



Agriculture and Markets

Food Product Recall Booklet

New York State Department of Agriculture and Markets
10b Airline Drive
Albany, NY 12235
www.agriculture.ny.gov

Table of Contents

<u>Introduction</u>	3
<u>Recall Flowchart</u>	4
<u>What is a Food Recall?</u>	5
<u>What Causes a Food Recall?</u>	5
<u>What Should a Food Business Do Once a Recall Has Been Initiated?</u>	6
<u>Step 1: Determine the Scope of Recall</u>	6
<u>Step 2: Determine the Depth of Recall</u>	6
<u>Step 3: Food Recall Classifications</u>	7
<u>Step 4: Prepare and Distribute Recall Notification Letters</u>	8
<u>Step 5: Prepare and Distribute Public Warnings</u>	8
<u>Step 6: Effectiveness Checks</u>	9
<u>Step 7: Status Reports</u>	10
<u>Step 8: Termination of Recall</u>	10
<u>Step 9: Record Retention</u>	10
<u>Model Recall Notification Letter</u>	11
<u>Example of Retail/In-Store Notification</u>	12
<u>Press Release Template</u>	13
<u>Health Warning Paragraphs</u>	14
<u>Sample Press Releases</u>	15 - 17
<u>Appendix A: Contaminants of Concern</u>	18

Introduction

The New York State Department of Agriculture & Markets (the Department) designed this Food Product Recall Booklet as guidance for the food businesses located in New York State to follow if in the event they need to initiate a food recall (recall).

A food business referred to in this guidance document is one that stores, manufacturers, distributes and/or sells food in the State of New York and is licensed, registered and/or inspected by the Department.

Cooperation between food businesses and the Department has proven to be very effective and efficient in removing potentially dangerous products from the market. Consumers benefit when food businesses and the Department cooperate to ensure that potentially harmful products are removed from sale.

While this guidance document may be a useful tool for a food business to follow if they need to initiate a food recall, this guidance is not intended to be an all-inclusive recall guidebook. Food businesses are free to use other sources for more comprehensive information regarding food recalls.¹ The Department strongly encourages food businesses work with their Food Safety Inspector if they have specific questions about initiating a recall.

