

Basic Standards for Home/Commercial Kitchens and Small Scale Food Processing Facilities

Prepared By:

NYS Department of Agriculture and Markets

Division of Food Safety and Inspection



Agenda

- ▶ Regulations
- ▶ Zoning/Jurisdiction - Licensing and *exemptions*
- ▶ Specialized processing (*HACCP*)
 - ▶ Acidified foods, Juice, Seafood, Low acid canned foods
- ▶ Overview of CURRENT GMPs
- ▶ Labeling
- ▶ Allergens
- ▶ Food recalls
- ▶ Employee training opportunities
- ▶ Scheduled processes/authorities
- ▶ FSMA
- ▶ Resources



Regulations - Why do we have them?

- ▶ The Federal government, individual states, cities and municipalities govern the operation of food processing facilities whether home kitchens or commercial facilities.
- ▶ When considering starting up a home or commercial kitchen, it is important to research the following:
 - ▶ Which agencies regulates/licenses your product,
 - ▶ Foods allowed and not allowed to be produced in each facility,
 - ▶ Local zoning laws governing the use of the building
- ▶ Foods that are regulated and require a [Article 20-C Food Processing License in New York](#)
 - ▶ This regulation applies to anything that is altered by *value-added* processing including but not limited to: baking, blending, brewing, curing, fermenting, freezing, grinding, pickling, canning, preserving, dehydrating, juicing, cider making, pickling, brining, bottling, packaging, repackaging, vacuum or reduced oxygen packaging, pressing, heating or cooking, smoking, roasting, or manufacturing.

Complete list in handout



Zoning Regulations? - Jurisdiction?

Covered in
handout!

Procedure	Home Kitchen	Home Annex (if licensable)	Commercial
Inspection	No, Potable water required (documented) - municipal or treated well water	Yes, Potable water required (documented) - municipal or treated well water	Yes, Potable water required (documented) - municipal or treated well water
Licensing	Non-potentially hazardous foods exempt from licensing by NYS Department of Agriculture & Markets (NYSDAM) Wholesale or retail is allowed at agricultural venues (farmers markets, craft fairs, etc.)	20-C license NYS Dept. of Agriculture & Markets Separate cleaning, sanitizing, and hand wash facilities. Easily cleanable walls, floor, and ceiling. Fee: \$400.00/2 years	20-C license NYSDAM Fee - \$400.00/2 years
Inspection Agency	NYSDAM May request review of processing procedures by recognized processing authority. Only normal kitchen facilities can be used.	NYSDAM	NYSDAM Food service facilities are inspected by the Department of Health.
Foods Allowed	Candy- non-chocolate, fudge Cakes not requiring refrigeration Cookies Brownies Double crust fruit pies Breads (Not containing Fruit/Vegetables) Rolls Fruit jams, jellies Spices, herbs (blending commercially dried) Snack items Baked goods (i.e. bread, rolls) for wholesale distribution or retail at farmers markets, craft fairs, etc.	Any processed food Process Review required for any shelf stable foods. May be required for other foods as well (i.e. fermented) Scheduled Process is required for Low acid and acidified foods packed in hermetically sealed containers. Must register and file with FDA	Any processed food Process Review required for any shelf stable foods. May be required for other foods as well (i.e. fermented) Scheduled Process is required for Low acid and acidified foods packed in hermetically sealed containers. Must register and file with FDA
Foods Not Allowed	Cakes which require refrigeration Pies containing milk, eggs or meat products Chocolates Low acid / acidified foods Etc.	Meat products - if more than 3% raw or 2% cooked <i>meat ingredients - USDA regulated</i>	<i>Meat products if more than 3% raw or 2% cooked meat ingredients - USDA regulated</i>
Zoning	Check with city/town Zoning /Planning Board Issues: Scale of operation, number of employees	Check with municipality Zoning/Planning Board Issues: scale of operation; number of employees 2nd kitchen may not be allowed on premise	Check with municipality Zoning/Planning Board Issues: scale of operation, number of employees

Home Processing Exemption

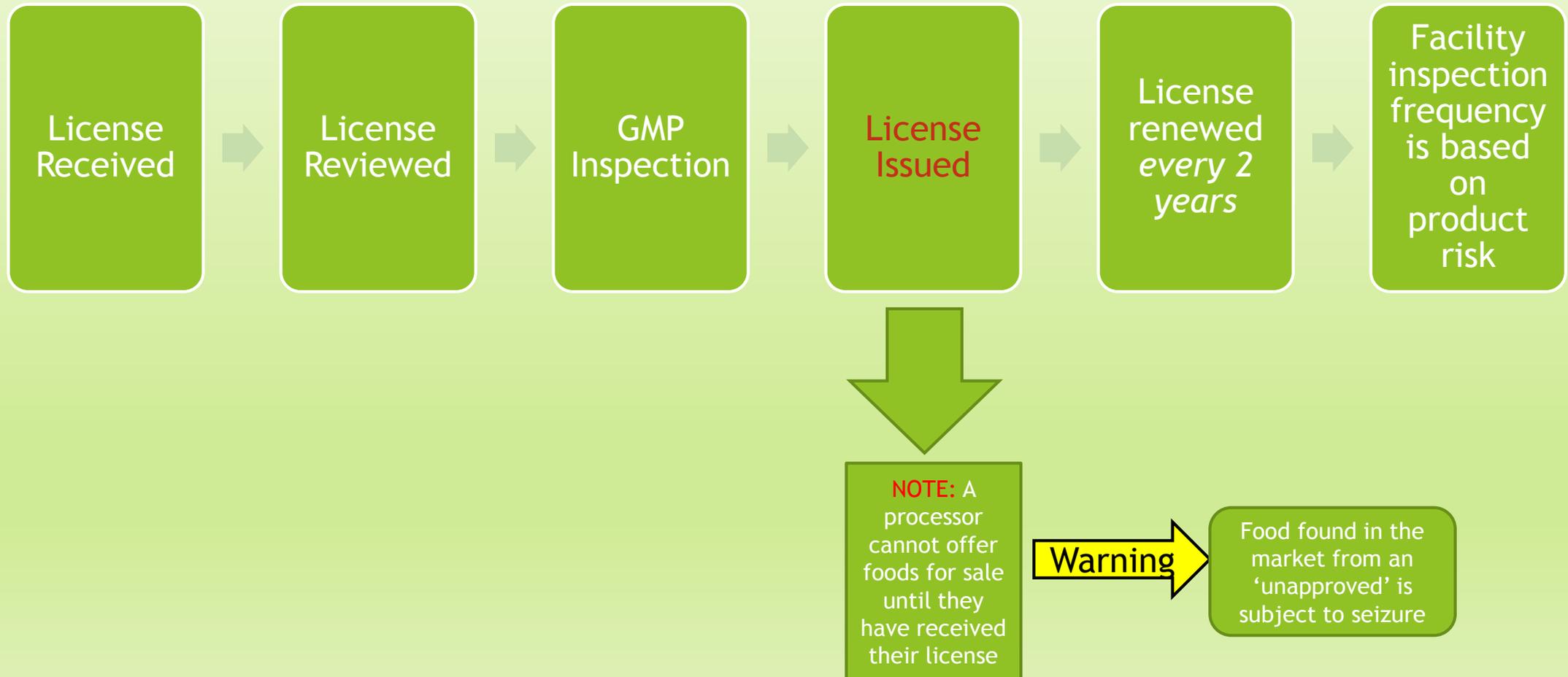
- ▶ New York State allows **non-hazardous** foods such as candy, cakes not requiring refrigeration, cookies, brownies, double crusted fruit pies, breads and rolls, standard fruit jams and jellies, repackaging commercially dried spices and herbs, and snack items to be produced in home kitchens.
- ▶ A review of processing procedures may be required for certain products before exemption is granted.
- ▶ Anyone seeking a Home Processing Exemption must contact the NYS Department of Agriculture & Markets. Home Processor information can be found on our website: https://www.agriculture.ny.gov/FS/consumer/FSI-898D_Home_Processor.pdf Any questions can be emailed to agr.sm.hpregistrations@agriculture.ny.gov

NOTE: An annual potable water test for bacteria is required for all home processors on private water supplies. Internet sales are not allowed under this exemption.

