QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

2.8.1 Allergen Management (Mandatory)

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating products shall be documented and implemented. The allergen management program shall include:
i. A risk analysis of those raw materials, ingredients, and processing aids, including food grade lubricants, that contain food allergens;
ii. An assessment of workplace-related food allergens that may originate from locker rooms, vending machines, lunchrooms, and visitors;
iii. A list of allergens that is applicable in the country of manufacture and the country(ies) of destination, if known;
iv. A list of allergens that is accessible to relevant staff;
v. The control of hazards associated with allergens and incorporated into the food safety plan, and
vi. Management plans for control of the identified allergens.

Gluten Free Facility

The PFF factory is a Gluten Free facility, therefore, the only place where Gluten is permitted is the break room. There is NO purchasing, handling, or processing of ingredients containing Gluten (a protein found in wheat, rye, barley and similar grains). Specific information concerning Gluten Free practices and controls is found in PFF Gluten Management Policy (QM 2.8a).

Responsibilities

Position	Responsibility
Compliance Manager (SQF Practitioner)	Ultimate Responsibility for Allergen Management system Review of preprinted labels Perform Internal Audits of system Answer staff or customer inquires about allergens
Service (R&D)	Consider Allergen implications when selecting new ingredients and when doing new formulations
QC/Compliance	Conduct allergen/gluten testing
Production (Scheduler)	Schedule in a way to minimize Allergen cross contamination
Materials (Purchaser)	Purchase from suppliers with Allergen Control programs, and be aware of “may contains”.
HACCP Team	Perform risk assessments of allergen containing raw materials, ingredients, packaging, processing aids, and food grade lubricants. Perform validation of food surface cleaning practice policy.
Mixing Supervisor Packing Supervisor	Oversee Allergen Cleans Review batch sheets for Allergens
Materials Department	Ensure Allergen Labeling occurs during receiving Ensure that ”less or like above” is followed (do not stack allergens over materials that don’t contain that allergen)
All Personnel	Adherence to this Allergen Management system Receive Allergen Management training Ask supervisors or Compliance Department if they are unsure of allergens contained in a material Report any instances of suspected allergen contamination

QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

Risk Analysis

During product realization, and during the annual review of the HACCP plan, a risk assessment is done by the HACCP team of all allergen-containing raw materials, ingredients, packaging, processing aids, and food grade lubricants. This risk analysis helps identify the potential for allergenic cross-contamination and applies the appropriate measures to control them. These measures are documented in the PFF Food Safety Plan.

Cleaning practices concerning food contact surfaces must also be validated as appropriate by the food safety team according to risk, legal requirements, and as sufficient to remove all potential allergens (including aerosols as appropriate) to prevent allergen cross-contamination.

Verification of Allergen Controls

The Allergen Management system must be reviewed by the Food Safety / HACCP Team at least annually and/or in the event of a non-conformance and updated if necessary. The Compliance Manager conducts allergen management system audits on-site at least annually. *Verification and Validation o*f proper handling must be done through inspection of cleaning techniques, scheduling practices, accuracy of information in the tracking of allergens, and results from 3rd party labs who perform allergen testing **annually** on finished products.

Risk analysis must be followed by the implementation of procedures for validation and verification of effectiveness concerning cleaning and sanitation of areas and equipment in which allergens are handled.

Allergen Register

A register containing materials and their allergens is maintained by the Compliance Department. This register generates the allergen information on production batch sheets. Copies of Spec sheets from material manufactures disclosing allergen risks are maintained by the Compliance Department with assistance from the Materials Department.

Allergens found at PFF for Blending and Packaging	
	Dairy / Milk
Tree Nut (Almond, Cashew, Pecan)	Egg
Milling Line - No Allergens Used	
Allergens not found at PFF	
Wheat/Gluten	Peanut
Crustaceans	Fish
Sesame	

QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

Accessible to Staff
Personnel working with allergenic materials have access to the allergen register and are also informed by their batch paperwork of allergens present. Ingredients with allergens show those allergens on their identification label.

Allergen Hazards and Controls
Hazard(s) associated with allergens (commonly anaphylactic shock) have been considered in the HACCP Plan, and controls have been established as part of the Pre Requisite Program and label inspection.

2.8.1.2 Instructions shall be provided to all relevant staff involved in the receipt or handling of raw materials, work-in-progress, rework, or finished product on how to identify, handle, store, and segregate raw materials and products containing allergens.

PFF personnel receive training on the types of food that can cause allergic reactions which also includes a briefing on what allergens are, and what allergens are handled at PFF.

2.8.1.3 Provisions shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

Allergen Identification and Segregation during Receipt, Storage, and Handling
The Compliance Manager and the Purchasing Supervisor work together to check raw materials and supplier information for the presence of allergens and label requirements. Together they must advise the Food Safety Team concerning potential raw material risks prior to use in manufacturing. This helps identify and control allergen hazards.

Purchases must only be made through approved suppliers and to approved specifications.

Suppliers are required to notify us prior to any changes regarding allergen status.This includes sending us an updated allergen matrix or allergen declaration, and an updated specification if allergens or new allergens are added to their facility or to shared lines that could impact our product.

Materials (ingredients, packaging materials, processing aids) containing allergens, list those allergens on their identification label(s). These allergens are also listed on the batch sheet.

Allergen Storage: Less or Like Above & Segregation
Allergen ingredient storage is limited to the allergen production room. Any batches being set up (majors / kitting and minors / pre-weighing) should have allergens added last and only added once the batch is brought into the allergen production room. These batches should not return to the main warehouse. The bin containing the allergen WIP will be stored in the allergen room.

QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

Any material stored below must contain all of the allergens stored above it. A material stored below may have all of those allergens and more, but not less.

Shelf	Permitted	Permitted	Not Permitted	Not Permitted
Top	No Allergen	No Allergen	Egg and Dairy	Egg
Middle	Egg	Egg	Egg	Tree Nut (no Egg)
Bottom	Egg and Dairy	Egg	No Allergen	Tree Nut

Storage of Finished Product (FIN)

FINs should be stored in their own area, but FINs containing allergens that are double packaged (inside a unit package inside a case packaging, or other bag in a box) may be stacked in any position (is exempt from Less or Like Above rules) due to the allergen being fully contained with negligible chance of cross contamination. FINs that are only unit wrapped or otherwise single barrier packaged, such as 25 or 50 lb bags, must follow Less or Like Above rules.