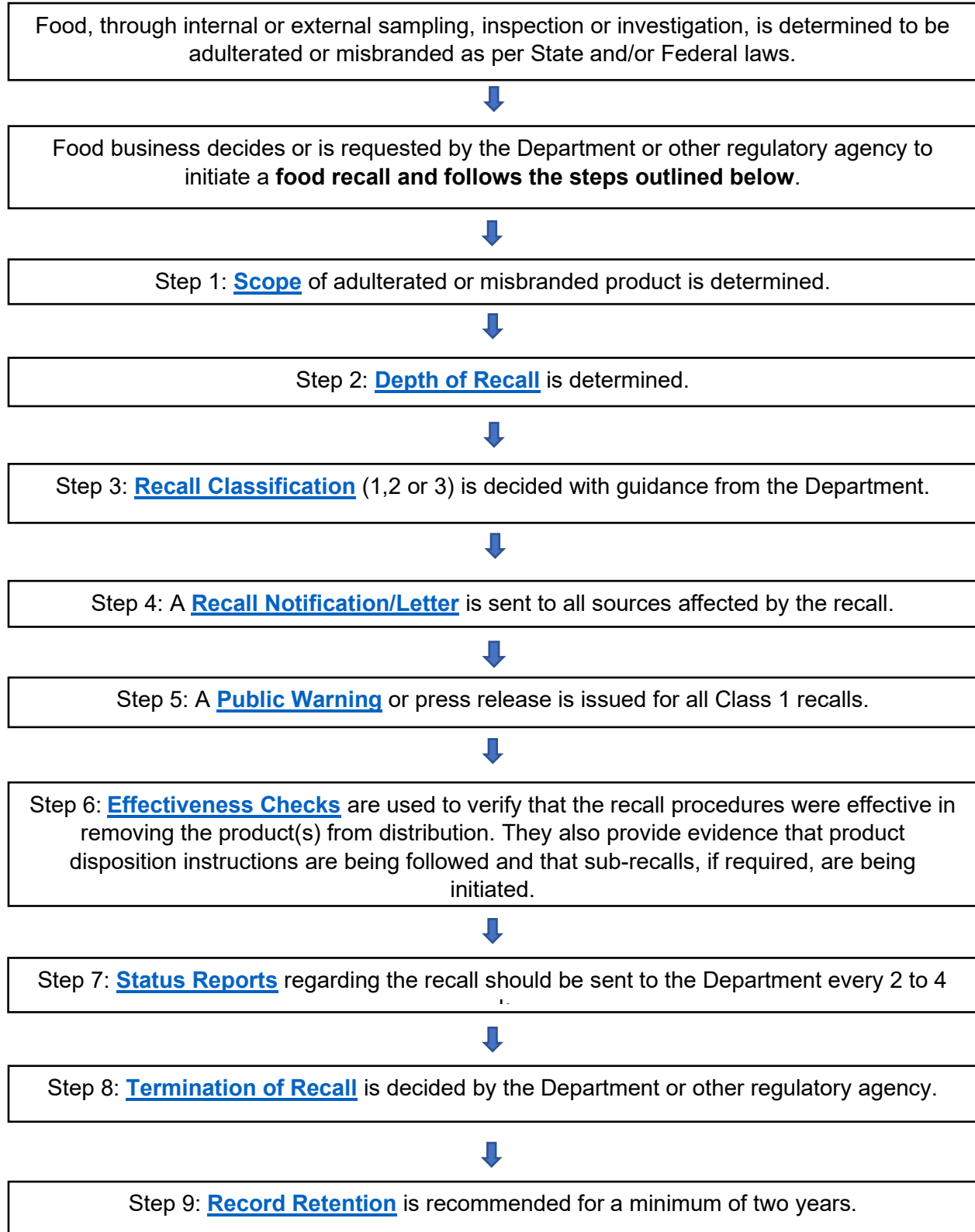
Contact Your Local New York State Department of Agriculture and Markets Office Listed Below to Connect with Your Food Safety Inspector:

ALBANY: Division of Food Safety and Inspection (518) 457-4492

BROOKLYN: Division of Food Safety and Inspection (718) 722-2876

¹ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

Food Recall Process Flow Chart



What is a Food Recall?

A **food recall** is a food businesses' removal of food products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of applicable state and federal laws.²³

Recalls are typically a voluntary action taken by a food business. In some cases, a food business will discover that one of its products is adulterated or misbranded and will initiate a recall entirely on its own. In other cases, the Department, or another federal or state regulatory agency, notifies a food business that one of its products is adulterated or misbranded and will request a recall. If the company refuses to recall the product, the Department or regulatory agency may issue a consumer alert and/or conduct seizures of available product. In addition, legal actions, such as penalties for seized items, may be imposed.

The Department recommends **all** food businesses have a recall plan in place, allowing them to act swiftly and effectively in the event of a recall. Currently, food businesses subject to Title 21 CFR 117, Subpart C 117.139 are required to have a written recall plan for any food with a hazard requiring a preventive control.

What Causes a Food Recall?

In general, a food recall will be initiated when internal or external sampling, consumer complaint investigations or inspections confirm a strong likelihood that biological, chemical or physical contamination is found in a food product at a level where it is considered adulterated or misbranded.

Examples of contaminants that cause a food recall include, but are not limited to:

- **Pathogens:** Disease-causing microorganisms. The most common pathogens in terms of food recalls are *Salmonella*, *E. Coli O175:H7* and *Listeria monocytogenes*.
- **Viruses:** Submicroscopic infectious agents that replicate only inside the living cells of an organism. The most common viruses in terms of food recalls are Norovirus, Hepatitis A & E and Rotavirus.
- **Undeclared Ingredients:** All major allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans), sulfites and FD&C approved colors and non-approved colors that are not properly stated on labels.
- **Chemical Contaminants:** Most often excessive heavy metals, such as lead, cadmium, arsenic and mercury.