- ▶ Some types of foods **may not** be produced in a home kitchen, as mandated by Federal regulations. These foods include :
 - ▶ Low acid and acidified (pickled) foods packed in hermetically sealed containers must be registered with the US Food and Drug Administration (FDA).
 - ▶ Meat products with more than 3% raw or 2% cooked meat ingredients in a completed product are regulated by the US Department of Agriculture (USDA).
 - ▶ Vacuum packaged and any other reduced oxygen packaged products.



20-C License Process -



Good Manufacturing Practices (GMPs)

Good manufacturing practices provide guidance for manufacturing, testing, and quality assurance of food to ensure that a food product is safe for human consumption.

All GMP guidelines follow a few basic principles:

1. **Instructions** and procedures must be written in clear and unambiguous language
2. **Records** produced during the manufacturing/food process (temperature controls, cleaning/sanitation schedules, training, batch, lot codes, etc) must be maintained

Provided in your handout

GMP Category	GMP Requirement For:
Personnel	<ol style="list-style-type: none"> 1. Disease control 2. Cleanliness 3. Education and training 4. Supervision of personnel with regards to these requirements
Building and Grounds	<ol style="list-style-type: none"> 1. Description of adequate maintenance of grounds/exterior of facility 2. Facility/kitchen construction and design to facilitate sanitary operations and maintenance
Sanitary Operations	<ol style="list-style-type: none"> 1. Cleaning/sanitizing of physical facilities, utensils, and equipment 2. Storage of cleaning and sanitizing substances 3. Pest control 4. Sanitation of food contact surfaces 5. Storage and handling of cleaned portable equipment and utensils
Sanitary Facilities and Controls	<ol style="list-style-type: none"> 1. Water supply 2. Plumbing 3. Sewage disposal 4. Toilet facilities 5. Hand-washing facilities 6. Rubbish and offal disposal
Equipment and Utensils	Design, construction, and maintenance of equipment and utensils
Processes and controls	Delineates processes and controls for: <ol style="list-style-type: none"> 1. Raw materials and other ingredients (separation, storage, rotation, etc) 2. Manufacturing operations (critical limits, allergen control, cross contamination, etc)
Warehousing/ Storage and distribution	Storage and transportation of final food product must protect against contamination and deterioration of the food and its container

GMP - Personnel

The facility management shall take all reasonable measures and precautions to assure the following:

- ▶ **Disease control.** No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contamination, shall work in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person, or of disease being transmitted by such person to other individuals.
 - ▶ Devise a policy
 - ▶ Share the policy with employees



GMP - Personnel

- ▶ **Cleanliness.** all persons, while working in direct contact with food preparation, food ingredients, or surfaces coming into contact therewith shall:
 - ▶ Wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty, to the extent necessary to prevent contamination of food products.
 - ▶ Wash their hands thoroughly (and sanitize if necessary to prevent contamination by undesirable microorganism) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
 - ▶ Remove all insecure jewelry and, during periods where food is manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
 - ▶ If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves should be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved.
 - ▶ Wear hair nets, headbands, caps, or other effective hair restraints.
 - ▶ Not store clothing or other personal belongings, eat food or drink beverages, or use tobacco in any form in areas where food or food ingredients are exposed or in areas used for washing equipment or utensils.
 - ▶ Take any necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals and medications.



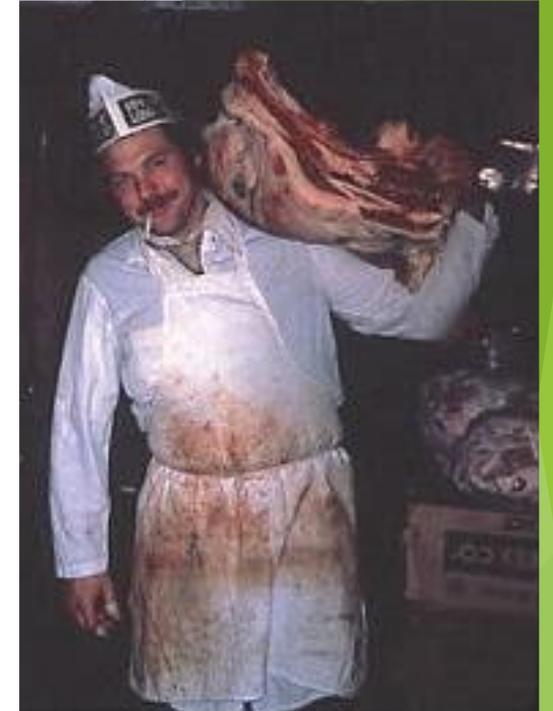
Personnel - The Good, the Bad and the Ugly



The Good



The Bad



The Ugly



Buildings and Grounds The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

GMP - Sanitary Operations

- ▶ You must have program in place to ‘maintain a clean and sanitary operation’.
- ▶ When possible a program must be available and documented for the following:
 - General maintenance of buildings and grounds
 - Animal and vermin control
 - Sanitation of equipment and utensils
 - Sanitation/cleaning of walls, floors, ceilings etc



Sanitary Operations - The Good, the Bad and the Ugly



The Good



The Bad



The Ugly



GMP - Sanitary Facilities & Controls

Each facility shall be equipped with adequate sanitary facilities and accommodations, including but not limited to the following:

- ▶ **Water supply**
- ▶ **Sewage disposal**
- ▶ **Plumbing**
- ▶ **Toilet facilities**
- ▶ **Hand-washing facilities**
- ▶ **Rubbish and offal disposal**



Sanitary Facilities & Controls The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

GMP - Equipment & Utensils

All plant equipment and utensils should be:

- ▶ suitable for their intended use,
- ▶ so designed and of such material and workmanship as to be adequately cleanable, and
- ▶ properly maintained.



Equipment The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

GMP - Processes and Controls

- ▶ Raw material and ingredients shall be **segregated** as necessary to assure that they are clean, wholesome, and fit for processing into human food
- ▶ Raw materials shall be **stored** under conditions that will protect against contamination and minimize deterioration.
- ▶ Containers and carriers of raw ingredients should be **inspected** on receipt and routinely to assure that their condition has not contributed to the contamination or deterioration of the products



GMP - Processes and Controls

- ▶ When **ice** is used in contact with food products, it shall be made from potable water
- ▶ Food-processing areas and equipment used for processing **human food** should not be used to process **non-human** food-grade animal feed or inedible products unless there is no reasonable possibility for the contamination of the human food.
- ▶ Processing equipment shall be maintained in a **sanitary condition** through frequent cleaning including sanitization where indicated.
- ▶ Insofar as necessary, equipment shall be **taken apart** for thorough cleaning.