Storage of Packaging Materials (PKG)

Packaging supplies must be stored in their own area or on top storage racks (when segregation is not possible). Packaging may not have allergen containing ingredients, WIP or single packaged FINS stacked above them.

2.8.1.4 Where allergenic material may be intentionally or unintentionally present cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross-contact.
Separate handling and production equipment shall be provided, where satisfactory line hygiene and clean-up or segregation are not possible.
2.8.1.5 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be documented and effectively implemented.
2.8.1.6 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

Prevention of Contamination during Cleaning

Equipment / Line Cleaning

Whenever the batch before has allergens that this batch doesn't, a food safety clean is needed.

Batch 1	Batch 2	Food Safety Clean Needed?	Reason
Egg, Tree Nut	Egg	Yes	Batch 2 doesn't contain Tree Nuts, so a clean is required to remove that allergen
Dairy	Tree Nut	Yes	Batch 2 contains a different allergen (Tree

			Nut) from Batch 1 (Dairy)
Egg	Egg, Tree Nut	No	Batch 2 contains all of the allergens that Batch 1 contained, therefore won't be contaminated
Egg	Egg	No	Batch 1 and Batch 2 contain the same allergens

Production (Mixing or Packing) Supervisors must review cleans to ensure they were done correctly. Scheduling should always be done in a way that minimizes allergen contamination risks. Minimizing allergen contamination also minimizes cleans required and leads to a more efficient schedule. Start production cycles with least allergen products, and end with the most allergen intensive.

Line Segregation There are separate rooms which contain bins, augers, and drop stations for allergen and non allergen materials.	
Material Type	**Room to Use**
ING with allergens WIP with allergens	**Allergen** Dump Station **only** **Allergen** Tote Dumper and Auger Filler **only**
ING with no allergens WIP with no allergens	**Non Allergen** Dump Station **only** **Non Allergen** Tote Dumper and Auger Filler **only**

All production food contact tools (utensils, scoops, buckets, and brushes) must be labeled and segregated according to their allergen use as much as possible. Employees working in the allergen room will wear a blue coat when instructed.

During batch preparation, operator(s) must use disposable paper or plastic bags for preparing dry ingredients (primarily during pre-weigh). Each label must be specific to the identified allergen on the premises.

Any new or used equipment coming into the facility must go through the commissioning process with approval from the Compliance and Maintenance Departments.

Any used, aftermarket, refurbished, or rehabilitated equipment will require prior approval from Kitchen with Confidence. Pure Functional Foods will notify Kitchens with Confidence prior to installation of equipment at CFFsupport@menutrinfo.com.

2.8.1.7 The product identification system (refer to 2.6.1.1) shall make provision for clear identification and labeling, in accordance with the regulatory requirements of those products produced on production lines and equipment on which foods containing allergens are manufactured.
2.8.1.8 The product trace system (refer to 2.6.2) shall take into consideration the conditions under which allergen-containing foods are manufactured and ensure full traceback of all ingredients and processing aids used.

QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

Identification and Trace Concerning Allergenic Ingredients

Mixing product batch sheets clearly record what materials and lots were used, and show what allergens are contained within the batch. WIP Lot code shows what bin the product was made in.

Finished Material product batch sheets show what WIP and other materials were used, and the FIN Lot code tells which production line was used.

2.8.1.9 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work-in progress and finished product are true to label with regard to allergens. Measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels, verification of labels on finished products as appropriate, and product change over procedures.

The Compliance Department (typically the Compliance Manager) and R&D reviews all labels and pre-printed materials (any material bearing an ingredient statement and/or allergen declaration) at receiving (QA inspection) and applies the identification label to the materials.

A pre-printed materials register with an example of each lot is also maintained for reference.

The batch sheets list all the materials required along with their allergen and certification status, the allergen and certification status of the part being made, and has an arming code preventing the mis-selection of parts.

Any destruction of obsolete pre-printed packaging is overseen by the Compliance Department. *(See also Waste Management for this topic)*

2.8.1.10 Re-working of product (refer to 2.4.6) containing food allergens shall be conducted under conditions that ensure product safety and integrity are maintained. Re-worked products containing allergens shall be clearly identified and traceable.

Rework

Rework of products containing allergens must be conducted according to the same allergen control criteria and methods as stated in this policy. Product safety and integrity must be maintained during rework and reworked products must be clearly identifiable and traceable. Scheduling rework must be done by properly taking into account any allergens present in any previous batches and the batch scheduled for rework on lines and machinery.

2.8.1.11 Sites that do not handle allergenic materials or produce allergenic products shall document, implement and maintain an allergen management program addressing at a minimum the mitigation of introduced or unintended allergens through supplier, contract manufacturer, site personnel, and visitor activities.

QM 2.8 Allergen Management

Rev 06/03/2025
Reviewed 06/03/2025

There are food dispensing machines in the facility, located at the main employee entrance foyer. Employees go through allergen training which includes hand washing when leaving the cafeteria and before entering production areas. Allergen signs and hand washing signs are posted in the employee cafeteria and in the entrance foyer as well as a sign reminding people where eating is allowed.

All contractors and visitors are escorted when they are in the building. The escorts are responsible for making sure that contractors, suppliers, and visitors are following all food safety programs while they are in the facility.
Suppliers are required to go through the supplier approval process which includes requiring an allergen program or statement be provided.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

2.6.1 Product Identification (Mandatory)

2.6.1.1 The methods and responsibility for identifying raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products during all stages of production and storage shall be documented and implemented to ensure:
i. Raw materials, ingredients, packaging, work-in-progress, process inputs, and finished products are clearly identified during all stages of receipt, production, storage, and dispatch; and
ii. Finished product is labeled to the customer specification and/or regulatory requirements.
2.6.1.2 Product start-up, product changeover, and packaging changeover (including label changes) procedures shall be documented and implemented to ensure that the correct product is in the correct package and with the correct label and that the changeover is inspected and approved by an authorized person. Procedures shall be implemented to ensure that label use is reconciled and any inconsistencies investigated and resolved. Product changeover and label reconciliation records shall be maintained.

