

# Business Risk & Food Safety

Nationwide Agribusiness

Risk Management Services



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## Today Topics

1. Trends in Food Product Liability Claims
2. Regulations – A Roadmap for Liability
3. Self-Inspections/Self-Audits
4. Supplier Approval
5. Nationwide & Tortilla Industry Association Program

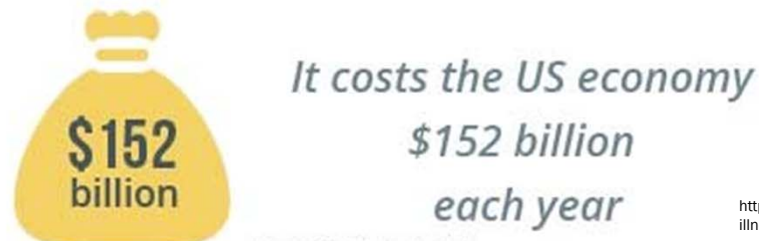


# 1. Trends in Food Product Liability Claims

- What is happening in the food industry and claims?
  - 3<sup>rd</sup> party faulty product (Property Damage)
    - 20 fold increase in \$ in a few years
  - Illness and Disease
    - Slight increase in \$
  - Labeling
    - Slight increase in \$



# Food Safety costs and lives in the U.S.



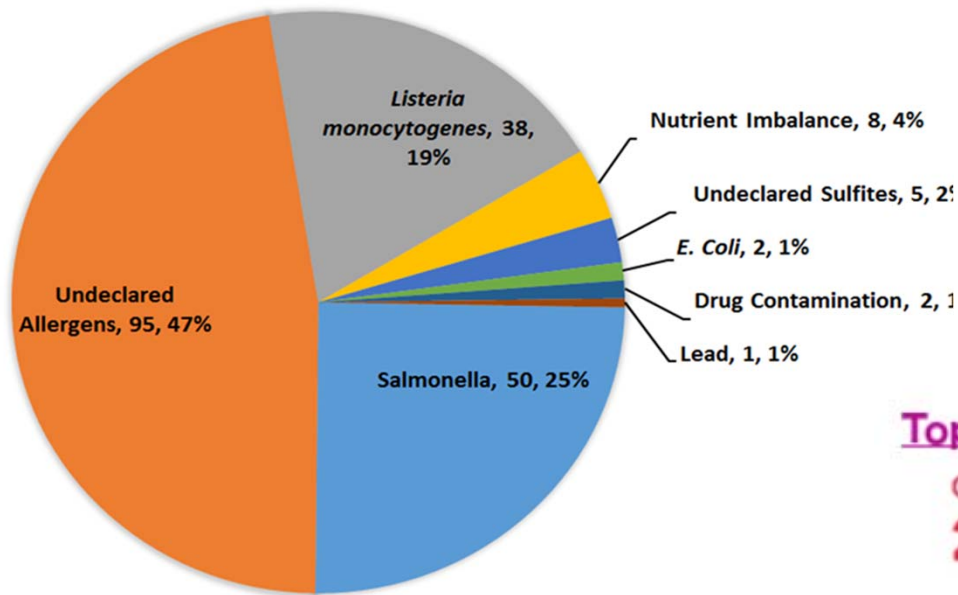
<https://www.consumerhealthdigest.com/health-conditions/foodborne-illnesses.html>



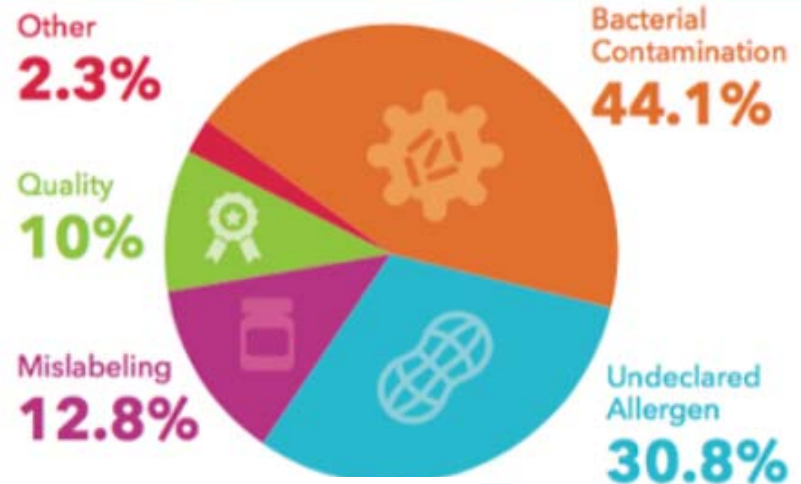
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# Food Safety costs and lives in the U.S.