Processes and Controls - The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

GMP - Warehouse, Storage and Distribution

- ▶ All food **packaging and storage**, should be conducted under such conditions and controls as are necessary to minimize the potential for undesirable deterioration or contamination of the processed product or ingredients
- ▶ Storage may require careful **monitoring** of such physical factors as:
 - ▶ Time,
 - ▶ Temperature,
 - ▶ Humidity,
 - ▶ Pressure,
 - ▶ Flow-rate
 - ▶ Processing operations as freezing, dehydration, heat processing, and refrigeration
- ▶ **Testing** procedures shall be utilized where necessary to identify sanitation failures or food contamination
- ▶ **Packaging** processes and materials shall not transmit contaminants or objectionable substances to the products



GMP - Warehouse, Storage and Distribution

- ▶ Meaningful **coding** of products sold or otherwise distributed from a manufacturing, processing, packing, or repacking activity should be utilized to enable positive lot identification to facilitate
- ▶ **Records** should be retained for a period of time that exceeds the shelf life of the product
- ▶ **Storage and transportation** of finished products should be under such conditions as will prevent contamination and will protect against undesirable deterioration of the product and the container



Warehouse, Storage and Distribution -The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

Allergens

- ▶ Food labels must **identify** the source of all major allergens in the food's ingredient list in simple language.
- ▶ **Unless** the food source of a major food allergen is part of the ingredient's **common and usual name** (e.g. milk, wheat), it must be labeled in one of two ways. It may be added in parenthesis after the ingredient (e.g. whey (milk), flour (wheat)) or can be identified at the end of the ingredient list in a "contains" statement (e.g. contains milk and wheat).
- ▶ What are the **major** food allergens in the US? Worldwide?
 - ▶ Milk,
 - ▶ Eggs,
 - ▶ Fish,
 - ▶ Crustacean shellfish (e.g. shrimp, crab, lobster),
 - ▶ Tree nuts (e.g. almonds, walnuts, pecans, etc.),
 - ▶ Peanuts,
 - ▶ Wheat,
 - ▶ Soybeans.



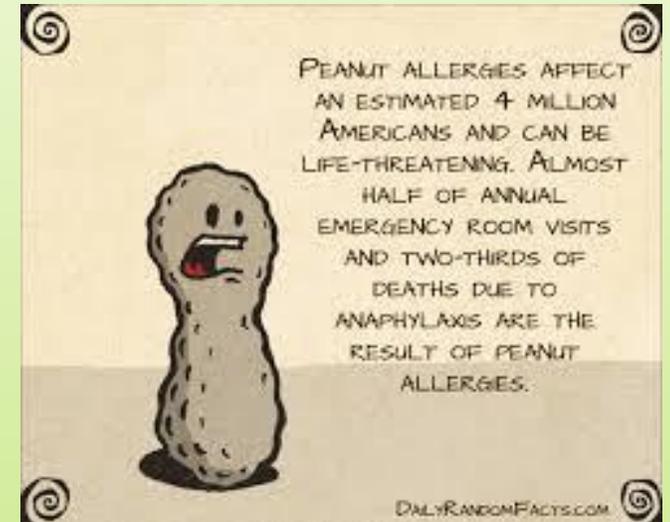
Allergens - The Good, the Bad and the Ugly



The Good



The Bad



The Ugly

Cross Contact/Contamination

What is cross-contact/contamination?

- ▶ Cross-contact occurs when a residue or trace amount of an allergen unintentionally crosses over into a product that doesn't have that allergen.
- ▶ Cross-contact (the inadvertent introduction of an allergen into a product) is generally the result of environmental exposure during food processing or handling.
- ▶ Cross-contact occurs when:
 - ▶ multiple foods are manufactured on the same processing line,
 - ▶ through the misuse of rework,
 - ▶ as a result of ineffective cleaning, or
 - ▶ from the generation of significant dust containing the allergen.



Cross Contact/Contamination

How can cross-contact be prevented?

Cross-contact cannot always be prevented. However, by developing and implementing an Allergen Control Plan, one can either *prevent* or at least minimize allergen cross-contact as much as possible.

- ▶ The [Allergen Control Plan](#) is a written document outlining controls put in place regarding the:
 - ▶ storage, handling, and processing of allergens and
 - ▶ the identification of places where cross-contact is likely to occur.

NOTE: Prevention and monitoring methods are included to prevent cross-contact.

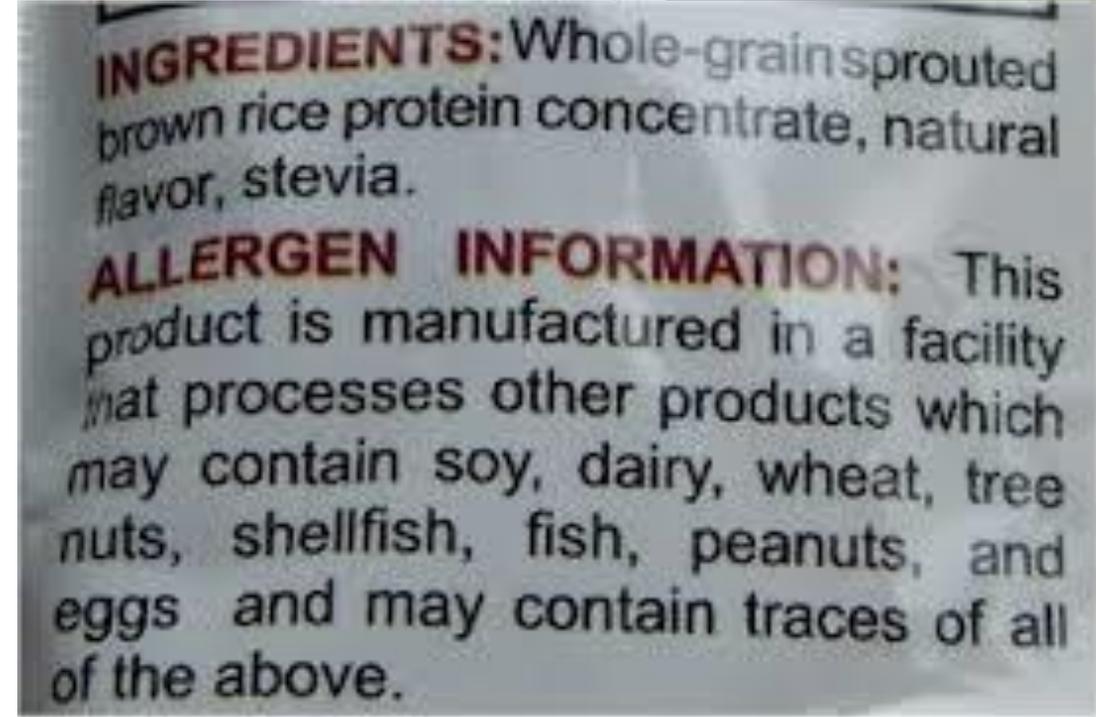
- ▶ An effective [Allergen Control Plan](#) should start with the production of raw materials, storage and handling of raw materials, and every step in the manufacturing process through the packaging and labeling of the finished product.
- ▶ The critical points where allergens may be introduced into the product during manufacturing should be identified and a system established to monitor these points to ensure unintentional cross contact is prevented.



