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## Getting To The Root: Effective Updates To Allergen Practice

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Don't Perpetuate the Problem



Get All of the Root...



...or the Weed Just Grows Back!



## Where the Weeds Can Grow



Product Development

Supply Chain Management

Material Receiving, Storage and Handling

Preventing Cross-Contact During Processing

Labeling and Packaging Controls

Sanitation and Changeover

## Allergens Lead Recalls



Hazard	2010	2011	2012	2013
<i>Salmonella</i>	36.6% (86)	38.2% (86)	28.1% (63)	28.7% (58)
<i>Listeria monocytogenes</i>	14.4% (33)	17.8% (40)	21.4% (48)	17.3% (35)
<b>Undeclared allergens</b>	<b>30.1% (69)</b>	<b>38.3% (75)</b>	<b>37.9% (85)</b>	<b>43.6% (88)</b>
Percentage (no. of entries)	82.1% (188)	94.3% (201)	87.4% (196)	89.6% (181)

Adapted from: Gendel, S.M., J.Zhu, N. Nolan, and K. Gombas. 2014. Learning from FDA Food Allergen recall and Reportable Foods. Food Safety Magazine.

## Causes of Allergen Recalls



Recall Cause	Number
Wrong label or package	82
Terminology not correct	59
Ingredient information not carried through	41
Cross-contact	28
Ingredient mislabeled	21

Adapted from: Gendel, S.M., J.Zhu, N. Nolan, and K. Gombas. 2014. Learning from FDA Food Allergen recall and Reportable Foods. Food Safety Magazine.

## Allergen Preventive Controls



- (2) *Food allergen controls.* Food allergen controls include procedures, practices, and processes to control food allergens. Food allergen controls must include those procedures, practices, and processes employed for:
  - (i) Ensuring protection of food from allergen cross-contact, including during storage, handling, and use; and
  - (ii) Labeling the finished food, including ensuring that the finished food is not misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

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## Sorting Allergen Recall Causes



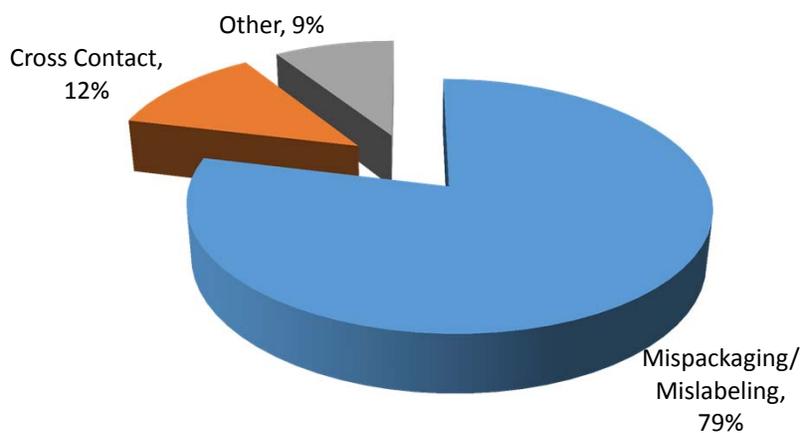
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## Simplified Allergen Recall Causes



### Recall Causes 2009-2012



How might this be addressed?

## Example: Finding the Cause



- Based on consumer complaints a company learned that its vegetarian Juicy Burger patties had been packed into its Savory Burger patty packages
- The Juicy Burger patties contain milk protein in the form of a cheese blend
- The Juicy Burger and Savory Burger products only feature slight differences in package design



## Example: Finding the Cause



- Plant appropriately scheduled non-milk patties before milk
- Batch sheets show ingredient scaling and staging was correct
- Plant had thorough controls in place for changing over from milk to non-milk products
- Non-milk packaging was left on machinery when milk-containing product began production

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## Example: Corrective Action



- Institute line-clearance procedure when changing from non-allergen product to allergen
- Add verification step to assure that packaging has been appropriately changed
- Install scanning system

## Getting the Tip of the Root



Description of Deviation: *Labels for product A were applied to product B because the operator selected the wrong stack of labels. The issue was discovered by the operator loading packages into cases.*

Actions Taken to Restore Order to the Process:

1. *Production was halted when error was discovered.*
2. *Product was segregated back to the last good check.*
3. *Product was relabeled with the correct label*
4. *Line operator was retrained on how to check the label before placing a new stack on the line and the importance of doing so. The procedure was emphasized with all operators as a teachable moment.*

*Adapted from the Food Safety Preventive Controls Alliance (FSPCA)*

## Pre-Printed Packaging Verification



- At the facility during production
  - Have controls in place to check-out and document packaging pulled into production
  - Cross-check and document replenishment materials brought to the line during production
  - Packages with multiple components (tubs, lids) need greater scrutiny
  - Document the amount of packaging returned to storage
  - During changeover, packaging materials shall be returned to storage before packaging materials for a subsequent run are brought to the line
  - Include line clearance procedures when going from non-allergen products to allergen products

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## Pre-Printed Packaging Verification



- At the printer
  - Restrict printers from doing multiple print runs in a single order if at all possible
  - Prohibit splices in rolls. If splices are necessary, the splices should include a detectable strip that can be used to trigger additional inspection at the facility
  - Cartons should have identifying marks so incorrect packaging is more easily identified in a stack
  - For systems using film, consider different sized cores for allergen and non-allergen films. If the allergen cores have a larger diameter, it would be impossible to fit non-allergen film onto the equipment

## Pre-Printed Packaging Verification



- At the facility before production
  - Assure all labels/pre-printed packaging materials accurately declare allergens
  - Maintain appropriate packaging material segregation
  - Partial pallets of packaging material should be stretch wrapped to assure no labels are mixed during storage
  - Plants shall assure obsolete labels are destroyed or controlled to prevent use

## Scanners and Vision Systems



- Plants should implement methods such as bar-code or matrix scanners to assure that packaging has not mixed with other packaging wherever possible.
- This should be a requirement if mixed print runs are allowed from the printer or if the plant makes several products with similar graphics
- Vision systems are a final verification, they should not be the **only** verification
- Workers need training so they can assure these systems are properly programmed

## Example: Training is Vital



- A snack facility has many different types of packaging for allergen and non-allergen products
- The facility packs a peanut containing product into a non-peanut labeled package

## Example: Training is Vital



Corrective actions include:

- Implementing package verification for which the operator records the UPC code and retains an imprint from each new roll
- Bar-code scanning system planned for installation

## Example: Training is Vital



Unfortunately...

After implementing the new recording procedure but before the scanners could be installed, a similar incident occurred.

## Example: Training is Vital



- A review of the records showed the operator properly recorded all numbers and saved imprints—including some for an incorrect film
- Worker was not properly trained on the appropriate action if the numbers did not properly match
- Teaching the “why” helps get all of the root!

## Watch the Entire Garden



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Questions?