

# FOOD PRODUCT RECALL BOOKLET

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

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#### **Introduction**

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

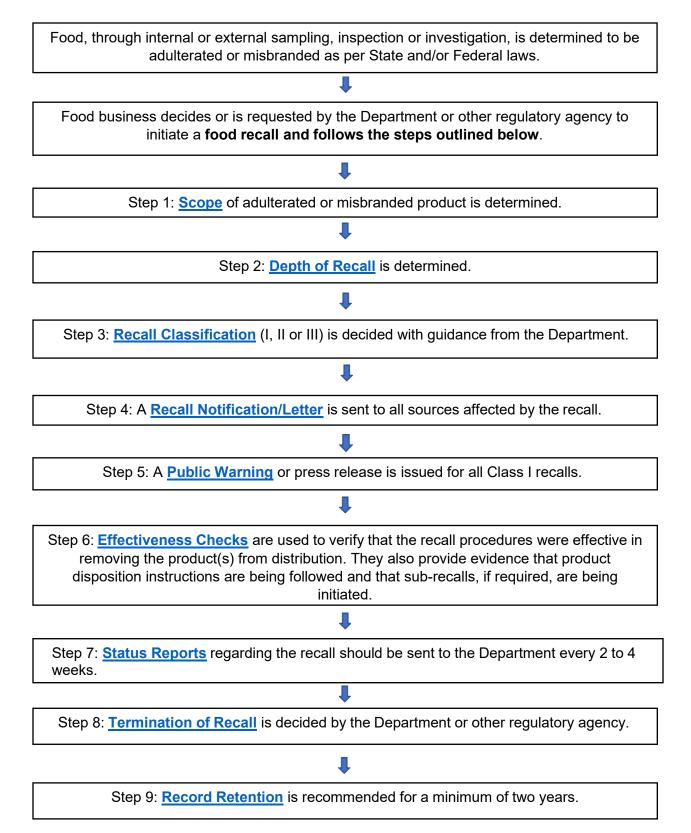
A food business referred to in this booklet is one that stores, manufacturers, distributes and/or sells food in the State of New York and is licensed, registered and/or inspected by the Department.

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

While this booklet may be a useful tool for a food business to follow if they need to initiate a food recall, this booklet 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.<sup>1</sup> The Department strongly encourages food businesses to work with their Food Safety Inspector if they have specific questions about initiating a recall.

<sup>&</sup>lt;sup>1</sup> 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.<sup>2</sup>, <sup>3</sup>

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 recall, a food safety consumer alert or similar<sup>4</sup> and/or conduct seizures of available product. In addition, legal actions, such as penalties for seized items, may be imposed.

The Department recommends <u>all</u> 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 thatbiological, 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:

- **Pathogenic Bacteria:** Disease-causing microorganisms. The most common pathogens in terms of food recalls are *Salmonella*, *E. coli* O157: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 and E and Rotavirus.
- **Undeclared Ingredients:** All major allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, sesame, wheat, and soybeans), sulfites, and Food Drug and Cosmetic (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, inorganic arsenic and mercury.

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

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

<sup>&</sup>lt;sup>4</sup> 21 USC 350I: Mandatory recall authority

- **Physical Matter Contaminants:** Items that do not 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 examples of contaminants that can initiate a recall.

#### 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 the below listed steps apply to all food recalls, except Step 5, which applies only to Class I 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 <u>Reportable Food Registry</u> (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:

Region	Address	Phone Number
Albany	10B Airline Drive	(518) 457-4492
	Albany, New York 12235	
Brooklyn	55 Hanson Place – 3rd Floor	(718) 722-2876
	Brooklyn, New York 11217-1583	
Buffalo	535 Washington Street Suite 303	(716) 847-3185
	Buffalo, New York 14203	
Hauppauge	Suffolk State Office Bldg., Room 13A, 4th Floor	(631) 952-3079
	250 Veteran's Memorial Highway	
	Hauppauge, New York 11788	
New Windsor	103 Executive Drive, 3rd Floor, Suite 300	(845) 220-2047
	New Windsor, New York 12553	
Rochester	1530 Jefferson Road	(585) 427-2273
	Rochester, New York 14467	
Syracuse	581 State Fair Blvd.	(315) 487-0852
	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 I 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 required<sup>5</sup> to prepare and issue a press release for all Class I 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 the New York food business initiating a recall to issue a press release as soon as the recall situations are identified. The food business will be informed that if it does not issue a press release within 24 hours, the Department will issue its own.