Cross Contact/Contamination

What is precautionary allergen labeling?

- ▶ Precautionary allergen labeling (sometimes also referred to as allergen advisory labeling) is a voluntary warning to consumers (e.g. may contain milk) added after the ingredient list.
- ▶ It's goal is to indicate a product not intended to contain a specific allergen(s) may sporadically contain that allergen due to unintentional and unavoidable cross-contact in the manufacturing process even after implementing a comprehensive Allergen Control Plan.



INGREDIENTS: Whole-grain sprouted brown rice protein concentrate, natural flavor, stevia.

ALLERGEN INFORMATION: This product is manufactured in a facility that processes other products which may contain soy, dairy, wheat, tree nuts, shellfish, fish, peanuts, and eggs and may contain traces of all of the above.



Traceability - Recall Plan

Traceability

- ▶ Ability to track food through the food system back to their source and forward to the next destination
- ▶ DOES NOT prevent a foodborne outbreak
- ▶ CAN quickly identify the source of a product and speed an investigation
- ▶ CAN limit damage to the consumer
- ▶ CAN prevent damage to the innocent 'processor'

Product Recall

- ▶ Recalls are actions taken by a firm to remove a product from the market.
- ▶ They may be conducted
 - ▶ on your own initiative,
 - ▶ By request of your buyer,
 - ▶ by NYSDAM/FDA request, or
 - ▶ by FDA order under court order.



Recall Plan Development

How to make your products traceable

- ▶ Keep records of
 - ▶ name of the product,
 - ▶ the ingredients & manufacturers,
 - ▶ the processing area,
 - ▶ processing dates (or group of dates),
 - ▶ LOT numbers, and
 - ▶ where it was sent.
- ▶ Use processing records, receipts, transportation bills, and storage records to provide documentation.
- ▶ Keep records for products that are held in storage before distribution

NOTE: ALWAYS
CHECK THAT IT
WORKS



Preparing for your 'Inspection' through a 'Self-Audit'

GMPs: Personnel 21 CFR, Part 110 Section 110.10

	Good	Needs Work
1. Are the employees well-trained in what they do? You can avoid many problems by making sure that your employees clearly understand their functions.		

2. In handling food products, do your employees wear hair covering, disposable gloves and clean clothing?
3. Are your employees wearing jewelry, ring bandages?

Do your employees have any illnesses, infections, or other conditions that could contaminate foods in the production area?

4. Do your employees wash and sanitize their hands properly?

Do you have washing facilities available for your employees?

Do they use them when their hands become soiled?

5. Do your employees maintain clean personal appearance?

6. Is the traffic within your plant controlled to prevent contamination of the production area?

Do visitors wear proper outfits and hairnets?

7. Have your employees been told the reasons for the precautions?

Has this training been done through GMP classes?

Is the training documented?

Total Checked:

GMPs: Production and Process Control 21 CFR, Part 110 Section 110.80

1. Are products stored on a first-in, first-out basis to reduce the possibility of contamination through spoilage? Are old products kept in front of the new to help in the rotation process?		
2. Are all incoming products dated to ensure a proper rotation of stocks and for internal tracking purposes?		
3. Are items overstocked? This increases the chances of spoilage and contamination.		
4. Are incoming vehicles inspected?		
5. Are dusty, faded or discolored containers checked regularly?		
6. Are all products spoiled by damage, insects, rodents or other causes stored in a designated "Quarantine Area" to prevent their contact with safe products?		
7. Are such quarantined items disposed of quickly to prevent the development of pest breeding places?		
8. Are incoming materials inspected for damage or contamination so that they can be rejected?		
9. Are unused materials properly resealed to prevent contamination?		
10. Are materials stored in a safe manner? Food related items should not be stored with non-food related items. Materials should be stacked so that vents and blowers are not blocked. Stacks of materials should be orderly for safety purposes.		
11. Do you have an effective recall procedure set up?		
Total Checked		

GMPs: Buildings and Facilities: Sanitation Operations: Pest Control 21 CFR, Part 110 Section 110.35 (a)(c)

	Good	Needs Work
1. Do you have professional pest control services?		
2. Do you check regularly on what the pest control operator is doing?		
3. Do you have documentation on what chemicals are being used?		
4. Are mites, weevils or roaches apparent in the plant? There should be no evidence of their presence.		
5. Do you have enough bait stations?		
6. Are you safe using fumigation safety?		
7. Are the pest control logs and documentation readily available?		
8. Are pesticides or application equipment stored safely?		
9. Are products stored on pallets and at least 18 inches away from the walls?		
10. Is your facility well-maintained?		
Total Checked:		

1. Is trash, debris and clutter picked up, both inside and outside the plant, so as not to provide hiding places for pests?

2. Are all sanitation chemicals used in the plant USDA/FDA approved?

3. Do employees eat, drink and use tobacco products only in designated areas, and not in the production area or warehouse?

4. Is the food spilled or uneaten by employees cleaned up quickly so as not to attract pests or breed bacteria?

5. Has old rodent excreta been cleaned up so you can spot any new activity?

6. Is garbage quickly removed and dumped in appropriate bins? It should not sit around your facilities to attract pests and develop odors.

7. Is the garbage kept covered? An open garbage pile is an excellent breeding ground for insects and rodents.

8. Is the water used in your firm from an approved source (either municipal supply or tested private source)?

9. Have you made sure there are no hoses left dangling in sinks or on the ground? Loss of pressure can cause a back flow that will contaminate your water supply.

10. Do your facilities have back flow and vacuum breaker valves to prevent contaminate your water supply?

11. Is there standing water around your firm (particularly in the production area, warehouse and pack-off area)?

Total Checked:

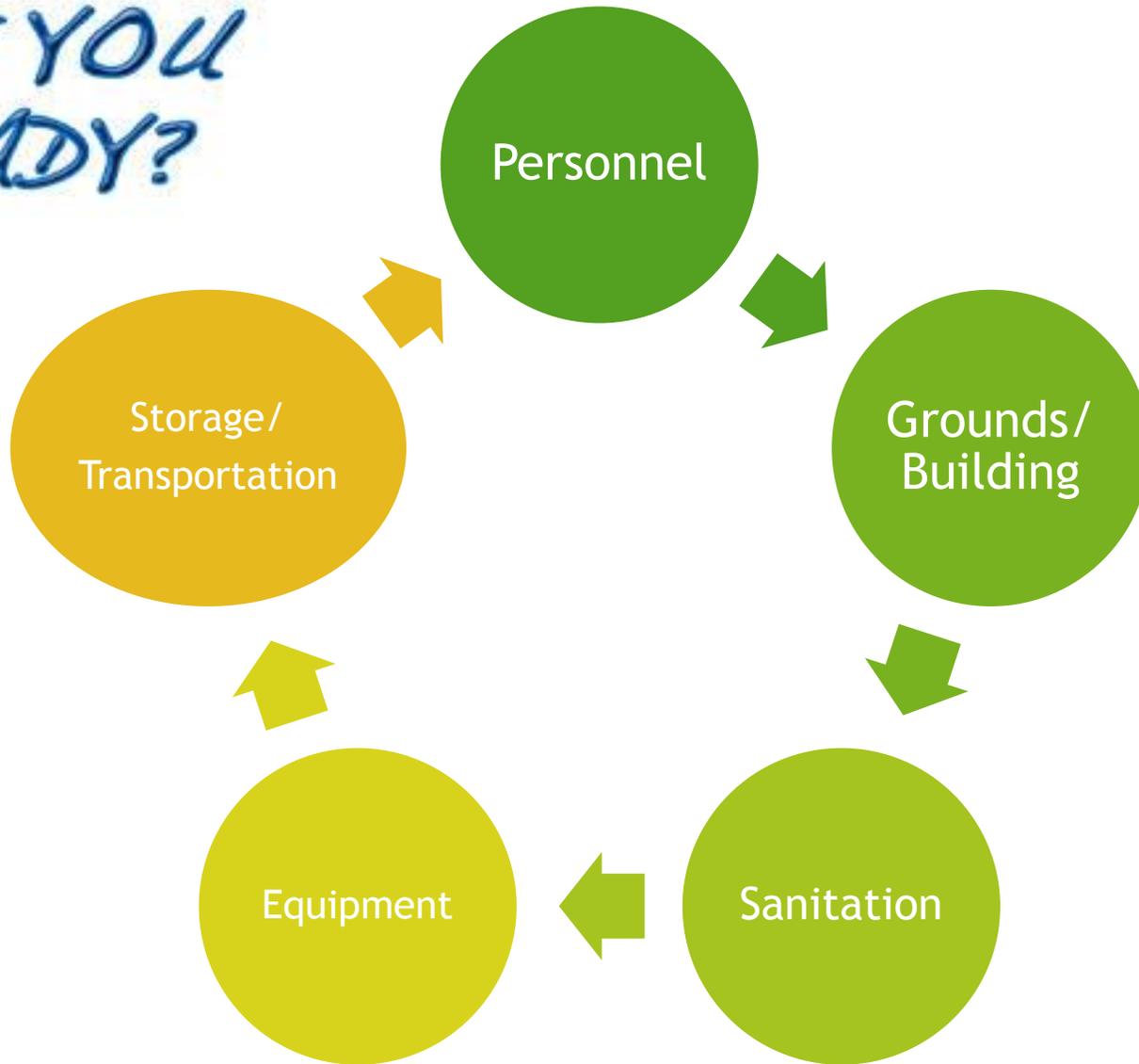
GMPs: Equipment 21 CFR, Part 110 Subpart C

	Good	Needs Work
1. Is all equipment that comes in contact with food cleaned and sanitized as often as necessary to prevent contamination of the product? You should follow appropriate cleaning schedules for each piece of equipment.		
2. Is the equipment designed, or otherwise suitable, for use in a food plant? For example, equipment for handling or processing foods cannot contain polychlorinated biphenyls (PCBs), which are very toxic (this does not apply to electrical transformers and condensers containing PCBs in sealed containers).		
3. Is there a build-up of food or other material on the equipment? This can serve as a breeding place for insects and bacteria.		
4. Is there any build-up or seepage of cleaning solvents or lubricants on your equipment, which can contaminate foods? All repairs on equipment should be of a permanent nature (e.g., no bobby pins in place of cotter pins), as temporary repair parts can break or rupture and get in the food product.		
5. Is the equipment hard to disassemble for clean-up and inspection? The more difficult it is, the less inclined you or an employee will be to clean it.		
6. Is there a lot of "dead space" in or around the machinery where food and other debris can collect as a nest for insects and bacteria?		
7. Can the surface of the equipment be sanitized?		
Total Checked:		





ARE YOU
READY?



Food Labeling

1. Where should label statements be placed on containers and packages?

Answer: There are two ways to label packages and containers:

- Place all required label statements on the front label panel (the principal display panel or PDP), or,
- Place certain *specified* label statements on the PDP and other labeling on the information panel (the label panel immediately to the right of the PDP, as seen by the consumer facing the product).

[21 CFR 101.1](#), [21 CFR 101.2](#), [21 CFR 101.3](#), [21 CFR 101.4](#), [21 CFR 101.5](#), [21 CFR 101.9](#), and [21 CFR 101.105](#)

2. What are the PDP and the alternate PDP?

Answer: The PDP, is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate PDPs. [21 CFR 101.1](#)

3. What label statements must appear on the PDP?

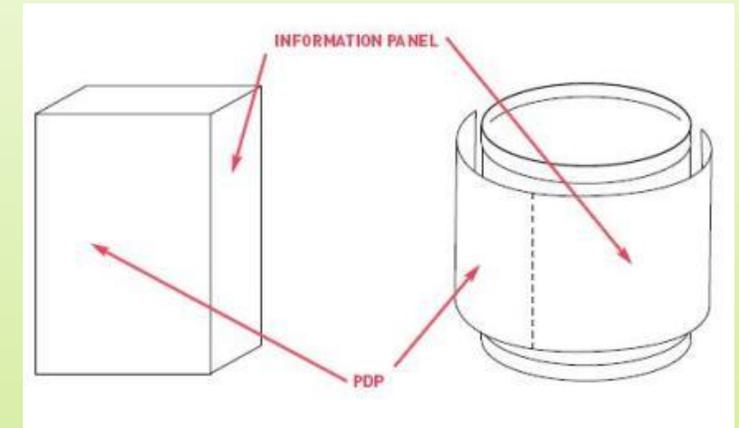
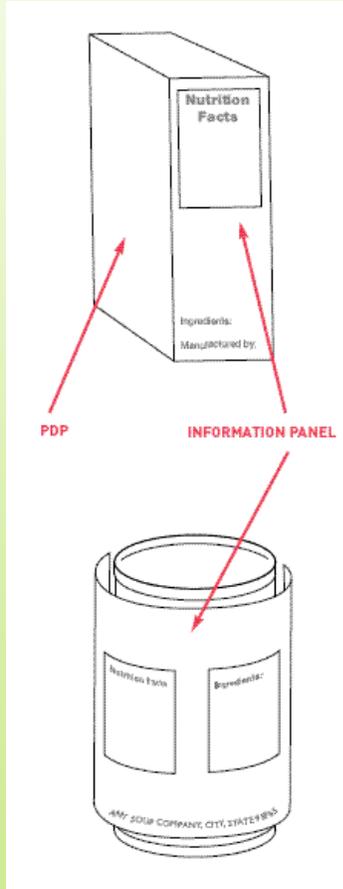
Answer: Place the statement of identity, or name of the food, and the net quantity statement, or amount of product, on the PDP and on the alternate PDP. The required type size and prominence are discussed in sections [4](#) and [5](#) of this guidance. [21 CFR 101.3\(a\)](#) and [21 CFR 101.105\(a\)](#).

4. Which label panel is the information panel?

Answer: The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the information panel is the next label panel immediately to the right. [21 CFR 101.2\(a\)](#)

5. What is information panel labeling?

Answer: The phrase "information panel labeling" refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labeling does not appear on the PDP. These label statements include the name and address of the manufacturer, packer or distributor, the ingredient list, nutrition labeling and any required allergy labeling. [21 CFR 101.2\(b\)](#) and [\(d\)](#), Section 403(w) of the FD&C Act



Food Labeling - Continued

6. What type size, prominence and conspicuousness is required?

Answer: For information panel labeling, use a print or type size that is prominent, conspicuous and easy to read. Use letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter "o". The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read. Do not crowd required labeling with artwork or non-required labeling.