FDA REGULATED PRODUCTS-REASONS FOR RECALL IN 2014



Top causes of FDA food recalls in Q4 2017



Source: Stericycle



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## 4 pieces of plastic (twice)

- Plastic found in ingredient
  - Ingredient was incorporated into product
  - \$3 million property damage
- Where did it come from?
  - Supplier?
  - Transportation?
  - At the manufacturer?
  - Documentation?
  - Downtime to clean facility?



# Labeling

- Organic vs. Non-Organic
- GMO vs. Non-GMO
- Kosher vs. Non-Kosher
- Undeclared Allergens

“We pay a lot of claims because a product wasn’t what it was supposed to be”





## 2. Regulations – A Roadmap for Liability

“Government regulation, to an insurance company, is a roadmap for liability for plaintiff attorneys.”

“You need to be in compliance, because lack of compliance really crushes you in the ability to defend a claim.”



## Food, Drug and Cosmetic Act

- A food shall be deemed to be adulterated:
  - 402 (a)(3) if it consists of any filthy, putrid, or decomposed substances
  - 402 (a)(4) if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated



## FDA Inspection Reports [402(a)(3)]

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**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

### **OBSERVATION 1**

Failure to manufacture, package and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, you are not monitoring protection of food, food packaging material, and food contact surfaces from adulterants as evidenced by:

- On 4/13/2017 a finished product sample #955568 of your firm's Roasted Cashew Butter bearing Lot#2125155 was collected and was analyzed by a FDA laboratory and found positive for *Listeria monocytogenes*, a foodborne pathogen.



## FDA Inspection Reports [402(a)(4)]



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# FDA Inspection Reports

## **Your significant cGMP violations include:**

1. You failed to exclude pests from your food plant to protect against contamination of food, as required by 21 CFR Part 117.35(c). Specifically,

A. Evidence of apparent cockroach activity and lack of effective measures to exclude cockroaches and other pests from the manufacturing and processing areas was observed during the inspection on November 29, 2017 and consisted of the following:



# Food Safety Modernization Act (FSMA)

- Where are you?
  - Preventive Controls
  - Foreign Supplier Verification
  - Sanitary Transportation
  - Intentional Adulteration



### 3. Self-Inspections / Self-Audits

Monthly

Pre-Operational

Food Safety Review

Glass and Brittle Plastics

Food Defense

Others?



## 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls for Human Food

### Subpart B – Current Good Manufacturing Practice

§117.10 Personnel

§117.20 Plant and grounds

§117.35 Sanitary operations

§117.37 Sanitary facilities and controls

§117.40 Equipment and utensils

§117.80 Processes and controls

§117.93 Warehousing and distribution

§117.95 Holding and distribution of human food by-products for use as animal food

§117.110 Defect action levels





## Personnel – 117.10

- Suitable outer garments
- Jewelry removed
- Hair restraint
- Personal items stored away from production areas
- No eating, drinking or tobacco use in production area
- Restricting persons with illness or open wounds
- Proper handwashing and sanitizing
- Adequate personal cleanliness
- Suitable gloves maintained in satisfactory condition





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## Plant and Grounds – 117.20

- Removal of debris, unused equipment and uncut vegetation
- Proper drainage of grounds
- Proper waste disposal
- Adequate space for operations and cleaning
- Proper separation of operations to prevent cross-contamination and allergen cross-contact
- Cleanable walls, floors and ceilings kept in good repair
- Prevent drip or condensate from contaminating the product
- Adequate lighting
- Guard against glass breakage
- Adequate ventilation that does not contaminate the product
- Screened openings to the outside





