

ALLERGENS

Why all the fuss?

CHIRAG BHATT
Director, Regulatory Affairs



THE OTHER COAST®

I'M HAVING MY ENVIRONMENTAL ACTION GROUP OVER FOR DINNER.

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9-9

TOULOSE, COULD YOU PUT THESE STEAKS ON THE GRILL?

WHAT IF ONE OF THEM IS VEGETARIAN?

THEY CAN EAT MY FISH IN PEANUT SAUCE.

NUT ALLERGIES.

OK. I'LL DO A TOMATO SALAD.

TOMATO ALLERGIES.

WHO CAN RESIST MY CLAMS IN WHITE WINE SAUCE?

A TEETOTALLER WITH A CLAM ALLERGY?

CHEESE AND CRACKERS?

I'M VEGAN.



Agenda

- What is?
- Why all the fuss?
- Solutions
- Allergen Control
- Q&A



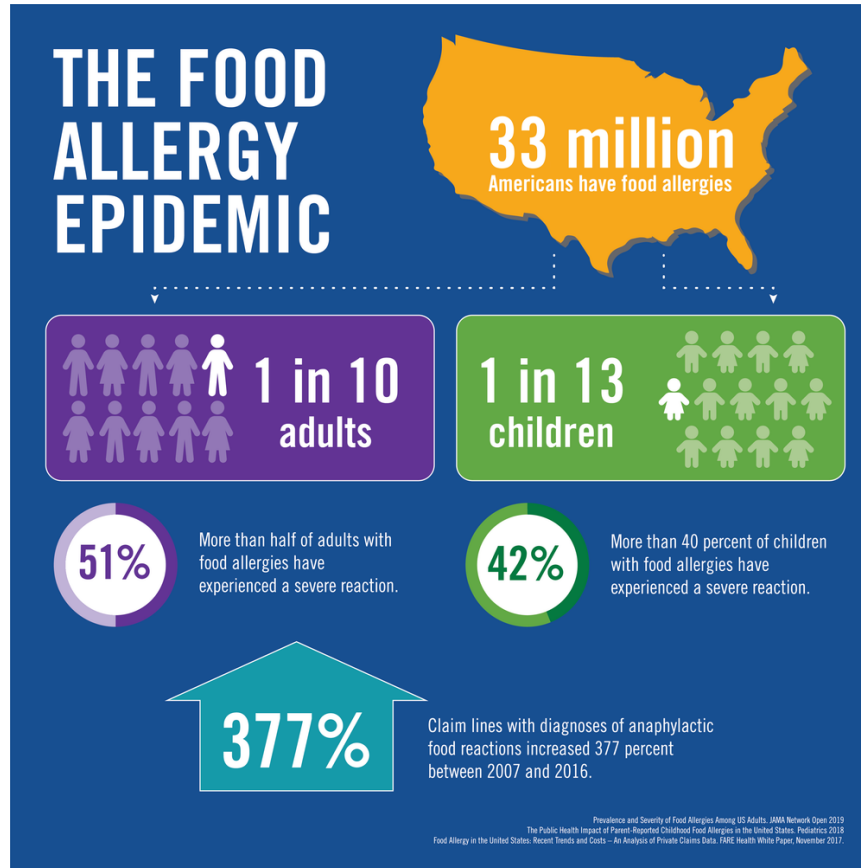
What is?

- **MEDICAL CONDITION**
- Exposure triggers harmful immune response
- Allergens are **PROTEINS**
- Mild to severe reaction (itchy to breathing)
- Anaphylaxis – serious and sudden
- Wheezing, shortness of breath, dizziness, paleness, tight throat, tongue/lips swelling, hives
- 30,000 ER visits, 2,000 hospitalized, 150 deaths

- 33 million Americans
- Children (<18) 5.6 million
- 40% children – allergic to more than 1
- Shellfish 24%, Dairy+Peanuts 36%



What is?



- FDA Risk Factor Study (2016 data) indicated that 70% PIC did NOT identify major allergens and related symptoms
- High number of food recalls
- Allergens – Top food safety concern
- 2004: FALCPA act – labeling requirements
- Food allergen awareness - training



TOP REASON FOR UNDECLARED ALLERGEN RECALLS AND PUBLIC HEALTH ALERTS:

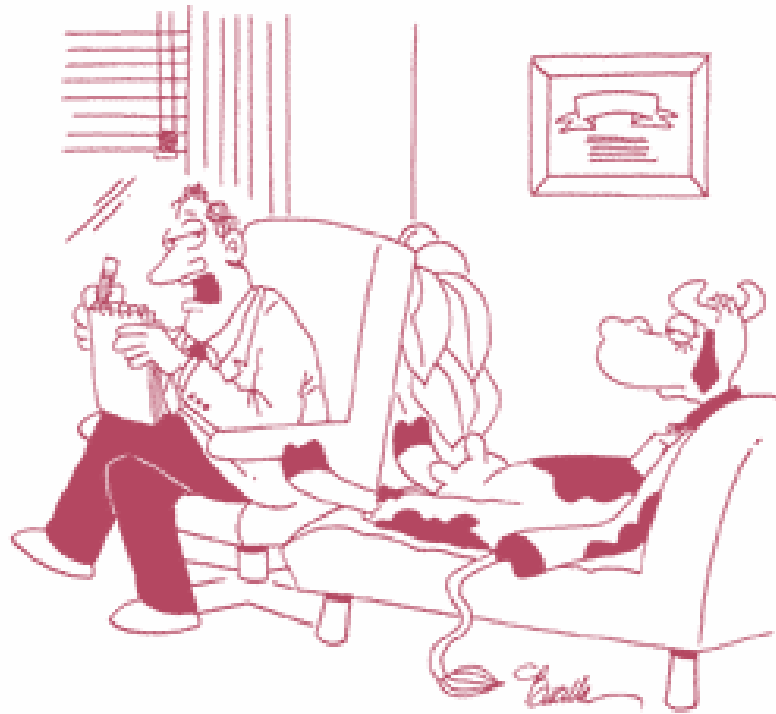
LOSS OF CONTROL DURING PACKAGING AND LABELING

- **Recalls due to undeclared allergenic foods.**
- **FDA issues firm press releases that list the most significant product action in the last 60 days, based on extent of distribution and the degree of health risk.**
- **Many food allergen recalls are included in these alerts and will eventually appear in an Enforcement Report.**

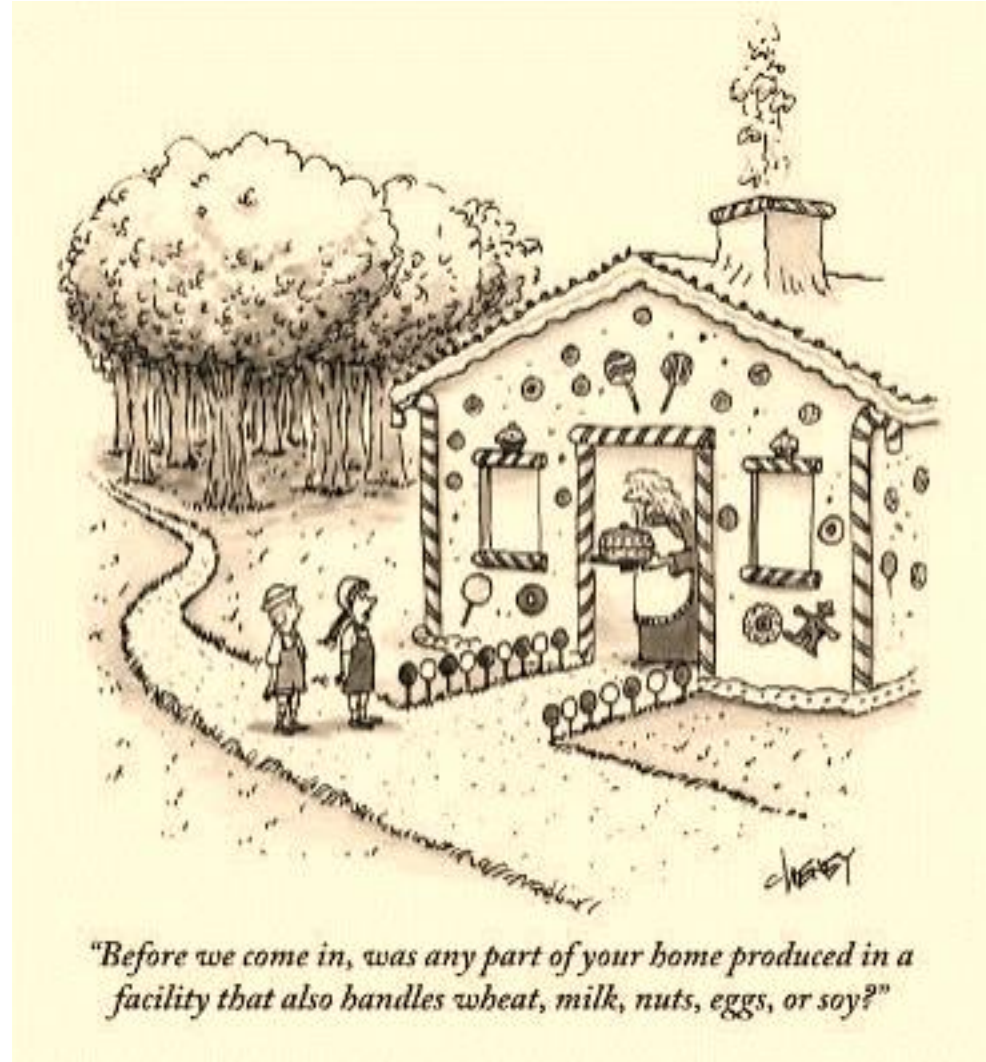


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"Hate is a pretty strong word. Are you sure you're not just lactose intolerant of your mother?"



"Before we come in, was any part of your home produced in a facility that also handles wheat, milk, nuts, eggs, or soy?"



What is?