² Article 17 Adulteration, Packing and Branding of Food and Food Products:
<https://www.nysenate.gov/legislation/laws/AGM/A17>

³ Article 3 Investigation; Practice and Procedure; Violations; Penalties:
<https://www.nysenate.gov/legislation/laws/AGM/A3>

- **Physical Matter Contaminants:** Items that don't belong in food, such as a piece of plastic, glass, metal shavings, bugs or filth.
- **Parasites:** Cryptosporidium spp., Giardia intestinalis, Cyclospora cayetanensis, and Toxoplasma gondii; roundworms such as Trichinella spp.

[Appendix A lists the contaminants of concern that are routinely sampled by the Department.](#)

What Should a Food Business Do Once a Recall Has Been Initiated?

If the recall was initiated through internal procedures, then the Department and other appropriate regulatory agencies should be notified.

If the recall was requested by the Department or a regulatory agency, work with the Department or the agency to expedite the following steps:

All of the below listed steps apply to all food recalls, except Step 5, which applies only to Class 1 recalls.

Step 1: Determine the Scope

This defines the type of product, when a product is made, where it is manufactured and the amount of product. It identifies all product(s), sizes and codes/lots to be included in the recall. The scope of a recall may change as new information is received, such as laboratory testing data and results.

Step 2: Determine the Depth of Recall

This defines the level of product distribution to which the recall is to extend:

- **Consumer or User level:** This includes household consumers as well as all other levels of distribution.
- **Retail level:** This includes all retail sales of the recalled product, including any intermediate wholesale level
- **Wholesale level:** This is the distribution level between the manufacturer and the retailers. This level may not be encountered in every recall situation (e.g., the recalling food business may sell directly to the retail or consumer/user level).

Knowing the level of product distribution will assist a food business in determining the best manner to distribute the recall notifications and the best disposition plan for handling the return/destruction/relabeling of the recalled product.

Step 3: Determine the Food Recall Classification

Class I recalls are the most serious and are deemed likely to cause serious adverse health effects or death.

When a food business conducts a Class I recall, the food business is required to file a report through the FDA's [Reportable Food Registry](#) (RFR) electronic portal as soon as practicable, but in no case later than 24 hours after the recall is initiated.

Class II recalls indicate that consumption of the food could cause a temporary health hazard, or the likelihood of serious adverse health issues is remote.

Class III recalls are situations where eating the food is unlikely to cause a health problem but rather violates regulations.

For Recall Classification Assistance Contact Your Local New York State Department of Agriculture and Markets Office Listed Below:

ALBANY: Division of Food Safety and Inspection (518) 457-4492
10B Airline Drive Albany, New York 12235

BROOKLYN: Division of Food Safety and Inspection (718) 722-2876
55 Hanson Place – 3rd Floor Brooklyn, New York 11217-1583

BUFFALO: Division of Food Safety and Inspection (716) 847-3185
535 Washington Street Suite 303 Buffalo, New York 14203

HAUPPAUGE: Division of Food Safety & Inspection (631) 952-3079
Suffolk State Office Bldg., Room 13A, 4th Floor
250 Veteran's Memorial Highway Hauppauge, New York 11788

NEW WINDSOR: Division of Food Safety & Inspection (845) 220-2047
103 Executive Drive, 3rd Floor, Suite 300 New Windsor, New York 12553

ROCHESTER: Division of Food Safety and Inspection (585) 427-2273
1530 Jefferson Road Rochester, New York 14467

SYRACUSE: Division of Food Safety and Inspection (315) 487-0852
New York State Fairgrounds
581 State Fair Blvd. Syracuse, New York 13209

Step 4: Prepare and Distribute Recall Notification Letters to Direct Businesses

A food business should prepare a recall notification letter and distribute it to all businesses that may have received the recalled product.

The recall notification letter must include the following:

1. Statement: “Urgent food recall”
2. Recalling food businesses’ name, address, phone number
3. Name of product(s) being recalled
4. Product packaging type and container size
5. Product manufactured/distributed by
6. Container code, including sell by or use by date, affected by the recall
7. Reason for the recall
8. Disposition of the recalled product (i.e., Product return process, on-site destruction, or re-labeling instructions)
9. Sub-recall action
10. Requested response – effectiveness check

[A model recall letter is available on page 11.](#)

A **sub-recall** must be initiated when a recipient of a recall communication has direct accounts that may have also received the affected product.

