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# **FDA Revision of GMPs**

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# Topics to Discuss

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- Background on food allergy
- Causes for concern
  - Undeclared allergens
  - Precautionary allergen statements
  - Rework

# Food Allergy - Background

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- 11 million Americans allergic to food
  - 6.5 million to fish or shellfish
  - 3.1 million to peanut or tree nut
  - Peanut allergy in children doubled from 1997 to 2002
  - Buying behavior of millions more affected
- Milk, egg, wheat and soy are the other major allergens

# **Food Allergy - Background**

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- Incidence of food allergy may not have peaked
- Trace amounts of allergens can cause fatal reactions
- There is no cure for food allergy
- Strict avoidance is the only way to prevent a reaction

# **Food Allergy - Background**

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- Severe allergic reactions to food result in 30,000 Emergency Department visits and up to 200 deaths per year in the U.S.
- Health and safety of food allergic individuals depends upon clear, accurate, reliable food labels

# Food Allergy - Background

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FAAN survey of 696 conference attendees asked

**“Have you ever called a food manufacturer for more information about a product’s ingredients?”**

- More than three-quarters reported calling food manufacturers for more information about a product’s ingredients

# **Food Allergy - Background**

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- Food Allergy is a significant food safety and public health issue
- People's lives depend upon knowing with certainty what is in a food item
- Some companies have embraced the issue, others have ignored it
- Compliance cannot be optional

# Undeclared Allergens

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- 1999 Recalls – 35% due to undeclared allergens
- Three Principal Factors
  - Ingredient statement omissions & errors
  - Cross contact from shared equipment
  - Human error

# Undeclared Allergens

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- FAAN members call in regularly to food manufacturers and the FDA to report reactions
- Dozens of products suspected of causing reactions due to undeclared allergens *have been confirmed* in testing by the Food Allergen Research and Resource Program of the University of Nebraska

# Undeclared Allergens - Case #1

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- FAAN member reported his daughter had a reaction to a cookie
- Manufacturer told him item was made on shared equipment
- Company acknowledged *cross-contact* was the problem

# Undeclared Allergens - Case #2

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- FAAN member told us her 16 month old son had a reaction to a frozen fudge product
- Company told her there was a “possibility it contained milk” because it was made on the same equipment as milk products and “*Employees aren’t careful these days*”

# Undeclared Allergens - Case #3

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- FAAN member reported a product indicating it contains “traces of *peanuts*”
- Her *tree-nut* allergic daughter had a reaction
- Company told her product was made on same line as product with *walnuts*
- No indication it *may contain walnuts*

# Undeclared Allergens - Case #4

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- FAAN Member purchased ½ gallon of Ice Cream
- Label stated “contains *milk*”
- While eating, encountered sliver of nut
- Company informed her all their ice creams made on shared equipment, but *no nut warning* was given

# Precautionary Allergen Statements

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- Allergen advisory or “may contain” statements were developed by the food industry as a way to communicate additional allergen information to those with food allergies
- Statements are voluntary
  - No standardization of messages
  - No rules for what they mean
  - No rules for when they can/should be used

# Precautionary Allergen Statements

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- 1996 FDA letter
  - “May contain statements cannot be used in place of GMPs”
- Proliferation of types of messages and number of products that contain them

# Precautionary Allergen Statements

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- Dec. 02, FAAN staffer went to a local supermarket in VA and sampled precautionary statements in four product categories: candy, cookies and crackers, snack foods (chips, snack bars), and other (i.e., cereal, bread, baked goods, etc.)
- Found **28** different precautionary allergen statements on the packages

# Precautionary Allergen Statements

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- Some companies use them
- Some don't use them
- Some use sparingly
- Others put them on *all* of their products

# Precautionary Allergen Statements

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- Consumers are confused and forced to spend more time decoding messages
- What do all of these statements mean?

# Precautionary Allergen Statements

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- One FAAN member asks -

- “Is there a big difference between  
‘may contain traces of peanuts’

and

- ‘manufactured in a facility that uses  
peanuts’?”

“Should we follow the same precautions for both of these warnings?”

# Precautionary Allergen Statements

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- After acknowledging cross contact as the result of an allergic reaction, a company told our member that when they order new packaging they would add a new warning to the label -  
*However, it might take several weeks.*

# Precautionary Allergen Statements

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- FAAN member reported that a chocolate bunny listed no peanut nor tree nut ingredients and featured no allergy warning
- Identical products had “May contain peanuts” on the label
- Manufacturer said all the bunnies made on the same equipment and *should all have a warning*

# Precautionary Allergen Statements

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## Consumer Confusion

- Consumers often don't read the ingredient statement if a product has a precautionary allergen statement
- Statements are sometimes inconsistent, thereby increasing risk of a reaction

# Precautionary Allergen Statements

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## Examples

Some companies think that *peanuts are the only allergen that warrants advisory labeling*

- Some have a “Contains Peanuts” statement even though it also contains other major allergens

# Precautionary Allergen Statements

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## Examples

Some companies think that peanuts and tree nuts are *interchangeable*

One company put "contains traces of *peanuts*" on the label of a product that is manufactured on equipment shared with *walnut-containing* food

# Precautionary Allergen Statements

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## Examples

"May contain peanuts and *other allergens not listed on the label*"

# Rework

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- No regulations re rework and allergens
- Mentioned in the Compliance Guidelines
- *Result* of not taking food allergen control seriously or keeping “like into like” when handling rework *can be deadly*

# Rework

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## Examples

- 21 year old with a known peanut allergy died after ingesting choc. chip cookies
- Peanuts not listed in ingredients, nor was there a precautionary statement
- Testing revealed 3,000 ppm

# Rework

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## Examples

- Prominent allergist with a known peanut allergy nearly died after ingesting ginger snap cookies
- Product had undeclared peanuts from rework
- If not for his training, ability to recognize symptoms and access to epinephrine, he *would not have survived.*

# Conclusions

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- Food allergic consumers depend on the FDA to protect them
- Their lives depend upon accurate, clear, and reliable labeling
- The agency ***must*** take the lead in food allergen controls, especially as it relates to labeling and good manufacturing practices

# Guidances vs. Regulations

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- Guidances are suggestions, therefore optional
- Regulations include shalls
- Consumers lives are dependent upon compliance - need shalls

# Conclusions

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- Ideal world would have manufacturers using separate equipment for allergen and non-allergen containing products, but this is *not* reality

# Conclusions

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- FDA must provide regulations regarding GMPs, rework and labeling so that *all* companies are doing the best they can regarding *separating, cleaning, packaging* and *labeling* of allergens

# Conclusions

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- Food allergen control measure should be part of the HACCP plan of all companies who use allergens, not just the few industry leaders who “get it”.

# Conclusions

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- Consumers can't manage their food allergies alone
- They *must* have accurate information on the label and proper food allergen management at the plant in order to avoid a reaction
- Lives depend on it!