- 70% of the total public health alerts and recalls were due to loss of control during the packaging and labeling processes.
- 15% of the mislabeled problems were from inadequate label approval.
- Remaining ones were from allergen cross contact during processing or from supplier failing to disclose specific allergen.
- Wrong packaging, wrong description (butter vs dairy), computer errors, or imported from other country
- 25% of these could have been avoided
- cGMPs, Preventive Controls, HACCP – not effective or not in place



Allergen Control Plan

- Product Design (Research and Development)
- Segregation of Foods or Ingredients - Receiving, Storage, Handling and Processing
- Supplier Control Programs for Ingredients and Labels
- Prevention of Cross-Contact During Processing
- Product Label Review & Label/Packaging Usage and Control
- Validated Allergen Cleaning Program
- Staff Training and Education

Keywords: Menu design and changes, receiving and storage (know the allergens), supplier has a plan, separate storage (when possible), dedicated utensils – equipment – containers, re-use and re-work of items/ingredients, color-coded, designated time/area, effective sanitation, adequate engineering/design, packaging and labeling accuracy and verification, facility design, SOPs, cleaning validation and verification, general and role specific training for everyone (and refreshers).



Label

Example 1:

Ingredients: Whey protein (milk), lecithin (soy), cherry, sugar, natural flavors (almond), salt.

Example 2:

Ingredients: Whey protein, lecithin, cherry, sugar, natural flavors, salt.

Contains: Milk, soy, and almond.

Food label - identify the food source of all major food allergens used to make the food. This requirement is met if the common or usual name of an ingredient already identifies that allergen's food source name (for example, buttermilk). OR the allergen's food source must be declared at least once on the food label in one of two ways.

1. In parentheses following the name of the ingredient.
e.g. "lecithin (soy)," "flour (wheat)," and "whey (milk)"

-OR-

2. Immediately after or next to the list of ingredients in a "contains" statement.

e.g. "Contains Wheat, Milk, and Soy."





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Allergen Controls in Manufacturing

**Jen Fernan, Director, FSQA &
Regulatory**

Allergens – Accurately labeled

- Must ensure allergens are accurately labeled
- Two major causes for undeclared allergens:
 - Incorrect labels used
 - Cross-contact from allergens in production



Ensuring Correct Labels



Labels/Packaging

- Secure HOLD upon receipt
- Approved prior to using in production
- Match schedule / batching sheet / label code
- Designated frequency
- Rework processes must be considered
- Documented process / verified
- Affix labels / packaging to records
- Line clearance protocols after run
- Verifications

Preventing Cross-Contact



Identifying Allergens

- Allergenic Ingredient List

Allergen Register

Form F-089

Revision: 15

Date: 7.28.2022

Reason: Updated Ingredients

Supplier	Item Code	Raw Material Name	Food Allergens in Ingredient Formulation								
			Wheat	Soy	Milk	Egg	Treenu	Pean	Shellfish	Fish	Sesame
Supplier A	000-1234	Ingredient A	X	X	X	X					
Supplier A	000-1235	Ingredient B	X	X	X	X					
Supplier A	000-1236	Ingredient C	X	X	X	X					
Supplier A	000-1237	Ingredient D	X	X	X	X					
Supplier A	000-1238	Ingredient E	X	X	X	X					

Identifying Allergens

- Allergenic Finished Goods List

Finished Product Allergen Register

Revision: 05

Date Issued: 2/23/2023

Lines	Name of Product	Countries Product Shipped To	Wheat	Soy	Milk	Egg	Treenut	Peanut	Shellfish	Fish	Sesame	Allergen Label Statement
X	Product A	US	X	X	X	X						Contains Wheat, Soy, Milk, Egg
X	Product B	US	X	X	X	X						Contains Wheat, Soy, Milk, Egg
X	Product C	US	X	X	X	X						Contains Wheat, Soy, Milk, Egg
X	Product D	US	X	X	X	X						Contains Wheat, Soy, Milk, Egg



Receiving Controls

- Verification of Allergenic Ingredients

Supplier	Item Code	Raw Material Name	Food Allergen			
			Wheat	Soy	Milk	Egg
Supplier A	000-1234	Ingredient A	X	X	X	X
Supplier A	000-1235	Ingredient B	X	X	X	X
Supplier A	000-1236	Ingredient C	X	X	X	X
Supplier A	000-1237	Ingredient D	X	X	X	X
Supplier A	000-1238	Ingredient E	X	X	X	X

INGREDIENT A

INGREDIENTS: WHEAT STARCH, YELLOW CORN FLOUR, SODIUM CASEINATE (MILK), EGGS, SOYBEAN OIL, CONTAINS 2% OR LESS OF: ARTIFICIAL FLAVOR, CINNAMON, EGG WHITES, EGG YOLKS, GUAR GUM, LEAVENING (BAKING SODA, SODIUM ACID PYROPHOSPHATE), MONO- AND DIGLYCERIDES, PROPYLENE GLYCOL MONO- AND DIESTERS OF FATTY ACIDS, SALT, SOY LECITHIN, SUGAR

Receiving Controls

- Trailer Inspection
 - Signs of spillage/damaged ingredients
 - Procedure if signs of cross-contact