The manner in which the recall notification is sent to the direct accounts may vary. The letters can be communicated via mail, email, direct messaging, etc. Where necessary, follow-up communication should occur for any direct account that fails to respond to a recall communication to ensure the direct account has received and understands the recall communication.

Step 5: Prepare and Distribute Public Warnings – Class 1 Recalls Only

Public notification is important, particularly in situations where the recalled product may pose a significant health hazard and may be in the hands of consumers. A food business is required⁴ to prepare and issue a press release for all Class 1 recalls.

[A press release template is available on page 13.](#)

[Sample press releases for different contaminants are available on pages 14 – 17.](#)

When public notification is necessary, the Department will work with New York food businesses initiating a recall to issue a press release as soon as the recall situations are identified. The food business will be informed if it does not issue a press release within 24 hours, the Department will issue its own.

⁴ U.S. Congress. (1934) United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 423(g).

The Department posts food safety alerts to notify consumers of Class 1 recalls initiated by the Division of Food Safety and Inspection and the Division of Milk Control and Dairy Services. Food safety alerts are available [here](#).

The Associated Press will only accept press releases via email. Recalls for products distributed in New York State only or the immediately surrounding states should be emailed to:

ALBANY
apalbany@ap.org

OR

NEW YORK CITY
apnyc@ap.org

Press releases for products distributed nationwide should be emailed to the Washington DC desk of the Associated Press at:

WASHINGTON, D.C.
wcdesk@ap.org

Retail Store Notifications:

Retail businesses selling products that are subject to a recall should post a public notification in stores to alert consumers.

[A model in-store notification is available on page 12.](#)

Step 6: Conduct Effectiveness Checks

Effectiveness checks should be used to verify the recall procedures successfully resulted in the removal of the affected product(s) from the food supply distribution chain. They should also provide evidence that product disposition instructions are being followed and that sub-recalls, if required, have been initiated. The recalling food business will ordinarily be responsible for conducting recall effectiveness checks.

The effectiveness checks are usually incorporated into the recall notifications. Effectiveness checks should be documented in the best manner available, such as via a telephone call log, a spreadsheet, electronic logs, email folders, paper reports, etc.

If the effectiveness checks reveal that the recall process is not achieving the intended goal, then additional steps should be taken to correct the process, such as reissuing the recall notice in another manner, contacting each entity a business sold its product to directly, etc.

[A template that can be used for effectiveness checks is available as part of the Model Recall Letter on page 11.](#)

Step 7: Prepare Status Reports

Food businesses affected by a food recall should compile the data received through their effectiveness checks and prepare a status report for the Department and any other state or federal agency consulting with the food businesses about the recall every two to four weeks until the recall is terminated. Status reports can be sent in the form of an email to the Department.

Step 8: Termination of Recall

When all reasonable efforts have been made to remove or correct the product(s) subject to a recall and proper disposition of the product(s) has concluded, a recall can be terminated. A food business should notify the Department and all other government agencies with which they have been interacting on the recall of their plans to consider a recall terminated. The government agency, federal or state, will determine when the recall is terminated. The Department will send a notification to the food business to indicate that corrective actions concerning the recall have been successfully completed.

Step 9: Record Retention

Food businesses are recommended to retain all records related to food recalls for a minimum of two years.⁵

⁵ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=117.315>

**MODEL RECALL LETTER
TO BE SENT BY RECALLING FOOD BUSINESS TO CUSTOMER**

Name, Address, & Telephone Number of Recalling Food Business

Date

CERTIFIED MAIL or via Email

Name & Address of Customer

URGENT RECALL LETTER *(Bold Print)*

Dear Customer:

Our food business is voluntarily recalling **(brand/name of product)** due to **(reason for recall)**. *The product is packaged in a (size) (container description including UPC code, product code and manufacturer or distribution information if not recalling food business).*

Our records show that your food business purchased **(amount)** case(s) of above product from us in the past **(months/years)**. We would like you to discontinue selling your existing stock of **(brand/name of product)** and return the recalled product to **(indicate name of food business's contact person)** as soon as possible. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall.