Parts Identification Process

Materials Received	
Step	**Process**
1	Parts received are compared to COAs and PO
2	Large Part Identification Label printed using program “Materials: Label Printer Gen2” which prompts for lot number and part.
3	Labels are applied to materials
	Items that come individually or just a few on a pallet get 1 label per item
	Materials that come as a pallet receive 4 labels per pallet, placed 1 per side on the product package (not the plastic wrap) on the bottom or 2nd to bottom layer of the pallet.
4	Materials are recorded on the “PO Receiver” printed from Bizowie

Material Handling - Batch Material Gathering / Kitting (Mixing)	
Step	**Process**
1	Scheduler Prints out Mixing Batch Paperwork and delivers to the warehouse desk
2	Material Handler uses Batch Paperwork provided by Bizowie to gather materials Every material gathered must match idem and lot number provided on batch sheet.
3	After all parts are gathered, the material handler counts the number of bags and compares them to the number listed on the batch sheet. Then signs theinitial box and records the number of bags.
4	Batch Paperwork is filled in the mixing room, the pallet is left in staging are for mixing

Mixing	
Step	**Process**
1	Pallet is retrieved, a person doing pre-weigh / minors (partial unit materials) gathers and weighs materials listed in the pre-weigh column. When complete they sign the “pre-weigh” by box.

2	All materials gathered are verified by item and count and verifier signs “Parts verified By” and records the number of full unit / kitted materials and pre-weigh materials.
3	Pallet is weighed on the pallet scale to ensure materials (deducting for bags and pallet) to ensure the materials are within range
4	Pallet is lifted up to the Mixing Drop Station (which contains the sifting screen) Bin is moved under the Drop station Batch paperwork is put into the pocket on the Bin, WIP tag added to bin QMR 011 (h)
5	Bin is tumble mixed
6	Any 2nd Cycle materials are added (primarily ING3000s that react with Sodium Bicarbonate, but also some ingredients needing less tumbling)
7	Batch paperwork and sample are taken to Quality Control for testing QC completes section regarding bake and gluten testing

Material Handling - Batch Material Gathering (Packing)	
Step	**Process**
1	Production Supervisor Prints out Packing Batch Paperwork and delivers to Kitting Supervisor
2	Kitting retrieves Packing Batch Paperwork and begins any labeling jobs required Labeled materials are delivered to Packing Room along with Batch Paperwork
3	Material Handler uses Batch Paperwork to gather materials Every material gathered must have a Large or Part Identification Label.
4	As materials are gathered, the initial box is signed off
5	Batch Paperwork is given to the production supervisor, the pallet is left in staging for packing

Packing	
Step	**Process**
1	Packing retrieves pallet and Packing paperwork Compare materials gathered to Packing paperwork Check WIP paperworks shows WIP has passed QC testing
2	Lift and Load Bin into upper mixing platform drop hopper
3	Make sure all machine settings match Product Spec side of Packing paperwork
4	Package materials per instructions. Team members sign box corresponding to task(s) done
5	Final inspection to ensure the product meets criteria. Sign “Final Verifier” box.
6	Once Final inspection has been done, product is handed off to Materials department

Material Handling - Material Gathering (Milling/Pressing)	
Step	**Process**
1	Scheduler Prints out Traveler Paperwork and delivers to the production line
2	Production personnel use production lot Traveler paperwork to gather materials as production progresses. Each tote of material gathered must be recorded.
3	As materials are gathered, the operator completes the traveler paperwork and the line supervisor signs off.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Milling	
Step	**Process**
1	Materials and lot numbers that are to be pulled for production are listed on the traveler paperwork
2	For every pallet prepared for production, the source lot, PFF lot, and pallet # are recorded on the Metal Detection Reject Log.
3	Traveler/Process Log Paperwork is reviewed at the end of each day with lot numbers and bag quantities recorded
4	When the job is completed, Milling Final Inspection is filled out recording source lots and PFF lots.
5	Batch paperwork and retains/samples are taken to Quality Control for testing. QC reviews paperwork and signs. Retains are given to QC for every source pallet run, with source lot and PFF lot recorded, as well as the pallet number.

Pressing	
Step	**Process**
1	Materials and lot numbers that are to be pulled for production are listed on the traveler paperwork.
2	For every pallet prepared for production, the source lot, PFF lot, and pallet # are recorded on the Metal Detection Test/Reject Record.
3	Traveler Paperwork is reviewed at the end of each day with lot numbers and bag quantities recorded
4	When the job is completed, Pressing Final Inspection is filled out recording source lots and PFF lots.
5	Batch paperwork and retains/samples are taken to Quality Control for testing. QC reviews paperwork and signs. Retains are given to QC for every source pallet run, with source lot and PFF lot recorded, as well as the pallet number.

Warehousing / Shipping	
Step	**Process**
1	Using Sales Order (SO) provided by scheduling, gather materials required for order
2	Record Materials for order on Shipping Record printed from Bizowie Ensuring part numbers, lot numbers, and quantities are included
3	Either Materials or Compliance Department record the Shipping Record Sales Order information into Bizowie.