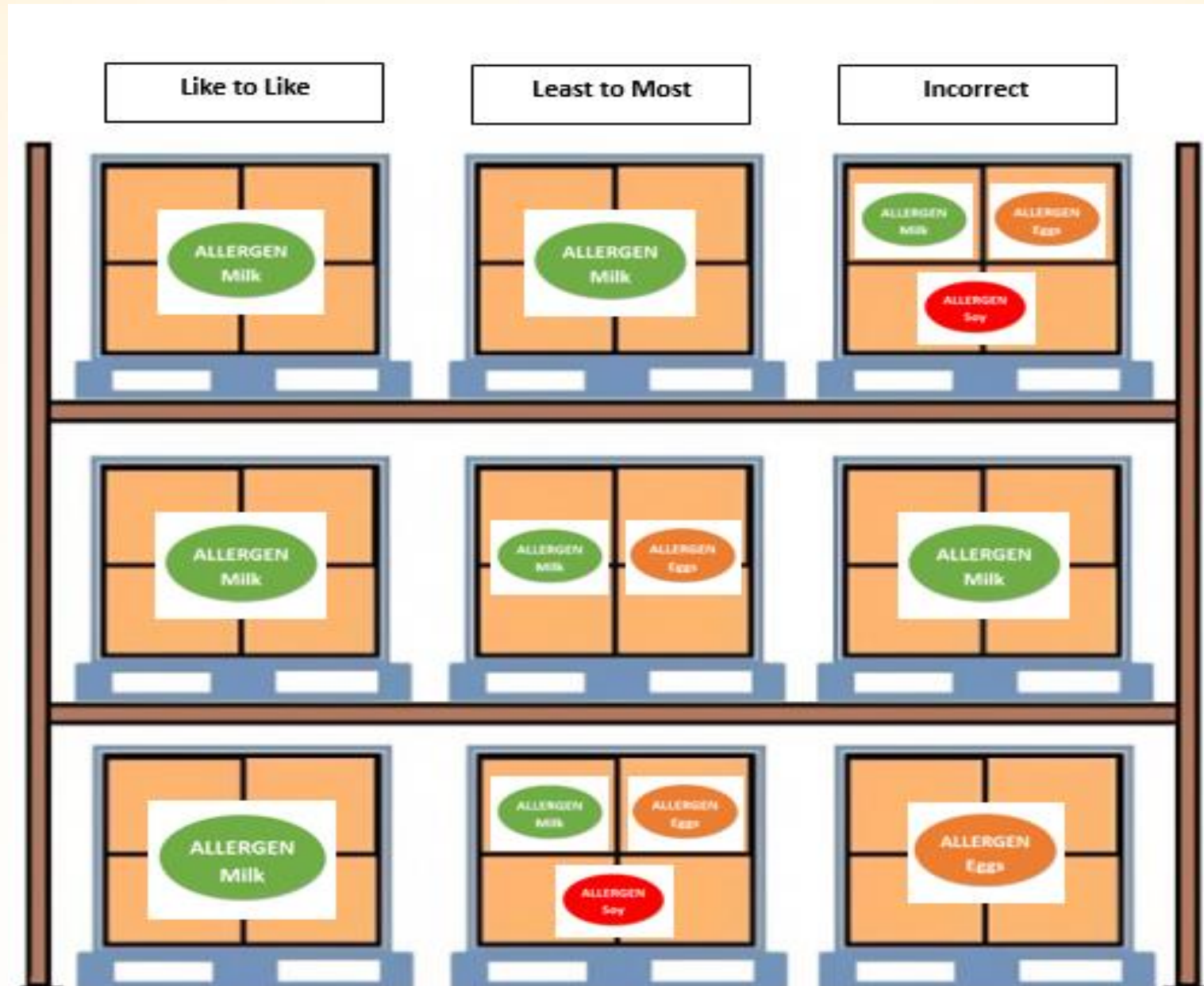
Storage Controls

- System for labeling allergenic ingredients

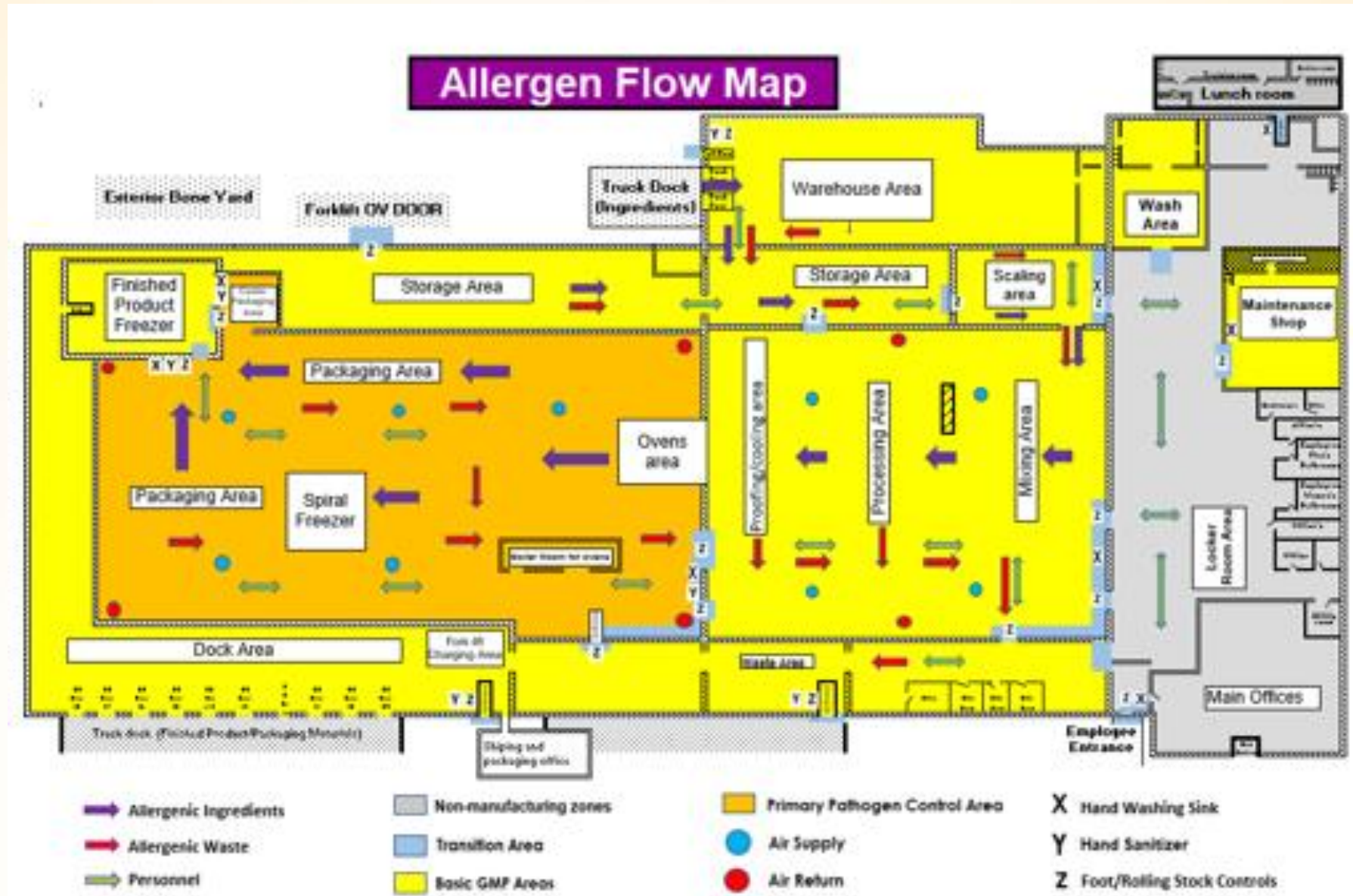


- Visible from ground level
- Multiple sides of the pallet

Storage Controls



Equipment and Facility Controls



Equipment and Facility Controls

- **Equipment Crossovers**
 - **Shields/catch pans/tarps**
- **People Crossovers**
 - **Dedicated personnel**
 - **Color coded smocks**

Handling Controls

- Allergen spills
 - Procedures for isolating and cleaning
 - Dedicated tools to clean
- Rework
 - Like to Like
 - Stored separate from non-allergen rework
- Holds
 - Segregated from non-allergen holds

