



# EFFECTIVE INDUSTRY FOOD ALLERGEN MANAGEMENT—A COMPREHENSIVE APPROACH



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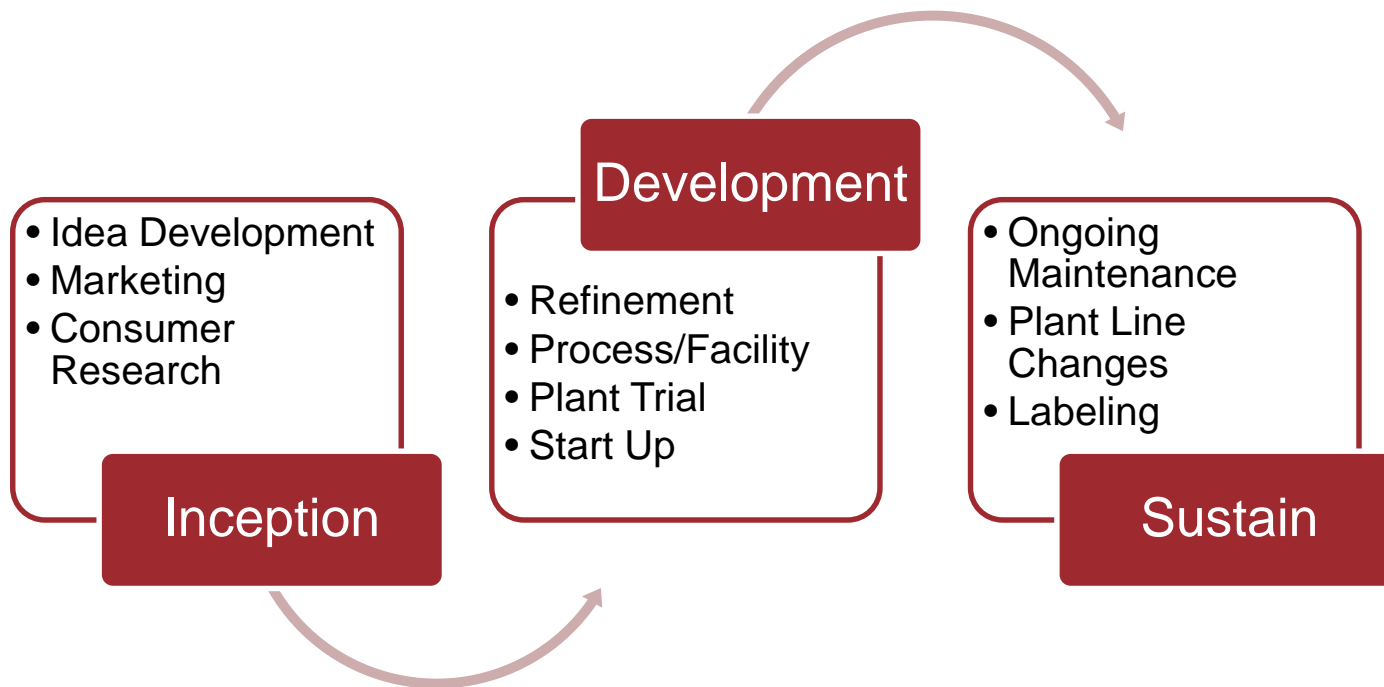
# Globally, Food Allergens Account for Many, if Not Most, Recalls

- More than 170 foods have been reported to cause allergic reactions
- Researchers estimate that up to 15 million Americans have food allergies, including 5.9 million children under age 18
  - 1 in 13 children or roughly 2 for every classroom
- ~30% of children with food allergies are allergic to more than one food
- The US CDC reports that the prevalence of food allergy in children increased by 50% between 1997 and 2011
- Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food
- About 1 in 3 children with food allergy reports being bullied as a result
- Caring for children with food allergies costs U.S. families nearly \$25 billion, annually

Information Derived from FARE - [www.foodallergy.org](http://www.foodallergy.org)

# Food Allergen Management Starts with the Food Industry

# Allergen Control Starts at the Product's Inception and Continues Throughout Its Lifecycle



# Inception Requires a Holistic Approach



Is This Value Added?