Records

The Compliance Department collects all records required for product identification including QMR 012's, mixing batch paperwork and packaging paperwork and ensures they have been added to electronic registers. Paper copies are located in the Compliance office.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Appendix 1: Part Identification Number Meaning All Parts are identified by a 3 Letter Prefix followed by a 4 digit number		
Prefix	**Range**	**Usage**
FIN	**Finished Goods** First 2 Digits specify the Customer, 3rd and 4th are sequential for the item FINs are the output of the Packing Room	
ING	**Ingredients** First digit identifies category, other digits are sequential within that category Most ING are received from vendors, but may also be made in facility	
	0000s	Flours, Powders, Starches
	1000s	Salts & Sweeteners
	2000s	Oils, Fats, Shortenings
	3000s	Leavenings, Gums, Emulsifiers
	4000s	Customer Owned
	5000s	Grains & Granulates
	6000s	Fruits, Flakes, Pieces
	7000s	Flavors, Herbs, Spices
	8000s	Nuts & Seeds
	9000s	Miscellaneous, Colors, Chocolates
PKG	**Packaging Materials** First digit identifies category, other digits are sequential within that category FCP = Food Contact Packaging PKG are received from vendors, 7000s are also printed on in facility	
	0000s	Bulk Bags (FCP)
	1000s	Corrugated boxes / inserts
	2000s	Retail Bags (FCP)
	3000s	Retail Boxes
	4000s	Seals (FCP)
	5000s	Film, Mylar, Form Fill (FCP)
	6000s	String (FCP) Glues, Tapes, Adhesives
	7000s	Blank / Raw Material for Labels, Stickers, Tickets printed in facility
	8000s	Retail Labels - printed out of facility
	9000s	Miscellaneous Packaging (some FCP)
WIP	**Work in Progress** Numbers are sequential in order of formula creation Most WIP are produced by the Mixing Room	

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Appendix 2: Part Identification Labels		
Size (Width x Height)	**Contains**	**Where Used**
Small (2” x 0.75”)	Part Number Lot Number QR Code Codes for Allergens, Certifications Date & Time Printed Workstation Printed at	Batch Paperwork (materials used) Product retrieved by Material Handling QMR 012(h) R&D Material Usage Log Product Package (when a R&D portion is taken out)
Large (6” x 4”)	Part Number Lot Number QR Code Description (including certification) Date Label Printed (usually date of receipt) Allergens / Gluten Test	Receiving Item Produced Label on Batch Paperwork (WIP or FIN)

Appendix 1 b: Part Identification Number Meaning

Milling Line System

All Parts are identified by a 3 Letter Prefix followed by a 5 digit number

Part	Range	Usage
Finished Goods Descriptive See >	Infinite Prefix + 00000-99999 EXAMPLE **SKW10100** **S**unflower **K**ernel **W**hole **###**(Part based) **##** (Mesh based) **Prefix** is generally based on raw input part description **###** is generally tied to prefix as a corresponding numeric value **##** is generally tied to mesh size but cannot allow for finer than 99 mesh. (Note: 20,25,30 aren’t necessarily mesh size but merely representative of mesh difference)	To identify finished goods

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

2.6.2 Product Trace (Mandatory)

2.6.2.1 The responsibility and methods used to trace product shall be documented and implemented to ensure:
i. Finished product is traceable at least one step forward to the customer and at least one step back from the process to the manufacturing supplier;
ii. The receipt dates of raw materials, ingredients, food contact packaging and materials, and other inputs are recorded (refer to 2.8.1.8 for traceback of allergen containing food products.);
iii. Traceability is maintained where product is reworked (refer to 2.4.6); and
iv. The effectiveness of the product trace system is reviewed at least annually, as part of the product recall and withdrawal review (refer to 2.6.3.2).
Records of raw and packaging material receipt and use and finished product dispatch and destination shall be maintained.

Responsibility & Methods

Product Trace at PFF is accomplished by recording the lot numbers at every step from receiving from Vendor (1 back) through mixing and packaging to shipping to Customers (1 forward). (A more in-depth process flow can be found in 2.6.1).

All departments are responsible for Product Trace, but the Materials Department has the majority of responsibility for recording the movement of materials, and the Compliance Department has responsibility for ensuring the system is functioning properly.

Primary Records for Trace Every transaction must be recorded either by paper log or electronically Each entry records date, employee, part number, lot number, and quantity.	
Forms	**Use**
PO Receiver and Shipping Record (Transport Logs)	Records information connected to shipping and receiving including truck inspection, and materials received, shipped, or breached on arrival
Bizowie Inventory Adjustment Records	Records Materials during Cycle Counts
Electronic Breach Register Materials: SRW ACCESS	Records materials breached Breached on Arrival are lost and unusable Materials Breached Inhouse may be salvageable
Electronic R&D Material Usage Register	Records materials used by R&D
Mixing Batch Sheet (WIP)	Records materials used by Mixing
Packing Batch Sheet (FIN)	Records materials used by Packing
Electronic Label Printing and Verification Worksheet	Records source lot and corresponding PFF lot
Electronic Ro-Tap Record	Records source lot and corresponding PFF lot for every pallet/sack produced
Pressing Batch Paperwork	Records materials used by Pressing from the Pre-Op Checklist, Traveler, Process Log, to the Final Inspection

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Milling Batch Paperwork	Records materials used by Milling from the Pre-Op Checklist, Traveler, Process Log, to the Final Inspection
QMR 030 Rework	Traces materials used during rework Rework also receives a custom Batch Sheet

Product Lots		
Part	**Lot Format**	**Linked**
FIN	Depends on Customer requirements Most common:date, line, sequence (which batch of the day)	Back by Packing Batch Sheet to WIP, PKG, & other materials used Forward by Bizowie
ING	Variable by vendor, must be supplier or lot is rejected	Back by Bizowie Forward by Mixing Batch Sheet
PKG	Variable by vendor, match what is provided by vendor If not provided by vendor use: (1) PO# (2) manufacture (3) receive date	Back by Bizowie Forward by Packing Batch Sheet
WIP	MMDDYYBS MM = 2 - digit Month, DD = 2 digit day YY = 2 digit year B = Bin number, S = Sequence (which batch of day)	Back by Mixing Batch Sheet Forward by Packing Batch Sheet
8 Character Parts (WIP and FIN)	Starts with 3 digits that are the Julian Date, then 2 digits that represent the year. For example, if production started on 12/15/2020 the lot would be (35020).	Bizowie

Product Trace Exercise

At least annually, a Product Trace exercise / test is done to ensure the system is working properly, this is typically coupled with a mock recall exercise.