Smaller type sizes may be used for information panel labeling on very small food packages as discussed in [21 CFR 101.2\(c\) & \(f\)](#).

Different type sizes are specified for the Nutrition Facts label. (see section 7)

The type size requirements for the statement of identity and the net quantity statement are discussed in sections 4 and 5 of this guidance. [21 CFR 101.2\(c\)](#)

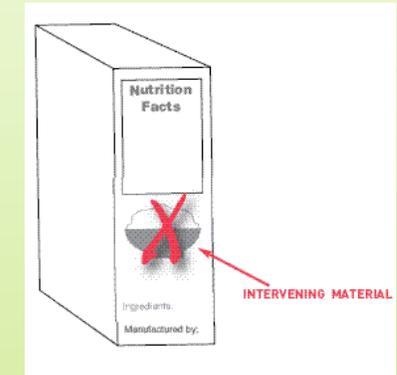
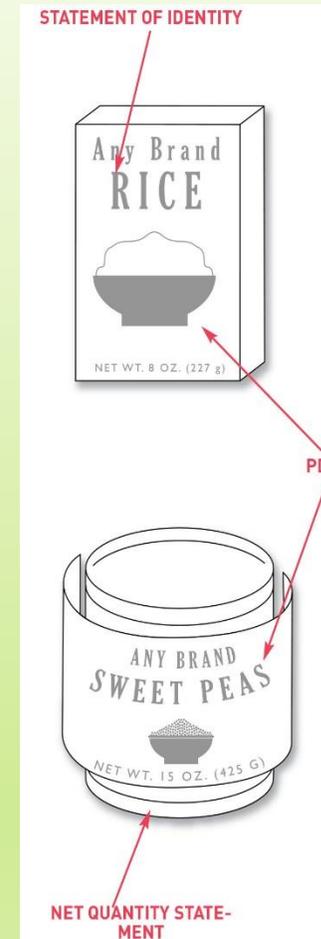
7. What is the prohibition against intervening material?

Answer: Information that is not required by FDA is considered intervening material and is not permitted to be placed between the required labeling on the information panel (e.g., the UPC bar code is not FDA required labeling). [21 CFR 101.2\(e\)](#)

8. What name and address must be listed on the label?

Answer: Food labels must list:

- Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for" or "distributed by");
- Street address if the firm name and address are not listed in a current city directory or telephone book;
- City or town;
- State (or country, if outside the United States); and
- ZIP code (or mailing code used in countries other than the United States). [21 CFR 101.5](#)



A SPOT THE DIFFERENCE B

HAZELS

Wild Blueberry Mix
Naturally flavored

SO GOOD

NET WT. 12oz



Enriched Bleached flour (niacin, iron, riboflavin), sugar, artificial blueberry bites (palm oil, corn flour, artificial flavor, red coloring), vegetable oil, baking soda, corn starch, salt, eggs, sodium silicoaluminate.

May contain: milk and soy

Serving Size: 1/6 pouch (31g), Servings per Container: 6
Amount Per Serving, Calories 120, Calories from Fat 25, %
Daily Value, Total Fat 2.5g (4%), Saturated Fat 1g (4%),
 Trans Fat, 1g, **Cholesterol** 0mg (0%), **Sodium** 230mg
 (10%), **Total Carb** 23g (8%)
 Sugars 11g, **Protein** 1g, Iron 2%, Thiamin 4%
 Riboflavin 2%, Niacin 2%,
 Not a significant source of dietary fiber, vitamin A and vitamin
 C and calcium.

* Percent Daily Values are based on a 2,000 calorie diet.

Distributed by Lazurne's LLC
 Hamilton, NY
 Hazelsfoods.com

HAZELS

Blueberry Muffin Mix
Artificially flavored



NET WT. 12 oz. (340g)

Enriched Bleached flour (wheat flour, niacin, iron, riboflavin), sugar, artificial blueberry bites (palm oil, corn flour, artificial flavor, red 40, blue 1), vegetable oil (sunflower, and peanut oil), baking soda, corn starch, salt, eggs, sodium silicoaluminate (anticaking agent).

Nutrition Facts	
Serving Size 1/6 pouch (31g mix)	
Servings Per Pouch 6	
Amount Per Serving	
Calories	120
Calories from Fat	25
% Daily Value*	
Total Fat 2.5g	4%
Saturated Fat 1g	4%
Trans Fat 1g	
Cholesterol 0mg	0%
Sodium 230mg	10%
Potassium 20mg	1%
Total Carbohydrate 23g	8%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 1g	
Iron 2%	• Thiamin 4%
Riboflavin 2%	• Niacin 2%
Folic Acid 1%	*

Not a significant source of vitamin A, vitamin C and calcium.
 *Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

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Take a look at the label and circle what you think is wrong with the picture!



Food Safety Training

- ▶ As required by Agriculture and Markets Law §251-z-312, the applicant for a food processing establishment license shall **furnish** evidence of his or her experience and competency to operate the establishment. One can demonstrate such competency by successfully completing a food safety course approved by the Department.
- ▶ The food safety course shall consist of not less than **eight hours** of training received within two years prior to the commencement of the license period or, if the program required the passing of a test, within five years prior to the commencement of the license period.
- ▶ The **program** shall cover one or more of the following topics:
 - ▶ New York State food safety statutes and regulations;
 - ▶ Food microbiology, including a review of pathogenic and spoilage microorganisms; food-borne illnesses, including causative agents, symptoms, and prevention;
 - ▶ HACCP (Hazardous Analysis Critical Control Point);
 - ▶ Cleaning and sanitation;
 - ▶ Personal hygiene;
 - ▶ Temperature control, including heating, cooling, and storage standards; and
 - ▶ Food security, including identifying risks, implementing preventive measures and pest control.



'Scheduled' Process Review

¹ NYCRR 271.9.3:

- ▶ A scheduled process or process review must be conducted on food products that ordinarily do not have a processing step that addresses the rationale for how the potential public health hazards and insanitary conditions addressed by the relevant regulatory sections will be alternatively addressed by the new process.
- ▶ The schedule process or process review must outline at a minimum recipe testing/formulation, critical control points (to avoid contamination and control hazards), processing steps, storage requirements, distribution and selling conditions/restrictions, etc.
- ▶ A scheduled process or process review of your new product can be obtained by contacting any of the parties listed under the 'Process Review¹' section on the website

¹ Listing of 'Recognized Processing Authority' is available for download from our website



'Scheduled' Process Review

The department requirements for producing a for wholesale distribution are as follows:

- ▶ Completion of a scheduled hazard/process review conducted by a recognized process authority¹.
- ▶ Completion of Article 20-C Food processing establishment license application.
- ▶ Compliance with 1NYCRR Part 261 - Current good manufacturing practices.
- ▶ Compliance with 1NYCRR Part 59.1 - Packaging and labeling of food (including statement of identify, net quantity statements, ingredients, warnings, refrigeration statements etc) See labeling slides

The department requirements for producing a product for retail sale are as follows:

- ▶ Adherence to a variance as required under 1NYCRR Part 271.9 - Retail food store sanitation regulations, compliance and enforcement.
- ▶ Completion of Article 20-C Food Processing Establishment license application.
- ▶ Compliance with 1NYCRR Part 271 - Retail food store sanitation regulations.
- ▶ Compliance with 1NYCRR Part 59.1 - Packaging and labeling of food (including warning refrigeration statements etc).