Tools/Utensils/Containers Controls

- Color Coding/Labeling



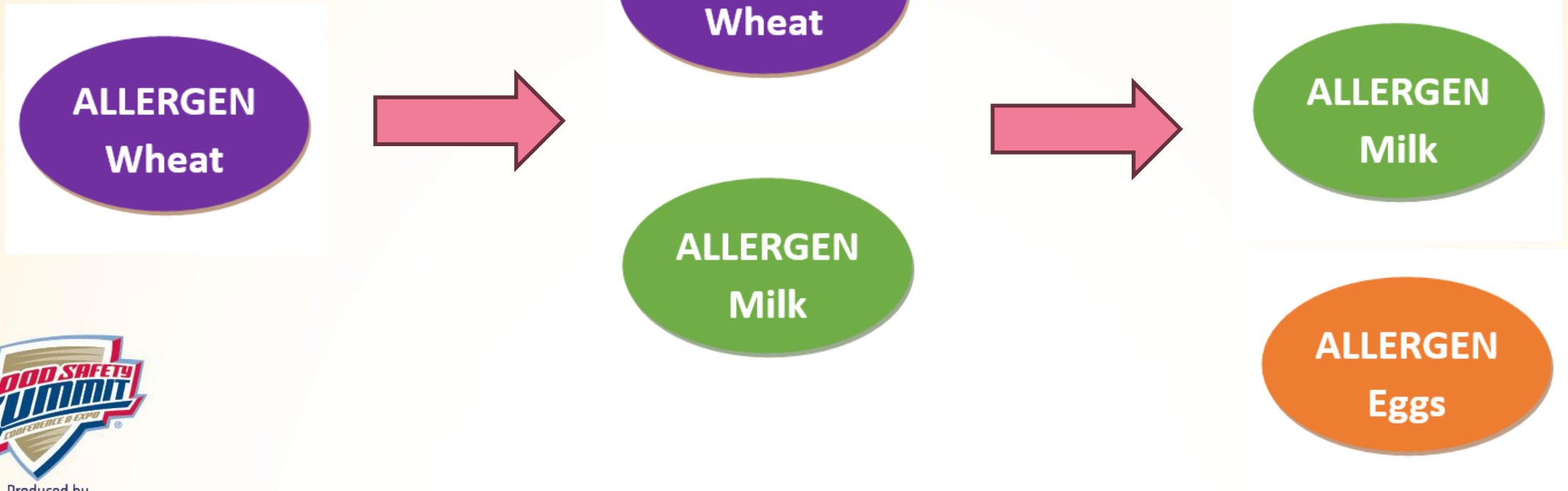
Red - Soy



Purple - Wheat

Product Scheduling Controls

- Progressive Scheduling



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Changeover Controls

- Changeover Matrix

Line	Leading Product Right	Item A	Item B	Item C	Item D	Item E
Trailing Product Down	Allergens	none	W	WM	WMS	WMSE
Item A	none	1, 2	3	3	3	3
Item B	W	1, 2	1, 2	3	3	3
Item C	WM	1, 2	1, 2	1, 2	3	3
Item D	WMS	1, 2	1, 2	1, 2	1, 2	3
Item E	M	1, 2	3	3	3	3

W = Wheat, M = Milk, S = Soy, E = Egg

1: Running change; no cleaning required.

2: Run system empty, line clearance, flush product through line.

3: Tooling change, complete system cleanout, and flush required.

Changeover Controls

- Line Clearance Procedure
 - Previous Product
 - ingredients removed from the line
 - inspect line to ensure no product remains
 - packaging removed from line; including rework areas
 - Next Product
 - correct ingredients and packaging staged



Communication

- Training
 - Allergens controlled in plant
 - Controls in place to prevent cross-contact
- Lines where allergens are running
 - Schedule
 - Signage



Communication

- Color Code Signage

		Color Coding Map										
		Color (English)	Containers/ Barrels/ bins/totes	Knife/Blades	Buckets/lids	Scoops	Scrapers	Brushes	Brooms (*Floor)	Dust pan (*Floor)	Mops (*Floor) Squeegees (*see each area use)	Shovels (*see each area use)
		Color (Spanish)	Contenedores/ Barrile/ contenedores/ bolsas	Cuchillo/Cuchilla	Cubos/tapas	Cucharadas	Raspadores	Cepillos	Escobas (*Piso)	Bandeja de polvo (*Piso)	Fregonas (*Piso) Squeegees (*Ver cada área de uso)	Palas (*Ver cada área de uso)
Allergen Handling Tools Herramientas de manejo de alérgenos	Soy (Soya)	Red Rojo	NA	NA	NA	Soy Allergen Scoop (Ingredient) Cucharada de alérgenos de soja (ingrediente) 	NA	NA	NA	NA	NA	NA
Allergen Handling Tools Herramientas de manejo de alérgenos	Wheat (Trigo)	Purple Morado	NA	NA	NA	Wheat Allergen Scoop (Ingredient) Cucharada de alérgeno de trigo (ingrediente) 	NA	NA	NA	NA	NA	NA

Auditing/Validation

- Are the controls being followed?
- Are they effective?

Allergen Management Assessment Example

Storage Assessment	Circle One		Corrective Action
Ingredients identified with allergen labeling	Yes	No	
Allergen stored below non-allergens	Yes	No	
Allergens of different kinds are not stored above each other (i.e., Walnuts are not stored on top of Pecans)	Yes	No	
Allergen containing ingredient spills are not observed and/or are properly cleaned up according to work instructions.	Yes	No	
Processing Assessment	Yes	No	
Allergen tools are used for weighing ingredients	Yes	No	
Allergens being weighed are segregated from non-allergens and are labeled	Yes	No	
Allergen rework labeled	Yes	No	
Allergen label/packaging being verified as described in procedure	Yes	No	
Allergen changeover/clean down being conducted as described in procedure	Yes	No	
Personnel Assessment	Yes	No	
Personnel handling allergens are trained	Yes	No	
Personnel handling allergens are aware of allergen running and appropriate precautions to be taken when handling allergens	Yes	No	



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Thank you!



Wendy's

- ≥ 7250 restaurants
- 33 countries worldwide
- $\geq 95\%$ Franchisees
- Wendy's and our franchisees employ over 240,000 people
- 70% of which are Millennials or younger
- 10 Languages spoken in our restaurants



Allergen RISK in Foodservice

Worldwide

- ~220 million people suffer food allergies
- ~ 2%–10% of the population
- Causes 1 death per 50 million people a year

In US

- 32 million people suffer food allergies
- ~ 11 % of people age 18 or older
- About 8% of children (1 of 13 children)



Top 10 Allergen Challenges

- Allergen identification in Ingredients
- Different Sources or Suppliers for SAME Product
- Space (storage & prep)
- Cross-Contamination
- Menu & Menu changes
- Food Handlers
- Time
- Cleaning and Sanitizing
- Allergen Knowledge