Records & Retention Period

Record keeping is the responsibility of the Compliance Department, paper records are stored in the Compliance office, and electronic records are managed by the Compliance Department. Records must be retained in accordance with Records Policy.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

2.6.3 Product Withdrawal and Recall (Mandatory)

2.6.3.1 The responsibility and methods used to withdraw or recall products shall be documented and implemented. The procedure shall:
i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
ii. Describe the management procedures to be implemented including sources of legal, regulatory and expert advice and essential traceability information;
iii. Outline a communication plan to inform site personnel, customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; and
iv. Ensure that SQFI, the certification body, and the appropriate regulatory authority are listed as essential organizations and notified in instances of a food safety incident of a public nature, or product recall for any reason.
2.6.3.2 The product withdrawal and recall system shall be reviewed, tested and verified as effective at least annually. Testing shall include incoming materials (minimum traceability one step back) and finished product (minimum traceability one step forward).
Testing shall be carried out on products from different shifts, and for materials (including bulk materials) that are used across a range of products and/or products that are shipped to a wide range of customers.
2.6.3.3 Records shall be maintained of withdrawal and recall tests, root cause investigations into actual withdrawals and recalls, and corrective and preventative actions applied.
2.6.3.4 SQFI and the certification body shall be notified in writing within twenty-four (24) hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

A product withdrawal/recall is a method of removing or correcting consumer products that require a remedy. Food recalls usually result from a perceived violation of laws administered by the Food and Drug Administration (FDA). A withdrawal/recall may be undertaken voluntarily, and at any time, by manufacturers and distributors. A request by the FDA for a recall is reserved for urgent situations and is to be directed to the firm that has primary responsibility for the manufactured product.

Responsibility and Methods

Pure Functional Foods (PFF) Senior Management is responsible for following this policy and must support the fulfillment of the details and actions taken if a defective product reaches a customer and must be recalled or withdrawn from the public.

Initial investigation and Response Procedures	
Step	**Description**
1	**Receipt of External Information** Since information may come from many sources, including individual consumers, an enforcement agency, or retailer, the first response action is to ensure investigation takes place. All customer complaints must follow PFF customer complaint handling procedure.
2	**Management & Compliance Manager preliminary risk assessment** Complaint information must be communicated immediately to the management and Compliance Manager who assess the situation status as Critical or Non-Critical. An attempt to define the problem must be made, including verification of the product defect and the extent of product affected.
3	**Critical / Non Critical assessed** **a.** If a recall or withdrawal is unlikely; the issue is handled through the standard complaint resolution process.

	b. If a recall or withdrawal is a potential; the issue must be immediately communicated to the Company CEO/PRESIDENT.
4	**Company CEO/President Notified** No responses are to be taken by anyone until the Company CEO/PRESIDENT (or in their absence, the nominated deputy) has been informed.
5	**Full Investigation** An investigation that includes a formal risk assessment of the situation must take place as soon as possible. Investigation normally includes full identification and traceability exercise for the suspect product by the following checks: **a.** Compliance with standard production processes. **b.** Compliance with Raw Material and Packaging Specifications. **c.** Department records of the product in question during its associated production cycle steps with references to final product standards. **d.** Checks of Cleaning procedures and condition of equipment. **e.** Condition & characteristics of product must be reviewed in various areas: PFF retains, warehouses, distribution centers, on store shelves, in transit. Note: It may be necessary to gather samples of the affected product to determine the cause & extent of defect. Analysis must be done by independent laboratories, if the issue requires.
6	**Justification status of Withdrawal/Recall** **a.** The Company CEO/PRESIDENT dictates that a withdrawal/recall is not justified and the issue is handled through the standard complaint resolution process. **b.** The Company CEO/PRESIDENT dictates that a withdrawal/recall is justified and the issue is escalated to the Product Recall Team. Note: A product withdrawal/recall can only be approved by the Company CEO/PRESIDENT, or in their absence, the nominated deputy.
7	**Product Recall Team assembled** The Company CEO/PRESIDENT is responsible to assemble the Product Recall Team in a timely fashion so that the withdrawal/recall is initiated in a timely manner. **The individuals who are in the Product Recall Team are the same individuals who are currently listed as members of the HACCP team in the current company HACCP plan.**
8	**Identify Products for Withdrawal/Recall** The Product Recall Team must formulate a Proposed Plan for locating and containing all products involved in the withdrawal/recall.
9	**Contact Private Label Customer(s)** *(Private Label)* Prior to public announcement or notification, the private label customer must be contacted by Senior Management. Product information including lot(s) and production dates impacted, along with incident details must be provided. This contact will also help to determine disposition and collection of the product, and may modify the Product Recall Plan.
10	**Notify applicable external contacts (authorities-customers-public)** The FDA, SQF, and Eagle require communication within 24 hours. Other certification bodies, State and Local regulatory authorities may also require notification of the situation.
11	**Finalized Product Recall Plan** Based on FDA recommendations, PFF Recall Team Proposed Plan, and Private Label

	Customer desires, a finalized Product Recall Plan is developed. This plan will outline public communication (including press releases and additional customer calls) as well as the procedure for disposition and collection of the impacted materials.
11 b	**Product Recall Team determination of disposition** **Based on Product Recall Team and Private Label Customer** **a.** If a disposition can be reached without physical examples of the product involved in the withdrawal/recall, it may be necessary that the product be discarded upon discovery to contain the situation. **b.** If a disposition can be reached without physical examples of the product involved in the withdrawal/recall, it may still be necessary to arrange for pickup and return to PFF if the situation allows for such. **c.** If no physical examples of the product involved in the withdrawal/recall are readily available and disposition is not possible without them, it is necessary to arrange for pickup and return to PFF.
12	**Receipt, Segregation and Hold** Upon arrival at the site, all products involved must be counted, segregated, tagged and put on the hold register until disposition is reached. Note: Private Label Customers may designate another facility for their quarantine location.
13	**Finalization of disposition** The final steps that address the known defects or threats must be corrected or neutralized and the issue resolved by proper disposition according to the Product Recall Plan.
14	**Resolve cause and make necessary changes** The withdrawal/recall may only be terminated upon the completion of the following items: · All suspect products have been accounted for and disposed of properly, including obtaining verification of product disposal or destruction. · The immediate risk to the public has been eradicated. · The root cause has been determined and all associated corrective actions are complete. · An official recall termination letter has been sent to the customer from the company CEO/PRESIDENT or Compliance Manager. · Management and Compliance Manager notify all department supervisors, via a company memo the issue has been resolved and normal production may resume.