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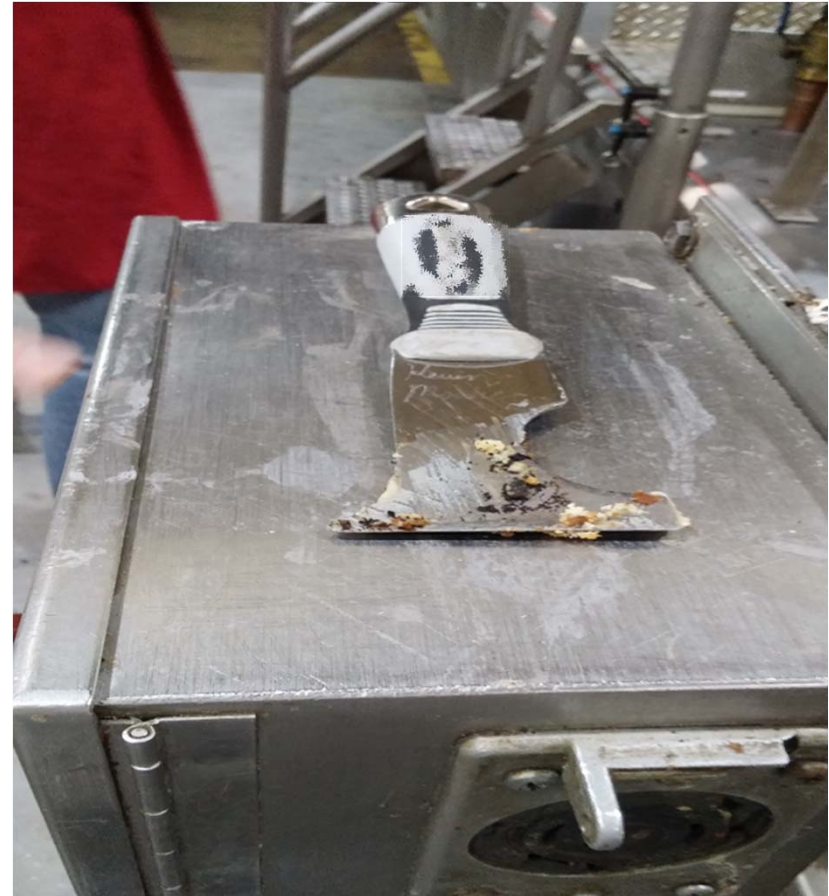
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## Sanitary Operations – 117.35

- Pest control safe and effective
- Food-contact surfaces cleaned and sanitized before use and after interruptions
- Non-food-contact surfaces cleaned as necessary
- Single service articles protected from contamination
- Recontamination of portable equipment and utensils prevented
- Plant maintained in good state of repair
- Cleaning operations not a source of contamination
- Cleaning and sanitizing compounds safe and free from contamination
- Unnecessary toxic chemicals not stored
- Toxic chemicals properly identified, stored and used



# Sanitary Operations?



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## Sanitary Operations 117.37 – Condition and Cleanliness of Food-Contact Surfaces

- Food-contact surfaces must be:
  - Smooth and easy to clean
  - Cleaned and sanitized as necessary to protect against allergen cross-contact and cross-contamination of food
- Potentially hazardous situations that may require Food Safety Plan documentation include:
  - Allergen cross-contact
  - Environmental pathogen harborage sites
  - Sanitation frequency to prevent pathogen growth





## Sanitary Operations?



## Sanitary Facilities and Controls 117.37

- Adequate water supply
- Proper plumbing
- Adequate floor drainage
- Proper sewage disposal
- Adequate, accessible, sanitary toilet facilities
- Convenient hand-washing and sanitizing facilities
- Proper trash and waste disposal





## Equipment and Utensils – 117.40

- Cleanable and maintained food-contact and non-food-contact areas
- Preclude adulteration
- Corrosion resistant and nontoxic food-contact surfaces
- Compressed gases properly filtered
- Freezers and coolers have temperature indicating devices and automatic temperature control or alarm
- Properly maintain accurate process control instruments





## Equipment and Utensils?



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## Processes and Controls – 117.80

- General
  - Adequate quality control procedures employed
  - Overall sanitation under the supervision of competent individuals
  - Adulterated foods must not enter commerce
- Raw materials and ingredients
- Manufacturing operations



# Raw Materials and Ingredients



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## Warehousing and Distribution – 117.93

Storage and transportation of food must be under conditions that protect against:

- Microbial growth
- Allergen cross-contact
- Contamination of the food with hazards
- Deterioration of the food and the container







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## 4. Supplier Approval

- What is the typical program?
  - Audits
  - Letters of Guarantee
  - Certificates of Analysis
  - Review of Food Safety Plans
  - Etc.



## “Beyond Food Safety” Supplier Approval

- What else can we consider?
  - Indemnification
  - Named Insured
  - Hold Harmless Agreements
  - Foreign or Domestic?
    - Rarely recover money from foreign suppliers if they are source of problem
  - Contracts?



# Insurance Exposures

- Chain of Commerce/Distribution
- Lack of Contracts (Suppliers and Customers)
- Do you sell final product or ingredients
  - Incorporation of insureds' ingredients into another product
- Who do you sell to?
  - Multiple Customers
  - Has one Primary Customer
  - Major Manufacturers
  - Big Box Stores



## Why do we care about incorporation?

- 2015 Spice recall
  - Undeclared peanut allergen in spice



## Nationwide & Tortilla Industry Association Program

For your **protecting**  
**what matters most** side

Nationwide is proud to be the Official Insurance Provider  
for Tortilla Industry Association.

Learn more at [Nationwide.com](http://Nationwide.com)  
Or email [TIAProgram@nationwide.com](mailto:TIAProgram@nationwide.com)



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