatory agencies must include:

- Reason for recall
- Brand names
- Product names
- Packaging (Type & Size)
- Package codes (Use by/Sell by)
- Packaging dates
- Photos of label or package
- Case codes
- Count/case
- Production dates
- Distribution areas
- School lunch (yes/no)
- Department of Defense (yes/no)
- Internet or catalog sales (yes/no)
- Amount produced (pounds)
- Amount held at establishment
- Amount distributed (pounds/cases)
- Distribution level (depth of the recall, if known)

Copies of actual or proposed communication strategies and proposed recall strategies should also be shared with the agency.

## Action Plan

1. Notification of potential problem.

2. Recall Team Group Meeting.

a. Identify Problem - Recall officer

b. Establish severity and magnitude - Team members

c. Determine Scope of Recall by reviewing records

Distribution records are maintained as necessary to facilitate identification and location of products that are recalled. These records can be used to quickly provide FDA or USDA/FSIS with requested information regarding product distribution. Records such as bills of sale, invoices, and shipping papers are kept with respect to each transaction in which any livestock, poultry or poultry food, meat or meat food product purchased, sold, shipped, received or otherwise handled by the establishment in connection with any business subject to the FMIA or PPIA. These records include names and address of consignees, shipment method, date of shipment, etc.

d. Decision of Action Mode - Recall Officer

e. Clarification of objectives and assignments - Recall Coordinator

3. Action Mode

a. Establish code date (s) of suspect product and total amount of product produced - Quality Control/Operations

b. Establish location of all suspect product – Distribution

c. Retain product in-house/Verify Quantity - Quality Control

d. Notify customers/brokers/outside storage facilities to retain all suspect product/Verify Quantity – Distribution (Sample letters are attached that will be updated to include specific situations as necessary)

e. Determine quantity of suspect product under retention (total available or under company control) - Quality Control-Shipping

f. FDA notification – Class 1 recalls require a Reportable Food Registry report to be filed within 24 hours. All recalls should also include a notification to the local District Office to allow their input into recall.

g. USDA notification- (USDA requires notification of recalls within 24 hours of initiating the recall) -Recall Officer

h. Media coverage needed – Marketing Department

(Media contacts reference in back of plan)

i. Media Contact – Director of Marketing

4. Communication

It will be the responsibility of each member of the recall Action Team to notify the Recall officer of any information obtained in indicating the possible need for product recall, market withdrawal, or stock recovery. This may be in the form of customer complaints, sales-broker comments, in-house findings, USDA or FDA notifications, etc. The Recall Officer will then make the decision as to whether a Recall Action Team meeting is needed.

The initial meeting should be designed to either offer direction to group members as to information needed or to review information, identify real or potential problems, and formulate recommendation for action.

All information obtained thereafter should be forwarded to the Recall Coordinator. This information will be reviewed with the Recall Officer for reassessment of previous decisions and problem status.

5. Product Retrieval

Product is to be returned to a central or controlled location. Strict inventory of incoming suspect product must be maintained. Suspect product must remain under QC Hold tags until disposition decision has been made. Any condemnation of product should be supported with appropriate evaluation and testing by an independent agency. It is also recommended to obtain the assistance of an independent expert to verify that appropriate actions have been taken.

Procedure:

a. Designate location for return of suspect product.

b. Establish written handling procedures for suspect product. This should be submitted to FDA or USDA for approval. It must include sorting guidelines. This usually involves the categories: 1. Good product (acceptable for use under USDA and company standards.) 2. Questionable product (this product is either suitable for correction/reconditioning or subject to further testing, and 3. Condemned.

c. Designate person (s) responsible for supervision of suspect product receipt and handling.

d. Suspect product should be itemized by category (1,2,3 above)

e. Records for "Questionable Product" must be maintained. This product is to remain under QA Hold Tags until corrected &/or further testing results are available.

f. Condemned product is to be denatured as per USDA guidelines and records prepared and retained for all condemned products.

g. Condemned product could be sent to a landfill per USDA guidelines and approval.

6. Effectiveness Checks

The purpose of effectiveness checks is to verify that all consignee/customers involved in the recall have received notification about the recall and have taken appropriate action. This is a means of assessing the progress and efficacy of a recall. FDA or FSIS will verify our effectiveness checks.

To assess the effectiveness of our recall, the recall team will compile the following information:

a. Pounds of each type of product implicated in the recall.
b. Labeling information for each product.
c. How much of the product is still "in house" or at other locations?
d. How many customers were affected?
e. How did we contact each customer?

f. Do we have documentation of the customers?
g. Do we have a written response acknowledging receipt of the recall information?
h. What actions were taken with the product? Who is responsible for these actions?
i. If the product was destroyed, was destruction witnessed and documented by responsible personnel? Were FDA/FSIS personnel present?
j. Do we have written documentation of
    1. When problem was identified?
    2. When customers were notified

7. Recall Assessment
The recall team will regularly report the results of the effectiveness of our efforts to retrieve the product to FSIS in order to keep them apprised of the status of recalls in progress. These reports will contain the following information unless otherwise specified:

    1. The number of consignee/customers notified of the recall
    2. The dates notifications were made
    3. The method of notification
    4. The number of consignee/customers responding to the recall communication
    5. The quantity of product each consignee/customer had on hand at the time the communication was received.
    6. The number of consignee/customers that did not respond
    7. The quantity of product returned or held by each consignee/customer
    8. An estimated time of completion of the recall.

8. Recall Conclusion

    The recall will conclude when all the available portion of total suspect product produced has been located and handled appropriately as deemed necessary by FDA or FSIS and company guidelines. Refer to FSIS Directive 8080.1 Rev 4 Attachment 3 for the complete FSIS Recall effectiveness checks and recall termination requirements or FDA's Guidance for Industry: Product Recalls, Including Removals and Corrections for recall termination.