<sup>&</sup>lt;sup>5</sup> U.S. Congress. (1934) United States Code: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 423(g).

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

ASSOCIATED PRESS info@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.

<u>A template that can be used for effectiveness checks is available as part of the Model</u> 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.<sup>6</sup>

#### **Food Safety Consumer Alerts**

In addition to following the prescribed recall process described above, the Department also issues "Food Safety Consumer Alerts" for each Class I and Class II Recall to broadly make consumers more aware of the contamination found in foods sold, distributed and/or manufactured in New York State. Food safety consumer alerts are shared with local media outlets and are posted on the Department's website. For more information on food safety consumer alerts please click here: <u>https://agriculture.ny.gov/food-safety-alerts</u>

<sup>&</sup>lt;sup>6</sup> https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=117.315

#### MODEL FOOD 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 and 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.

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 receive this recall letter. Please sign and email (*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 questions 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/Other (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,

(Recall Food Business Representative)

(Signature)

#### MODEL 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)

#### MODEL PRESS RELEASE TEMPLATE

#### FOR IMMEDIATE RELEASE COMPANY CONTACT AND PHONE NUMBER

<u>DATE</u>

#### "FOOD BUSINESS XYZ" RECALLS PRODUCT DUE TO POSSIBLE HEALTH RISK

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

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

<u>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.</u>

<u>Status of the number of and types of related illnesses that have beenCONFIRMED</u> 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 guestions may contact the company at 1-800-XXX-XXXX.")

#### Example of 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, *L. monocytogenes* infection can cause miscarriages and stillbirths among pregnant women.

**Botulism** is a potentially fatal form of food poisoning and 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 that 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 a <u>specific type of allergen (e.g., peanuts, tree nuts [chestnuts, Brazil nuts, walnuts, hazelnuts, pecans, pine nuts, cashews], eggs and sulfites</u>) run the risk of a 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, *L. monocytogenes* 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 #6666666 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 *L. 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 #6666666 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 #6666666 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 staff 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 inbreathing, weakness of other muscles, abdominal distension, and constipation may also be common symptoms. People experiencing these problems should seek immediate medical attention.

No illnesses 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.

## SAMPLE FOOD SAFETY CONSUMER ALERT

#### FOR IMMEDIATE RELEASE

DATE

#### ABC APPLE JUICE FROM ABC FOOD & CO IS RECALLED DUE TO ELEVATED LEVELS OF INORGANIC ARSENIC

New York State Agriculture Commissioner Richard A. Ball today alerted consumers that ABC Apple Juice, manufactured by ABC Food & Co., located at 123 Alphabet Drive, Albany, NY, is recalled due to elevated levels of inorganic arsenic. Exposure to inorganic arsenic is associated with adverse human health effects, including cancer, diabetes, adverse birth outcomes, and cardiovascular and neurodevelopmental effects. No illnesses have been reported to date. Consumers concerned about an injury or illness associated with this product should immediately contact a healthcare provider.

ABC Apple Juice sold in 16-ounce bottles with UPC Code #123456789 and a "best if used by" date of January 1, 2023, are subject to this recall. A photo of the product is included in this consumer alert. The product was sold at Groceries-R-Us throughout New York State after July 1, 2022.

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 product tested above the action level for inorganic arsenic set by the U.S. Food and Drug Administration.

Consumers who purchased ABC Apple Juice products covered under this recall are urged to discard the product. Consumers with questions may contact ABC Food & Co at 1-800-000-0000.

About Food Safety Consumer Alerts: The New York State Department of Agriculture and Markets issues "Food Safety Consumer Alerts" for each Class I and Class II recall to make consumers more aware of contamination or adulteration found in foods sold, distributed, and/or manufactured in New York State. Food safety consumer alerts are shared with media outlets and are posted on the Department's website. <u>Click here</u> for more information on food safety consumer alerts.