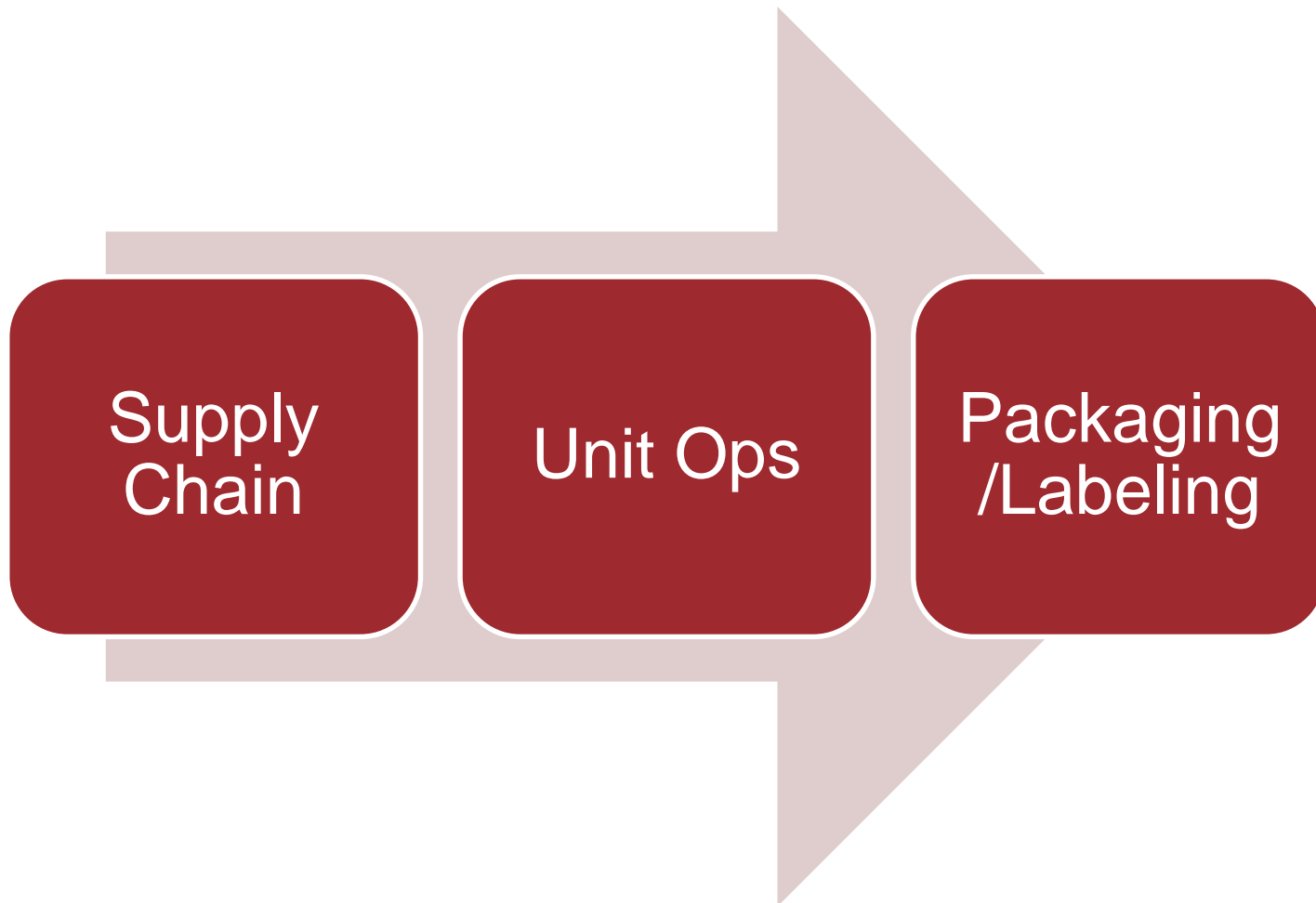
How Will This Affect the Allergic Consumer?



What is The Cost of Management?



# The Development Process Is Not Trivial



# Supply Chain Analysis Helps Determine Risk and Labeling



# Suppliers Must Comply With Specific Standards

- Suppliers must have a documented allergen control plan
  - Includes having Supplier Allergen Control Expectations
- Written assurance from suppliers that purchased ingredients do not contain any undeclared allergens (i.e. company and/or regulatory compliance, etc.)
- Suppliers are required to provide notification of any changes in the allergen status of the ingredient *prior to making such change*
- Suppliers are to ensure that ingredients are shipped in clearly marked, sealed containers that are not damaged or broken



# In Most Cases, Supplier Manufacturing Sites Should Be Audited

- Depending on risk, audit your suppliers to assess the effectiveness of their allergen control plan
  - Ensure the plan is being implemented by “walking the floor”
  - Allergen control should be a high priority
- Review suppliers allergen cleaning procedures to ensure that they are properly validated on a regular basis, or whenever there is a change that may affect the allergen status
- Review past audit scores and/or conclusions to understand their compliance to safety and regulatory standards

# Sustainability Requires Adherence to the “3 Ss”



Segregate

Schedule

Sanitize\*  
(Includes  
Sanitary  
Design)