Best Practices

- Supply Management
- Operational Allergen Controls:
 - Identification and separation of storage and use;
 - cross-contact areas & equipment;
 - Risk assessment for new products and/or menus
- Risk assessment prior to approval of procedural changes or equipment that may introduce allergens
- CLEAR Identification to Customers
- Employee Allergen Training to include major food allergens and what to do in case of an allergic reaction



Q

&

A

Protecting our Customers

Wegmans

Food You Feel Good About®



SUPPLIER CODES OF PRACTICE

- Commitment to our values drives our decisions
- Our role as a Retailer and a Manufacturer
- Our Wegmans Brand has equity with our Customers
- Strong Codes of Practice and PLA provide a standard

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OF FOOD & PEOPLE

CARE • HIGH STANDARDS • MAKE A DIFFERENCE • RESPECT • EMPOWER

Wegmans Wellness Keys

Make it easy to select a variety of foods that meet your specific needs and preferences.



1 Burger Provides:
1/2 WHOLE GRAIN SERVING
Toward your goal of 3 per day



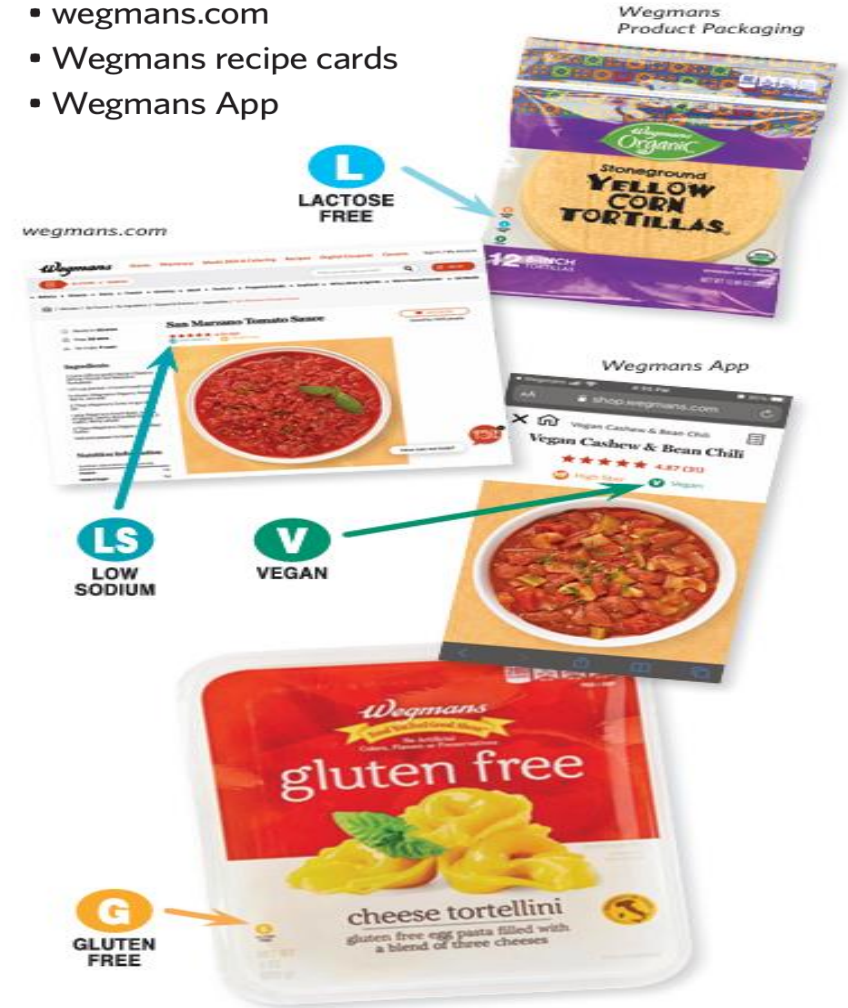
These easy-to-recognize "dots" on our Wegmans Brand products and recipes show you at a glance how each food helps you meet your health and wellness goals.

Each Wellness Key alerts you to important nutritional information. Some are for everyone, like Heart Healthy or High Fiber, while others, like Gluten Free or Lactose Free, are meant for people with specific dietary needs.

This guide explains exactly what each Wellness Key means. Keep it handy for your meal planning and shopping.

Look for Wellness Keys here:

- Wegmans Brand product packaging
- wegmans.com
- Wegmans recipe cards
- Wegmans App



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Wegmans Wellness Keys



GLUTEN FREE

Ingredients are not derived from wheat, rye, barley or oats, and the final product must have <20 ppm gluten from unavoidable gluten present due to inadvertent cross contact. Used on products and recipes.



GLUTEN FREE
with Oats

Ingredients not derived from wheat, rye or barley. Contains certified gluten-free oats. The final product must have <20 ppm gluten from unavoidable gluten present due to inadvertent cross contact. Used on products.



VEGAN

No ingredients have been derived from animals, including meat, fish, dairy, eggs, honey, or anything made from these. For example, a noodle made with eggs would not be vegan. Used on products and recipes.