Product Recall Plan and Investigation

All investigation results must be reported to and circulation restricted to the Product Recall Team. The receptionist or sales representative must direct calls in and out pertaining to the withdrawal/recall to the company CEO/President. Any resulting information must be kept with the Customer Complaint Investigation Form (QMR 003) or the associated Non Conformance, or relayed directly to the Product Recall Team.

Emergency Contacts

Emergency contact information is listed in Crisis Management Policy if needed to execute this policy.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Private Label Brand Withdrawal/Recall

For Withdrawal/Recalls of private label products this sequence of events must take place.

Private Label Withdrawal/Recall:
Some responsibility and tasks must be handled by the customer involved in the private label withdrawal/recall, such as relaying associated complaint information and tracking of product.

Removal of product from distribution is the responsibility of the private label customer. PFF will work together with the customer, in conjunction with legal and insurance regulations to determine specific recall notification steps.

Product Recovery and Disposition for any withdrawal/recall:
All defective products must be physically recovered and returned to PFF as allowed by customer cooperation. The Logistics Manager oversees the operation of recovery. Depending on the nature and severity of the defect, recovered product may be segregated to an off-site facility until a disposition plan can be formulated. This limits the spread of contamination to the production facility. In the most severe cases, where continued exposure to the public poses a greater health risk, suspect products, where possible, must be destroyed at the source of discovery.

The Compliance Manager must work with the management to ensure accurate counts of suspect products take place according to the Product Recall Team action plan.

Deliberate or Malicious Contamination
The product at risk may have been caused by deliberate contamination. This information may come from the initial communication. A special course of action may be necessary as the problem will become a legal and/or criminal matter. Deliberate or Malicious contamination will be handled as required in accordance within the jurisdiction of the F.B.I.

In order to verify its effectiveness the Product Recall procedure is subjected to a timed test at least annually and the results of the exercise recorded and reviewed by the senior management team to identify and implement areas for improvement.

Records of withdrawals/recalls shall be maintained. PFF observes CEO/President or Compliance Manager Recall Termination letter and Non Conformance/Correct Action tracking as acceptable retention.

Withdrawal/recall involving product in market place
If a product involved in a product withdrawal/recall is in the marketplace, then an attempt must be made to gather it. PFF must state the situation to customers who distributed the product and request that customers attempt to gather the affected product out of circulation and be made ready for handling and disposition. If customers have acknowledged their awareness of the situation and yet make no effort to gather product, PFF is not responsible for customer inaction, as cooperation is the customer’s prerogative and customer assumes liability for such items.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Proceeding & following investigation

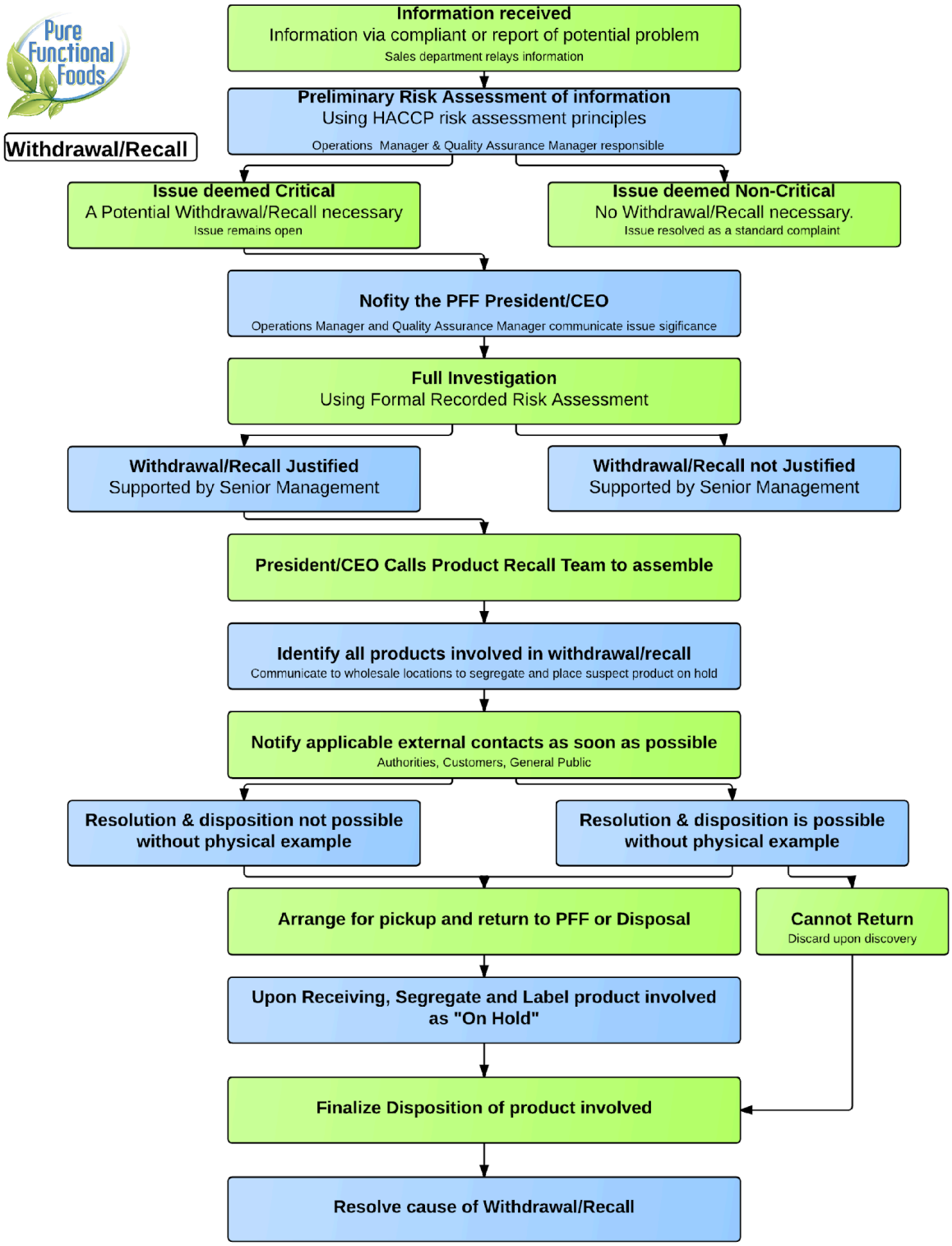
Withdrawal/Recall investigation must take into account the batch or lot that is proceeding and following the one in question due to the potentials of carry-over. Example: If sequentially numbered batch 2 is found to have an issue, then batches 1 and 3 must be investigated as well due to the possibility of carry-over.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Pure Functional Foods Brand Withdrawal/Recall

For Withdrawal/Recalls of PFF brand products this sequence of events must take place.