In order to advise the **(regulatory authority)** about the effectiveness of this recall, please inform us of the quantity of the above product on hand immediately after you received this recall letter. Please sign and email to **(email address)** or FAX **(FAX number)** this letter back to us as soon as possible.

Thank you for your cooperation in this recall. If you have any question regarding this recall, please feel free to contact **(food business's contact person)** at **(contact person's telephone number)**.

(This space would contain dual language portion of the letter)

Quantity on Hand: _____ **Cases/Cans/Packages** *(Circle One)*

Was a sub-recall required: _____ YES _____ NO *If yes, please attach copies of recall notifications sent to accounts.*

I have removed the product(s) listed above from sale and followed the disposition instructions as prescribed in the recall notification.

(Customer/Business Name)

Sincerely,

(Signature) (Recall Food Business Representative)

Example of Retail/In-Store Notification

Voluntary Recall Notice

We were notified on <DATE> that traces of <ADULTERANT> were present in <PRODUCT> produced on <DATE(S)> in our store. We believe this to be an isolated occurrence in this one batch. We have had no other reports of <ADULTERANT> to date and are cooperating fully with the New York State department of Agriculture and Markets with regards to the investigation of this incident.

If you have any <PRODUCT> at all with a packed on date of <DATE> and sell by date of <DATE>, please return it for a full refund.

We appreciate your business and if you have any further questions, please feel free to call the store manager <NAME> at <PHONE NUMBER> or corporate office at <PHONE NUMBER>.

Thank You,

(Store Owner's Name)

PRESS RELEASE TEMPLATE

FOR IMMEDIATE RELEASE
COMPANY CONTACT AND PHONE NUMBER

DATE

FOOD BUSINESS RECALLS PRODUCT DUE TO POSSIBLE HEALTH RISK

Name of Food Business of **City, State** is recalling **Quantity and/or Type of Product**, because it may be contaminated with **Contaminant Name**, **Health Warning Paragraph (see examples below)**

Product was distributed **Listing of the states and areas where the product was distributed and how it reached consumers (e.g. through retail stores, mail order, direct delivery)**.

Specific information on how the product can be identified (e.g. type of container [plastic/metal/glass], size and appearance of the product, the product's brand name, flavors, codes, expiration dates, UPC code, etc.

Status of the number of and types of related illnesses that have been CONFIRMED to date (e.g. "No illnesses have been reported to date.")

Brief explanation about what is known about the problem, such as how it was revealed, and what is known about its source. An example of such a description –"The contamination was discovered after sampling by New York State Department of Agriculture and Markets Food Inspectors and subsequent analysis of Food Laboratory personnel revealed the presence of Listeria monocytogenes in the (product name)."

Information on what consumers should do with the product and where they can get additional information (e.g. "Consumers who have purchased Brand X are urged to return it to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.")

Health Warning Paragraphs for Use in Press Releases

Listeria monocytogenes is an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people and others with weakened immune systems. Although healthy persons may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, ***Listeria*** infection can cause miscarriages and stillbirths among pregnant women.

Botulism is a potentially fatal form of food poisoning, can cause the following symptoms: general weakness, dizziness, double-vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

E. coli 0157:H7 causes a diarrheal illness often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called *Hemolytic Uremic Syndrome (HUS)*. *HUS* is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death.

Salmonella is an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e. infected aneurysms), endocarditis and arthritis.

Undeclared Allergens: People who have an allergy or severe sensitivity to **specific type of allergen (e.g. peanuts, tree nuts [chestnuts, brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews], eggs and sulfites)** run the risk of serious or life-threatening allergic reaction if they consume these products.

Uneviscerated Fish: The sale of uneviscerated fish is prohibited under New York State Agriculture and Markets regulations because *Clostridium botulinum* spores are more likely to be concentrated in the viscera than any other portion of the fish. Uneviscerated fish have been linked to outbreaks of botulism poisoning. Symptoms of botulism include dizziness, blurred or double vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

Sulfites: People who have a severe sensitivity to sulfites run the risk of serious or life-threatening reactions if they consume these products.