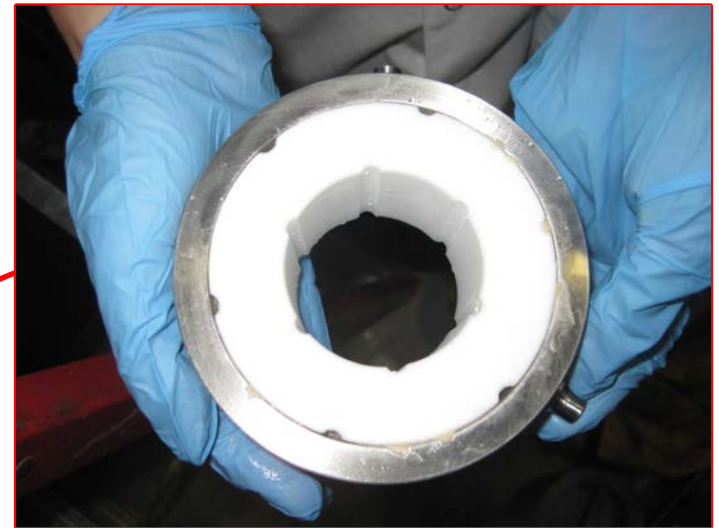
# Unit Operations Must Be a Consideration When Managing Allergens

Sanitary Design

Management of other Allergens

Ability to Inspect

# “Visually Clean” is the Gold Standard, but Be Careful



# Understanding Unit Ops. Is Critical



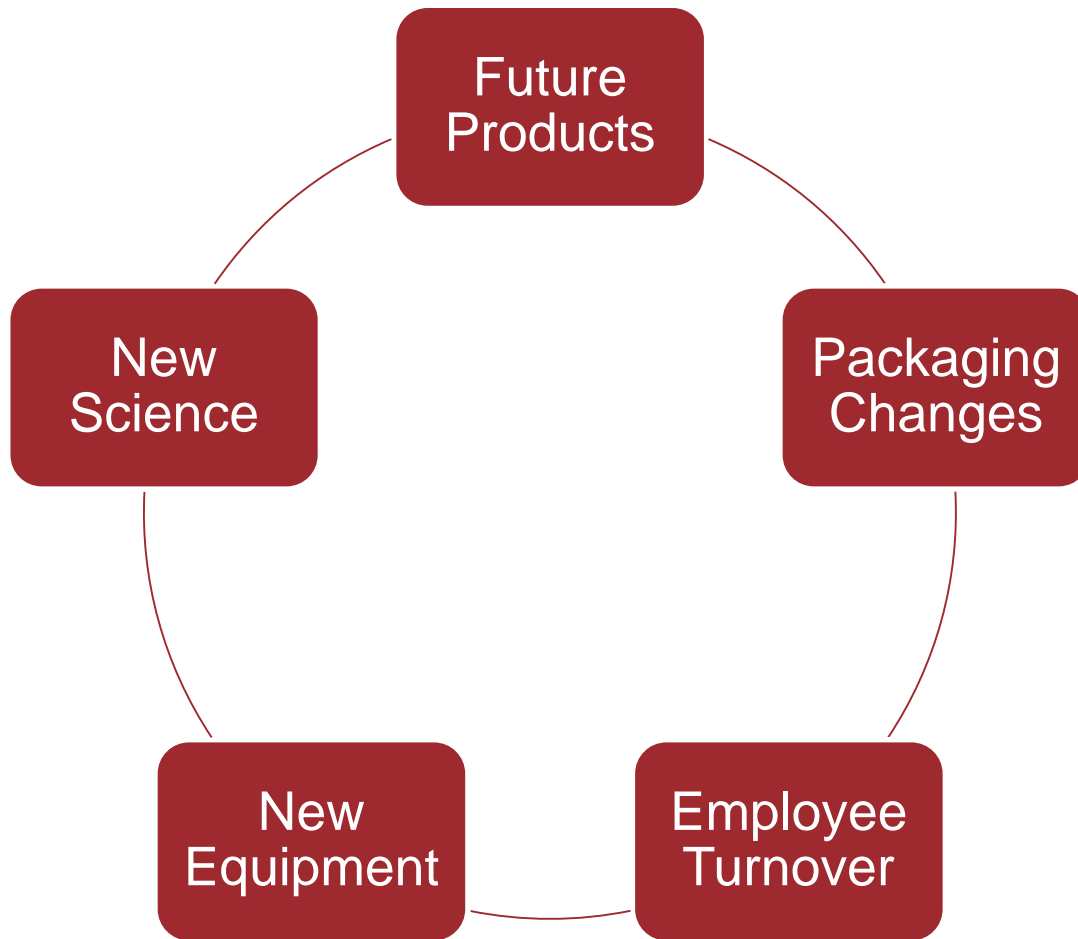
# Sanitary Design of Equipment Is Extremely Important



# “KISS” – “Keep it Simple Stupid” Is a Concept That Is Critical to Sanitary Design



# Management is Not Finite – It Requires Ongoing Maintenance





# In the End, It's Important to Ask the Right Questions\*

- Do we really need to add this ingredient or product to our portfolio?
- Is this a dedicated line or other products produced that contain different food allergens?
- Can we adequately clean the line after an allergenic run?
- If we cannot adequately clean, do we cross label?
  - Labeling in lieu of GMPs is illegal
- What is the form of the allergen?
  - Particulate?
  - Homogenous mix?
- How do we train our employees?
- Is there any new science we need to consider?

\*not a comprehensive list

# Food Safety Is Non-Negotiable, It is Foundational



Helping the world *thrive*

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