2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

2.6.4 Crisis Management Planning

2.6.4.1 A crisis management plan based on the understanding of known potential dangers (e.g. flood, drought, fire, tsunami, or other severe weather event, warfare or civil unrest, computer outage, pandemic, loss of electricity or refrigeration, ammonia leak, labor strike) that can impact the site's ability to deliver safe food, shall be documented by senior management outlining the methods and responsibility the site shall implement to cope with such a business crisis. The crisis management plan shall include as a minimum:

i. A senior manager responsible for decision making, oversight and initiating actions arising from a crisis management incident;
ii. The nomination and training of a crisis management team;
iii. The controls implemented to ensure any responses do not compromise product safety;
iv. The measures to isolate and identify product affected by a response to a crisis;
v. The measures taken to verify the acceptability of food prior to release;
vi. The preparation and maintenance of a current crisis alert contact list, including supply chain customers;
vii. Sources of legal and expert advice; and
viii. The responsibility for internal communications and communicating with authorities, external organizations and media.

PFF Senior Management has prepared this policy / plan in order to deal with a business crisis or emergency situation that may impact the ability to produce safe food.

Risks (Known Potential Dangers)			
Natural Disasters		**Local / Structural**	
Earthquake - Low	**Snow/Blizzard** - High	**Fire** - Moderate	**Phone / Internet Loss** - High (not essential to production work, can be accessed off-site)
Wildfire - Moderate	**Flood** - Low	**Catastrophic building failure** - Low	**Drain Backup** - Moderate
Tornado - Low	**Pandemic** - Low	**Power / Water Loss** - Moderate	

Senior Management

The PFF President has made known their responsibilities concerning safe food, therefore, Senior Management shall consult the Crisis Management Team in the event of a crisis.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

Crisis Management Team Nominated employees retain those positions until otherwise stated by Senior Management.			
Name	**Position**	**Responsibility**	**Contact #**
Dean Weed	President Service Dept Manager	Head of Crisis Management Team Communicate with Customers & Media Nominate Employees to team Contact Insurance Providers Review all written communications concerning the crisis prior to release	315-406-7996
Dana Weed	Vice President (PCQI Trained)	Assist Crisis Management Team head Assist Compliance Manager Contact FDA & Public Authorities	315-283-8684
Viorela Buzica	SQF Practitioner (PCQI Trained)	Ensure team members are properly trained & know policy Maintain records of the annual review & verification in the Compliance office	315-294-0733
All Members	- Act as the “first point of contact” for crisis situations - Quickly contact and assemble team when made aware of a crisis - Quickly and collectively evaluate the situation, formulate an action plan, and communicate with company President (if not already present) - Continual communication with each other throughout the crisis - Be involved in the annual crisis management exercise and policy review		

Concerning Crisis Control and Crisis Response Measures

If no solution to the crisis incident can be made in a timely manner to address a believed food safety risk, then PFF will utilize the services of Raymond Hadley (a Gluten Free SQF certified facility). The contingency plan for utilizing the services of our secondary source may be utilized immediately until full control, assessment and correction can be obtained at PFF.

Risk Assessment prior to release of food product

Pending a risk assessment, all products within the facility at the time of a crisis that have been deemed suspect are subject to the policy and controls as dictated by Control of Nonconforming Material, Control of Product Rework, and Product ID Trace / Recall.All products tagged “Hold” during a crisis can only be released from Hold /Quarantine for use (production, distribution, or other) by completion of this policy and approval of the Company President.

All communications to and from the company regarding the crisis must be directed to the Company President.

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025

If a product recall or withdrawal is required, then it must follow the procedure outlined in the Product Recall Policy.

2.6.4.2 The crisis management plan shall be reviewed, tested and verified at least annually with gaps and appropriate corrective actions documented. Records of reviews of the crisis management plan shall be maintained.

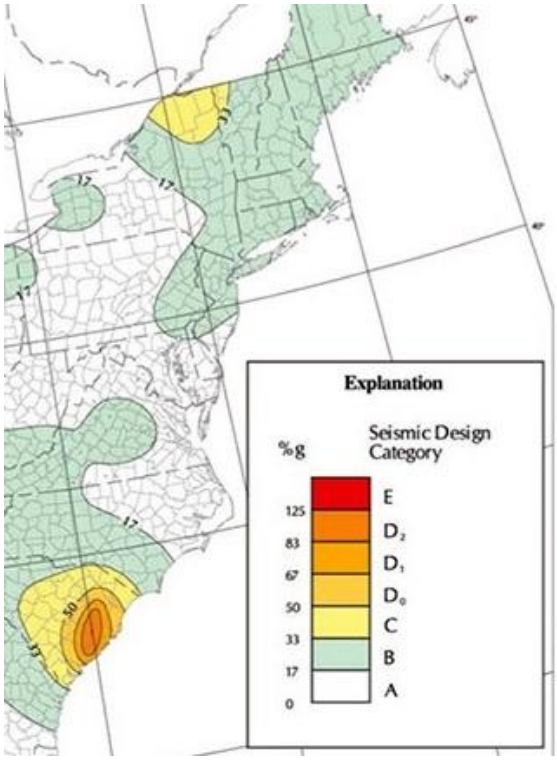
Yearly Test

PFF will review the Crisis Management plan and conduct a test of the plan on at least a yearly basis. The yearly test is performed by selecting one of the known potential dangers as identified above on a rotating basis, and going through a mock scenario of what methods and options we have at our disposal to mitigate risk and get back to normal business function without compromising food safety. This event must be recorded and filed alongside previous tests.