¹ Listing of 'Recognized Processing Authority' is available for download from our website



Helpful Resources for Small Scale Food Processors

- ▶ Request the publication: *Small Scale Food Entrepreneurship: A Technical Guide for Food Ventures* from Elizabeth Keller, 315-787-2273 or esk15@cornell.edu or access the online version: http://www4.gsb.columbia.edu/filemgr?file_id=738927
- ▶ Product development, processing and distribution assistance is also available from Nelson Farms at SUNY Morrisville - 315-655-8831 or www.nelsonfarms.org
- ▶ To learn about small scale food processing activities in NYS, join the NYS Small Scale Food Processors Association: www.nyssfpa.com and become a member of Pride of NY - 800-554-4501



NYSDAM - *Excellent* Food Safety Resources

Review the following Circulars on the NYSDAM website:

- ▶ **Circular 951 - Pursuant to the Licensing of Food Processing Establishments**
- ▶ **Circular 938 - Rules and Regulations Relating to Food Processing Establishments**
- ▶ **Circular 933 - Good Manufacturing Practices**

BE READY FOR YOUR NEXT NYSDAM INSPECTION BY CHECKING OUT OUR INSPECTION CHECKLIST/CATEGORIES



Regional Offices of the NYS Department of Agriculture and Markets

Division of Food Safety and Inspection

55 Hanson Place,
Brooklyn, NY 11217-1583
Phone: 718-722-2876

Division of Food Safety and Inspection

Electric Tower Building, 535 Washington
Street, 2nd Floor Suite 203,
Buffalo, NY 14203
Phone: 716-847-3185

Division of Food Safety and Inspection

900 Jefferson Road, Rochester, NY 14623
Phone: 585-487-0200

Division of Food Safety and Inspection

NYS Fairgrounds - Art and Home Center, Syracuse, NY 13209
315-487-0852

US FDA

300 Pearl Street, Suite 100, Buffalo, NY 14202
716-551-4478

US FDA New York District Office

158-15 Liberty Avenue, Jamaica, NY 11433
718-662-5447

United States Department of Agriculture - Food Safety Inspection Service (USDA FSIS)

5 Washington Square, Albany, NY 12205
518-457-4492



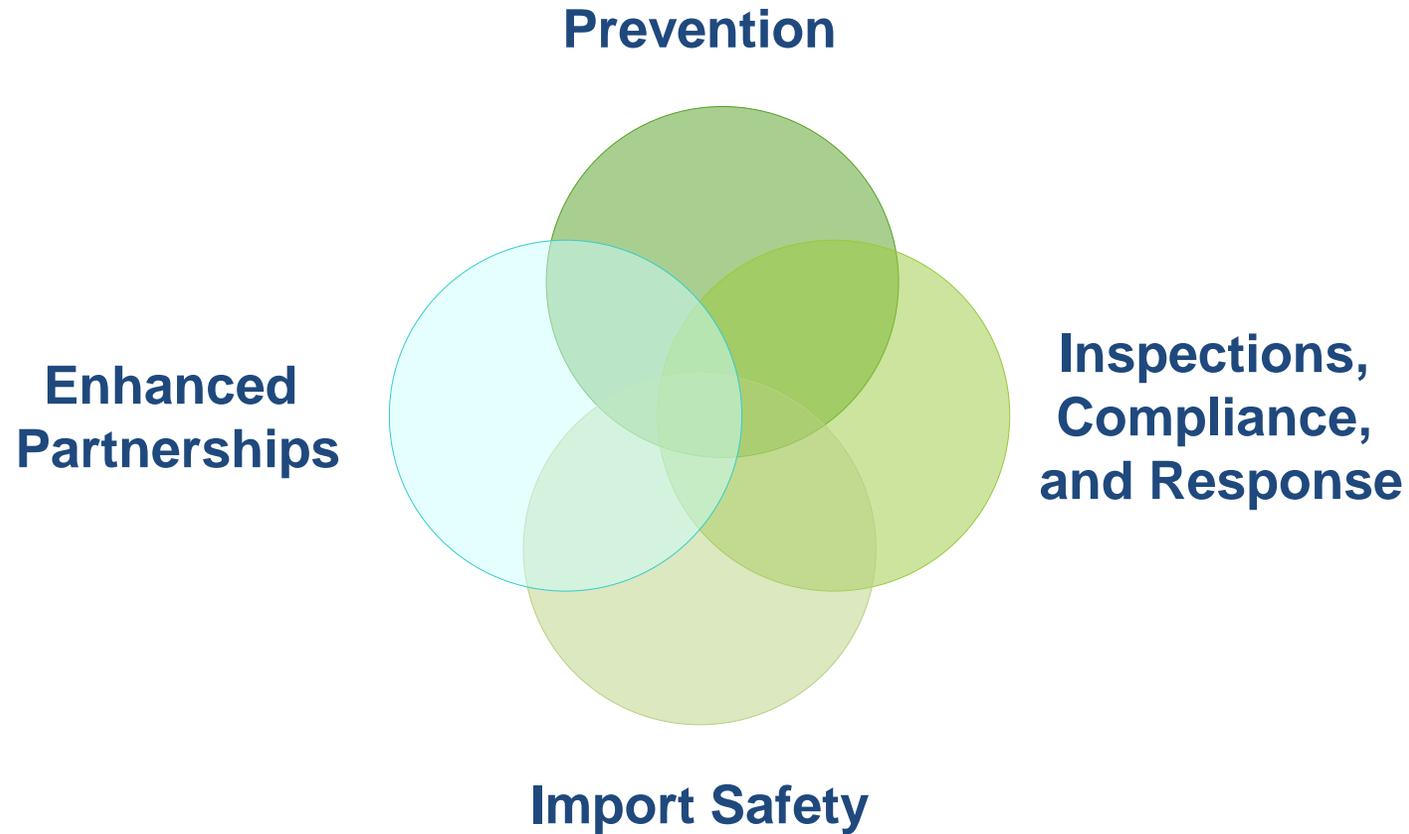
Focus on Prevention

**FDA Food Safety
Modernization Act (FSMA)**

Why is the law needed?

- ▶ **Foodborne illness is a significant burden**
 - ▶ About 48 million (1 in 6 Americans) get sick each year
 - ▶ 128,000 are hospitalized
 - ▶ 3,000 die
- ▶ **Food supply more high-tech and complex**
 - ▶ 15 percent of U.S. food supply is imported
 - ▶ More foods in the marketplace
 - ▶ New hazards in foods not previously seen

Main Themes of the Legislation



General Approach to FSMA

FSMA Preventive Controls

- ▶ Comprehensive preventive controls for human and animal food facilities
- ▶ Prevention is not new, but Congress has given FDA explicit authority to use the tool more broadly
- ▶ Produce safety standards
- ▶ Supplier verification standards
- ▶ Import standards
- ▶ Transportation standards



HACCP

- ▶ HACCP (Hazard Analysis & Critical Control Points) Plans are mandated by FDA regulations for certain products and processes, specifying procedures to be followed to minimize contamination and to minimize/eliminate chemical, physical and biological hazards when processing foods.
- ▶ HACCP plans are required for wholesale sale (not for retail) of:
 - ▶ Seafood,
 - ▶ Dairy,
 - ▶ Meat and poultry products,
 - ▶ Juice and cider processing facilities

Registration with FDA? Processors and food facilities are required to register with the FDA according to the Bioterrorism Act of 2002.