### Appendix A: Examples of Contaminants That May Initiate a Recall and/or Consumer Food Safety Alert by NYS Department of Agriculture and Markets

(Disclaimer: This list does not contain every violation which may initiate a recall. Certain recalls may be reclassified due to the type, and/or level of contaminant found. Note: Not every laboratory analysis listed is conducted at the NYSAGM Food Laboratory)

	Class I	Class II	Class 3	<b>Reference</b>
Biological				
Campylobacter species	If present in ready to eat food	N/A	N/A	FDA: Bad Bug Book
Clostridium botulinum	If present	N/A	N/A	FDA: Bad Bug Book
Cryptosporidium	If present	N/A	N/A	FDA: Bad Bug Book
Cyclospora cayetanensis	If present	N/A	N/A	FDA: Bad Bug Book
<i>E. coli</i> O157:H7	If present	N/A	N/A	FDA: Bad Bug Book and USDA: E.coli 0157:H7
Fish species	N/A	N/A	Species mislabeled	FDA: Fish Species
Hepatitis A virus	If present	N/A	N/A	FDA: Bad Bug Book
Listeria monocytogenes	If present in ready to eat foods	N/A	N/A	FDA: Listeria Link
Norovirus	N/A	If present	N/A	FDA: Bad Bug Book
<i>Staphylococcus aureus</i> (Staph) toxins	If present in ready to eat food	N/A	N/A	FDA: Bad Bug Book
Salmonella species	If present in ready to eat food	N/A	N/A	FDA: Salmonella Link

	Class I	Class II	Class 3	<u>Reference</u>
<b>Chemical</b>				
				FDA:Aflatoxin and
Aflatoxin	N/A	20 ppb or above	N/A	FDA:Aflatoxin in Milk
		If undeclared and		CFR: Alcohol Link
Alcohol	N/A	above 0.5% volume	N/A	
AICOHOI	IN/A	Volume		FDA: Antibiotics in
				Milk & CFR: New
Antibiotics in Milk	If present	N/A	N/A	Animal Drugs
		Levels Vary		FDA: Antibiotics in
Antibiotics in Fish	N/A	(See Reference)	N/A	Fish
				FDA: Antibiotics in
Antibiotics in Honey	N/A	10 ppb or above	N/A	Honey
				NYS: Current
Cadmium	N/A	1 ppm or above	N/A	Cadmium Levels
		1 ppm with a		NYS: Current
		proposed action		Cadmium Levels
		level of above		NYS: Proposed
Cadmium in Spices	N/A	0.260 ppm <sup>7</sup>	N/A	Levels
Ciguatera (fish toxin)	If present	N/A	N/A	FDA: Fish Toxins
				CFR: Cyclamates
Cyclamates	N/A	If present	N/A	
			Over 30% Fat	CFR: Fat in Ground
			above 1% of	<u>Beef</u>
			declared fat on	
Fat in Ground Beef	N/A	N/A	the label	
			If labeled as pure	NYS: Honey
			honey and	Authenticity
			additives (such	
Honoy Authonticity	N/A	N/A	as corn syrup) are found.	
Honey Authenticity	IN/A	IN/A		NYS: Current
				Inorganic Arsenic
Inorganic Arsenic	N/A	1 ppm or above	N/A	Levels
				FDA: Inorganic
Inorganic Arsenic in				Arsenic in Apple
Apple Juice	N/A	10 ppb or above	N/A	Juice
11			-	NYS: Current
				Inorganic Arsenic
		1 papers with -		Levels
		1 ppm with a		NYS: Proposed Level
Inorgania Araania in		proposed action level of above		
Inorganic Arsenic in	N/A	$0.210 \text{ ppm}^7$	N/A	
Spices		0.210 ppm	IN/A	

<sup>&</sup>lt;sup>7</sup> Implementation of the proposed action levels will occur over a time period of 18 months. The start date will be posted on the spices section of our website when it has been determined