LOW FAT

Less than 3g fat per serving of individual foods. Used on products and recipes.



LOW SODIUM

Less than 140mg sodium per serving of individual foods. Used on products and recipes.



ALLERGENS

Contains or may contain (we specify which of the following) Crustacean Shellfish, Eggs, Fish, Milk, Peanuts, Soy, Tree Nuts, Wheat.

Note: The allergen key is only used on Wegmans Brand packaged products, not on recipes. It appears on the back or side panel near the ingredient statement.



LACTOSE FREE

Ingredients do not contain lactose, the natural sugar found in milk. Used on products and recipes.



Both keys indicate how a serving of the recipe or product counts toward your goal of 3 servings of whole-grain foods each day. Used on products and recipes.



PALEO FRIENDLY

Ingredients support a Paleo style of eating. Foods typically allowed include meat, fish, shellfish, poultry, eggs, vegetables, fruits, nuts, and seeds. Foods typically not allowed include grains, potatoes, milk and dairy products, beans, and peas. Used on products and recipes.



HIGH FIBER

Must contain at least 5g fiber per serving of individual foods. Used on products and recipes.



HIGH CALCIUM

Must contain at least 20% of the daily value for calcium (260mg) per serving of individual foods. Used on products and recipes.



HEART HEALTHY

Low in fat and no more than 1g saturated fat, 480mg sodium, and 60mg cholesterol per standard serving of an individual food. Contains at least 10% of the daily value for one of the following: protein, dietary fiber, vitamin D, calcium, iron or potassium. Used on products and recipes.

Note: "Meal-type products" contain a combination of servings from two or more food groups. These products have different nutritional criteria than servings of individual foods. Single proteins (meat, poultry, game, and seafood) also have different nutritional criteria.

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Training and Support

- Signage
- Computer Based Interactive Training
 - Overall Food Safety
 - Allergen Training
 - Advanced Training for Managers
- HACCP Training for Leaders
- Job Aides for all In-Store Produced Items
- Food Safety Support Team (Company Wide Teams)
 - Food Safety Trainers
 - Assessors and Auditors
 - SSOP Coordinator
 - Food Scientists

Out of concern for our customers who have

Food Allergies



We want you to know that our in-store prepared products **may come into contact with food allergens** due to shared preparation areas.

Let us know if you have questions about ingredients.

Wegmans
2/17 Department

ALLERGENS



Training and Support

140+ Store Food Safety Coordinators and Specialists

This role identifies, educates, coaches and provides training on food safety issues that may cause illness or injury to employees and customers. You'll be the subject-matter expert in your store and work hands-on with employees to build trusting relationships, understand daily operations and suggest modifications to work processes, equipment, and the environment to reduce risk factors and ensure company policies and procedures are followed.

Food Allergies - What You Need to Know

9 Most Common Food Allergens



Peanuts



Tree Nuts



Wheat



Fish



Eggs



Milk



Soy



Crustacean Shellfish



Sesame

These 9 Allergens cause 90% of the food allergic reactions in the US.
Others include sulfites, mustard, celery, strawberries, chocolate, to name a few.

- **Food Allergies Can Be Life Threatening!**
 - Food allergic reaction symptoms include hives, tingling sensation in the mouth, face, tongue, lip and/or throat swelling, difficulty breathing, asphyxiation, and loss of consciousness
 - Treat every customer question seriously! Answer truthfully if you are not sure.
 - It's OK to say you don't know. Call a supervisor if you need help.
- **Show Accurate Ingredient Information When Asked.**
 - Let the customer read these and make his/her decision to consume.
 - All packaged foods **MUST** have a complete and accurate ingredient statement reflecting ALL ingredients within the package.
- **Food Production Areas in Our Stores Are NOT Allergen-Free.**
 - Allergens may be present due to shared preparation areas.
 - Very small amounts of a food allergen can cause a reaction in some people.
 - Cross-contact can occur through shared sheet pans, pots, pans, bowls, utensils, cutting boards, single use fryers, grills, gloves/hands.
 - Food Equipment must be thoroughly washed, rinse and sanitized between allergens.
 - Wash Hands thoroughly and change gloves when switching between allergens.

If a Customer has an allergic reaction, notify management, and call 911.

Wegmans

Rev May 2022

Food Allergies

If a Customer Says They Have a Food Allergy

- Take it seriously. Allergic reactions can be life-threatening.
- Be ready to discuss ingredients and food preparation with the customer.
- Communicate the allergy to the kitchen staff.
- Let the customer know when you are unsure if a menu item contains the food allergen.
- Always let the customer make their own informed decision.

Prevent Cross-Contact

- Keep allergen-containing foods separate from other foods.
- Avoid shortcuts, such as picking nuts out of a salad. Even a tiny amount of an allergen can cause a severe and potentially life-threatening reaction.
- Consider all sources of cross-contact, such as shared surfaces, fryer oils, and cooking splatter.

Before Preparing Allergy-free Foods

- Wash, rinse, and sanitize, or change: utensils, cutting boards, and food-contact surfaces.
- Wash your hands and change gloves.





If a customer has an allergic reaction, call 9-1-1