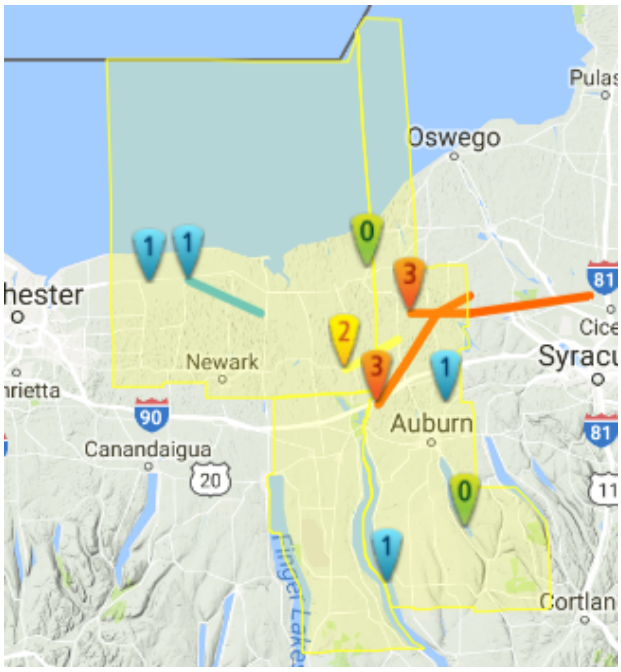
Emergency Contacts			
Name	**Description**	**Phone**	**Email**
FDA	Federal Food Safety	866.300.4374 301.796.8240 Recall Coordinators 718.662.5577	orahqrenyk@fda.hhs.gov
NY Agriculture & Markets	State Food Safety	315.487.0852	www.agriculture.ny.gov
SQF	SQF	202.220.0635	foodsafetycrisis@sqfi.com
GFCO	Gluten Free Certification Organization	253.833.6655	gfco.alerts@gluten.org
Eagle	Food Safety Certifying Body	800.795.3641	foodsafety@eaglecertificationgroup.com
Raymond Hadley	Emergency BackUp Manufacturer	800-252-5220	acct@raymondhadley.com
Delmonico	Insurance Company	(315) 472-4242	Jed@DelmonicoInsurance.com
Riccardo Galbato	Attorney	315.252.1234	www.galbatolaw.com

2.6 Product Traceability and Crisis Management

Rev 02/01/2024
Reviewed 03/13/2025



FEMA - Earthquake Risk - White (Low)

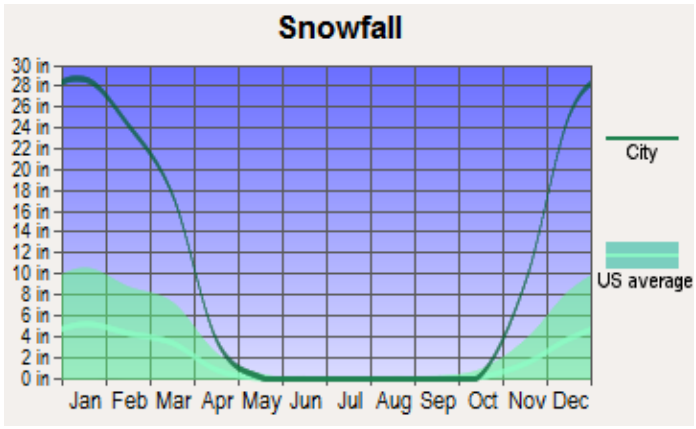


Tornado Risk - 10 Tornadoes in Wayne, Cayuga or Seneca Counties since 1969

E	Map/Forum	SPC #	Date	Time	State(s)	Fujita	Fatalities	Injuries	Width	Length
		231	1969-06-02	14:30:00 3	New York	3	0	0	10	17.5
		520	1980-06-09	11:20:00 3	New York	1	0	0	200	9.9
		241	1983-05-02	19:15:00 3	New York	3	1	0	200	20
		400	1991-04-30	14:20:00 3	New York	1	0	0	23	0.1
		525	1993-06-15	12:05:00 3	New York	0	0	0	100	0.5
		127	2002-05-31	15:00:00 3	Pennsylvania, New York (overall summary)	1	0	1	300	1.5
		127	2002-05-31	14:55:00 3	Pennsylvania	1	0	0	300	0.5
		127	2002-05-31	15:00:00 3	New York	1	0	1	300	1
		272	2003-05-11	13:30:00 3	New York	1	0	0	50	2.3
		68	2004-04-18	11:43:00 3	New York	0	0	0	75	1
		761	2007-06-21	13:46:00 3	New York	1	0	0	100	1.5
E	Map/Forum	SPC #	Date	Time	State(s)	Fujita	Fatalities	Injuries	Width	Length
		343871	2011-08-21	13:15:00 3	New York	2	0	0	200	7.88

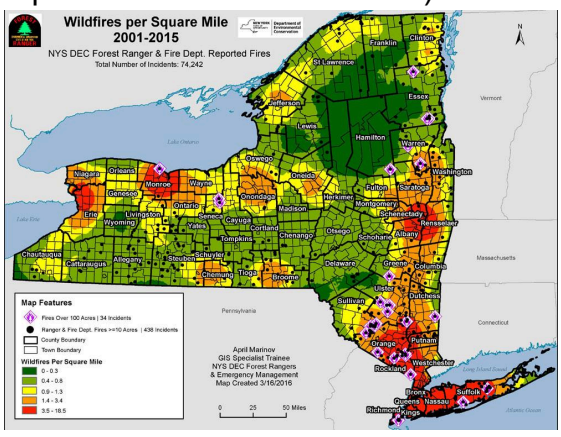
Summary Definitions [?]

Date(s) (yyyy-mm-dd)	Tornadoes	Fatalities	Highest Fatalities	Injuries	Highest Injuries	Longest Path	Widest Path
1969-06-02 - 2011-08-21	10	1 person	1 person	1 person	1 person	20 miles	300 yards



Snow Risk - High

Wildfire Risk - Moderate risk (0.9 -1.3 per Square Mile from 2001 - 2015)



Flood Risk - zone C “Minimal Risk” according to FEMA Flood Maps 3612290015C & 3612060001B