	Class I	Class II	Class 3	<u>Reference</u>
				FDA: Inorganic
				Arsenic in Rice
Inorganic Arsenic in Rice				<u>Cereal</u>
Cereals for Infants	N/A	100 ppb or above	N/A	
			If labeled as pure	NYS: Juice
			juice and found/	Authenticity
			not in	
			compliance with standard for that	
Juice Authenticity	N/A	N/A	juice.	
				NYS: Current Lead
Lead	Above 25 ppm	1 ppm or above	N/A	Action Levels
		1 ppm with a		NYS: Current Lead
		proposed action		Action Levels
Lead in Spices	Above 25 ppm	level of above 0.210 ppm <sup>8</sup>	N/A	<u>NYS: Proposed</u> Levels
Lead in Spices		0.210 ppm	IN/A	FDA: Action Levels
Fruits, Vegetables				Draft Guidance
(excluding single-				
ingredient root				
vegetables), Mixtures				
(including grain and meat-based mixtures),				
Yogurts,				
Custards/Puddings, and				
Single-Ingredient Meats		1 ppm with a		
Intended for Babies and		proposed action		
Children Less Than Two	Above 25 ppm	level of above 10		
Years Old; Lead in Processed Root	Above 25 ppm	ppb <sup>9</sup>	N/A	FDA: Action Levels
Vegetables (single				Draft Guidance
ingredient) Intended for		1 ppm with a		
Babies and Children		proposed action		
Less Than Two Years		level of above 20	N1/A	
Old; Lead in Processed Dry	Above 25 ppm	ppb <sup>9</sup>	N/A	FDA: Action Levels
Infant Cereals Intended		1 ppm with a		Draft Guidance
for Babies and Children		proposed action		
Less Than Two Years		level of above 20		
Old	Above 25 ppm	ppb <sup>9</sup>	N/A	
Lead in Can Seams	N/A	If found	N/A	CFR: Lead Solders

 <sup>&</sup>lt;sup>8</sup> Implementation of the proposed action levels will occur over a time period of 18 months. The start date will be posted on the spices section of our website when it has been determined
<sup>9</sup> Implementation of the proposed action levels will occur over a time period of 18 months after the FDA

announcement

	Class I	Class II	Class 3	Reference
			If nutritional	CFR: Label Analysis
			labeling is found	
			outside of	
			allowance for	
			declared values. Label format is	
			incorrect. The	
			label is not in	
Label Analysis	N/A	N/A	English, etc.	
				NYS: Maple Syrup
			If found/ not in	<u>Grade</u>
			compliance with standard for the	
Maple Syrup Grade	N/A	N/A	labeled grade	
Melamine	N/A	If present	N/A	FDA: Melamine
				CFR: Minerals Link
			If found outside	
Minanala		N1/A	of allowance for	
Minerals	N/A	N/A	declared values	FDA: Mycotoxins
Mycotoxins	If present	N/A	N/A	
Unallowed Colors	N/A	If present	N/A	<u>CFR: Uncertified</u> Colors
				NYS: Oil Authenticity
			If found/ not in	
			compliance with	
			standard for olive	
Olive Oil Authenticity	N/A	N/A	oil as labeled	FDA: Patulin
Patulin	N/A	50 ppb or above	N/A	
		As per EPA		CFR: Pesticides
Pesticides	N/A	tolerances	N/A	
PFOA / PFOS in Water	N/A	4 ppt or above	N/A	EPA: PFOA & PFOS
Poison Screen	If present	N/A	N/A	
			If found outside	CFR: Food Labeling
			of allowance for	
Protein	N/A	N/A	declared values	
				FDA: Food Defect
Rancidity	N/A	If determined	N/A	Handbook.
Rodenticides	If present	N/A	N/A	EPA: Rodenticides
			If found outside	CFR: Food Labeling
			of allowance for	
Sodium	N/A	N/A	declared values	
			If found outside	CFR: Soluble Solids
			of allowance for	
			the product	
Soluble Solids	Ν/Α		(usually jams	
Solids	N/A	N/A	and jellies)	