Registration information may be found at:

<https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>



HACCP -vs- FSPC

HACCP

- ▶ Built on a foundation of GMP's and prerequisite programs
- ▶ Focuses on specific Process Control Steps
- ▶ Hazard Analysis
- ▶ HACCP Plan - All CCP's have critical limits.
- ▶ Monitoring, Corrective Actions, Verification, Record Keeping
- ▶ What you will do

Food Safety Preventive Controls

(aka FSMA)

- ▶ Built on a foundation of GMP's and prerequisite programs
- ▶ HACCP on Steroids - Includes other elements in addition to process control steps
- ▶ Hazard Analysis - Includes radiological hazards
- ▶ Food Safety Plan - not all preventive controls have critical limits.
- ▶ Monitoring, Corrective Actions, Verification, Record Keeping
- ▶ How you will do it



Components of Preventive Controls for Human Foods Rule

Key Requirements:

Establish a **Food Safety System** that includes an analysis of hazards and risk based preventive controls leading to the creation of the **Food Safety Plan**...

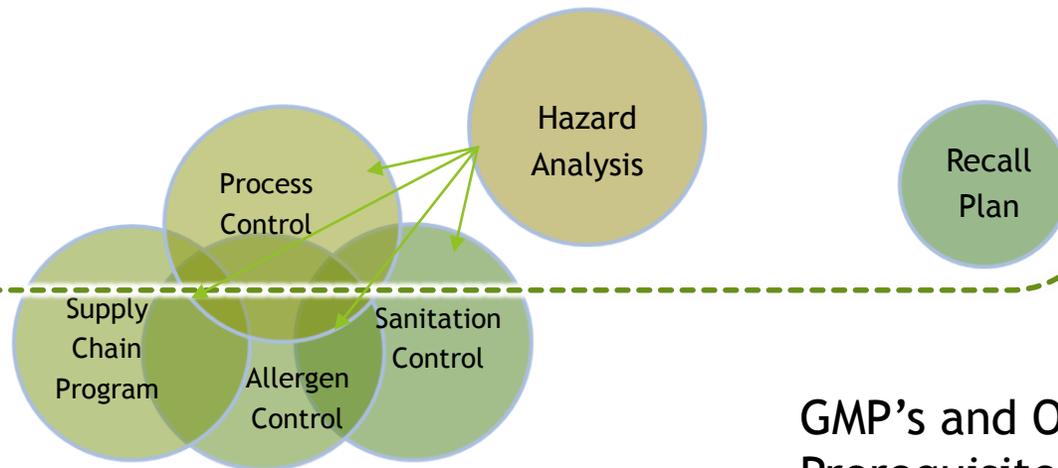
- Hazard Analysis
- Preventive Controls
- Oversight
 - Monitoring
 - Corrective Action & Corrections
 - Verification



Contents of a Food Safety Plan

Food Safety Plan

Including procedures for monitoring, corrective action and verification



GMP's and Other Prerequisite Programs



Modified Requirements for Qualified Facilities (Section 103)

Facility is exempt if:

- ▶ Defined as very small business;

OR

- ▶ The facility has a limited annual monetary value of sales

Limited annual monetary value of sales is defined as:

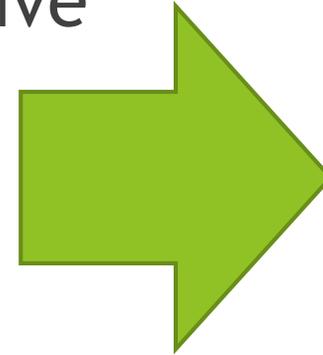
- ▶ During the last 3 years, sales were less than \$500,000;

AND

- ▶ Sales to "Qualified End Users" exceed sales to others

Examples of Compliance with Prevention Standards

- ▶ Current Good Manufacturing Practices (cGMPs)
- ▶ Sanitation
- ▶ Training for supervisors and employees
- ▶ Hazard Analysis and Risk-Based Preventative Controls
 - ▶ Food Safety Plan
 - ▶ Hazard analysis
 - ▶ Preventive controls (chemical, physical, biological)
 - ▶ Control monitoring, verification, validation
 - ▶ Recall contingency plan
- ▶ Supplier verification activities



Will FSMA
apply to
YOU?

[Check out
our website
for further
details](#)

Transportation of Food

Sec. 111. Sanitary Transportation of Food

Addresses implementation of the Sanitary Food Transportation Act of 2005, which requires persons engaged in food transportation to use sanitary transportation practices to ensure that food is not transported under conditions that may render it adulterated.

- ▶ Specific exemptions to this include:
 - ▶ Transportation of Grade “A” milk and milk products
 - ▶ Food establishments authorized by the regulatory authority to operate when engaged as receivers, or as shippers and carriers in operations in which food is delivered directly to consumers, or to other locations the establishments or affiliates operate that serve or sell food directly to consumers. (Examples include restaurants, supermarkets and home grocery delivery services.)
 - ▶ Businesses transporting molluscan shellfish (such as oysters, clams, mussels or scallops) that are certified and inspected under the requirements established by the Interstate Shellfish Sanitation Conference’s (ISSC) National Shellfish Sanitation Program (NSSP) and that transport the shellfish in vehicles permitted under ISSC authority.

Import Prevention Program

Sec. 301 Foreign Supplier Verification Program (FSVP)

- ▶ Requires importers to conduct risk-based foreign supplier verification activities to verify that food imported into the United States is not adulterated and that it was produced in compliance with FDA's preventive controls requirements and produce safety standards

Sec. 307. Third Party Auditor Accreditation

- ▶ Can be used by importers for supplier verification under FSVP
- ▶ The following third party certifying bodies specialize in food safety inspection and sanitation (please be advised, however, that NYSDAM makes no representation as to the competency of any particular certifying body nor should or will it be held liable for any action taken by a certifying body:
 - ▶ <http://www.sqfi.com/>
 - ▶ <http://www.mygfsi.com/>
 - ▶ <http://www.brcglobalstandards.com/>
 - ▶ <http://www.primuslabs.com/services/AuditorTypes.aspx>

FDA and NYSDAM FSMA Implementation Approach

FDA Implementation

- ▶ Items are prioritized based on public health protection
- ▶ Engage with stakeholders to help determine reasonable and practical ways to implement preventive control provisions
- ▶ Implementation progress at <http://www.fda.gov/fsma>

Registration with the FDA will be key!

NOTE: FDA registration does not substitute the need to notify NYSDAM of your business or completion of license application

NYSDAM Implementation (multiple year approach)

- ▶ Conduct outreach to determine Industry size, exemptions, applicability
- ▶ Develop a dataset of ‘affected’ facilities
- ▶ Classify facilities : Facilities will be ranked according to their risk classification and prioritized based on public health protection
- ▶ Educate those affected
- ▶ Engage stakeholders to help determine reasonable and practical ways to implement preventive control provisions
- ▶ Work with stakeholders to implement provisions
- ▶ Visit and work with affected facilities (large, small, very small) to identify gaps with compliance and educate accordingly
- ▶ Begin inspection protocol
- ▶ Begin enforcement protocol

Questions?



Don't forget to pick up all your resource guides/handouts!!