



FEDERAL FOOD SAFETY LAW AND EMERGING DISEASE

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Foodborne Illness



- **CDC estimates**
 - 76 million cases of foodborne illness per year, with 325,000 hospitalizations and 5000 deaths
 - known pathogens account for only 14 million cases
 - 62 million cases are from unknown agents

FDA's Food Safety Statutes



- **Federal Food, Drug, and Cosmetic Act**
- **Public Health Service Act**

Food, Drug, and Cosmetic Act



- Food is deemed to be “adulterated”
 - if it contains an added substance that may render the food injurious to health
 - if it is prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health
- Food is deemed to be “misbranded”
 - if the labeling is false or misleading

Adulteration --

What Should FDA Consider?

- **Product**

- **What's the substance? Is it an "added" substance?**
- **Is it in the food?**
- **Does it meet the "may render injurious" standard?**

Adulteration --

What Should FDA Consider?

- **Production**

- **What's the "insanitary condition"?**
- **Could have rendered the food injurious to health? What's the harmful substance?**

Misbranding --

What Should FDA Consider?



- **What's the harm?**
- **Is the cause known?**
- **Is the effect on consumers material?**
- **Are there steps consumers can take to address the harm?**

Public Health Service Act



- **FDA can promulgate regulations to prevent the introduction, transmission, or spread of communicable diseases**

PHS Act --

What Should FDA Consider?



- **What's the communicable disease?**
- **Why and how will the controls prevent its introduction, transmission, or spread?**

Where Do Emerging Diseases Fit?

- These standards don't distinguish between emerging and established diseases
- Can they be identified with/in food?
 - Analytical methods
 - Outbreaks
 - Epi studies
- Are there controls?

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