	Class I	Class II	Class 3	<u>Reference</u>
Sugar	N/A	N/A	If found outside of allowance for declared values	CFR: Food Labeling
Undeclared FD&C Certified Colors	N/A	If present	N/A	<u>CFR: Undeclared</u> <u>FD&amp;C Certified</u> <u>Colors</u>
Undeclared Eggs	150 ppm or greater	N/A	N/A	FDA: Food Allergens
Undeclared Fish	If present	N/A	N/A	FDA: Food Allergens
Unapproved Ingredients/Additives	N/A	If present	N/A	CFR: Title 21
Undeclared Milk	150 ppm or greater	N/A	N/A	FDA: Food Allergens
Undeclared Peanuts	10 ppm	N/A	N/A	FDA: Food Allergens
Undeclared Allowed Preservatives	N/A	N/A	If present	CFR: Title 21
Undeclared Unallowed Preservatives	N/A	If present	N/A	CFR: Title 21
Undeclared Sesame Seed	If present	N/A	N/A	FDA: Food Allergens
Undeclared Shellfish	If present	N/A	N/A	FDA: Food Allergens
Undeclared Soy	If present	N/A	N/A	FDA: Food Allergens
Undeclared Sulfites	10 mg or more/per serving	Between 3.7-9.9 mg/per serving	Below 3.7 mg/ per serving	<u>CFR: Sulfites</u> and <u>Sulfite Recall Paper</u>
Undeclared Tree Nuts	If present	N/A	N/A	FDA: Food Allergens
Undeclared Wheat, Oats, Corn	N/A	If present	N/A	FDA: Food Allergens
Vanilla Authenticity	N/A	N/A	If found outside of allowance for vanilla standard of identity	<u>CFR: Vanilla Product</u> <u>Standards</u>
Wheat Allergen in Foods Intended to be Gluten Free	N/A	20 ppm or above	N/A	CFR: Gluten-Free Food Labeling

	Class I	Class II	Class 3	Reference
Physical				
Evisceration in	Viscera in fish cavity present over 5			FDA: Uneviscerated Processed Fish
Processed Fish	inches	N/A	N/A	
Filth	N/A	N/A	lf found	FDA: Defect Handbook
Foreign Objects	N/A	N/A	If found	<u>FDA: Defect</u> <u>Handbook</u>

### Appendix B: An Overview of the NYS Department of Agriculture & Markets Process and Interagency Collaboration when a Food Product that is Sold Inside NYS is Subject to Recall/Food Safety Consumer Alert

# (Disclaimer: This process may change based on the severity of the situation, whether a nationwide recall has been initiated or other mitigating factors)

Foods manufactured, packaged, distributed and sold by companies operating within New York State

- •NYSAGM collects and tests food products (see appendix A) from retail stores, manufacturers and distributors
- If contamination is found, the process to remove the product from sale begins
- If retailer: NYSAGM works with them to remove the contaminated lots from their store(s) and identify through invoices where the product was purchased
- If manufacturer or distributor: NYSAGM requests a recall be initiated to remove the contaminated lots from their facility and entire distribution network
- •NYSAGM sends out a food safety consumer alert to inform the public of the issue with the product
- •As the recall progresses, NYSAGM monitors to verify the effectiveness of the recall
- •When sample results are from food products made or distributed by a NY firm and sold in other states, NYSAGM shares the laboratory results of Class 1 or Class 2 recalls with the FDA

Foods manufactured outside NYS or shipped in-state by an out-of-state distributor, NYSAGM shares this information with the FDA

- •NYSAGM requests the product within NY is recalled, and sends out a food safety consumer alert to inform the public of the issue with the product
- •NYSAGM shares the laboratory results of interstate Class 1 and Class 2 recalls with the FDA
- •FDA reviews the NYSAGM laboratory data results
- If FDA concurs with the result, and if outside of NYS and/or the NY District, the FDA may take regulatory action if within their district and/or will share this information with their counterpart in the district that the foods were manufactured
- If the FDA does not concur with the result, the FDA may not take any regulatory action against the firm

Foods manufactured outside NYS, or shipped in-state by an out-of-state distributor, NYSAGM shares this information with the State regulatory agency where the company is located

- •NYSAGM requests the product within NY is recalled, and sends out a food safety consumer alert to inform the public of the issue with the product
- •NYSAGM shares the laboratory results with the State regulatory official in the state where the manufacturer is located
- The State regulatory official reviews the NYSAGM laboratory data results
- If the State regulatory official concurs with the result, that State may take their own regulatory action against the firm
- If the state regulatory official does not concur with the result, that State may not take their own regulatory action against the firm

NYSAGM receives laboratory results from the FDA or another State regulatory official for a product manufactured or distributed by a NYS company,.

- •NYSAGM receives laboratory results from the FDA or another State regulatory official regarding an in-state manufactuer
- •NYSAGM reviews the laboratory data and if they concur, works with the manufacturer or distributor to recall the product and sends out a food safety consumer alert to inform the public of the issue with the product