SAMPLE PRESS RELEASE - PATHOGENS

XYZ Inc.
123 Smith Lane Anywhere, NY
FOR IMMEDIATE RELEASE
Sam Smith / 555-555-5555

DATE

XYZ RECALLS “SNACKIES” DUE TO POSSIBLE HEALTH RISK

XYZ Inc. of Anywhere, NY, is recalling its 5 ounce packages of “Snackies” food treats because they may be contaminated with *Listeria monocytogenes*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people and others with weakened immune systems. Although healthy persons may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

The recalled “Snackies” were distributed nationwide in retail stores and through mail orders. The product comes in a 5 ounce, clear plastic package marked with lot #666666 on the top and with an expiration date of 12/12/20 stamped on the side. The product UPC code is 74635-82361.

No illnesses have been reported to date in connection with this problem.

The contamination was discovered after sampling by New York State Department of Agriculture and Market Food Inspectors and subsequent analysis by Food Laboratory personnel revealed the presence of *Listeria monocytogenes* in some 5 ounce packages of “Snackies.” Production of the product has been suspended.

Consumers who have purchased 5 ounce packages of “Snackies” are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

SAMPLE PRESS RELEASE - UNDECLARED INGREDIENTS

XYZ Inc.
123 Smith Lane Anywhere, NY
FOR IMMEDIATE RELEASE
Sam Smith / 555-555-5555

DATE

XYZ ISSUES ALLERGY ALERT ON UNDECLARED PEANUTS IN “SNACKIES”

XYZ Inc. of Anywhere, NY, is recalling its 5 ounce packages of “Snackies” food treats because they may contain undeclared peanuts. People who have allergies to peanuts run the risk of serious or life-threatening allergic reaction if they consume these products.

The recalled “Snackies” were distributed nationwide in retail stores and through mail orders. The product comes in a 5 ounce, clear plastic package marked with lot #666666 on the top and with an expiration date of 12/12/20 stamped on the side. The product UPC code is 74635-82361.

No illnesses or allergic reactions involving this product have been reported to date.

The recall was initiated after routine sampling by New York State Department of Agriculture and Markets Food Inspectors and subsequent analysis by Food Laboratory personnel revealed that the peanut-containing product was distributed in packages that did not reveal the presence of peanuts.

Consumers who have purchased 5 ounce packages of “Snackies” are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

SAMPLE PRESS RELEASE - UNEVISCERATED FISH

XYZ Inc.
123 Smith Lane Anywhere, NY
FOR IMMEDIATE RELEASE
Sam Smith / 555-555-5555

DATE

XYZ ISSUES ALERT ON UNEVISCERTED “HERRING IN OIL”

XYZ Inc. of Anywhere, NY, is recalling its 5 ounce packages of “Herring in oil” because the product was found to be uneviscerated.

The recalled “Herring in oil” were distributed nationwide in retail stores. The product comes in a 5 ounce, clear plastic package marked with lot #666666 on the top and with an expiration date of 12/12/20 stamped on the side. The product UPC code is 74635-82361.

The recall was initiated after routine sampling by New York State Department of Agriculture and Markets Food Inspectors and subsequent analysis by Food Laboratory revealed the product was not properly eviscerated prior to processing.

The sale of uneviscerated fish is prohibited under New York State Agriculture and Markets regulations because *Clostridium botulinum* spores are more likely to be concentrated in the viscera than any other portion of the fish. Uneviscerated fish have been linked to outbreaks of botulism poisoning. Symptoms of botulism include dizziness, blurred or double vision and trouble with speaking or swallowing. Difficulty in breathing, weakness of other muscles, abdominal distension and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

No illness have been reported to date in connection with this problem.

Consumers who have purchased 5 ounce packages of “Herring in oil” are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-800-XXX-XXXX.

Appendix A: Contaminants of Concern Routinely Sampled by NYS Department of Agriculture and Markets

COMING SOON