9. Recall Follow-up

    The recall team will evaluate the recall to determine whether things could be handled

differently, and what if any improvements should be made to the plan.

Further the Recall Team conducts a mock recall at least annually to verify the effectiveness of the plan.

**Media Contact Information**

**Add local newspaper contacts and local media contacts – if you can get to know some one at these locations before a crisis – all the better!!!!**

## 4-9. SOP Inspection Sifter

## Batch Dry Ingredient Inspection with Audit Form

1. Sifters (60 mesh) are inspected for any foreign material or abnormal wear prior, during and after use and the appropriate cleaning.

2. Batch sift dry ingredients through clean sifters (60 mesh) to verify foreign materials are not present

3. If no foreign materials are found, record it on the Sifter Log.

4. If anything is abnormal, stop operation, inform Supervisor and Quality Assurance immediately for evaluation. Quality Assurance will record appropriate corrective action and product disposition.

| Facility Name: Frozen Boiled Noodles Plant 5 | ISSUE DATE | PAGE |
|---|---|---|
| ADDRESS : 1 xx-cho, xx-shi, 000-0000 XX | SURPERSEDES | PRODUCT CODE |

# Sifter Log

**Date: _____**

| Time | Batch | Ingredient | Acceptable (Y/N) | Visual Inspection | Initial | Corrective Action |
|---|---|---|---|---|---|---|
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Supervisor (Name and Date): _____

# 4-10. STORAGE AREA GMP AUDIT

# STORAGE AREA GMP AUDIT

| STORAGE AREA | ACCEPT -ABLE | UNACCEP- TABLE | CORRECTIVE ACTION |
|---|---|---|---|
| 1. RETURNED GOODS: CONTROLED PROPERLY SPOILS INTO SPOILS CAGE. | | | |
| 2. PALLET TRANSFER STATION FUNCTIONS | | | |
| 3. GENERAL HOUSEKEEPING. | | | |
| 4. GENERAL EMPLOYEES PRACTICES. | | | |
| 5. COMBO BINS OF WOOD, CARDBOARD, MISC. GARBAGE TO BE DISCARDED WHEN FULL. | | | |
| 6. TRANSPORT CARRIERS MUST BE ADEQUATELY PROTECTED. | | | |
| 7. PROPER STORAGE AREA TEMPERATURE TO BE MONITORED DAILY | | | |
| 8. SAFEGUARD ALL PRODUCTS AGAINST POTENTIAL LEAKS AND DRIPS AND NOTIFY PROPER PERSONNEL IMMEDIATELY. | | | |
| 9. CLEAN UNDER PALLET FLOW RACKS AS NEEDED. | | | |
| 10. MAKE SURE PRODUCTS ARE LOADED ON CLEAN TRUCKS. | | | |
| 11. NO GUM CHEWING, JEWELRY, OR WATCHES IN DISTRUBUTION CENTER. | | | |

AUDITOR _____

DATE _____

TIME_____

REVIEWER_____ DATE_____

## 4-11. GMP Inspection of Production Areas Audit

| Facility Name: Frozen Boiled Noodles Plant 5 | ISSUED: August 31, 2017 | PAGE |
|---|---|---|
| ADDRESS : 1 xx-cho, xx-shi, 000-0000 XX | SURPERSEDES: January 23, 2018 | PRODUCT CODE |

## OPERATIONAL DAILY GMP AUDIT

| **PRODUCTION AREA:** | **ACCEPT-ABLE** | **UNACCEPT-ABLE** | **CORRECTIVE ACTION** |
|---|---|---|---|
| 1. TOOLS SHOULD BE PROPERLY STORED. | | | |
| 2. SANITIZER SOLUTION AND HANDIPS ARE AVAILABLE AND COORECT CONCENTRATION. | | | |
| 3. PRODUCT ON FLOOR IS PROPOERLY DISCPOSED | | | |
| 4. DOORS MUST BE KEPT CLOSED TO OUTSIDE. | | | |
| 5. GENERAL HOUSEKEEPING. | | | |
| 6. ALL WASH STATIONS SHOULD BE ACCESSIBLE, SOAP AND TOWEL CONTAINERS FILLED AND FUNCTIONAL. | | | |
| 7. HOSES SHOULD BE STORED SO THAT THEY ARE NOT TOUCHING THE FLOORS. | | | |
| 8. WOOD PALLETS SHOULD BE KEPT IN SPECIFIED CONTROL AREAS. | | | |
| 9. TRASH RECEPTACLES SHOULD BE CONVENIENTLY LOCATED. | | | |
| 10. OVERHEADS ARE CLEAN AND FREE OF LOOSE DEBRIS. | | | |
| 11. NO CONDENSATION IN THE PRODUC-TION AREA. | | | |
| 12. NO GUM CHEWING, JEWELRY, WATCHES, IN PRODUCTION AREA. EMPLOYEES ARE WEARING GLOVES, APPROPRIATE HEAD GEAR, FROCKS, ETC. | | | |
| 13. PRODUCT AND INGREDIENTS ARE PROPERLY LABELED AND CONTAINERS COVERED WHEN NOT IN USE OR BEING MOVED. | | | |
| 14. OTHER. | | | |

AUDITOR _____

DATE _____

TIME_____

REVIEWER_____ DATE_____

米国食品安全強化法
「ヒト向け食品に関する現行適正製造規範ならびに危害分析およびリスクに応じた予防管理」規則にかかる食品安全計画雛形（麺）＜英語原文＞

2018 年 3 月作成

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